OFFICE OF HEALTH ANALYTICS
All Payer All Claims Data Reporting Program
Kate Brown, Governor

Oregon Health Authority
421 SW Oak Street, Suite 850
Portland, OR 97204
oregon.gov/oha/HPA/ANALYTICS

APAC-3 - Application for APAC Data Files

Instructions

Only fill out this form when instructed by All Payer All Claims (APAC) program staff. To begin a request for APAC Limited or Custom data sets, complete and submit an APAC-2 Pre-Application form first. Please fully complete all sections in this form, and attach any necessary supporting documents with your submission. Once OHA has received your completed application, staff will contact you regarding any costs or further information. Send this completed form to:

APAC.Admin@dhsoha.state.or.us
Or
Office of Health Analytics - APAC
421 SW Oak Street, Suite 850
Portland, OR 97204

If you have questions while completing this form, please follow these steps:

1. Visit the APAC website for more information about the APAC Reporting Program at http://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx.
2. Visit the APAC Data Request page for more information about the data request process at http://www.oregon.gov/oha/HPA/ANALYTICS/Pages/APAC-Data-Requests.aspx.
3. Review the APAC Frequently Asked Questions to determine if your question has already been answered at http://www.oregon.gov/oha/HPA/ANALYTICS/APAC%20Page%20Docs/APAC-FAQ.pdf.
4. If you still have questions,
    a. Direct questions about APAC or this application to: APAC.Admin@dhsoha.state.or.us
    b. Direct data privacy questions to: dhsprivacy.help@state.or.us
    c. Direct data security questions to: dhsinfo.security@state.or.us

Guidelines for Receiving APAC Data

Before requesting data, please ensure your organization has the capability and resources to import and analyze these data sets. 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.

- APAC data sets will be encrypted and sent in delimited text files over secure FTP. Public Use data sets are tab-delimited; Limited and Custom data sets are pipe-delimited.
- APAC data sets can be as large as 85 GB *per year* of data. For example, an All Pharmacy Claims file for 2013 contains more than 37 million rows and is 6 GB; a 2014 All Medical Claims file contains more than 111 million rows and is 41 GB; and an Episodes of Care file for 2015 will comprise over 163 million rows and occupies more than 84 GB.
- Software capable of importing and analyzing APAC data sets includes SAS, SQL Server, R, and SPSS. APAC data sets are generally too big for Microsoft Excel and Access.
- Requesters should review the most recent APAC Data Issue Log on the APAC Data Request webpage. This is a log of known issues in APAC data and requesters should anticipate the effects of these issues on their projects—and caveat their analyses accordingly. The log is updated as new issues are identified and/or known issues are corrected.

Data Request Review Process

For Limited and Custom data sets, OHA will review this form for completeness and to ensure the minimum amount of data necessary is requested. Once the request passes OHA's initial review, it will be sent to the Data Review Committee (DRC) for further evaluation. Applications requesting direct identifiers may also require review by the Department of Justice (DOJ). After the application passes these reviews, OHA makes the final determination to grant or deny the data request.

The DRC is an advisory body convened by OHA that evaluates requests for Limited and Custom data sets to help determine whether applications comply with state and federal guidelines for using APAC data. At a minimum, the DRC evaluates requests for whether:

- Proposed project purpose is allowable under OHA policies and state and federal laws;
- IRB documentation is required and if submitted, sufficient;
- Proposed privacy and security protections are sufficient;
- Minimum amount of data necessary to complete the project is requested;
- Further clarification is needed.

The DRC meets monthly and reviews requests in the order received (the meeting schedule is posted on the DRC website). Applications are posted for public comment for at least two weeks prior to DRC review. If an application is received within two weeks of the next DRC meeting, it will not be reviewed until the next month's DRC meeting. The DRC may ask the requester for additional information before completing their review. OHA strongly encourages requesters to thoroughly complete the application as soon as possible to account for unanticipated delays. Requests for Limited data sets typically take 2-4 months to complete. Requests for Custom data sets typically take 2-6 months to complete.

SECTION 1: PROJECT INFORMATION

1.1 Contact Information: Please provide the project contact information below.

Applicant name (Principal Investigator or Director of project): Maria Rodriguez, MD, MPH

Title: Improving access to care through pharmacist prescription of hormonal contraception

Organization: OHSU

Address: 3181 SW Sam Jackson Park Rd.

City: Portland State: OR Zip: 97239

Phone: 503-494-8311

Email: rodrigma@ohsu.edu (Additional contact: Rani George; georgra@ohsu.edu)

Application Date: 10/4/18

1.2 Project Staff: Please list any additional staff who will be working on this project. (List only staff who will have direct access to the data.)

Name:	Menolly Kaufman	Role:	Research Associate	Email:	harme@ohsu.edu
Name:	Kim Yee	Role:	Research Associate	Email:	yeki@ohsu.edu
Name:	Matt Goerg	Role:	Senior Research Assistant	Email:	goerg@ohsu.edu
Name:	Kyle Tracy	Role:	Statistical Analyst	Email:	tracyk@ohsu.edu
Name:	Thomas Meath	Role:	Research Associate	Email:	meath@ohsu.edu
Name:	Konrad Dobbertin	Role:	Research Associate	Email:	dobberti@ohsu.edu
Name:	Christina Charlesworth	Role:	Research Associate	Email:	charlesw@ohsu.edu
Name:	Jiaming Huang	Role:	Senior Research Assistant	Email:	huanjiam@ohsu.edu
Name:	John McConnell	Role:	Director	Email:	mconnjo@ohsu.edu

Section 2: Project Summary

2.1 Project title: Improving access to care through pharmacist prescription of hormonal contraception

2.2 Project Purpose:

a. Describe the purpose of the project.

The purpose of the project is to evaluate Oregon's 2016 policy to allow pharmacists to prescribe hormonal contraception (HC) without a clinic visit. The study will evaluate effect of pharmacist prescription of HC on prevention of unintended pregnancies and 12-month contraceptive continuation rates.

In passing House Bill 2879 in 2016, Oregon became the first of seven states to allow pharmacists to directly prescribe hormonal contraception ("HC"), including the pill, patch, or ring, without a clinic visit. Two years following the passage of this policy, the majority of retail pharmacists across the state of Oregon are now certified by the Board of Pharmacy to prescribe HC.

To identify the impact of this policy, we need to evaluate the implementation of the policy, and its effect on unintended pregnancy. Pharmacist participation is voluntary, so full implementation of the policy, and access to contraception in pharmacies will not occur without their enthusiastic support. In this study, we will identify motivators and barriers for pharmacists in prescribing contraception, and obtain their input on interventions to facilitate their participation. To measure the effect of the practice on unintended pregnancy rates, a robust, yet simple, surveillance system is needed. We will modify and test a method to actively monitor the safety, efficacy and acceptability of women accessing HC directly from pharmacists.

We will utilize two distinct and complementary methodologies to evaluate the effect of pharmacist prescription of HC on prevention of unintended pregnancy and 12-month contraceptive continuation rates. We will conduct a prospective clinical cohort study to directly measure the impact on contraceptive continuation, rates of unintended pregnancy, and to understand who is accessing contraceptive care in pharmacies. We will concurrently undertake a retrospective cohort study using medical claims data (APAC) to evaluate the state level effect of the policy. The combination of these methodologies allows us to identify key individual measures, such as pregnancy intention and usual place of care, while also examining the impact of pharmacist prescription of HC at the state level.

b. Describe how the project supports OHA's mission and aims (stated below).
   - OHA mission: Helping people and communities achieve optimum physical, mental and social well-being through partnerships, prevention, and access to quality, affordable healthcare.
   - OHA Aims:
     - Improving the lifelong health of Oregonians;
     - Increasing the quality, reliability, and availability of care for all Oregonians;
     - Lowering or containing the cost of care so it's affordable to everyone.

Reduction of unintended pregnancy is important to both improve health and reduce public costs. Pharmacist prescription of HC is a strategy that can both reach new contraceptive users and improve continuation rates among existing users by removing the barrier of a clinic visit. Pharmacist prescription of HC expands the scope of pharmacists who choose to participate in the program to screen women and to prescribe HC. A national survey of women at risk of unintended pregnancy found that 68% of women were interested in using pharmacies to directly access HC without a prescription. Several studies have established that women can self-screen and non-physicians can safely evaluate for contraindications to HC use.

2.3 Research Questions: What are the key research questions or hypotheses of the project?

Aim 1. Estimate the effect of pharmacist prescription of hormonal contraception (HC) on women's convenient access to care.

Hypothesis 1a. As compared with clinician-only prescription, pharmacist prescription of HC will: 1) increase number of women who are new users of HC, and 2) increase the supply of HC dispensed at each visit among reproductive age women with public and private insurance.
Hypothesis 1b. The average out-of-pocket payments for HC will not be different among women who receive HC from pharmacists compared with clinicians.
Hypothesis 1c. Women who receive HC from a pharmacist will find services as acceptable as women who receive HC from clinicians.

Aim 2 Compare the safety of HC prescriptions from pharmacists with clinicians.

Hypothesis 2a. Women with contraindications to estrogen use who receive HC from pharmacists will be less likely to be prescribed a combined (estrogen-containing) contraceptive compared to women who receive

2.4 Methodology: Describe the proposed methodology and analytic plan for the project (you may attach a 1-3 page description). Be sure to include in your description:

- Proposed sample selection algorithm;
- Any filters that will be used to limit the data requested, such as: year, zip code, age range, procedure codes, diagnosis codes, etc. Refer to the Data Element Workbook for a list of standard filters (you may include additional filters.);
- Why the proposed analytic methods were chosen.

The purpose of the project is to evaluate Oregon's 2016 policy to allow pharmacists to prescribe hormonal contraception (HC) without a clinic visit. The study will evaluate effect of pharmacist prescription of HC on prevention of unintended pregnancies and 12-month contraceptive continuation rates.

In passing House Bill 2879 in 2016, Oregon became the first of seven states to allow pharmacists to directly prescribe hormonal contraception ("HC"), including the pill, patch, or ring, without a clinic visit. Two years following the passage of this policy, the majority of retail pharmacists across the state of Oregon are now certified by the Board of Pharmacy to prescribe HC.

2.5 Products or Reports:

a. Describe the intended product or report that will be derived from the requested data and how this product will be used.

The findings may be disseminated in journal publications. We will work closely with the Oregon Health Authority and the Oregon Board of Pharmacy to share findings for any policy briefs, fact sheets and other materials with a broad audience.

b. Will the results of this project be publicly available and free of cost?

☒ Yes ☐ No

If no, please explain.

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

a. Anticipated Start Date:
b. Anticipated Publication/Release Date: Start date: 10/1/18; End date:9/30/21; Pub date: 10/30/22
c. Anticipated End Date:

2.7 Funding Source:

a. What is the project's funding source?

Grant from the Laura and John Arnold Foundation

b. Disclose all actual and potential conflicts of interest.

None

2.8 Organizational Experience: Briefly describe your organization and the organization's experience with projects of similar scope.

The Center for Health Systems Effectiveness (CHSE) has extensive experience analyzing claims data and preparing large-scale evaluations of the health care systems. We have produced analyses for the state on behalf of the Sustainable Healthcare Expenditures Workgroup, Oregon's State Innovation Model, and Oregon's CCO Medicaid 1115 Waiver.

2.9 Third Parties: Do you intend to engage any third parties in this project?

☒ Yes ☐ No

If yes, please describe the organization(s) and their role in the project. If any third parties will be handling APAC data, those staff must be listed in Section 1.2 Project Staff.

A key collaborator will be the Oregon State University's College of Pharmacy. They will provide NPIs of all pharmacists certified to prescribe HC in Oregon. They will not access APAC data.

SECTION 3: DATA SHARING AUTHORIZATION

3.1 Direct identifiers. What level of data identifiers are you requesting (***choose only one***)?

☒ Protected health information, but no direct identifiers (as outlined in 45 CFR 164.514(e)).

☐ 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 may require specific approvals, such as Institutional Review Board (IRB) approval, patient consent, and/or review by the Department of Justice.

3.2 Covered Entity: Is applicant part of a covered entity?

☒ Yes ☐ No

3.3 Purpose of Data Request:

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

☒ 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)

☐ Work done on OHA's behalf by a Business Associate (refer to 45 CFR 160.103 for definition). If an OHA contract exists for the work in which data is needed, purpose of request is most likely a business associate request.)

☐ Treatment of patient by health care provider (refer to 45 CFR 164.506 (c)(2) for definition)

☐ Payment activities performed by covered entity or health care provider (refer to 45 CFR 164.506 (c)(3) for definition)

b. Justify how the project falls into the category chosen above (3.2a).

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

As explained in Section 2.2b, this proposed project will conduct research that is meant to further OHA's mission and aims.

3.4 Human Subjects Research: Human subjects research is subject to approval by your organization's Institutional Review Board.

a. Does your project have approval for human subjects research from your organization's Institutional Review Board for this project? (IRB protocol and approval memo are mandatory for all research requests and requests for Medicare FFS data.)

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

If yes, attach IRB application and approval memo and complete parts b-e below.

■ IRB application and approval memo attached.

b. Describe how this application is within the scope of the current IRB approval.

See attached protocol. IRB approval includes APAC cohort analysis.

c. Describe why the approving IRB has jurisdiction over this project.

The study will be conducted under OHSU research and only takes place in Oregon. OHSU has conducted numerous health services research studies with APAC data under OHSU IRB.

d. 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):

This is a retrospective review of several million subjects' claims data spanning several years. Obtaining written consent from each individual would not be possible. Therefore, we are seeking waived consent.

e. On what date does the IRB approval expire?

The IRB expires on May 14, 2019.

SECTION 4: DATA ELEMENTS

4.1 Limited Data Sets. Refer to the Data Element Workbook for more information about the data elements included in each Limited data file. *Please note*: OHA will only provide the minimum necessary required data for the project at hand. In other words, you will only receive those data elements that you request and adequately justify.

a. Are you requesting a Limited data set?

☐ Yes ■ No

If yes, please complete parts b and c below.

b. In the table below, indicate which Limited data file(s) you are requesting (refer to Section 6 for the cost of each file).

		Payer					
		All Payers[1]	Medicaid	Medicare Advantage	Commercial Insurance	OEBB/ PEBB[2]	Medicare FFS[3]
Claims Data File	Episodes of Care[4]	☐	☐	☐	☐	☐	☐
	All Medical Claims[5]	☐	☐	☐	☐	☐	☐
	Hospital Inpatient Claims	☐	☐	☐	☐	☐	☐
	Emergency Department Claims	☐	☐	☐	☐	☐	☐
	Ambulatory Surgery Claims	☐	☐	☐	☐	☐	☐
	Ambulatory Outpatient Claims	☐	☐	☐	☐	☐	☐
	All Pharmacy Claims	☐	☐	☐	☐	☐	☐

c. Please indicate the year(s) requested for the data files selected above.

☐ 2011 ☐ 2012 ☐ 2013 ☐ 2014 ☐ 2015 ☐ 2016

[1] All Payers includes Medicaid, Medicare Advantage, and Commercial Insurance (including OEBB/PEBB).
[2] OEBB/PEBB is a subset of Commercial Insurance and will be included in requests for "All Payers" and "Commercial Insurance". Choose OEBB/PEBB if you want this specific subset of payer data only,
[3] Medicare FFS data will only be given to projects in which OHA is funding and directing. Projects requesting Medicare FFS data will also need to be approved by requester's Institutional Review Board.
[4] Episodes of Care file contains all medical claims, all pharmacy claims, and fields from the Medical Episode Grouper (MEG). MEG is a proprietary grouping algorithm that creates episodes that describe a patient's complete course of care for a single illness or condition. If requesting Episodes of Care file, no other data file is needed.
[5] All Medical Claims file includes hospital inpatient, emergency department, ambulatory surgery and ambulatory outpatient claims, and other hospital treatment settings. If requesting all medical claims, you do not need to request these other data sets.

4.2 Custom Data Sets. Refer *Data Elements Collected by APAC* section of the APAC Data User Guide to view elements that are available in APAC. *Please note:* OHA will only provide the minimum necessary data for the project. In other words, you will only receive those data elements that you request and adequately justify.

a. Are you requesting a Custom data set?

■ Yes ☐ No

4.3 Data Element Workbook: For both Limited and Custom data set requests, please complete the Data Element Workbook according to the instructions on the "Instructions" tab, including providing a justification for each element requested, and attach it to this application.

■ Data Element Workbook completed and attached, including justifications for each element requested and payers tab completed.

4.4 Minimum Necessary Requirement: In addition to providing justification for each data element requested in the data element workbook, please explain why the project could not be conducted without the requested APAC data:

The study will use data on health care spending for millions of Oregonians, including spending by commercial, Medicaid, Medicare Advantage, and Medicare fee-for-service coverage. Obtaining authorization from each individual would be logistically and financially unfeasible.

As explained in Section 2.4, this study requests the minimum necessary data. We have limited our request to females aged 12-51 during the study year. We have requested medical and pharmacy claims for this cohort in order to ascertain medical history and build comorbidity indices and risk scores. Because OHSU has clinical experts who will be reviewing aggregate data results, OHSU/CHSE will implement exclusion criteria and clinical algorithms in-house in order to reflect iterative decisions from these clinical experts.

One of CHSE's core values is transparency. In keeping with this core value, we will readily submit all code documentation related to creation of our analytic datasets and data analyses to assure OHA we are purposefully and responsibly using the data requested.

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).

We will omit statistics or analysis of subgroups based on fewer than 50 individuals from any publications. We do not anticipate that stratifications planned for this study (e.g., analysis of data by type of service or geography, such as county) will result in subgroups of fewer than 50 individuals.

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.

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? *Please note:* Linking at the individual patient level is only allowed in certain circumstances, and should be strongly justified.
   Aggregate ☐ Facility ■ Patient ☐

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

A key collaborator will be the Oregon State University's College of Pharmacy. They will provide NPIs of all pharmacists certified to prescribe HC in Oregon. They will not access APAC data. Because describing providers--both pharmacists and clinicians--is a key component of this study, CHSE will conduct the linkage of provider attributes in the OSU file to providers in the APAC file. OSU researchers will not have access to any APAC data.

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

We are only linking on a single variable (NPI) for providers, not patients, which minimizes re-identification. We will be reporting our results in aggregate form. All OHSU staff have training and follow strict rules on confidentiality and privacy through the OHSU Research Integrity program.

5.3 Data Security:

a. Attach copies of data privacy and security policies for the requesting organization and any third-party organizations that may have access to the requested data.

■ Data privacy and security documents attached.

b. Describe your plans to manage access to the APAC data throughout the duration of the project, including:
   - Ensuring compliance with all applicable federal and state laws and regulations regarding privacy and security of PHI and electronic health information, including but not limited to HIPAA and the HITECH Act;
   - Ensuring any third parties accessing the data agrees to the same terms and conditions for securing and protecting the data as the requesting organization;
   - Designation of a single individual as "Custodian" of APAC data, responsible for oversight of APAC data, reporting any breaches to OHA, and ensuring data is properly destroyed upon project completion.

Throughout this project, data will be managed according to OHSU's data privacy and security policies. These include Policies 01-05-012: Confidentiality of Health Information and ISD-700-00001: Information Security Rule (attached). The following text highlights specific policies that will be used to manage the data: All data will be transmitted via secure file transfer protocol and stored on secure servers. Only staff listed on the data use agreement (DUA) and IRB protocol for this study will have access to the data. Staff will only be able to access the data through OHSU's network, which requires use of strong passwords. Data will be analyzed using standard statistical computing applications on the secure servers, and will be destroyed within 60 days of project completion.

c. Describe your personnel safeguards, including:
    - Procedures to restrict access to only those individuals with a need to know the information maintained in the requested data, and limit access to only the minimum data necessary;
    - Training for project personnel on how to properly manage protected health information and electronic health information;
    - Confidentiality agreements in place with all project personnel;
    - Written agreements in place with project personnel to follow organizational security and privacy policies, including a security risk management plan for APAC data.

OHSU staff complete annual research integrity training, which includes data security and confidentiality. Staff treat all data containing individually identifiable information as confidential, and never transfer such data electronically via email or other means. Staff shred any paper records containing individually identifiable information (however, CHSE does not anticipate that paper records will be used for this study). Only staff listed on the DUA for this study will have access to the data. All staff listed on the DUA will have APAC research experience and familiarity with guidelines and regulations pertaining to the data.

d. Describe your technical and physical safeguards, including:
   - Procedures to keep APAC data encrypted at rest and in transit;
   - Procedures for restricting transmission of APAC data, and method for secure transmission if needed;
   - User account controls, such as password protections, maximum failed login attempts, lockout periods after idle time, user audit logs, etc.;
   - Electronic device protections, such as anti-virus or anti-malware software, firewalls, and network encryption;
   - Procedures for restricting remote access to APAC data, and using encrypted connections if necessary to access data remotely;
   - Procedures for storing hard copy data, such as locked file cabinets and offices;
   - If applicable, procedures for handling direct identifiers, including storing identifiers separately from other APAC data.

Data will be transmitted electronically following secure file transfer protocols established between OHSU and OHA. All files will be stored on secure servers at OHSU's Advanced Computing Center,which includes extensive physical and technical safeguards. Files will only be accessible by individuals listed in this agreement by login with a unique ID and password combination.

e. Describe your administrative safeguards. You may refer to specific sections in the attached organizational privacy and security policies.

Only individuals listed on this agreement will have access to the data, which is stored on OHSU's network behind OHSU's firewall. Individuals will only be able to access the data through OHSU's network which requires authentication through use of strong passwords.

f. What tools and applications do you plan to use to access the data?

We plan to use several statistical packages to analyze and access the data: SAS, Stata, and R.

g. Data must be destroyed within 60 days after the completion of the project, 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 project has completed?

Data will be destroyed within 60 days of project completion by deleting data and wiping the hard drive so that no information can be recovered.

h. Does any of the staff working on this project have a history of data or security breach?

☐ Yes ■ No

If yes, what procedures have been implemented to prevent future breach?

SECTION 6: COST OF DATA

6.1 Cost of Data: If requesting a Limited data set, please calculate the cost below. (This table should match the files/years selected in Section 4.) ***Please include payment with the application.*** Checks should be made to Oregon Health Authority and will not be cashed until application is approved. If requesting a Custom data set, an invoice will be sent if/when OHA approves request.

		Payers					
		All Payers	Medicaid	Medicare Advantage	Commercial Insurance	OEBB/PEBB	Medicare FFS
Claims Data File	Episodes of Care	☐ $3,000	☐ $1,000	☐ $1,000	☐ $1,000	☐ $1,000	☐ $1,000
	All Medical Claims	☐ $1,500	☐ $500	☐ $500	☐ $500	☐ $500	☐ $500
	Hospital Inpatient	☐ $375	☐ $125	☐ $125	☐ $125	☐ $125	☐ $125
	Emergency Department Claims	☐ $375	☐ $125	☐ $125	☐ $125	☐ $125	☐ $125
	Ambulatory Surgery Claims	☐ $375	☐ $125	☐ $125	☐ $125	☐ $125	☐ $125
	Ambulatory Outpatient Claims	☐ $375	☐ $125	☐ $125	☐ $125	☐ $125	☐ $125
	All Pharmacy Claims	☐ $1,500	☐ $500	☐ $500	☐ $500	☐ $500	☐ $500
	a. Total each column						
	b. Add column totals						
	c. Enter number of years of data requested						
	d. Multiply rows b and c						
	e. OHA Production Cost	$560					
	f. Add rows d and e for Total Payment						

☒ **Check box if payment is not included because Custom data set is requested.**

☐ **Check box if payment is not included for another reason. Please explain.**

SECTION 7: CHECKLIST AND SIGNATURE

7.1 Checklist: Please indicate that all of the following have been completed:

- ■ All questions are answered completely.
- ■ Data Element Workbook with justifications is attached, including justifications for each element requested and payers tab completed.
- ■ IRB approval memo is included, if applicable. (IRB protocol and approval memo are mandatory for all research and requests for Medicare FFS data.)
- ■ Copies of data privacy and security policies for the requesting organization, and any third-party organizations, are attached.
- ■ Payment is included, if applicable. If requesting a Custom data set, an invoice will be sent at a later date.
- ■ Requester has the capability and resources to import and analyze these data sets. (See Guidelines for Receiving APAC data on page 2 of this application.) 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.
- ■ Requester has reviewed the most recent APAC Data Issue Log on OHA's website. This is a log of known issues in APAC data and requesters should anticipate the effects of these issues on their projects and caveat their analyses accordingly. The log is updated as new issues are identified and/or known issues are corrected.

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

Applicant Signature (Project PI or Director)

11/8/18
Date

Rodriguez

Return completed form to APAC.Admin@dhsoha.state.or.us.

Completed form may also be printed and mailed to:
APAC Program Manager
Office of Health Analytics
421 SW Oak St., Suite 850 – APAC
Portland, OR 97204

Staff Use Only

Application Number: _____
(Should correspond with APAC-2 Pre-Application Number)

The Oregon State Legislature authorized APAC in 2009 to measure and improve the quality, quantity, cost and value of health care services. Oregon Revised Statutes and Administrative Rules provide guidelines for APAC data collection, use and release and the Oregon Health Authority (OHA) is responsible for APAC oversight. APAC contains protected health information and data that identifies people. OHA is responsible for ensuring compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the protection of people's health information, identity and privacy. OHA ensures that data requests comply with HIPPA, protect the privacy of members and their health information, are justified and that OHA shares only the minimum necessary data.

The purpose of the data elements workbook is for data requesters to specify APAC data options and provide the justification for each APAC data element requested for their project described in their APAC3 application. OHA uses the data elements workbook and the APAC3 data request application to assess HIPPA compliance and risks and to determine if the projects meets the APAC data use and release guidelines. **Data requesters must complete the data request options worksheet and the data elements worksheet in the data elements workbook and submit the workbook with their APAC3 application.**

Please answer each of the following questions about APAC data request options and submit with your APAC data request:

Please indicate the year(s) of data requested	2011	2012	2013	2014	2015	2016	2017
			x	x	x	x	x

Do you want out-of-state people included in claims & elligibility data?	Yes	No
		x

Do you want denied claims included?	Yes	No
		x

Do you want orphan claims included?	Yes	No
		x

Do you want self-insured eligibility and claims data included?	Yes	No
	x	

Do you want PEBB and OEBB eligibility and claims data included?	Yes	No
	x	

Do you want to limit claims by allowed amount?	No	Yes, limit to greater than zero	Yes, limit to greater than or equal to zero
	x		

What payer types do you want?	Commercial	Medicaid	Medicare (commercial only)	CMS Medicare (Restricted access. Available to OHA only)
	x		x	

What medical claim types do you want?	All medical claims	Inpatient hospital	Emergency department	Outpatient	Ambulatory surgery	Ambulance	Transportation	Hospice	Skilled Nursing Facility
		x	x	x	x				x

Do you want professional services included with the medical claim types?	Yes	No
	x	

Do you want pharmacy claims?	Yes	No
	x	

Do you want monthly eligibility data?	Yes	No
	x	

Do you want member demographic data?	Yes	No
	x	

Do you want provider data?	Yes	No
	x	

Do you want billed premium data?	Yes	No

Do you want billed premium data?		x

Do you want claims and eligibility data for selected age groups only?	All ages	Exclude people 65 yrs and older	Specify age requested:
			12-51

Do you want to limit claims and eligibility data by gender?	Include all	Include only female	Include only male
		x	

Do you want to limit medical claims data to selected diagnoses?	No	Yes. List diagnosis codes
	x	

Do you want to limit pharmacy data to selected NDC codes or therapeutic classes?	No	Yes. List NDC codes or therapeutic classes codes
	x	

Are you requesting identifiable data?	No	Zip code	County	Address	Name	Month of birth	Month of death	Date of birth	Date of death
		x	x			x			

The APAC data elements workbook is organized by the APAC data structure described in the APAC User Guide and Data Dictionary: claims, member static demographics, monthly eligibility, provider data and billed premiums. Data elements available for both medical and pharmacy claims are listed first and followed by data elements available only for medical claims, only for pharmacy claims, monthly eligibility, demographics provider data and billed premiums. Description and values are listed for each data element. A check mark in the payer reported column indicates that the data element was reported directly by payers.The payer reported threshold column indicates the amount of missing or data error allowed in the quarterly data submission. A check mark in the public use data column indicates that the data element is in public use data sets. A check mark in the limited column indicates the data element is available for a limited data request. Data elements with no check mark in the limited column are only available by custom data request. Data elements with restricted or limited access are listed last and require more detailed information about the purpose and data security and may be subject to review by the Oregon Department of Justice.

Instructions: Mark each data element requested with an X in the first column. Delete all data elements not requested. Provide a justification for each data element requested in the last colum. Save the data elements workbook and attach to your APAC data request.

Mark requested data elements with an X in this column	Data Element	Description	Values	Payer Reported	Payer Reported Threshold	Vendor Created	Public Use Data	Limited data	Justification	Modification-limitation
	Data Elements Available for Both Medical and Pharmacy Claims:									
x	Fromdate or fill date or from_date	Service begin date or pharmacy fill date	YYYY-MM-DD	x	0.0%			x	Needed to understand utilization patterns (e.g. whether a prescription for drug X occurred after a diagnosis of Y)	
x	Todate or to_date	Service end date	YYYY-MM-DD	x	0.0%			x	Needed to understand utilization patterns (e.g. whether office visit was within a certain time period of a pregancy or contraception initiation.)	
x	Personkey or MI_Person_key	Unique identifier created for a person across payers and years	Numeric			x		x	Needed to identify services for the same individual	
x	Clmid or Claim_ID_Key	Payer specific claim identifier created from the payer reported claim identifier. Not unique across payers and years. Claims can have one or more service lines per identifier. There are some claims without an identier 2011-2013 (null identifier). The ID is Zero (0) when the claim row is incurred but not reported (IBNR) and not an actual claim	Numeric			x		x	Needed to de-duplicate claim lines	
x	Claim line or SV_line	Claim service line number	Numeric	x	0.0%			x	Needed to de-duplicate claim lines	
x	CS_Claim_ID_key	Vendor proprietary Health care grouper (HCG) determined continous stay claim identifier in an inpatient facility	Numeric			x		x	Used as part of an algorithm to determine service setting, particularly when other fields that identify service (e.g. POS, rev_code) are missing. Service setting will be used to assess changes to how women access contraceptive care.	
x	clmstatus or sv_stat	Claim status	P, D, E, R	x	0.0%			x	Needed to de-duplicate claim lines	
x	hcg or HCG_MR_line	HCG is the lowest level of the vendor health care grouping system	See HCG table			x	x	x	Used as part of an algorithm to determine service setting, particularly when other fields that identify service (e.g. POS, rev_code) are missing. Service setting will be used to assess changes to how women access contraceptive care.	
x	HCG_Setting	Highest level of the HCG system. One of five categories	1 (inpatient), 2 (outpatient), 3 (professional), 4 (prescription drug), 5 (ancillary) See HCG table			x			Used as part of an algorithm to determine service setting, particularly when other fields that identify service (e.g. POS, rev_code) are missing. Service setting will be used to assess changes to how women access contraceptive care.	
x	qtydisp or quantity or qty or SV_Units	Quantity or count of services delivered; Revenue code count for inpatient hospitalization and CPT count for outpatient services; Quantity of pharmaceutical dispensed	Numeric	x	0.0%	x	x	x	Needed to analyze utilization	
x	APAC_Product_code	Payer reported product code from claims data	See product code table	x	0.0%		x		Needed for analysis separating individuals covered under HMO plans vs. individuals covered in PPO plans	
x	Age_on_DOS	age on date of service	Numeric			x			Extra layer of validation to ensure we are only capturing services for age-eligible individuals	

x	Attid or att_prov_key	Vendor created unique identifier for attending, rendering or pharmacy provider based on payer reported unique identifier. Identifier is payer specific and not unique across payers or years	Numeric		1.2%	x		x	Used to link contraceptive services claims to specific provider NPI and specialty in the provider table. For justification of NPI and specialty, see "Provider Data" element justifications.	
x	ATT_PROV_CW_KEY	Vendor created unique attending provider identifier across payers and years				x			Needed to link clinicians across payers and years	
x	Billid	APAC assigned billing provider ID	Text	x	1.2%			x	Needed to track where patients are receiving contraception care.	
x	Entity or bill_prov_name	Name of the entity that generated the bill for the service. Medical billing provider or pharmacy name. Name is payer specific and not unique across payers or years	Text	x				x	If attributable provider is missing, pharmacy name will be checked for valid value	
x	COB or COB_stat	Coordination of benefit claim	Y (yes), N (no)	x	1.2%			x	Needed to adjust for individuals with coverage from multiple plans	
x	Paid or amt_paid	Payment made by payer. Does not include expected copayment, coinsurance and deductible that patient is responsible to pay to the provider	Two decimal places. 0 if amount equals zero. Blank if missing.	x	0.0%		x	x	Needed to track expenditures (independent variable for access to pharmacist-prescribed HC outcome)	
x	Copay or amt_copay	Expected Co-payment by the member	Two decimal places. 0 if amount equals zero. Blank if missing.	x	0.0%			x	Needed to provide granularity on beneficiaries' copay for HC (independent variable for access to pharmacist-prescribed HC outcome)	
x	Coins or amt_coins	Expected Co-insurance by the member	Two decimal places. 0 if amount equals zero. Blank if missing.	x	0.0%			x	Needed to provide granularity on beneficiaries' coinsurance for HC (independent variable for access to pharmacist-prescribed HC outcome)	
x	Deduct or amt_deduct	Expected Deductible by the member	Two decimal places. 0 if amount equals zero. Blank if missing.	x	0.0%			x	Needed to provide granularity on beneficiaries' deductible for HC (independent variable for access to pharmacist-prescribed HC outcome)	
x	OOP or amt_pat_paid	Expected Patient paid amount. Amount patient paid. Required if co-payment, co-insurance or deductible are missing	Two decimal places. 0 if amount equals zero. Blank if missing.	x	0.0%		x	x	Needed to provide granularity on beneficiaries' OOP expenses for HC (independent variable for access to pharmacist-prescribed HC outcome)	
	Data Elements Avaliable Only for Medical Claims:									
x	TOB or UB_bill_type	Type of bill on the uniform billing form (UB)	See type of bill table	x	1.2%			x	Needed to categorize claims by service setting and type	
x	POS	Industry standard place of service code	See place of service table	x	1.2%		x	x	Needed to categorize claims by service setting and type	
x	ICD version or ICD_10_OR_HIGHER	Specifies the claim ICD version ICD9 or ICD10	9 or 10	x	0.0%		x	x	The U.S. transitioned from ICD-9 to ICD-10 codes in October 2015. This element is needed to identify diagnosis and procedure codes under the new system.	
x	dx1 or ICD_DIAG_01_Primary	Principal diagnosis. ICD-9 for dates of service before 10/01/2014 and ICD-10 after	Alphanumeric	x	1.2%		x	x	Diagnoses codes, along with procedure codes and NDC, are required to calculate comorbidity indicators, flag contraindicated conditions, and ascertain medical history. See "Additional Notes and Justification" section in APAC-3	
x	dx1 description or ICD_DIAG_DESC_PRIMARY	Primary diagnosis description	Text			x			While not all diagnosis codes are populated for every claim, codes from dx2 through dx13 improve accuracy of comorbidity measures.	

x	dx2 or ICD_DIAG_02	Principal diagnosis. ICD-9 for dates of service before 10/01/2014 and ICD-10 after	Alphanumeric	x	1.2%			x	While not all diagnosis codes are populated for every claim, codes from dx2 through dx13 improve accuracy of comorbidity measures.	
x	dx3 or ICD_DIAG_03	Principal diagnosis. ICD-9 for dates of service before 10/01/2014 and ICD-10 after	Alphanumeric	x	1.2%			x	While not all diagnosis codes are populated for every claim, codes from dx2 through dx13 improve accuracy of comorbidity measures.	
x	dx4 or ICD_DIAG_04	Principal diagnosis. ICD-9 for dates of service before 10/01/2014 and ICD-10 after	Alphanumeric	x	1.2%			x	While not all diagnosis codes are populated for every claim, codes from dx2 through dx13 improve accuracy of comorbidity measures.	
x	dx5 or ICD_DIAG_05	Principal diagnosis. ICD-9 for dates of service before 10/01/2014 and ICD-10 after	Alphanumeric	x	1.2%			x	While not all diagnosis codes are populated for every claim, codes from dx2 through dx13 improve accuracy of comorbidity measures.	
x	dx6 or ICD_DIAG_06	Principal diagnosis. ICD-9 for dates of service before 10/01/2014 and ICD-10 after	Alphanumeric	x	1.2%			x	While not all diagnosis codes are populated for every claim, codes from dx2 through dx13 improve accuracy of comorbidity measures.	
x	dx7 or ICD_DIAG_07	Principal diagnosis. ICD-9 for dates of service before 10/01/2014 and ICD-10 after	Alphanumeric	x	1.2%			x	While not all diagnosis codes are populated for every claim, codes from dx2 through dx13 improve accuracy of comorbidity measures.	
x	dx8 or ICD_DIAG_08	Principal diagnosis. ICD-9 for dates of service before 10/01/2014 and ICD-10 after	Alphanumeric	x	1.2%			x	While not all diagnosis codes are populated for every claim, codes from dx2 through dx13 improve accuracy of comorbidity measures.	
x	dx9 or ICD_DIAG_09	Principal diagnosis. ICD-9 for dates of service before 10/01/2014 and ICD-10 after	Alphanumeric	x	1.2%			x	While not all diagnosis codes are populated for every claim, codes from dx2 through dx13 improve accuracy of comorbidity measures.	
x	dx10 or ICD_DIAG_10	Principal diagnosis. ICD-9 for dates of service before 10/01/2014 and ICD-10 after	Alphanumeric	x	1.2%			x	While not all diagnosis codes are populated for every claim, codes from dx2 through dx13 improve accuracy of comorbidity measures.	
x	dx11 or ICD_DIAG_11	Principal diagnosis. ICD-9 for dates of service before 10/01/2014 and ICD-10 after	Alphanumeric	x	1.2%			x	While not all diagnosis codes are populated for every claim, codes from dx2 through dx13 improve accuracy of comorbidity measures.	
x	dx12 or ICD_DIAG_12	Principal diagnosis. ICD-9 for dates of service before 10/01/2014 and ICD-10 after	Alphanumeric	x	1.2%			x	While not all diagnosis codes are populated for every claim, codes from dx2 through dx13 improve accuracy of comorbidity measures.	
x	dx13 or ICD_DIAG_13	Principal diagnosis. ICD-9 for dates of service before 10/01/2014 and ICD-10 after	Alphanumeric	x	1.2%			x	While not all diagnosis codes are populated for every claim, codes from dx2 through dx13 improve accuracy of comorbidity measures.	
x	px1 or ICD_Proc_01_Principle	The main or principal inpatient surgery ICD code	Alphanumeric	x	1.2%		x	x	Needed to characterize patient's services received and calculate historical risk score for each patient	
x	px2 or ICD_Proc_02	Inpatient surgery ICD code 2	Alphanumeric	x	1.2%			x	While not all procedure codes are populated for every claim, codes from px2 through px13 are useful for analyzing utilization and quality where populated	
x	px3 or ICD_Proc_03	Inpatient surgery ICD code 3	Alphanumeric	x	1.2%			x	While not all procedure codes are populated for every claim, codes from px2 through px13 are useful for analyzing utilization and quality where populated	
x	px4 or ICD_Proc_04	Inpatient surgery ICD code 4	Alphanumeric	x	1.2%			x	While not all procedure codes are populated for every claim, codes from px2 through px13 are useful for analyzing utilization and quality where populated	

x	px5 or ICD_Proc_05	Inpatient surgery ICD code 5	Alphanumeric	x	1.2%			x	While not all procedure codes are populated for every claim, codes from px2 through px13 are useful for analyzing utilization and quality where populated	
x	px6 or ICD_Proc_06	Inpatient surgery ICD code 6	Alphanumeric	x	1.2%			x	While not all procedure codes are populated for every claim, codes from px2 through px13 are useful for analyzing utilization and quality where populated	
x	px7 or ICD_Proc_07	Inpatient surgery ICD code 7	Alphanumeric	x	1.2%			x	While not all procedure codes are populated for every claim, codes from px2 through px13 are useful for analyzing utilization and quality where populated	
x	px8 or ICD_Proc_08	Inpatient surgery ICD code 8	Alphanumeric	x	1.2%			x	While not all procedure codes are populated for every claim, codes from px2 through px13 are useful for analyzing utilization and quality where populated	
x	px9 or ICD_Proc_09	Inpatient surgery ICD code 9	Alphanumeric	x	1.2%			x	While not all procedure codes are populated for every claim, codes from px2 through px13 are useful for analyzing utilization and quality where populated	
x	px10 or ICD_Proc_10	Inpatient surgery ICD code 10	Alphanumeric	x	1.2%			x	While not all procedure codes are populated for every claim, codes from px2 through px13 are useful for analyzing utilization and quality where populated	
x	px11 or ICD_Proc_11	Inpatient surgery ICD code 11	Alphanumeric	x	1.2%			x	While not all procedure codes are populated for every claim, codes from px2 through px13 are useful for analyzing utilization and quality where populated	
x	px12 or ICD_Proc_12	Inpatient surgery ICD code 12	Alphanumeric	x	1.2%			x	While not all procedure codes are populated for every claim, codes from px2 through px13 are useful for analyzing utilization and quality where populated	
x	px13 or ICD_Proc_13	Inpatient surgery ICD code 13	Alphanumeric	x	1.2%			x	While not all procedure codes are populated for every claim, codes from px2 through px13 are useful for analyzing utilization and quality where populated	
x	proccode or Proc_code	The Current Procedural Terminology (CPT) code or the Healthcare Common Procedure Coding System (HCPCS) code	Alphanumeric	x	1.2%		x	x	Procedure codes needed to identify type of service utilized	
x	mod1	CPT or HCPCS modifier with all digits and numeric codes https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html	See modifiers table	x	1.2%			x	Procedure code modifiers are needed to analyze utilization and quality	
x	mod2	CPT or HCPCS modifier with all digits and numeric codes https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html	See modifiers table	x	1.2%			x	Procedure code modifiers are needed to analyze utilization and quality	
x	mod3	CPT or HCPCS modifier with all digits and numeric codes https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html	See modifiers table	x	1.2%			x	Procedure code modifiers are needed to analyze utilization and quality	
x	mod4	CPT or HCPCS modifier with all digits and numeric codes https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html	See modifiers table	x	1.2%			x	Procedure code modifiers are needed to analyze utilization and quality	
x	revcode or rev_code	Revenue code	Numeric	x	1.2%			x	Needed to categorize claims by service setting and type	

x	msdrg	MS DRG is a Medicare grouping system that classifies inpatient hospital services into one of approximately 750 groups.	Text			x	x	x	Needed to analyze utilization measure (past medical history/dependent variable)	
	Data Elements Available Only for Pharmacy Claims:									
x	NDC	National Drug Code	Text	x	1.2%		x	x	Needed to identify pharmaceutical used	
x	rxdays	Number of days that the drug will last if taken at the prescribed dose	Numeric	x	1.2%		x	x	Needed to characterize prescribing practices	
x	RX_Refills	Count of times prescription refilled	Numeric	x	1.2%				Needed to characterize prescribing practices	
x	rxcompound	Indicates if it is a compound drug	1 (no), 2 (yes) , Null, [0 and 9 are not valid values]	x	1.2%			x	Needed to characterize pharmaceuticals received (so compound drugs are not counted singly)	
x	Pharmacy city	Pharmacy city	Text	x	1.2%				Needed to characterize pharmacy location to better describe pharmacist prescribing practices	
x	Pharmacy zip	Pharmacy zip	Text	x	1.2%				Needed to characterize pharmacy location to better describe pharmacist prescribing practices	
	Data Elements Available for Member Demographic Data (static except for age related data elements):									
x	personkey or MI_Person_key	Unique identifier created for a person across payers and data years	Numeric			x		x	Patient key used to track utilization within enrollees, and to establish population denominator.	
x	gender or Mem_gender	Member Gender	M (male), F (female), and U (unknown)	x	1.2%		x	x	Used to confirm gender restriction	
x	YOB	Member year of birth	YYYY			x		x	Combined with YEARMONTH, this will help us to determine when members age in/out of the cohort	
x	Age	Age of the member calculated based on month of eligibility	Numeric			x			An important independent variable in multivariable modeling. Extract will be limited to only those age 12-55 at any time during the extract year	
	Data Elements Available for Monthly Member Eligibility Data:									
x	YEARMONTH and incurred_year_and_month	Year and month service or eligibility occurred	YYYYMM			x			Enrollment units at the year-month level will allow us to flexibly test results across a spectrum of enrollment lengths	
x	patid and member ID and member_key	Payer specific unique person identifier created from payer reported identifier. Not unique across payers and years	Numeric	x	0.0%				Key to link with patient utilization.	
x	personkey or MI_Person_key	Vendor created unique identifier for a person across payers and years	Numeric			x			Needed to identify unique individual across time	
x	prod or APAC_Product_code	Payer reported product code from eligibility data only and not claims data. No null values	See product code table	x	0.0%				Needed for analysis separating individuals covered under HMO plans vs. individuals covered in PPO plans	
x	MM_UNITS	Flag that indicates medical coverage for the month for the member	Numeric: 1 (yes), 0 (no)			x			Used to test results across a spectrum of enrollment lengths	
x	RX_UNITS	Flag that indicates prescription drug coverage for the month for the member	Numeric: 1 (yes), 0 (no)			x			Used to test results across a spectrum of enrollment lengths	
x	TPA_OR_PBM_DUPLICATE_MM	Identifies duplicate member months reported by third party administrator or pharmacy benefit manager for the month	1 , 2 , 0			x			Used to deduplicate prior to enrollment checks	
x	(tbd)	Field MA offered to create which identifies members with dual Commercial-Medicaid enrollment							Because CHSE is receiving Medicaid data from a different source, OHA will flag those members who have dual Commercial-Medicaid coverage	

x	(tbd)	Field MA offered to create which flags the self-insured members							Due to APAC submission requirements, claims for self-insured members no longer need to be submitted. This results in a big change in APAC demographics. OHA to create a flag to identify the self-insured, and CHSE will decide how to handle these individuals based on utilization patterns and similarity to the rest of the cohort	
	Data Elements Available for Provider Data:									
x	ATT_PROV_CW_KEY	Vendor created unique attending provider identifier across payers	Integer			x			Needed to characterize provider (link from claims table to provider attribute table)	
x	prov_key or ATTID or att_prov_key	Payer specific identifier number for the attending, servicing, or rendering medical or pharmacy provider. Identifier is not unique across payers	Integer		1.2%	x		x	Key to link with attending provider key in claims	
x	Prov_NPI	Provider National Provider Identification (NPI) registry number	Text	x	1.2%				Needed to identify contraception access for patients receiving care from providers at clinics with novel strategies for improving contraception prescribing.	
x	billid	APAC assigned billing provider ID	Text	x	1.2%				Needed to characterize provider (link from claims table to provider attribute table). Will be used if attributable provider absent	
x	Bill_Prov_Key	Unique identifier generated for billing provider	Numeric			x			Needed to characterize provider (link from claims table to provider attribute table). Will be used if attributable provider absent	
	Restricted Access Data Elements that Require Strong Justification and Detailed Data Security and Release Plan:									
x	member month of birth	Member month of Birth	MM			x			Needed only in the instance that the person turned 12 (aged into cohort) or 56 (aged out of cohort) in the year. Having this information at the member (not service) level allows us to include individuals in need of services (the measure denominator) that didn't necessarily receive them.	MOB requested only for members who age to 12 years during a calendar year and members who age to 52 years old during a calendar year
x	MEMBER_COUNTY	Member county of residency derived from zip code. Static from latest quarterly data submitted	Text			x			Needed as an independent variable in statistical models to account for person-level demographic effects and provider (pharmacist) network adequacy	
x	ZIP or member_zip	Static from latest quarterly data submitted	Numeric	x	1.2%				Needed as an independent variable in statistical models to account for person-level demographic effects. We can create an encrypted zipcode file. See "Additional Notes and Justifications" section in APAC-3	Zip code data will be provided in a stand-alone file separate from claims. Zip code data will be used to create geographic area flags designated by the data requester and distance to provider flags. Zip code data will not be accessed after flag creation. Zip code will not be linked to claims directly. No further access to zip code will occur without prior written approval from OHA.

OREGON HEALTH & SCIENCE UNIVERSITY
OHSU

IRB MEMO

Research Integrity Office
3181 SW Sam Jackson Park Road - L106RI
Portland, OR 97239-3098
(503)494-7887 irb@ohsu.edu

APPROVAL OF SUBMISSION

May 15, 2018

Dear Investigator:

On May 15, 2018, the IRB reviewed the following submission:

IRB ID:	STUDY00016158	MOD or CR ID:	MODCR00006261
Type of Review:	Modification and Continuing Review		
Title of Study:	Reducing unintended pregnancy through pharmacist prescription of contraception: the Oregon experience.		
Title of modification	Continuing Review 2018		
Principal Investigator:	Maria Rodriguez		
Funding:	Name: Society of Family Planning (SFP), PPQ #: 1009695; Name: Robert Wood Johnson Fnd, PPQ #: 1009691		
IND, IDE, or HDE:	None		
Documents Reviewed:	• Intro letter - Women receiving contraception • Follow Up Survey for Women • Protocol v1 • Newsletter_v1 • Information_Sheet_for_Pharmacists_v1 • Information_Sheet_for_Women • Flyer_v1 • Pharmacist Interview • Baseline Survey for Women • Website_v1 • Internet_Ad_v1 • Pharmacist Survey		

The IRB granted final approval on 5/15/2018. The study is approved until 5/14/2019.

Review Category: Expedited Category #s 5 and 7

Copies of all approved documents are available in the study's **Final** Documents (far right column under the documents tab) list in the eIRB.

Ongoing IRB submission requirements:

- Six to ten weeks before the expiration date, you are to submit a continuing review to request continuing approval.
- Any changes to the project must be submitted for IRB approval prior to implementation.
- Reportable New Information must be submitted per OHSU policy.
- You must submit a continuing review to close the study when your research is completed.

Guidelines for Study Conduct

In conducting this study, you are required to follow the guidelines in the document entitled, "Roles and Responsibilities in the Conduct of Research and Administration of Sponsored Projects," as well as all other applicable OHSU IRB Policies and Procedures.

Requirements under HIPAA

If your study involves the collection, use, or disclosure of Protected Health Information (PHI), you must comply with all applicable requirements under HIPAA. See the HIPAA and Research website and the Information Privacy and Security website for more information.

IRB Compliance

The OHSU IRB (FWA00000161; IRB00000471) complies with 45 CFR Part 46, 21 CFR Parts 50 and 56, and other federal and Oregon laws and regulations, as applicable, as well as ICH-GCP codes 3.1-3.4, which outline Responsibilities, Composition, Functions, and Operations, Procedures, and Records of the IRB.

Sincerely,

The OHSU IRB Office

Reducing unintended pregnancy through pharmacist prescription of contraception: the Oregon experience

Principal Investigator: Maria I. Rodriguez, MD MPH

eIRB # 16158

Protocol Version 2.0

1) Objectives:

Aim 1: To determine facilitators and barriers for pharmacists participating in direct HC provision by documenting their experience with the program. A longitudinal survey of Oregon pharmacists to further investigate their practices and attitudes will be conducted. We will complete in-depth interviews with a subgroup of pharmacists, both regularly prescribing and not prescribing contraceptives, to elicit further information regarding key barriers and facilitators to providing contraception, as well as input on potential interventions to increase participation. We are ideally suited for this research because we have extensive, on-the-ground knowledge of the Oregon healthcare system. We anticipate that lack of time and inexperience with counseling will be the most commonly reported barriers to provision.

Aim 2: To determine contraceptive initiation, continuation and incident pregnancy rates between women receiving hormonal contraception from a pharmacist versus other prescriber.

We will use both prospective and retrospective study designs in this aim. A prospective cohort study recruiting women who present for contraception in pharmacies, and a retrospective analysis of contraceptive outcomes using a state wide database.

2) Background:

Direct prescription of hormonal contraception (HC) by pharmacists, without a doctor's visit or medical prescription, is a strategy to improve access to contraception and reduce unintended pregnancy[3,4]. A national survey of women at risk of unintended pregnancy found that 68% of women were interested in using pharmacies directly to access HC[5].

Oregon is the first state in the nation to *implement* legislation, as of January 1, 2016, expanding the scope of pharmacists to prescribe short-acting HCs. House Bill (HB) 2879 allows pharmacists to directly prescribe HC including the patch and pill, without a medical prescription. Women over 18 years of age can either initiate or continue HCs with a pharmacist, and women under 18 can continue a prescription. The Oregon Board of Pharmacy convened a multidisciplinary task force to

guide policy implementation. Screening checklists and a referral algorithm based on the *Medical Eligibility Criteria for Contraceptive Use* must be used when providing care.

This proposal builds on and leverages ongoing collaboration with the state. Our study team actively participated in the state task force co-developing the screening checklists, editing the training modules, as well as designing, performing, and completing a baseline survey of pharmacists' attitudes and interest prior to policy implementation. Preliminary results indicate that while a majority of pharmacists are interested in direct provision (57% of pharmacists surveyed would like to offer services), only 39.1% of pharmacists surveyed were planning on participating. While pharmacists agreed that the program would improve access and reduce unintended pregnancy in Oregon, 61% cited a need for additional training, in particular with respect to counseling women. Concerns about the liability (74%) and costs (55%) were also given as barriers to participation. **As pharmacists have not previously provided HC in the United States, this research addresses the gap in knowledge about barriers and facilitators to successful task sharing of contraceptive provision.** It will also provide data on how this practice affects unintended pregnancy rates.

To identify the impact of this policy, we need to evaluate the implementation of the policy, and its effect on unintended pregnancy. Pharmacist participation is voluntary, so full implementation of the policy, and access to contraception in pharmacies will not occur without their enthusiastic support. In this study, we will identify motivators and barriers for pharmacists of prescribing contraception, and obtain their input on interventions to facilitate their participation. To measure the effect of the practice on unintended pregnancy rates, a robust, yet simple, surveillance system is needed. We will modify and test a method to actively monitor the safety, efficacy and acceptability of women accessing HC directly from pharmacists.

4) Study Design :

Aim 1: **To determine facilitators and barriers for pharmacists participating in direct HC provision by documenting their experience with the program**.

Hypothesis 1a: Two key barriers to pharmacist prescription of contraception will be shortage of staff time and inexperience in counseling women on contraceptive options and pregnancy risk.

Hypothesis 1b: Pharmacists practicing within chains will be more likely to prescribe contraception.

Hypothesis 1c: Interventions such as electronic counseling tools will be of interest to pharmacists.

We will use mixed-methods to evaluate pharmacists' experience with contraception provision, and assess how this changes over time. A link to an electronic survey will be sent to pharmacists licensed in Oregon six and 12 months after policy implementation (approximately June 2016 and

January 2017). The survey will elicit information on pharmacist demographics (age, years of practice, sex, pharmacy zip code), contraceptive prescribing practices (number of contraceptives prescribed, referral pattern), and experience with the program. We will specifically focus on motivators and barriers to prescribing contraception in pharmacies, as pharmacist participation is fundamental to the success of this policy. Three reminder emails will be sent to complete the survey. To strengthen survey response rate, all respondents who voluntarily provide their email, will be entered in a drawing for a $200 gift card to Amazon.com.

Survey responses will be collected in Research Electronic Data Capture (REDCap) and exported to Stata (StataCorp LP,College Station, Texas, USA). REDCap is a secure, web-based application designed to support data capture for research studies. We will use descriptive statistics to characterize the sample and evaluate contraceptive knowledge, motivation to participate in the program and perception of barriers to direct provision. Logistic regression models will be used to examine the association between time since implementation of policy and prescription of contraception. We will also examine the potential association between pharmacist demographic variables and contraceptive provision. We will test for interactions of potential moderators using the likelihood ratio test. Covariates will include age, sex, urban/rural pharmacy location defined using zip code, and clinical services currently offered (e.g. emergency contraception provision).

To add depth to the quantitative data, we will conduct a qualitative assessment of the pharmacist experience with prescribing. At the end of the quantitative survey, pharmacists will be asked if they are willing to be interviewed about their experience, and to provide their contact information if they agree. In our preliminary survey of pharmacists, we had good success with requesting permission to contact participants. We will complete in-depth interviews with 20 pharmacists. Out of the sample of pharmacists agreeing to be interviewed, we will assess the distribution of prescriptions written. We will seek to interview 10 pharmacists in the bottom quartile and 10 pharmacists in the top quartile for total number of prescriptions written. A semi-structured interview guide will be used to elicit information on key barriers and facilitators of contraception prescription in pharmacies. A systematic review of the published literature will be done to identify any existing interventions targeting contraception provision by pharmacists. From this review, a list of potential interventions will be drafted by the study team. We will specifically ask pharmacists to comment on a range of potential interventions, such as an electronic counseling tool, pharmacy locator map and additional contraceptive education, and their perceived utility in strengthening their prescription of contraception. Pharmacists completing the approximately 45-60 minute interview will be compensated for their time ($100).

Interviews will be transcribed and common themes identified. Findings will be presented at a stakeholder meeting that will include pharmacists, pharmacy managers, contraceptive experts and policy makers at the state. The PI has been working closely with a multi-disciplinary team since the legislation was passed, as well as meeting with key state legislators, establishing a rapport that will facilitate the proposed stakeholder meeting. The goal of the meeting will be to review findings and to obtain consensus on an intervention to strengthen quality contraception provision in pharmacies.

Aim 2: To determine contraceptive initiation, continuation and incident pregnancy rates between women receiving hormonal contraception from a pharmacist versus other prescriber.

Hypothesis 2a Rates of unintended pregnancy will be lower among women receiving HC from a pharmacist than from another prescriber.

Hypothesis 2b. Twelve month contraceptive continuation rates will be higher among women receiving HC from a pharmacist.

We are utilizing both a prospective and retrospective observational study design. The combination of these methodologies allows us to identify key individual measures, such as acceptability of services and pregnancy intention, while examining the impact at the state level. The prospective clinical cohort study will provide longitudinal data about ease of access, HC use over time, and incident pregnancies. Primary data collection allows us to better understand the effect of the intervention on outcomes prioritized by women. The retrospective cohort study will utilize the All Payer All Claims (APAC) database, and provide a comprehensive state-level view of the practice of HC provision by both pharmacists and clinicians and improve the generalizability of our prospective clinical cohort. The APAC cohort provides population level data that is prioritized by public health officials and policymakers.

Plan for prospective clinical cohort

In the clinical cohort, we are interested not only in the overall *population level effect* of pharmacist provision of HC, regardless of individual behaviors (intent to treat), but also in the *effect on those who did or did not switch* provider types (policy effect on the treated). We will identify women who report switching provider types - from clinician to pharmacist or vice-versa – at each 4 month interval. We will examine sample characteristics by baseline intent to continue and by reported switching to assess whether switching is associated with socio-demographic characteristics. Our longitudinal design means that provider type group assignment can be time varying – we will assign observations to the pharmacist or clinician group based on reported behaviors at the 4 month follow up data collection points. We will control for intent to continue HCs for 12 months at baseline as well as reported switching behaviors as potential confounders in multivariable analyses. For the population-

level (intent-to-treat) assessment, we will classify women by group at baseline (clinician or pharmacist) and ignore subsequent switching behavior.

We will examine missingness in the prospective clinical cohort by comparing characteristics of those missing data and those not missing data to identify potential patterns in missingness (e.g. data not missing at random). If there is substantial missing data (more than 5% in a variable) in the clinical cohort study, we will conduct sensitivity analyses using multiple imputation approaches and compare those results with complete case results.

To test our hypothesis, we will modify the active surveillance process utilized in the clinical setting across multiple countries to demonstrate the safety of drosperinone-containing oral contraceptives [1,2]. Our university participated in this trial, and our research unit has experience with the methodology for making initial contact, recruiting, and retaining study subjects. We will recruit women between the ages of 18 to 50 initiating HC directly at pharmacies participating in the study as well as a standard care control group, those women obtaining new prescriptions from a medical doctor (**see recruitment process**). We will exclude women who are not English speaking, have permanent or long-acting contraception, or who are using contraception for indications other than to prevent pregnancy.

The baseline survey will obtain information regarding the individual's age, pregnancy and contraceptive history, and any medical conditions that may impact contraceptive use. We will also ask basic demographic information such as insurance status, if they have a primary or women's care provider, where they usually obtain contraception from, and their reasons for obtaining contraception from a pharmacist (if applicable). Pregnancy intention will also be assessed. We will also evaluate what women were told in terms of how to take the pill, expected side effects, and medical history to identify specific contraindications to estrogen (e.g. history of hypertension, tobacco use, migraines with aura). Follow-up surveys will be administered at three, six and 12 months by a trained study coordinator via the REDCap system (see Appendix C). Information on continued contraceptive use, satisfaction, any side effects experienced and where care was sought will be obtained. Our primary outcome will be contraceptive continuation at 12 months.

Plan for APAC cohort

Oregon's All Payer All Claims (APAC) database is comprised of medical and pharmacy claims and enrollment information for Oregon residents, as collected from commercial health insurance carriers, licensed third party administrators, pharmacy benefit managers, Medicaid managed care organizations, and Medicare parts C and D. We will utilize this database to calculate overall contraceptive continuation and pregnancy rates among female HC users state wide stratified by prescribing provider type (pharmacist versus other). ICD 9 and 10 diagnosis and procedure codes will be

utilized to capture study outcomes. All multivariable analyses will account for data clustering (non-independence of observations) at the clinical site level (pharmacy), woman level, and prescriber level (in the APAC, using a unique provider ID) using robust standard errors or multi-level generalized estimating equation (GEE) method[2] or a fixed-effects approaches where appropriate

5) Study Population

Number of Subjects:

Aim 1 The survey will be administered electronically to all licensed pharmacists in Oregon (approximately 3,500). Our goal will be a 90% response rate.

Aim 2

Cohort study

We plan to recruit 350 women (175 in each group) with the intention of retaining 90% of the study population at one year of follow-up (or less than 10% lost to follow-up). This sample size will give us 80% power to detect a 15% difference in contraceptive continuation rates at 12 months. To allow for a 10% loss to follow-up, we will actively recruit 390 subjects.

Approximately 5000 new prescriptions for HC have been written by pharmacists since the policy was implemented. These numbers are expected to increase through the spring as more pharmacists complete the mandatory training. We estimate that 50% of women approached will be willing to complete the survey, and estimate six months for enrollment. We will work with Albertsons Companies, Rite Aid and Fred Meyers to identify the pharmacies where the most prescriptions are written for HC to maximize opportunities for study recruitment.

The study may be stopped before this number is enrolled for a variety of reasons, including slow enrollment, determination that the procedures are infeasible or other reasons but any previously enrolled subjects will be followed to study completion. If our target enrollment is less than 50% at three months, we will increase the incentive by $10. Appendix E contains the baseline and followup surveys.

APAC cohort

We will include a 12 months look-back period and 48 months (24 months prior and 24 months post policy change) of APAC claims from January 1, 2013-December 31, 2017, a minimum of 600,000 claims. Using a cohort of all women aged 12-51 years who are eligible to receive HC, we will first identify all HC prescriptions. We will identify provider type using National Provider Identifier (NPI) numbers.

Inclusion and Exclusion Criteria:

Aim 1 Pharmacists who are currently licensed and practicing in Oregon will be eligible to participate in the survey.

Aim 2 We will recruit women between the ages of 18 to 50 initiating HC directly at pharmacies participating in the study as well as a standard care control group, those women obtaining new prescriptions from a medical doctor (**see recruitment process**). We will exclude women who are not English speaking, have permanent or long-acting contraception, or who are using contraception for indications other than to prevent pregnancy.

Recruitment Methods: Albertson's Companies, which owns Safeway & Albertson pharmacies, Fred Meyers and Rite Aid are local champions of HB2879 and are other significant contributors to this research. These supermarket pharmacies exist across the state in diverse communities. Informational tear-tab fliers regarding the study will be posted in participating pharmacies. Fliers will have the research unit number to call for more information, and an OHSU study website address where women can enter their location and find the addresses of participating stores in their area.

Additional recruitment methods will focus on print, internet and radio advertising efforts, including: Facebook, Instagram, Spotify, OPB, Craigslist and BITCH Magazine regionally targeted campaigns. OHSU platforms will also be utilized, including study listings on the Center for Women's Health website, which will link to the study web page, and notice in the Women's Health Research newsletter. Women presenting to initiate new HC therapy (either with the pharmacist or with a prescription from a traditional provider) will be identified by the pharmacy staff at participating stores. Pharmacy employees will receive a detailed letter explaining their role in study recruitment. Similar to the procedures successfully used in EURAS-OC study, a sealed study packet will be handed out to women at the time of receipt of HC [2]. The study packet will contain an introduction letter, informational sheet, and a brief survey. The survey will be available in both paper format (with stamped, addressed envelope enclosed) and an electronic link to a web-based format will be provided. Submission of forms by either mechanism will be accepted. Data will be entered into Research Electronic Data Capture (REDCap) hosted at OHSU. REDCap is a secure, web-based application designed to support data capture for research studies.

The information sheet will include permission to contact the subject returning the baseline survey and study consent will be contacted by study staff to confirm eligibility and determine preferred contact method (phone, mail or email). A $10 Amazon credit or disbursement check will be sent for

each survey returned, and if a subject completes all of the surveys, they will receive an extra $25 credit at study completion.

Consent Process:

Women presenting to pharmacies for a new prescription of HC, prescribed by either a pharmacist or other health care provider will be given a sealed study packet by the pharmacy staff. The study packet will contain a letter, study information sheet, a baseline survey, and a stamped return envelope. The study information sheet (Appendix D) will describe the purpose of the study and eligibility criteria. It will be clear that participation is voluntary and will not affect care received. The information sheet will ask permission to contact the woman and her preferred method of communication (email address, phone number and mailing address).

Consent will be submitted prior to completing the online survey via an initial signature page. Participants will be given the Information Sheet in their study packet to retain and will confirm consent through accessing a link to web-based survey. Participants will complete this on their own time, in their choice of environment. They will not be able to access the Baseline survey until they complete the consent.

Alternatively, the study packet will include a mail-in option of the consent page and baseline along with an addressed and stamped envelope. Participants may choose to return both their consent and survey pre-paid by mail.

6) Procedures:

Data and Specimens

Handling of Data and data banking.

Data will be collected on paper surveys or electronically, subjects enrolled will be able to select the most convenient method for them. Survey data will be managed using REDCap (Research Electronic Data Capture), a secure web-based application which supports data collection and data management for research studies. Data monitoring will be ongoing. Paper files will be stored in locked filing cabinets in restricted access offices at OHSU. Electronic data will be stored on restricted drives on the OHSU network on encrypted computers. Access will be restricted to study personnel.

Sharing of Results with Subjects.

7) Data Analysis.

We will use tabulations, descriptive statistics and visualizations to examine socio-demographic variables of our study population. We will use bivariate tests to compare socio-demographic characteristics (age, insurance status, and rural/urban residence) of our study sample with HC users overall in the state, stratified by prescriber type (pharmacist versus all other providers). Self-reported contraceptive continuation and pregnancy rates at one year from our study sample will be calculated and compared with state level contraceptive continuation and pregnancy rates among HC users overall, and stratified by prescriber type. We can calculate state level rates of contraceptive continuation and pregnancy rates among HC users stratified by prescribing provider type (pharmacist versus other) in the APAC database. This will allow us to assess how our study cohort compares with statewide users of HC, which will speak to the generalizability of our findings.

8) Privacy, Confidentiality and Data Security

Confidentiality of personal health information will be maintained according to HIPAA requirements for research. All subjects will receive a study number to which all subsequent data will refer. Personal identifiers will not be on questionnaires, data, abstract sheets, or in the main database. All data will be kept in locked files or a password protected computer in the Principal Investigator's (PI) office. We will do our best to keep information confidential by keeping it coded and on password-protected computer.

9) Risks and Benefits

Risks to Subjects: The major risk to women is loss of confidentiality. To minimize this risk, confidentiality of personal health information will be maintained according to HIPAA requirements for research. All subjects will receive a study number to which all subsequent data will refer. Personal identifiers will not be on questionnaires, data, abstract sheets, or in the main database. All data will be kept in locked files or a password protected computer in the Principal Investigator's (PI) office. We will do our best to keep information confidential by keeping it coded and on password-protected computer.

Potential Benefits to Subjects: There is no direct benefit to subjects.

References

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3. Grossman D. Moving oral contraceptives over the counter as a strategy to reduce unintended pregnancy. *Annals of internal medicine* 2013; **158**(11): 839-40.

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5. Landau SC, Tapias MP, McGhee BT. Birth control within reach: a national survey on women's attitudes toward and interest in pharmacy access to hormonal contraception. *Contraception* 2006; **74**(6): 463-70.

Appendix A. Information sheet and survey to be emailed to pharmacists

OREGON HEALTH & SCIENCE UNIVERSITY

Information Sheet for Pharmacists

IRB#_____

TITLE: **Pharmacist prescription of short-acting contraceptive methods**

PRINCIPAL INVESTIGATOR: Maria I. Rodriguez, MD rodrigma@ohsu.edu

PURPOSE:

We are inviting you to participate in a brief survey regarding recent Oregon legislation authorizing pharmacist provision of hormonal contraception without a prescription (HB 2879: http://gov.oregonlive.com/bill/2015/HB2879/). Oregon is the second state in the nation to pass this type of legislation, and was the first state to implement it this winter.

PROCEDURES:

We anticipate that this survey will take approximately 10 minutes of your time. Participation in this survey is completely voluntary and anonymous.

You may choose to stop participating at any time during the survey. Any completed responses will be included and analyzed in the final results. The results of this survey will inform the Oregon task force helping to support pharmacists in the implementation of this legislation.

At the end of the study you will have the option to provide contact information if you are willing to participate in an interview by members of the Pharmacy task force for legislation HB 2879 to further expand your thoughts and concerns about provision of hormonal contraceptives by pharmacists in Oregon.

If you have any questions, concerns, or complaints regarding this study now or in the future, or you think you may have been injured or harmed by the study, contact:

Maria I. Rodriguez, MD MPH
Assistant Professor Obstetrics and Gynecology
OHSU
rodrigma@ohsu.edu

If you have any questions regarding the enactment of HB2879 please contact:
Fiona Karbowicz, R.Ph.
Oregon Board of Pharmacy
fiona.karbowicz@state.or.us

RISKS:
Although we have made every effort to protect your identity, there is a minimal risk of loss of confidentiality.

BENEFITS:
You may or may not benefit from being in this study. However, by serving as a subject, you may help us learn how to benefit patients in the future.

COSTS:
It will not cost you anything to participate in this study. If you choose to provide your email, you will be entered in a drawing for a $200 Amazon gift card.

CONFIDENTIALITY:
In this study any identifiable information collected about you will not be linked to the survey, so there is little chance of breach of confidentiality. The contact information you provide to be contacted by the Oregon Pharmacy task force for legislation HB 2879 will not be linked to the survey and will be stored separately from your survey answers. If you provide your contact information, you are agreeing that the Oregon Pharmacy task force may contact you for future interviews regarding legislation HB 2879.

PARTICIPATION:

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to the IRB at (503) 494-7887 or irb@ohsu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get more information or provide input about this research.

You may also submit a report to the OHSU Integrity Hotline online at https://secure.ethicspoint.com/domain/media/en/gui/18915/index.html or by calling toll-free (877) 733-8313 (anonymous and available 24 hours a day, 7 days a week).

You do not have to join this or any research study. If you do join, and later change your mind, you may quit at any time. If you refuse to join or withdraw early from the study, there will be no penalty or loss of any benefits to which you are otherwise entitled.

The participation of OHSU students or employees in OHSU research is completely voluntary and you are free to choose not to serve as a research subject in this protocol for any reason. If you do elect to participate in this study, you may withdraw from the study at any time without affecting your relationship with OHSU, the investigator, the investigator's department, or your grade in any course. If you would like to report a concern with regard to participation of OHSU students or employees in OHSU research, please call the OHSU Integrity Hotline at 1-877-733-8313 (toll free and anonymous).

Appendix B Survey of pharmacists

HB 2879 Survey:

Oregon pharmacists knowledge of legislation allowing and interest in prescribing hormonal contraception

Demographics

1. **Are you currently practicing as a pharmacist <u>in Oregon</u>?**

Yes

No – end of survey (not eligible)

2. **What is your age?**

<30

30-39

40-49

50-59

>60

3. What is your sex?

Female

Male

Other

4. Which of the following best represents your racial or ethnic heritage? Choose all that apply.

American Indian or Alaskan Native

Asian

Black/African-American

Hispanic or Latino

Native Hawaiian or Pacific Islanders

White

More than one race

Unknown

5. Please select the degrees and certifications you hold. Check all that apply.

BS Pharm

PharmD

Pharmacy residency or fellowship

Certifications (e.g. BSPS)

MPH

MS/MBA

PhD

Other_____

6. What year did you first receive your pharmacy license?

<1960

1960-1969

1970-1979

1980-1989

1990-1999

2000-2004

2005-2009

>=2010

7. What is your current practice site? Please select the site that represents the majority of your practice

-chain community pharmacy

-compounding pharmacy

-county or community health

-educational or research institution

-family planning clinic

-home infusion

-hospital pharmacy

-independent community pharmacy

-mail order

-nuclear pharmacy

-pharmacy benefit manager

-policy/planning/regulatory/licensing agency

-public health department

-skilled nursing facility/long term care

-Other_____

8. Which of the following describes your primary position?

-manager

- owner

-staff

-other

9. Are you currently working full (>32 hours/week) or part time?

□ Full-time

□ Part-time

10. What percentage of your time are you directly working with patients (filling or dispensing medications and communicating with patients or other health care professionals to support these activities)

11. What is the zip code of the pharmacy you work in?

If working in more than one pharmacy, answer for the pharmacy you primarily work in.

12. Which of the following clinical services do you currently provide at your pharmacy? Check all that apply.

Contraception prescribing

Emergency Contraception (PlanB®) provision

Medication therapy management

Immunizations

Travel immunizations

Health screenings (e.g cholesterol, blood pressure or diabetes) or coaching (smoking cessation)

Point of Care Testing (e.g. strep, influenza, Hep-C, A1c)

Medical doctor/PA/NP on staff or available for phone/video consults and prescriptions

Other, please specify

13. In the United States, there are a variety of hormonal contraception methods. Select the option which best describes your current knowledge for counseling on the routine and rare side effects, and compliance considerations of the following hormonal contraceptive methods:

Select 1 to 5, not knowledgeable to highly knowledgeable

Combined estradiol-progestin oral contraceptive pill

Progestin-only oral contraceptive pill (e.g Micronor®)

Transdermal contraceptive patch (e.g, OrthoEvra®)

Contraceptive vaginal ring (e.g, Nuvaring®)

Injectable progestin contraceptive (e.g, Depo-Provera®)

Progestin implant (e.g, Nexplanon®)

Intrauterine device (e.g., copper IUD, Mirena®, Skyla®, Liletta®)

14. Select the option which best describes your current knowledge on effectiveness, contraindications, initiation, and the recognition and management of routine and rare side effects of the following hormonal contraceptive methods:

Select 1 to 5, not knowledgeable to highly knowledgeable

Combined estradiol-progestin oral contraceptive pill
Progestin-only oral contraceptive pill (e.g Micronor®)
Transdermal contraceptive patch (e.g, OrthoEvra®)
Contraceptive vaginal ring (e.g, Nuvaring®)
Injectable progestin contraceptive (e.g, Depo-Provera®)
Progestin implant (e.g, Nexplanon®)
Intrauterine device (e.g., copper IUD, Mirena®, Skyla®, Liletta®)

15. Have you previously heard of HB2879, the new Oregon legislation allowing pharmacists to directly prescribe the contraceptive pill or patch without a medical doctor's prescription?

Yes
No

16. Select the option which best describes your current views towards contraceptive prescribing by pharmacists:

Select 1 to 5, Strongly disagree to Strongly Agree

- Pharmacist prescription of hormonal contraception is an important health and community service.
- I plan to prescribe or am currently prescribing hormonal contraception in my pharmacy.
- Provision of hormonal contraception fits easily within my current practice site.
- I am comfortable following an algorithm or protocol to determine eligibility for hormonal contraceptive use.
- I need additional training on contraception to comfortably and safely provide hormonal contraception.
- Providing hormonal contraception within my pharmacy is not currently feasible.

17. Which of the following services would you be interested in offering? Assume that training and reimbursement are provided.

Please check all that apply.

Initiating therapy with hormonal contraceptives (with a prescription).

Managing side effects from hormonal contraceptives

Transitioning women from one contraceptive delivery system to another (e.g pill to patch or ring)

Initiating and administering injections of hormonal contraception (Depo Provera®)

Inserting progestin implants (Nexplanon®)

18. In which of the following areas would you want to receive additional training?

Please check all that apply.

Effectiveness of various forms of contraception.

General information about hormonal contraception.

Risks and benefits of hormonal contraception.

How to identify women with medical contraindications to hormonal contraception.

How to rule out pregnancy

Pre-conceptual counseling

Helping women select the best contraceptive method for their life goals

Advising women about recommended reproductive health screening tests (e.g pap smears, pelvic exams, sexually transmitted infections).

Billing for pharmacy services related to the provision of contraceptive services

19. I have prescribed hormonal contraception under the new law.

Yes

No

If Yes, please go to Question 20

If No, please go to Question 21

20. For each of the potential reasons given FOR providing hormonal contraception below, please select the option which best describes your views regarding the importance of providing pharmacy-based hormonal contraceptives.

Select 1 to 5, Strongly disagree to Strongly Agree

Increased access to contraception for women.

Reduction of unintended pregnancy.

Increased job satisfaction for pharmacists.

Increased scope of practice for pharmacists.

Strengthen collaboration between pharmacists and other members of the health care team.

Other_____

21. For each of the potential reasons given FOR NOT providing hormonal contraception below, please select the option which best describes your views regarding the importance of these barriers, when attempting to provide pharmacy-based hormonal contraceptives.

Select 1 to 5, Strongly disagree to Strongly Agree

Need for additional training.

Reimbursement for pharmacist services.

Cost considerations in starting a new service.

Liability concerns.

Corporate policies.

Lack of a private area for patient counseling.

Shortage of pharmacy staff to provide service.

Personal or religious objections to hormonal contraceptive use.

Resistance from general public.

Resistance from physicians and other health-care professionals

Other_____

The following questions should *only be filled out* by pharmacists certified to prescribe hormonal contraception:

22. What percentage of contraceptive services are billed to a third party medical insurance?

23. If your pharmacy is charging patients directly for pharmacy contraceptive services, please enter the typical or average amount charged.

24. Have you had patients request a prescription for contraception but be unable to afford the product or service fee?

Yes (if yes, please provide an estimate as to how many)

No

25. What is the average amount of time it takes you to screen, prescribe, and counsel on hormonal contraception for a new patient?

26. How long have you been prescribing hormonal contraception?

<1 month

2 months

3 months

4 months

5 months

27. Right now, how many prescriptions do you write for hormonal contraception per month?

<10

10-20

21-50

>50

28 Would you be willing to participate in an interview by members of the Pharmacy task force for legislation HB 2879 to further expand on your thoughts and concerns about provision of hormonal contraceptives by pharmacists in Oregon?

Yes – please provide your contact information below

No

If you wish for us to contact you, please enter your **contact information** in the boxes below

---

Name and Surname

Which is your preferred contact method(s)?

Telephone number

Email

If you provide your contact information, you are agreeing that the Oregon Pharmacy task force may contact you for future interviews regarding legislation HB 2879.

Thank you for taking part in this survey. If you have any questions or concerns about the survey, you may contact the research team at:

Maria I. Rodriguez, MD MPH

Assistant Professor Obstetrics and Gynecology

OHSU

rodrigma@ohsu.edu

Appendix C In Depth Interview Guide for Pharmacist interviews

Hello. My name is XXX, I am from XXX. I am part of a study team that is studying pharmacist prescription of contraceptive use.

We are interested in your ideas, experiences, and suggestions about prescribing contraception in pharmacies. The research is being conducted to get more information about your experiences, as health care providers; to help us build further support services for contraceptives use/

I will ask you some questions related to your daily work and related to your clients. There are no right or wrong answers – we are seeking your opinions and thoughts.

As explained to you earlier, this conversation is completely confidential – what we discuss here will not be reported in any way that could be linked to you. You have the right to refuse to answer any of the questions in this interview.

This interview is likely to take about an hour.

Interviewer switches on recorder and starts with questions:

Please could you state your name, age and profession for the recorder. Please also indicate what pharmacy you are working and in which area.

Let's first talk about your role and the reach of the services you provide here.

1. What is your role at the pharmacy?
2. How many contraceptive prescriptions, on average, do you write monthly?
3. How many contraceptive prescriptions, on average, do you think you fill monthly?

Let's then talk a little about your consultations to prescribe contraceptives in general.

1. Can you describe a typical consultation for contraception? What is it like? How long does it take? What issues are covered?
2. Do you have many adolescents requesting services?
3. What contraceptive methods do you most commonly recommend? Are there any that you do not offer to women under age 20?
4. Do you experience any problems in prescribing and dispensing contraception in general, compared with other clinical services you offer? If yes, what are these like? What is easy about providing contraceptive services? What is most difficult about it?
5. How often do you have to refer women to a clinic? Describe what this encounter would typically be like.
6. Have you had women calling or visiting to ask follow-up questions about side effects of the contraceptive prescribed? Can you describe these visits for me.

Let's talk a little more about the services provided here

1. Do you feel you have all the resources you need to inform and support women in using contraception?
2. What would you do improve these services? What do you think is excellent about them?

3. Would you be interested in offering expanded range of contraceptive methods? Injection? Implant? Probe: if yes, what would you need? If no, why?

We are planning an intervention which would support pharmacist prescription of contraception. We would like your feedback on what intervention would be most useful to you in your practice. We are considering studying an electronic tool to streamline counseling and screening; development of a physician consult line with facilitated referral; or alternative reimbursement.

1. What do you think of the proposed interventions?
2. What would be important to include in such an intervention?
3. Would you participate in such an intervention? What would encourage you to participate? What would discourage you from participation?

This was my last question. I would now like to ask if you have anything to add on the topic, something related to contraceptive services in pharmacies?

Appendix D Information sheet and surveys (baseline and follow-up) for women enrolled in study

Information Sheet for Women Receiving Prescriptions

IRB#_____

TITLE: **Pharmacist prescription of short-acting contraceptive methods**

PRINCIPAL INVESTIGATOR: Maria I. Rodriguez, MD rodrigma@ohsu.edu

PURPOSE:

We are inviting you to participate in a research project regarding recent Oregon legislation authorizing pharmacist provision of hormonal contraception without a prescription (HB 2879: http://gov.oregonlive.com/bill/2015/HB2879/). Oregon is the second state in the nation to pass this type of legislation, and was the first state to implement it this winter. We want to understand women's experiences with pharmacist prescribed contraception in order to ensure safe and effective services.

PROCEDURES:

If you have any questions, concerns, or complaints regarding this study now or in the future, or you think you may have been injured or harmed by the study, contact:

Maria I. Rodriguez, MD MPH
Assistant Professor Obstetrics and Gynecology
OHSU
rodrigma@ohsu.edu

RISKS:

Although we have made every effort to protect your identity, there is a minimal risk of loss of confidentiality.

BENEFITS:

You may or may not benefit from being in this study. However, by serving as a subject, you may help us learn how to benefit patients in the future.

CONFIDENTIALITY:

To minimize this risk, confidentiality of personal health information will be maintained according to HIPAA requirements for research. All subjects will receive a study number to which all subsequent data will refer. Personal identifiers will not be on questionnaires, data, abstract sheets, or in the main database. We will do our best to keep information confidential by keeping it coded and on password-protected computer.

We may request your social security number in order to process any payments for participation.

COSTS:

It will not cost you anything to participate in this study. You will receive a $10 Amazon or Target gift card for each of the first three surveys you complete. There are a total of 4 surveys over 1 year. If you complete the l 4th surveys, you will receive a $25 gift card at study end.

PARTICIPATION:

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to the IRB at (503) 494-7887 or irb@ohsu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get more information or provide input about this research.

You may also submit a report to the OHSU Integrity Hotline online at https://secure.ethicspoint.com/domain/media/en/gui/18915/index.html or by calling toll-free (877) 733-8313 (anonymous and available 24 hours a day, 7 days a week).

You do not have to join this or any research study. If you do join, and later change your mind, you may quit at any time. If you refuse to join or withdraw early from the study, there will be no penalty or loss of any benefits to which you are otherwise entitled.

The participation of OHSU students or employees in OHSU research is completely voluntary and you are free to choose not to serve as a research subject in this protocol for any reason. If you do elect to participate in this study, you may withdraw from the study at any time without affecting your relationship with OHSU, the investigator, the investigator's department, or your grade in any course. If you would like to report a concern with regard to participation of OHSU students or employees in OHSU research, please call the OHSU Integrity Hotline at 1-877-733-8313 (toll free and anonymous).

Appendix E Baseline Survey for women participating in cohort study

Appendix C – Staff checklist and Minimum Necessary Review (MNR) for limited, custom or Business Associate requests

Staff Reviewer: Mary Ann Evans

Agreement Number: 4928

Purpose

The purpose of the staff checklist for limited, custom or Business Associate requests is to:

1. Assess whether applicant completely and adequately filled out the APAC-3
2. Complete the Minimum Necessary Review to:
    a. Assess whether OHA is disclosing no more than a limited data set
    b. Provide criteria for assessing if the organization's data request is the minimum necessary to accomplish the purposes stated in the application or amendment.

Instructions

Complete all sections. If you check "no" on any question, please detail in the "notes" section why you checked "no" and what applicant must do in order to receive a "yes". If there are tasks in which the applicant receives a "yes", but staff reviewer has concerns, please describe concern in the "notes" section and be sure to pass along that concern to DRC in the DRC review form. For the Minimum Necessary Review, provide the rationale for the response in the "notes" section.

Task	Yes	No	N/A	Notes
Section 1 complete and responses adequate?	x			
Section 2 complete and responses adequate?	x			
Section 3 complete?	x			
Only chose one box in question 3.1?	x			
Only chose one box in question 3.3a?	x			
Adequately justified in 3.3b how project falls into category chosen in question 3.3a?	x			
If IRB review is required for this project, (IRB is required for all research requests or requests for Medicare FFS data) is IRB protocol and approval memo attached? (OHA may use DRC as a "Privacy Board" for Business Associates that don't have an IRB, but need Medicare FFS data. Please talk to Program Manager if this is the case.)	x			
IRB registered with US Department of Human Services, Office of Human Research Protections? (Write IRB number and expiration in "notes")	x			https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/irb-and-fwa-status/index.html

Task	Yes	No	N/A	Notes
IRB accredited? (Write accrediting agency in notes)				https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/irb-and-fwa-status/index.html
IRB's approval has been verified?	x			
IRB disclosed and mitigated all actual conflicts of interest with the approval research or the IRB has no actual conflicts of interest	x			
If actual conflict of interest exists, is documentation attached?			x	
May DRC rely on IRB's review?	x			
Adequately justified in 3.4b how the project is within the scope of the current IRB approval?	x			
Adequately described in 3.4c why the approving IRB has jurisdiction over this project?	x			
Adequately described in 3.4d why the project could not be conducted without a waiver of individual authorization?	x			
Does IRB have more than 3 months left on the approval memo, as outlined in 3.3e?	x			
Section 4 complete?	x			
Data Element Workbook attached?	x			
Do all requested elements have a year requested, filters applied and justification response in Data Element Workbook?	x			
If requesting a limited data set, does Data Element Workbook align with response in 4.1b-c?			x	
If requesting a custom data set, is it clear what elements are being requested?	x			
Is the Payers tab completed in the Data Element Workbook?	x			
If requesting Medicare FFS data, is the project at least partially funded and directed by OHA? (Per our DUA with CMS, Medicare FFS data may be shared outside of OHA for research **if** OHA is partially funding and directing the project.)			x	

Task	Yes	No	N/A	Notes
If requesting a limited data set, does Payers tab align with response in 4.1b?				
If requesting a custom data set, is it clear what payers are being requested?	x			
Passes Minimum Necessary Review?	x			
Adequately justified each data element requested (provide rationale and list any data elements not adequately justified in notes)?	x			
Adequately described filters and algorithms for including and excluding claim lines (provide rationale and list strengths and weaknesses of algorithms in notes)?	x			See modification and limitations column listed in the data elements workbook
Consider the elements requested and whether additional elements can be excluded, redacted, or additionally filtered without unreasonably impairing the ability to accomplish the project purposes. Is data requested the minimum necessary? (If no, identify data elements that may be excluded, redacted, or additionally filtered in notes.)				See modification and limitations column listed in the data elements workbook
Section 5 complete?	x			
Techniques described are adequate to prevent re-identification in 5.1?	x			
If project requires linkage to another data source, does PI adequately justify necessary linkages in 5.2c?	x			
If project requires linkage to another data source, does PI propose adequate steps to prevent re-identification in 5.2d?	x			
Organization's data privacy and security policies attached?	x			
If any third parties are identified in Section 2, are third party data privacy and security policies attached?	x			
Adequately described data management plans in 5.3b?	x			

Task	Yes	No	N/A	Notes
Adequately described personnel, technical, physical and administrative safeguards in 5.3c-e?	x			
Adequately described plans for destruction of data in 5.3g?	x			
Adequately described procedures implemented to prevent future breach if staff working on the project have a history of security breach in 5.3h?	x			
Section 6 complete?	x			
If limited data is being requested, is payment included?			x	
Does question 4.1 correspond with files selected and number of years input in row c of payment table?			x	
Is cost calculated correctly?			x	
If payment is not included, are one of the boxes (found below the cost chart in 6.1) checked?	x			
If payment is not included for "another reason", is there an explanation?			x	
Does explanation make sense and, if needed, have you discussed explanation with APAC Program Manager?			x	
Section 7 complete?				
All checklist boxes checked?	x			
Application signed?	x			
Using your professional opinion, does this application fall into one of the categories below. If yes, please write the category in the "notes". If no, please explain in the "notes" section if the applicant did not adequately explain their application and any follow-up questions you may have OR if the purpose described in the application simply does not fall into one of the categories below.	x			

Allowed Purposes for Sharing APAC Data

Limited Data Sets

1. Limited data sets may ONLY be shared for research, public health activities or health care operations. 45 CFR 164.514(e)
    - *Per DOJ: We CAN share limited data sets for health care operations of requesting entity.*
2. We may share a limited data set with a Business Associate if a limited data set will meet the Business Associate's needs.
    - *Per DOJ: Execute a modified BAA and DOJ's preference is that the BAA is attached to the contract*

Notes

- Limited data sets may be shared with covered and non-covered entities if a DUA is executed.
- Research requests for limited data sets must have IRB approval.
    - Per Stacy on 11/23/15

Data with Direct Identifiers

1. Direct Identifiers may be shared with Business Associates for work done on OHA's behalf. 45 CFR 164.502(e)
    - *Per DOJ: Execute a modified BAA and DOJ's preference is that the BAA is attached to the contract*
2. Direct Identifiers may be shared with another covered entity for the purposes of OHA's own treatment, payment or health care operations. 45 CFR 164.506(c)(1)
    - *Per DOJ: Execute a modified BAA, instead of DUA, with non-covered entity component of OHA*
3. Direct Identifiers may be shared with a health care provider for treatment. 45 CFR 164.506(c)(2)
4. Direct Identifiers may be shared with another covered entity or health care provider for payment activities of the entity that receives the information. 45 CFR 164.506(c)(3)
5. Direct Identifiers may be shared with another covered entity for health care operation activities of the entity <u>receiving</u> the data IF both entities have had a relationship with the individual who is subject to the PHI being requested and the PHI pertains to such relationship and the disclosure is for quality assurance and similar activities or for the purpose of health care fraud and abuse detection or compliance. 45 CFR 164.506(c)(4)
6. Direct Identifies may be shared with a public health authority for the purposes of preventing or controlling disease, injury, disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; or at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority. 45 CFR 164.512(b)
7. Direct Identifiers may be shared with researchers that have an IRB approval. 45 CFR 164.512(i)(1)(i)
8. Direct Identifiers may be shared with researchers if research participant authorizes the use or disclosure of information about him or herself. 45 CFR 164.508. Authorization must include elements in 45 CFR 164.508(c)(1)-(2).

Notes:

- Direct Identifiers can be shared with covered entities for TPO as described above.

- Direct Identifiers can be shared with Business Associates, Public Health and researchers, if guidelines above are met. In these instances, the requesting organization does not necessarily have to be a covered entity

Medicare FFS Data

1. Per our DUA with CMS, Medicare FFS data may be used for Oregon's Health System Transformation efforts as described in our DUA with CMS.
2. Furthermore, Medicare FFS data may be shared outside of OHA for research **if** OHA is partially funding and directing the project and a privacy board or IRB have given approval.
3. Any document creation from this data must adhere to CMS cell suppression policy: No cell 10 or less may be displayed.

Appendix D—Staff review for DRC (standardized for all Health Analytics' data requests)

Office of Health Analytics Application Number: _4928_____

Staff Review Checklist: Mary Ann Evans

Staff Name:

1. Data Source(s) Requested:

	APAC	

2. Application materials included:

Application	Y
Payment	N/A
Data Elements Worksheet	Y
IRB Approval	Y
DUA	N/A

3. Has the requestor provided an overview of the project and adequately explained the need for the data? Y

   Notes:

4. Has the requestor adequately justified the need for the specific data files and elements requested? Y

   Notes:

5. Has the requestor asked for the minimum necessary data to accomplish the stated purpose? Y

   Notes:

6. Has the requestor adequately described safeguards in place to protect the data and comply with privacy and security requirements? Y

   Notes:

7. Recommendation for request: Approve

Notes: