Oregon Health Authority

All Payer All Claims Application for Limited or Custom Data Files
APAC-3

OHA DRTS: 4951 Advanced methodological techniques obstetric

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

PROJECT INFORMATION

Project Title: Advanced methodological techniques in obstetric data.

Principal Investigator: Jonathan Snowden, Ph.D.

Title of Principal Investigator: Assistant Professor

Organization: OHSU-PSU School of Public Health

Address: 3181 SW Sam Jackson Park Road, Mail code: CB-669

City: Portland State: OR Zip Code: 97239

Telephone: (503) 494-0904

Email: snowden@ohsu.edu

Application Date: 09/20/2019

SECTION 1: PROJECT STAFF

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

Name Menolly Kaufman Role Data Analyst, PhD student
Email harme@ohsu.edu

Name Mekhala Dissanayake Role Data Analyst
Email dissanam@ohsu.edu

Name Paige Snow Role Data Analyst
Email snow@ohsu.edu

Name Role
Email

Name Role
Email

Attach additional sheets as needed.

1.2 Technical Staff: Please list any additional staff who will be maintaining the data file(s) or otherwise assisting in the transfer or receipt of the data files. Files will not be transferred to anyone who is not listed on this application as either project staff or technical staff.

Name Menolly Kaufman Role Data Analyst, PhD student
Email harme@ohsu.edu

Name Role
Email

SECTION 2: PROJECT SUMMARY

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

The purpose of this study is to implement advanced methodological techniques to identify causal pathways and to predict maternal health outcomes in a large population of childbearing women by utilizing health care claims data from Oregon. We will manage the data using established methods to generate a births-level dataset of all deliveries occurring in Oregon during study years (Ailes et al., Birth Defects Res A Clin Mol Teratol. 2016 Nov; 106(11): 927–934). We will then use this dataset to study risk factors for adverse outcomes before, during, and after birth, enabling comparison to health outcomes in other settings. Health outcomes include prenatal and intrapartum factors, obstetric procedures, and postpartum care and complications. The outcomes we aim to predict include: 1) vaginal birth after cesarean delivery (VBAC), 2) preeclampsia, 3) fetal/neonatal morbidity, and 4) maternal morbidity. The causal aims are: 1) to characterize prevalence of maternal health care utilization and morbidities; 2) to characterize racial/ethnic and insurance-type disparities in maternal and infant outcomes; 3) to determine what proportion of selected intrapartum and postpartum morbidities and disparities are due to preexisting maternal health conditions or childbirth care versus health care utilization; and 4) to assess how maternal morbidity after the first birth affects women's risk of outcomes during and after her next pregnancy and delivery.
Please see attachment for more detail.

2.2 Research Questions: What are the key research questions or hypotheses of the project? If this project is research and has been approved by an Institutional Review Board (IRB), the research questions must align with the IRB approval documentation.

The prediction hypotheses are as follows: 1-2) maternal factors (e.g., age and insurance status), care received, and prior pregnancy outcomes affect VBAC success and preeclampsia incidence; 3) fetal/neonatal morbidities may be predicted with reasonable accuracy and are explained by maternal, prenatal, and labor characteristics, and 4) maternal morbidities may also be predicted and share some but not all predictors with neonatal outcomes. Causal hypotheses are as follows: 1) morbidities in Oregon are lower than in most US settings, but higher than in Western Europe, 2) incidence of morbidities is elevated among publicly-insured and racial/ethnic minority women; 3) a substantial share of the morbidity disparity owes to childbirth care and postpartum care utilization; 4) morbidity and care in the postpartum period strongly predict outcomes in future pregnancies.

2.3 Products or Reports: Describe the intended product or report that will be derived from the requested data and how this product will be used.

We anticipate developing manuscripts for scientific journal publication and paper presentation (as poster format or oral presentation) at various scientific meetings. The products will be used as communication to maternity child health professionals and the public to improve practice, policy, and general knowledge.

Potential meetings include: The Annual Meeting of the Society of Maternal-Fetal Medicine, The Annual Meeting of the Society of Epidemiological Research, The Academy Health Annual Research Meeting, and The Annual Meeting of the Society of Perinatal Epidemiology

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

a. Anticipated Start Date: 12/01/2019
b. Anticipated Publication/Release Date: 06/01/2020
c. Anticipated End Date: 12/01/2024

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

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

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

SECTION 3: DATA REQUEST

3.1 Purpose of the Data Request:

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

- ☒ Research (refer to 45 CFR 164.501 for definition)
- ☐ Public health activities (refer to 45 CFR 164.512(b) for definition)
- ☐ Health care operations (refer to 45 CFR 164.501 for definition)

  Covered entity? ☐ Yes ☐ No

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

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

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

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

The purpose of our research project is to evaluate maternal health outcomes in Oregon by implementing advanced statistical methods to test prediction and causal hypotheses. The products of this systematic analysis will contribute to the evidence-base that is essential to inform policy, practice, and populations.

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

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

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

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

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

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

☑ IRB application and approval memo are attached.

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

This application and the scope of the IRB approval are inclusive; the content of this application is within the scope of the IRB approval, which also includes a Western European dataset allowing for a global comparison. All data analysis for this project will take place at OHSU. Only OHSU personnel will have access to the data, and the analysis will be conducted on OHSU-owned and maintained computers and servers. So, the OHSU IRB jurisdiction is appropriate.

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

IRB approval for this project did require a waiver of the HIPAA individual authorization requirement and was approved with approval of the project [see IRB application and approval].

d. On what date does the IRB approval expire? 09/4/2021

SECTION 4: DATA ELEMENTS

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

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

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

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

APAC is available from 2010-2017 and includes the approximately 40,000 annual births in Oregon. Included are claims data for all health care services that a woman may use in the intrapartum and postpartum periods, including inpatient, outpatient, and emergency department (ED) claims. Also included are pharmacy claims, to assess degree of adherence to medication for chronic conditions (i.e., hypertension and diabetes) and whether this is associated with complications. APAC captures health care utilization across care settings and over time and draws from nearly all payers in the state of Oregon: public, private, and out of pocket. By providing statewide data on all birthing individuals regardless of insurance status and linked across insurance changes, this resource enables us to assess prenatal and postpartum care and health over time, regardless of "churn" (i.e., unavailability of data caused by insurance changes in single-payer datasets). Without access to the APAC data for utilization and insurance status, it would not be possible to reach valid conclusions on our prediction and causal hypotheses that are generalizable to childbearing Oregonians and their families. This is especially true for women in the prenatal and postpartum periods, where (due to changes in Medicaid eligibility associated with pregnancy), a large share (estimated 25-30% of women) will change insurance coverage. Thus, a dataset that tracks individuals across changes and discontinuities in insurance coverage is critical for our proposed project.

In order to meet the minimum necessary requirement, we have requested filters in the data elements workbook to reduce the number of birth level observations that we receive from APAC. We are interested in pregnancy, intrapartum, and postpartum events in birthing individuals who are both cisgender and transgender, so we have not requested a filter based on gender. Because we are interested in the childbearing population, we have requested that individuals under 15 years of age and above 50 years old be filtered out. Further, we have requested to limit the observations by procedure codes and pharmacy codes relevant to this time period for birthing individuals (the prenatal and postpartum periods). Some relevant procedure codes are described in our supplement (Ailes

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).

Research findings will be published with small cell sizes in mind; rare events (i.e. infant death, maternal death) will be reported to avoid identification of individuals. We will follow best practices to make the risk of loss of privacy very low. These practices include suppressing cell counts lower than 30 and subpopulations lower than 50 as well as publishing data only in aggregate (never at the individual level).

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

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

☐ Yes ☒ No

If yes, please complete parts b-d below.

b. At what level will data be linked?

☐ Aggregate ☐ Facility ☐ Person

c. If required to link

☐ Authorized to provide data for linking at OHA

☐ Not authorized to provide data for linking at OHA

☐ Unknown

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

We do not plan to link the APAC data set in any way to another data set. Although this project involves birth events and a comparison to outcomes in a Western European setting, we want to be explicit that we do not plan to link the APAC data set to vital records, to grouped/aggregated data (e.g., census data), to records from the Western European data set, nor any other data source. We will not link APAC data to any other data in any fashion, and we understand an amendment approval would be necessary in order to do so.

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

5.3 Data Security:

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

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

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

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

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

Upon completion of the project, the custodian is responsible for the destruction of the data from all OHSU systems and servers assuring all folders are empty and there is no cache memory of the data, which is documented in a log. The custodian will delete the dataset from the secure and HIPAA-compliant ACC server where the data are housed (ensuring that no cache memory of the data remains), and will document this deletion in the data log. The custodian will have another IRB-approved analyst on the project confirm destruction of the data and documentation in the log.

SECTION 6: COST OF DATA

6.1 COST OF DATA:

If you are requesting **only data elements marked with an x** in the limited column in the APAC data elements worksheet, calculate the cost using the table below. Payment must be received before the data will be provided. An invoice is available to facilitate payment if requested.

If you are requesting **any data elements not marked with an x** in the limited column in the APAC Data Dictionary, an invoice will be sent after OHA approves the request. The invoice must be paid before the APAC team will provide the approved data.

	Payers			
	All Payers	**Only Commercial Medicare**	**Only Commercial Insurance**	**Only OEBB/PEBB**
Claims Data:				
All Medical and pharmacy claims	☐$3,000	☐$1,000	☐$1,000	☐$1,000
All medical claims (no pharmacy)	☐$1,500	☐$500	☐$500	☐$500
All pharmacy claims (no medical)	☐$1,500	☐$500	☐$500	☐$500
Only hospital inpatient claims	☐$375	☐$125	☐$125	☐$125
Only emergency department claims	☐$375	☐$125	☐$125	☐$125
Only ambulatory surgery claims	☐$375	☐$125	☐$125	☐$125
Only outpatient claims	☐$375	☐$125	☐$125	☐$125
Enrollment data				
Billed premium data				
Provider data				
a. Total each column				
b. Sum across column totals				
c. Number of years of data				
d. Multiply rows b and c				
e. OHA Production Cost				$560
f. Add rows d and e for Total				

SECTION 7: CHECKLIST AND SIGNATURE

7.1 Checklist: Please indicate that the following are completed:

- ☑ I acknowledge that payment will not be refunded if OHA fulfills the data request, but the receiving entity does not have the capability to import or analyze the data
- ☑ All questions are answered completely
- ☑ Data Element Workbook is attached to email or printed application (data options and data element worksheets completed)
- ☑ IRB approval memo is attached to email or printed application, if applicable
- ☑ Data privacy and security policies for the requesting organization, and any third-party organizations are attached to the email or printed application

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

Signature Jonathan Snowden Digitally signed by Jonathan Snowden Date: 2019.09.18 15:24:05 -07'00' Date

Printed name Jonathan Snowden, Ph.D.

Title Assistant Professor

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

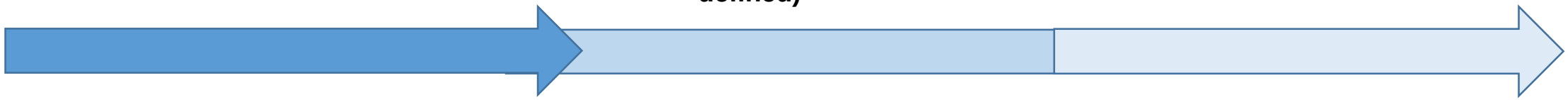
Completed forms may also be printed and mailed to:

APAC Program Manager
Office of Health Analytics
421 SW Oak St., Suite 850 – APAC
Portland, OR 97204

Definition of population of interest: All births (live births + stillbirths) in Oregon, 2010-2017. Births identified using refined Ailes algorithm (appendix)
Time window of interest: Pregnancy (Up to 15 months before birth) through 9 months postpartum

Causal aims:

1) to characterize prevalence of maternal health care utilization and morbidities;
2) to characterize racial/ethnic and insurance-type disparities in maternal and infant outcomes;
3) to determine what proportion of selected intrapartum and postpartum morbidities and disparities are due to preexisting maternal health conditions or childbirth care versus health care utilization; and
4) to assess how maternal morbidity after the first birth affects women's risk of outcomes during and after her next pregnancy and delivery



	1. Pregnancy (up to 15 mos before birth)	**2. Birth (how population is defined)**	3. Postpartum (out to 9 mos after birth)
Data requested	Insurance status (exposure, Aim1) Insurance changes (i.e. churn, exposure, Aim1) Care provided by midwife or physician (confounder) Prenatal care utilization (confounder) Maternal risk conditions (confounders, Aim2) - Chronic hypertension, type 1 or 2 diabetes, renal disease, preeclampsia/eclampsia, GDM Age (confounder) Race/ethnicity (confounder)	Insurance status (exposure, Aim1) Insurance changes (i.e. churn, exposure, Aim1) Care provided by midwife or physician (confounder) Induction of labor (confounder) Augmentation of labor (confounder) Mode of delivery (confounder) Episiotomy (confounder)	Insurance status (exposure, Aim1) Insurance changes (i.e. churn, exposure, Aim1) Care provided by midwife or physician (confounder, effect modifier) Primary care utilization (outcome) Contraceptive care (outcome) ED visits (outcome) Hospital readmissions (outcome) Complications (outcome, Aim2 and Aim3) - Hypertensive complications (see appendix) - Birth-related complications (see appendix) Medication adherence among hypertensive and diabetic women (mediator, Aim 3)

Section 2.1 Project Purpose Attachment
4951 APAC 3
Snowden

Research shows that prenatal care utilization influences post-partum health and behaviors. Our research aims to characterize post-partum utilization and complications and assess if prenatal utilization, delivery, insurance status and provider characteristics influences post-partum utilization. In addition, there is little research on optimal post-partum care utilization and post-partum preventive care that may mitigate severe maternal morbidity and mortality.

In order to address our research questions, we are requesting all claims data from eligible participants 15 months prior to delivery (hospital admit date for birth event) to 9 months after delivery (hospital discharge date for birth event). Given the lack of research on post-partum care utilization, we aim to characterize all post-partum care utilization across settings (inpatient, emergency department use, outpatient visits, specialist visits, behavioral health, and pharmacy) regardless if the provider included a pregnancy or post-partum diagnoses code on the claim. Since the traditional post-partum period is 42 days after birth, we hypothesize that many providers do not document pregnancy or post-partum diagnoses codes for health conditions or complications if they occur 42 days after delivery. For example, if a participant is diagnosed with pregnancy induced hypertension but has continuous follow-up visits for hypertension in the post-partum period past the traditional 42 days; providers may no longer include pregnancy related codes on the claim. Further, our research aims to describe all utilization in the post-partum period, not disease specific utilization, we are requesting all claims 9 months after delivery discharge regardless of documented diagnoses code on the claim. Because some outcomes are rare (e.g., postpartum preeclampsia, <1%), we are requesting data from all years, in order to aggregate data across years and maximize sample size and power for analyses.

In addition, we are requesting all claims for eligible participants at least 15 months before delivery hospital admission. We are requesting data that extends beyond the prenatal period to detect comboridibities that are not documented in prenatal specific claims but impact prenatal and post-partum health. Much like our post-partum claims request, we are also interested in utilization across settings regardless of documented diagnoses.

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Information justifying the following specific variables:

Paid amounts (need copayment, coinsurance, deductible): we aim to characterize how financial burden (e.g., costs of services to the member) is associated with obstetric and postpartum care utilization.

High deductible: (Same as for paid amounts)
Billed premium data: (Same as for paid amounts)

Pharmacy data: we aim to assess the degree to which adherence to medication for chronic condition management (e.g., chronic hypertension and Type 1 or 2 diabetes) is associated with postpartum complications.

Primary versus Secondary insurance information (goes back to coinsurance): we want to capture the full picture of insurance and payments to quantify financial burden on patients, to assess whether this is associated with postpartum care utilization. Primary and secondary insurance information allows us to identify dual eligible beneficiaries and capture the full picture of insurance type, utilization and financial burden. Research shows that dual eligible beneficiaries are high utilizers of the health care system because complex health care needs. We are requesting primary and secondary insurance information to assess whether dual eligibility is associated with postpartum care utilization.

Groupers: we seek to group claims within an individual continuous care episode and by care setting (i.e., MEG groupers and HCG groupers for setting of car). Therefore, we request medical episode group (MEG) code and related descriptive variables to group encounters (inpatient, emergency department and outpatient) and other claims across care settings, providers and insurance types within a single care episode. In addition, we seek to identify episodes of care unrelated to pregnancy to identify the impact of pre-delivery episodes of care impact post-partum care utilization and complications.

Provider data: we seek to characterize how provider-level factors are associated with delivery of obstetric and postpartum care, and intrapartum and postpartum complications. For example, is certified nurse-midwife care during birth associated with more or less postpartum care utilization during the postpartum period (as compared to physician care)? Is postpartum care delivered by certified nurse-midwives associated with more or less postpartum complications? Therefore, we request from the provider file the NPI, the provider type as well as the top three specialties the provider reports. We seek to characterize if provider-level factors, such as provider type and specialty, are associated with patterns of prenatal utilization, obstetric care, post-partum care utilization and post-partum complications. We are requesting the top three specialties because providers often report multiple specialties in addition to their primary specialty. In addition, the provider NPI is necessary in order to link provider type and specialty back to claims data.

Member month data: necessary for linking claims across time within an individual.
Monthly eligibility and enrollment data: necessary for linking claims across time within an individual. The member month eligibility data allows us to accurately capture insurance plan enrollment and changes in enrollment over time. One of the primary exposures of interest of our research is insurance "churn" or changes in insurance status or payer during the prenatal, birth and post-partum period. The enrollment data allows us to accurately account for women in the post-partum period that have coverage from any insurance plan but do not seek care.

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Sample selection algorithm:
We will manage the data using established methods to generate a births-level dataset of all deliveries occurring in Oregon during study years (Ailes et al., Birth Defects Res A Clin Mol Teratol. 2016 Nov; 106(11): 927–934). Specifically, we will use a host of Diagnostic Related Groups (DRG) codes, Procedure Codes (HCPC and ICD-9) and ICD-9 diagnosis codes to identify pregnancies and the relevant birth outcomes (e.g., live birth, stillbirth, spontaneous abortion, etc). We have included as a supplement to this form a list of the DRG, HCPC, and ICD-9codes that we will used to identify pregnancies (following Ailes et al.). Although this algorithm has not yet been updated to reflect ICD-10, it will enable us to identify births pre-ICD-10, and we will work on mapping this ICD-9 identification algorithm onto ICD-10.

This identification algorithm will narrow claims down to births events and terminated pregnancies, and we will generate analytical data sets made up of pregnancy outcomes, plus the utilization and associated claims in the prenatal period (i.e., up to 9 months before birth) and postpartum period (traditionally defined as 6 weeks postpartum; we will extend our analytical time-frame to 6 months postpartum, to identify utilization and claims beyond this traditional window that may nonetheless be informative for our study aims). This approach will reduce the full datasets that are released down to our population of interest (i.e., childbearing individuals); beyond this, we will not apply filters because births to people of all ages and demographic characteristics and in all years are relevant for our study questions.

Analytical methods and justification:

Advanced methodological techniques for prediction and causation will be applied to the data. In particular, we will use machine learning techniques to enable data-driven model building for the prediction of the outcomes of the prediction study – vaginal birth after cesarean delivery, preeclampsia, and maternal morbidity. For each outcome, a list of candidate variables to submit to machine learning algorithms will be selected. After variable selection, the data will be analyzed by standard machine learning algorithms (e.g. classification and regression trees (CART), k-nearest neighbors, random forest). The justification for these approaches is that they will enable us to identify key predictors of high-priority outcomes (e.g., VBAC, postpartum hemorrhage) in a nonparametric framework, without imposing investigator or clinician assumptions about which variables are most important and in what combinations/functional forms.

For the analysis of associations and causal effects related to prenatal care, intrapartum care and outcomes, and postpartum care and outcomes, we will conduct univariate, bivariate, and multivariable analyses as appropriate. We will fit multivariable regression models (e.g., negative-binomial models, logistic regression models, linear regressions) to estimate how health care utilization and maternal/neonatal outcomes are associated with the predictors of interest, including race/ethnicity, socioeconomic status, prenatal morbidities, and childbirth care variables. The justification for these methods is that we seek to understand the crude/unadjusted associations between predictors and utilization/health outcomes, and also the associations when adjusted for important covariates.

Analyses described above will be conducted stratified by the relevant racial/ethnic and socioeconomic variables: race/ethnicity and insurance-type. We will conduct descriptive analyses within strata of these racial/ethnic and SES groups, in multiple time frames of interest. We will conduct a mediation analysis using an inverse-probability weighted (IPW) approach to estimate the proportion of the racial and SES disparities that are mediated by preexisting maternal morbidities, differences in childbirth care, and postpartum care utilization. Finally, we will perform G-computation and propensity score analyses, with a list of variables to either match on (propensity score analysis) or control for (G-computation) to be determined by the researchers. The justification for this approach is that we seek to understand what proportion of the disparity in postpartum care and outcomes is mediated through maternal health and childbirth care/outcomes.

Analysis the Oregon APAC data will take place on our HIPAA-compliant, encrypted OHSU-issued computers and on our HIPAA-compliant, encrypted remote server maintained by OHSU's Advanced Computing Center (described in section 5.3).

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

September 20, 2019

Dear Investigator:

On 9-20-2019, the IRB reviewed the following submission:

IRB ID:	STUDY00018953	MOD or CR ID:	MOD00022666
Type of Review:	Modification		
Title of Study:	Advanced methodological techniques in obstetric data		
Title of modification	Protocol and variable list update		
Principal Investigator:	Jonathan Snowden		
Funding:	None		
IND, IDE, or HDE:	None		
Documents Reviewed:	• Appendix 2 - APAC variables 9.18.2019.xlsx • IRB_Protocol - v2.0 - 9.18.2019.doc		

The IRB granted final approval on 9/20/2019. The study is approved until 9/4/2021.

Review Category: Expedited-Minor Modification

Copies of all approved documents are available in the study's **Final** Documents (far right column under the documents tab) list in the eIRB. Any additional documents that require an IRB signature (e.g. IIAs and IAAs) will be posted when signed. If this applies to your study, you will receive a notification when these additional signed documents are available.

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

Application & Certification for Waiver or Alteration of the HIPAA Authorization requirement

Research Integrity Office
Mail code L106-RI
Portland, Oregon 97239-3098
Phone: 503-494-7887
Fax: 503-346-6808

Version 6.0
Updated 12.17.2014

Protected Health Information (PHI) = health information plus one or more individual identifiers (see Section III).

eIRB Number: 18953

Researcher Name:	Jonathan	Snowden
Study Title:	Advanced methodological techniques in obstetric data.	

SECTION I: Purpose of Waiver or Alteration of HIPAA Authorization

1. **PARTIAL WAIVER:**
   - A. Waiver is requested to disclose PHI from one covered entity to another for the purposes of contacting and recruiting individuals into the study. — A. ☐
   - OR
   - B. Waiver is requested to collect PHI over the phone, fax, internet or e-mail from study participants. — B. ☐
   - OR
   - C. Waiver is requested to use PHI for research purposes for individuals who are unable to provide authorization and no LAR is available. — C. ☐
   - OR
   - D. Waiver is requested for any other use and disclosure for ONLY part of the research project. **Describe:** — D. ☐

   ***NOTE:** In cases of a partial waiver, the researcher must obtain HIPAA Authorization from eligible subjects for any use or disclosure of PHI beyond what's approved under the partial waiver.*

2. **FULL WAIVER:** Waiver is requested for complete access, use, and creation of records containing Protected Health Information, but **only** as described in the IRB approved application. — ☒

3. **ALTERATION OF AUTHORIZATION:** Permission is requested to remove some, but not all, of the required elements of an Authorization***. When requesting an alteration, a copy of the proposed altered authorization form must be submitted for review. — ☐

   NOTE: Alterations are often needed in sham or placebo studies when identification of a required HIPAA element would affect the results of the study.

SECTION II: Description of health information to be collected (e.g., "blood pressure," "x-rays").

A research database comprised of adminstrative data from hospital discharge and vital records in the state of Oregon and from Sweden. This will include zip code and claims date, and prodecure dates.

SECTION III: Will any of the following elements be recorded for the study? (Check all that apply.)

- ☐ Patient/Subject Names
- ☐ Age information for those over 89
- ☒ Geographic subdivisions smaller than a State, with first 3 zip digit exceptions.
- ☐ Telephone numbers
- ☐ Fax numbers
- ☐ Electronic mail addresses
- ☐ Social Security Numbers
- ☐ Medical record numbers
- ☐ Account numbers
- ☐ Certificate/license numbers
- ☒ Dates (except year)
- ☐ Device identifiers and serial numbers
- ☐ Vehicle identifiers and serial numbers, including license plate numbers
- ☐ Web Universal Resource Locators (URLs)
- ☐ Internet Protocol (IP) address numbers
- ☐ Biometric identifiers, including finger and voice prints
- ☐ Full face photographic images and any comparable images
- ☐ Health plan beneficiary numbers
- ☐ Results of a genetic test
- ☐ None of the above

Section IV: Will you be sharing PHI *(health information plus one or more identifiers)* with anyone outside of OHSU?

Note: Only answer "yes" if you will share PHI under this waiver, without getting signed

YES ☐ **NO** ☒

If yes, what PHI will be shared, who may receive it, and how will it be identified?

If yes, indicate your plan for compliance with Accounting of Disclosures requirements:

☐ This study will enroll **50 or more** subjects. The study was entered into the Accounting of Disclosures System on (date):

authorization from the subjects and without obtaining a Data Use Agreement (DUA).	☐ This study will enroll **fewer than 50** subjects. The person responsible for entering each subject into the Accounting of Disclosures System is:
Section V: Describe the reasons that the research could not practicably be conducted without obtaining a waiver for access to the PHI.	The datasets that researchers will access involve a great number (over 1 million records) of patient medical information. Therefore individual subjects cannot be consented. The dataset does not involve contact information for researchers to contact individual subjects
Section VI: Describe the plan to protect the PHI from improper use and/or disclosure. Include how data will be stored and/or coded.	All research data will be kept in a password protected, OHSU-secure computer or in a secure server maintained by the Karolinska Institutet in Sweden accessed through a two-step authentication remote desktop. Only research staff listed on study will have access to this data. All data collected will not be individually identifiable.
Section VII: Describe your plan for maintenance of the identifiers after the research project has ended. (*This section pertains to data collected under the waiver only.*)	☒ Destroying data or de-identifying data by removing all 18 identifiers. ☐ Maintaining identifiable or coded data for storage in a research repository for the conduct of future research.

*****Authorization Required Elements (for question #3):**

- A description of the PHI to be used or disclosed, identifying the information in a specific and meaningful manner.
- The names or other specific identification of the person or persons (or class of persons) authorized to make the requested use or disclosure.
- The names or other specific identification of the person or persons (or class of persons) to whom the covered entity may make the requested use or disclosure.
- A description of each purpose of the requested use or disclosure.
- Authorization expiration date or expiration event that relates to the individual or to the purpose of the use or disclosure ("end of the research study" or "none" are permissible for research, including for the creation and maintenance of a research database or repository).
- Signature of the individual and date. If the individual's legally authorized representative signs the Authorization, a description of the representative's authority to act for the individual must also be provided.

Important Notice to Researchers

This waiver or alteration applies only to the use and/or disclosure of PHI as described above. In submitting this request, you certify that the PHI described above will not be reused or re-disclosed to any other person or entity not specified in this form, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.

If the results of a genetic test (as defined in ORS192.531) are obtained as part of this research under a partial or complete waiver, requirements for notification and opt out must be met as described in the OHSU Policy for Accessing Tissue Specimens or Information at OHSU for Anonymous or Coded Genetic Research. The plan for compliance with this policy should be outlined in the protocol if applicable.

This waiver or alteration request is approved by the IRB Chair or other Designated Reviewer upon approval of the associated project in the eIRB system.

Approval of this request confirms that:

- **The research could not practicably be conducted without the waiver or alteration;**
- **The research could not practicably be conducted without access to and use of the PHI;**
- **The use or disclosure of the PHI involves no more than minimal risk to the privacy of the subjects as a result of:**
  - **An adequate plan to protect the PHI from improper use and disclosure;**
  - **An adequate plan to destroy any identifiers contained in the PHI at the earliest opportunity consistent with the research; and**
  - **Adequate written assurances that the PHI will not be reused or re-disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.**

Section 5.3 Security Attachment
4951 APAC 3
Snowden

Access Management:
OHSU is committed to protecting the confidentiality, privacy, and security of protected health information as required by all applicable state and federal laws and this commitment is required of all OHSU members at all times (Confidentiality and Health Information Policy No. 01-05-012, pp 1-8 of attachment). In this setting, the principal investigator is the Custodian of the data and will ensure that only OHSU analysts who have both OHA approval and OHSU IRB approval may access the APAC data on the server. The Custodian ensures that the scope of the research is within the scope of this application and the IRB application and that data are properly destroyed at the time a project has been completed. We do not anticipate any third parties accessing the data, however if this becomes necessary, the Custodian will ensure that the third parties have appropriate approvals by OHA and OHSU to access the data including abiding by the OHSU Confidentiality of Health Information policy mentioned above. Upon completion of the project, the custodian is also responsible for the destruction of the data from all OHSU systems and servers assuring all folders are empty and there is no cache memory of the data, which is documented in a log.

Personnel Safeguards:
The Custodian of the APAC data is responsible for restricting access to the data for only OHSU analysts with proper approvals. All OHSU research personnel must complete extensive Responsible Conduct of Research, Research Integrity, and Ethical Conduct of Human Subjects Research training (including annual booster courses). This training ensures that all research personnel on this project will comply with the relevant regulations as relates to confidentiality, data security, and research integrity. The custodian will also personally train all research staff on these principles, and will maintain confidentiality agreements with each. Only a minimum number of OHSU analysts may access APAC data as required to fulfill their job. As detailed above, every OHSU analyst is required to complete training on privacy and information security guidelines and policies before commencing work through an e-learning platform. Upon training completion, all OHSU analysts commit to protecting health information according to OHSU policy in conjunction with state and federal laws. The Custodian of that APAC data also obtains verbal and written verification that OHSU analysts understand how to comply with these policies in their day to day tasks to ensure continued security of the data throughout the project. This regulatory and ethical compliance also includes a security risk management plan for APAC data, as well as the other data resources that we work with. As part of this risk management plan, all approved research personnel agree to abide by the relevant regulations, and in instances where protocols are not followed, are responsible for immediately notifying the Custodian, so that the relevant authorities (including APAC) can be notified, and corrective actions can be taken. We do not anticipate any such protocol noncompliance, but the security risk management plan provides a clear system for corrective actions and notifying relevant parties in this unlikely occurrence.

Technical and Physical Safeguards:
APAC data will be stored on our secure, HIPAA- and IRB-compliant server maintained by OHSU's Advanced Computing Center (ACC). Access to the folders containing APAC data will be restricted, using Microsoft Active Directory permissions, to analysts who have appropriate approvals to access APAC data as directed by the Custodian. All systems accessing OHSU's secure network and/or storing data must be password protected and must have OHSU-approved encryption tools and software to protect against viruses and malware. Teleworking is available to some OHSU analysts and must be approved in advance

(Teleworking Policy No. 03-30-140, pp 9-12 of attachment). Teleworking analysts must have access to a secured, encrypted workstation offsite that complies with OHSU standards. No OHSU member shall store, locate, or leave any protected health information or their workstation in any unsecured location or area, either physically or virtually; we will apply the same degree of security to the APAC data.

We will not transmit APAC data in any way (neither in part nor in whole), nor will we make any virtual or hard copies of the data. Data analysis will take place only on the secure server environment, conducted by analysts approved by APAC and by OHSU's IRB, and using a remote connection to access our unique, custom dataset provided by OHA. Password protections are required for all OHSU Members on all devices, where passwords must meet minimum attributions for complexity and security. Seven unsuccessful attempts to login within thirty minutes results in an account lockout mechanism. OHSU computers have an automatic logoff after a predetermined time of inactivity and audit software to determine when and where protected health information has been accessed. We are not requesting direct identifiers in this data request.

Administrative Safeguards:
OHSU implements administrative safeguards to protect health information that include policies, training, sanctions for non-compliance, and audit procedures. OHSU policies are first described generally (p 13); they require that each user have a unique identification (p 19), and that users enable two-factor authentication (p 22). Passwords may never be shared and must have a minimum standard with at least eight characters and the inclusion of alpha, numeric, and capitalized character (p 25). OHSU members must never leave their computer unlocked or unattended and must secure and log off all electronic sessions when not active (p 30). OHSU-approved encryption is required for all devices accessing the OHSU network (p 32). OHSU maintains audit controls and logs for all electronic protected health information (p 38). Accessing electronic restricted information is managed by a steward or custodian of the organization (p 41). Electronic media reuse and disposal is controlled by the custodian and the information technology department to ensure the security of protected health information on those devices (p 47). Physical safeguards for computing devices include screen locks, two-factor authentication, and restricted physical access (p 50). OHSU members may report security incidents to the information technology department, information privacy and security office, or the office of public safety (p 63). Two trainings are required to start work via the e-learning platform: (1) OHSU Information Security and (2) Information Privacy and Security Essentials. Additionally, the custodian of the APAC data takes on additional responsibility ensuring OHSU analyst compliance with appropriate security practices.

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	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	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				

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 exclusions:
			Exclude below 15 yrs & above 50 yrs

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	We propose using the approach outlined in the APAC-3 form

Do you want to limit pharmacy data to selected NDC codes or therapeutic classes?	No	Yes. List NDC codes or therapeutic classes codes
		x - see "Medi-Span GPIs" tab

Are you requesting identifiable data?	No	Zip code	County	Address	Name	Month of birth	Month of death	Date of birth	Date of death
	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
	Data Elements Available for Both Medical and Pharmacy Claims:								
x	Year or incurred_year	Year of service or eligibility occurred	YYYY			x	x	x	Necessary to distinguish between years
x	Fromdate or fill date or from_date	Service begin date or pharmacy fill date	YYYY-MM-DD	x	0.0%			x	Necessary to identify when utlization occurred and properly interpret duplicate claim lines
x	Todate or to_date	Service end date	YYYY-MM-DD	x	0.0%			x	Necessary to identify when utlization occurred and properly interpret duplicate claim lines
x	Paydate or paid_date	Payment date	YYYY-MM-DD	x	0.0%			x	Necessary to identify when utlization occurred and properly interpret duplicate claim lines
x	Patid or member ID or member_key	Unique person identifier created from payer reported identifier for each plan. Not unique across payers and years	Numeric	x	0.0%			x	To group all claims by individual and payer
x	Personkey or MI_Person_key	Unique identifier created for a person across payers and years	Numeric			x		x	Necessary to group claims within an individual across coverage changes
x	Relation	Member's relationship to the subscriber i.e., child and/or spouse	See Relationship Table	x	1.2%				Used to group claims within a family (birthing individual with infant)
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	Necessary to properly interpret duplicate claim lines
x	Claim line or SV_line	Claim service line number	Numeric	x	0.0%			x	Necessary to properly interpret 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 to group claims from a single inpatient stay
x	Form_type	Type of claim. If revenue code (MC054) is not null and does not contain values like ('','0','00','000','0000') then 'U' is assigned otherwise 'H' is assigned. Rx claims are defaulted to 'D'	U=UB, H=CMS1500, D=Prescription drug			x			Used to distinguish claim types
x	clmstatus or sv_stat	Claim status	P, D, E, R	x	0.0%			x	Necessary to properly interpret 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 to identify and distinguish levels and settings of utilization
x	HCG_MR_Line_Desc	Description of HCG MR_LINE	Text			x			Used to identify and distinguish levels and settings of utilization
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 to identify and distinguish levels and settings of utilization
x	HCG_MR_Line_Group	Second level of the HCG system	HIP (hospital inpatient), HOP (hospital outpatient), PHY (professional), RX (prescription			x			Used to identify and distinguish levels and settings of utilization
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	Used to idenitfy quantity of services utilized

x	Medicareflag	Medicare coverage flag derived from HCG based on plan benefit package line (PBP). PBP is based on CPT/HCPCS, revenue and diagnosis codes.	Y (yes), N (no). See HCG PBP Table for more information		1.2%	x			Used to identify dual eligible participants
x	Payer_LOB	Payer line of business from derived from payer reported product code from eligibility data only and not claims data. Orphan claims assigned null.	Commercial, Medicaid, Medicare or null. See product code table for crosswalk			x			To identify insurance type
x	Paytype or payer_type	Payer reported payer type codes from eligibility data only and not from claims data	C, D, G, P, T, U	x				x	To identify insurance type
x	MC001_APAC _Payer_type	Payer reported payer type codes from claims data	C, D, G, P, T, U	x					To identify insurance type
x	MC001_APAC _Payer_type_desc and claims payer type	Payer type description	(C) Carrier, (D) Medicaid, (G) Other government agency, (P) Pharmacy benefits manager, (T) Third-party administrator, (U) Unlicensed entity			x		x	To identify insurance type
x	APAC_Product_code	Payer reported product code from claims data	See product code table	x	0.0%		x		Used to group individual claims within an episode of care.
x	APAC_Product_code_code_and_desc	Product code description	See product code table			x			Used to group individual claims within an episode of care.
x	Claim_specific_LOB	Derived from payer reported product code from eligibility data only and defaulted to a specific LOB for some identifed payers	See claim specific LOB payer table			x			Used to determine who paid the claim.
x	medflag	Indicates medical coverage for the month when claim occurred	Numeric: 1 (yes), 0 (no)	x	0.0%				To categorize patient insurance
x	rxflag	Indicates pharmacy coverage for the month when claim occurred	Numeric: 1 (yes), 0 (no)	x	0.0%				To categorize patient insurance
x	Age on DOS	age on date of service	Numeric			x			Needed to categorize individuals by age
x	agegrp	Five year age groups calculated based on month of date of service	0-4,5-9,10-14 etc			x	x		Needed to categorize individuals by age
x	ATT_PROV_CW_KEY	Vendor created unique attending provider identifier across payers and years				x			Used to study provider-level factors in maternity care
x	Billid	APAC assigned billing provider ID	Text	x	1.2%			x	Used to enable linkage to provider data
x	Network_indicator	Indicator of whether service received in or out of network	1 (in network), 2 (National network), 3 (out-of-network)	x	0.0%				Used to study provider-level factors in maternity care
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	Necessary to properly interpret duplicate claim lines
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	Used to study insurance level factors in seeking care
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	Used to study insurance level factors in postpartum care

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	Used to study insurance level factors in postpartum care
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	Used to study insurance level factors in postpartum care
	Data Elements Avaliable Only for Medical Claims:								
x	POS	Industry standard place of service code	See place of service table	x	1.2%		x	x	Used to identify setting of utilization
x	Adm_date	Admission date required for inpatient hospitalizations	YYYY-MM-DD	x	1.2%				Used to group claims within an admission.
x	Dis_date	Discharge date required for inpatient hospitalization	YYYY-MM-DD	x	1.2%				Used to group claims within an admission.
x	admtype	Admission type is required for inpatient claims	1 (Emergency), 2 (Urgent), 3 (Elective), 4 (Newborn), 5 (Trauma Center), 9 (Information Not Available)	x	1.2%				Needed to categorize admissions as births, or emergent postpartum complications, etc.
x	admsrc	Admission source is required for inpatient claims	See admission source table	x	1.2%				Needed to identify transfers of care.
x	admdiag	Admitting diagnosis required for inpatient claims. ICD-9 for dates of service before 10/01/2014 and ICD-10 on or after	Alphanumeric	x	1.2%				Needed to identify complication/condition requiring admission.
x	ptstatus or dis_stat	Status for member discharged from the hospital	See discharge status table	x	1.2%		x	x	To assess outcome of cases
x	los	length of inpatient hospital stay. Length of stay equals discharge date minus admission date	Equals 1 or more for inpatient hospitalizations			x	x	x	To assses outcomes(LLOS)
x	ICD version or ICD_10_OR_HIGHER	Specifies the claim ICD version ICD9 or ICD10	9 or 10	x	0.0%		x	x	To distinguish ICD code version
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	To define cases, outcomes, comorbidities
x	dx1 description or ICD_DIAG_DESC_PRIMARY	Primary diagnosis description	Text			x			To define cases, outcomes, comorbidities
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	To define cases, outcomes, comorbidities
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	To define cases, outcomes, comorbidities
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	To define cases, outcomes, comorbidities
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	To define cases, outcomes, comorbidities
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	To define cases, outcomes, comorbidities
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	To define cases, outcomes, comorbidities
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	To define cases, outcomes, comorbidities

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	To define cases, outcomes, comorbidities
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	To define cases, outcomes, comorbidities
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	To define cases, outcomes, comorbidities
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	To define cases, outcomes, comorbidities
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	To define cases, outcomes, comorbidities
x	px1 or ICD_Proc_01_Principle	The main or principal inpatient surgery ICD code	Alphanumeric	x	1.2%		x	x	To define outcomes and related procedures
x	px2 or ICD_Proc_02	Inpatient surgery ICD code 2	Alphanumeric	x	1.2%			x	To define outcomes and related procedures
x	px3 or ICD_Proc_03	Inpatient surgery ICD code 3	Alphanumeric	x	1.2%			x	To define outcomes and related procedures
x	px4 or ICD_Proc_04	Inpatient surgery ICD code 4	Alphanumeric	x	1.2%			x	To define outcomes and related procedures
x	px5 or ICD_Proc_05	Inpatient surgery ICD code 5	Alphanumeric	x	1.2%			x	To define outcomes and related procedures
x	px6 or ICD_Proc_06	Inpatient surgery ICD code 6	Alphanumeric	x	1.2%			x	To define outcomes and related procedures
x	px7 or ICD_Proc_07	Inpatient surgery ICD code 7	Alphanumeric	x	1.2%			x	To define outcomes and related procedures
x	px8 or ICD_Proc_08	Inpatient surgery ICD code 8	Alphanumeric	x	1.2%			x	To define outcomes and related procedures
x	px9 or ICD_Proc_09	Inpatient surgery ICD code 9	Alphanumeric	x	1.2%			x	To define outcomes and related procedures
x	px10 or ICD_Proc_10	Inpatient surgery ICD code 10	Alphanumeric	x	1.2%			x	To define outcomes and related procedures
x	px11 or ICD_Proc_11	Inpatient surgery ICD code 11	Alphanumeric	x	1.2%			x	To define outcomes and related procedures
x	px12 or ICD_Proc_12	Inpatient surgery ICD code 12	Alphanumeric	x	1.2%			x	To define outcomes and related procedures
x	px13 or ICD_Proc_13	Inpatient surgery ICD code 13	Alphanumeric	x	1.2%			x	To define outcomes and related procedures
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	Necessary to identify births, other procedures and encounters
	proc_desc	CPT and HCPCS code descriptions	Text			x		x	Necessary to identify births, other procedures and encounters
x	proc_code_ family_ID	High level grouping procedure codes from HRT HCPCS code reference	Text			x			To identify categories of procedure utilized before, during and after birth event.
x	proc_code_ family_level_1	Highest level procedure code groups from HRT HCPCS	Text			x			To identify categories of procedure utilized before, during and after birth event.
x	proc_code_ family_level_2	Second Highest level procedure code groups from HRT HCPCS	Text			x			To identify categories of procedure utilized before, during and after birth event.
x	proc_code_ family_level_3	Lowest level procedure code groups from HRT HCPCS	Text			x			To identify categories of procedure utilized before, during and after birth event.
x	proc_code_ ahrq_ccs	Agency for Healthcare Research and Quality (AHRQ) clinical classification grouping of procedure codes (CPT or HCPCS)	Text			x			To identify categories of procedure utilized before, during and after birth event.
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	Necessary to properly interpret duplicate claim lines
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	To define outcomes and related procedures
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	To define outcomes and related procedures
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	To define outcomes and related procedures
x	revcode or rev_code	Revenue code	Numeric	x	1.2%			x	Necessary to properly interpret duplicate claim lines
x	rev_code_desc	Revenue code description	Text			x			Necessary to properly interpret duplicate claim lines
x	MI_MS_DRG_Code	Vendor derived DRG code version 25+	Text			x			Used to group services into categories for outcome definition.

x	MI_MS_DRG_desc	Vendor derived DRG code description version 25+	Text			x			Used to group services into categories for outcome definition.
x	MI_MS_DRG_Code_and_desc	Vendor derived DRG code and description version	Text			x			Used to group services into categories for outcome definition.
x	msdrg	MS DRG is a Medicare grouping system that classifies inpatient hospital services into one of approximately 750 groups.	Text			x	x	x	Used to group services into categories for outcome definition.
x	ms_drg_desc	MS DRG code description	Text			x			Used to group services into categories for outcome definition.
x	ms_drg_code_and_desc	MS DRG code and description	Text			x			Used to group services into categories for outcome definition.
x	megcode	Medical episode group (MEG) is a vendor proprietary grouping algorithm that creates episodes of care that describe a patient's complete course of care for a single illness or condition	Alphanumeric			x	x	x	Necessary to group individual claims within an episode of care.
x	megdesc	MEG episode description	Alphanumeric			x	x	x	Necessary to group individual claims within an episode of care.
x	megbodysys	MEG body system uses a proprietary grouping algorithm and groups episodes of care into body systems	Alphanumeric			x	x	x	Necessary to group individual claims within an episode of care.
x	megstage	MEG stage of the given episode	Alphanumeric			x	x	x	Necessary to group individual claims within an episode of care.
x	megtype	MEG Type of care episode	Alphanumeric			x	x	x	Necessary to group individual claims within an episode of care.
x	megcomplete	MEG indicator that episode is complete.	1 (yes), 0 (no)			x	x	x	Necessary to group individual claims within an episode of care.
x	megnum	MEG unique identifier for a single episode	Numeric			x	x	x	Necessary to group individual claims within an episode of care.
x	megdays	MEG duration of episode in days	Numeric			x	x	x	Necessary to group individual claims within an episode of care.
x	MEG_Episode_Months_duration	Total number of months	Numeric						Necessary to group individual claims within an episode of care.
x	megprorate	MEG prorated episode allowed amount allocation for the given service line. This field allows a user to sum detail lines for an overall episode count. Summing this field over all related service lines for a given episode will yield a result of 1.	Numeric			x	x	x	Necessary to group individual claims within an episode of care.
	MEG_EPISODE_count_paid_prorate	Prorated episode paid amount allocation for service line	Numeric			x		x	
x	megoutlier	MEG indicator for an outlier episode	1 (yes), 0 (no)			x	x	x	Necessary to identify outlier episodes.
x	meglow	MEG indicator for low outlier episode	1 (yes), 0 (no)			x	x	x	Necessary to identify outlier episodes.
x	meghigh	MEG indicator for high outlier episode	1 (yes), 0 (no)			x	x	x	Necessary to identify outlier episodes.
x	MEG_Min_Incurred_Month_start_date	MEG start month for episode	Text			x			Necessary to place episodes of care in time, and to ensure claims are within the same episode.
x	MEG_Max_Incurred_Month_start_date	MEG end month for episode	Text			x			Necessary to place episodes of care in time, and to ensure claims are within the same episode.
	Data Elements Available Only for Pharmacy Claims:								
x	NDC	National Drug Code	Text	x	1.2%		x	x	Necessary to identify prescription fills
x	NDC_Code_and_Prod_Name	NDC code and NDC_Prod_Name	Text			x			Necessary to identify prescription fills
x	rxclass or Ther_class	NDC therapeutic class. Medi-Span defined grouping of drugs with the same therapeutic properties	The first 10 characters of Medi-Span's Generic Product Identifier (GPI)			x	x	x	Necessary to identify prescription fills
x	Main	NDC therapeutic class. Medi-Span defined grouping of drugs with the same therapeutic properties. Name of class	Text			x			Necessary to identify prescription fills
x	Product_description	Drug name, dose, strength	Text			x			Necessary to assess whether patients are taking recommended medication.
x	brand_status_rollup	Roll up indicates if brand or generic	Text			x			Necessary to assess patients taking generic or brand name drugs
x	qtydisp	Quantity dispensed	Numeric	x	1.2%		x	x	Necessary to assess whether patients are taking recommended medication.
x	rxdays	Number of days that the drug will last if taken at the prescribed dose	Numeric	x	1.2%		x	x	Necessary to assess whether patients are taking recommended medication.
x	RX_Refills	Count of times prescription refilled	Numeric	x	1.2%				Necessary to assess whether patients are taking recommended medication.
	Data Elements Available for Member Demographic Data (static except for age related data elements):								
x	patid or member ID or member_key	Payer specific unique person identifier created from payer reported identifier. Not unique across payers and plans	Numeric	x	0.0%			x	to group all claims by individual
x	personkey or MI_Person_key	Unique identifier created for a person across payers and data years	Numeric			x		x	Necessary to properly interpret duplicate claim lines

x	gender or Mem_gender	Member Gender	M (male), F (female), and U (unknown)	x	1.2%		x	x	For demographic analysis of cases
x	YOB	Member year of birth	YYYY			x		x	For demographic analysis of cases
x	race or mem_race	Member race reported by payer. Static from latest quarterly data submitted. Race data for 59% of unique people is missing or unknown.	4 (Asian), 2 (Black or African American), 3 (American Indian or Alaskan Native), 5 (Native Hawaiian or Pacific Islander), 1 (White), 6 (other or multiple races), 9 (unknown) and 0 (not defined)	x			x	x	For demographic analysis of cases
x	ethn or mem_ethnicity	Member ethnicity reported by payer. Static from latest quarterly data submitted. Ethnicity data for 72% of unique people is missing or unknown.	1 (Hispanic), 2 (Not Hispanic), 3 (unknown), Null	x			x	x	For demographic analysis of cases
x	lang or Mem_language	Primary spoken language; Static from latest quarterly data submitted. Payers report three-character string from ANSI/NISO https://www.loc.gov/standards/iso639-2/php/code_list.php Vendor recodes ANSI/NISO to numeric codes. Language data for 50% of unique persons is missing	Numeric. See language table	x			x	x	For demographic analysis of cases
x	MSA or Mem_MSA	Member metropolitan statistical area defined by US Census. Static from latest quarterly data submitted	Text			x	x	x	For demographic analysis of cases
x	STATE or Mem_state	Member State. Static from latest quarterly data submitted	Two letter abreviation	x	1.2%			x	For demographic analysis of cases
x	urban	Zip codes grouped into urban and rural identified by OHA. Static from latest quarterly data submitted	1 (Urban), 2 (not Urban)			x	x		For demographic analysis of cases (previously given zip code)
	Data Elements Available for Monthly Member Eligibility Data:								
x	YEAR and incurred_year	Year of service or eligibility occurred	YYYY			x			Used to determine member enrollment and to link individuals across time and plans
x	YEARMONTH and incurred_year_and_month	Year and month service or eligibility occurred	YYYYMM			x			Used to determine member enrollment and to link individuals across time and plans
x	incurred_month_start_date	First day of the month the service or membership occurred	YYYY-MM-DD			x			Used to determine member enrollment and to link individuals across time and plans
x	incurred_cal_quarter	Quarter month the service or eligibility occurred	Numeric			x			Used to determine member enrollment and to link individuals across time and plans
x	personkey or MI_Person_key	Vendor created unique identifier for a person across payers and years	Numeric			x			Used to determine member enrollment and to link individuals across time and plans
x	Medicare_coverage_ flag	Medicare coverage reported by payer. X (other), C (Medicare part C only), D (Medicare part D only), CD (Medicare parts C and D), B (Medicare Part B), AB (Medicare parts A and B), Z (none), Null and blank	X , C , D , CD , B , AB , Z , Null and blank	x	1.2%				Used to determine member enrollment and to link individuals across time and plans
x	PAYER_LOB	Payer line of business derived from payer reported product code from eligibility data only and not claims data. Orphan claims assigned null.	Commercial, Medicaid, Medicare or null. See product code table for crosswalk			x			Used to determine member enrollment and to link individuals across time and plans
x	paytype or MC001_APAC _Payer_type	Payer type codes reported by payer for eligibility data only and not from claims data	C, D, G, P, T, U	x					Used to determine member enrollment and to link individuals across time and plans

x	MC001_APAC _Payer_type_desc	Payer type description	(C) Carrier, (D) Medicaid, (G) Other government agency, (P) Pharmacy benefits manager, (T) Third-party administrator, (U) Unlicensed entity			x			Used to determine member enrollment and to link individuals across time and plans
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%				Used to determine member enrollment and to link individuals across time and plans
x	APAC_Product_code_code_and_desc	Product code description	See product code table			x			Used to determine member enrollment and to link individuals across time and plans
x	EFF_DATE	First day of the month member enrolled	YYYY-MM-DD	x	0.0%				Used to determine member enrollment and to link individuals across time and plans
x	TERM_DATE	Last day of the month member enrolled	YYYY-MM-DD	x	0.0%				Used to determine member enrollment and to link individuals across time and plans
x	primary or primary_insurance	Primary Insurance Indicator	Y (primary insurance), N (secondary or tertiary insurance). If unknown, default to Y	x	0.0%				Used to determine member enrollment and to link individuals across time and plans
x	Prod_type	Derived type of membership. If member eligible for medical and payer is not behavioral health and is not pharmacy plan and is not Medicare part D then equals medical. If member eligible for pharmacy and payer is not behavioral health then equals pharmacy. Behavioral health if payer is behavioral health. The behavioral health type was created to mark duplicate medical member months. Medical Coverage is assigned if Medical_coverage_flag (ME018) =1 and payer is not behavioral health and payer type (ME001) is not pharmacy and product_code (ME003) is not pharmacy or Medicare part D. Rx Coverage is assigned if Prescription Drug Coverage Flag (ME019) =1 and payer is not behavioral health and submitter_abbr column does not equal 'OMIP'. Behavioral Health is assigned if Medical_coverage_flag (ME018) =1 and payer is behavioral health. Prod_type or prod_type_Key necessary for analysis of member months	Text: medical, rx, dental, behavioral, vision [No dental or vision in APAC]			x			Used to determine member enrollment and to link individuals across time and plans
x	Prod_type_key	Generated number that represents the type of membership Prod_type. This key is used to join claims with monthly member data for efficiency. Necessary for analysis of member months	Integer: 0 (combined), 1(medical member month), 2 (pharmacy member month), 4 (vision member month), 6 (behavioral health member month)			x			Used to determine member enrollment and to link individuals across time and plans
x	MM_UNITS	Flag that indicates medical coverage for the month for the member	Numeric: 1 (yes), 0 (no)			x			Used to determine member enrollment and to link individuals across time and plans
x	RX_UNITS	Flag that indicates prescription drug coverage for the month for the member	Numeric: 1 (yes), 0 (no)			x			Used to determine member enrollment and to link individuals across time and plans

x	Sub_MM_UNITS	Flag that indicates medical coverage for the month for the subscriber	Numeric: 1 (yes), 0 (no)			x			Used to determine member enrollment and to link individuals across time and plans
x	Sub_RX_UNITS	Flag that indicates prescription drug coverage for the month for the subscriber	Numeric: 1 (yes), 0 (no)			x			Used to determine member enrollment and to link individuals across time and plans
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 determine member enrollment and to link individuals across time and plans
x	TPA_OR_PBM_DUPLICATE_MM_Desc	Description of duplicate member months reported by third party administrator or pharmacy benefit manager	1 (medical member month duplication), 2 (pharmacy member month duplication, 0 (no duplication)			x			Used to determine member enrollment and to link individuals across time and plans
x	HDHP	High Deductible Health Plan Flag	Y (Yes), N (No)	x	1.2%				Used to assess whether individuals on HDHP utilize preventive services differently.
x	Enrollment_key	Vendor generated number that represents an enrollment record. Key can be used to join claims and enrollment				x			Used to join enrollment data and claims
	Data Elements Available for Provider Data:								
x	Prov_CW_Key	Vendor created unique provider identifier across payers	Integer			x			Used to analyze provider-level factors that affect care and outcomes.
x	ATT_PROV_CW_KEY	Vendor created unique attending provider identifier across payers	Integer			x			Used to analyze provider-level factors that affect care and outcomes.
x	spec or Attending_MI_Specialty	Vendor derived provider specialty for attending, servicing or rendering provider	See Health care provider taxonomy codes www.nucc.org			x		x	To evaluate type of care delivered
x	billid	APAC assigned billing provider ID	Text	x	1.2%				Necessary to properly interpret duplicate claim lines
	Data Elements Available for Billied Premium Data:								
	Restricted Access Data Elements that Require Strong Justification and Detailed Data Security and Release Plan:								
	Restricted Access Data Elements that Are Never Shared or Rarely Shared, require Strong Justification, Detailed Data Security and Release Plan, and Subject to DOJ review:								

Medi-Span GPIs

Drug Group - Drug Class	Drug Group	Drug Class	22 Endocrine and Metabolic Agents
			ANTIDIABETICS
27-10	27	10	Insulin
27-15	27	15	Amylin Analogs
27-17	27	17	Incretin Mimetic Agents (GLP-1 Receptor Agonists)
27-20	27	20	Sulfonylureas
27-25	27	25	Biguanides
27-28	27	28	Meglitinide Analogues
27-30	27	30	Diabetic Other
27-50	27	50	Alpha-Glucosidase Inhibitors
27-55	27	55	Dipeptidyl Peptidase-4 (DPP-4) Inhibitors
27-57	27	57	Dopamine Receptor Agonists - Antidiabetic
27-60	27	60	Insulin Sensitizing Agents
27-70	27	70	Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors
27-99	27	99	Antidiabetic Combinations
			31 Cardiovascular Agents
			CARDIOTONICS
31-10	31	10	Phosphodiesterase Inhibitors
31-20	31	20	Cardiac Glycosides
			ANTIANGINAL AGENTS
32-10	32	10	Nitrates
32-20	32	20	Antianginals - Other
			BETA BLOCKERS
33-10	33	10	Beta Blockers Non-Selective
33-20	33	20	Beta Blockers Cardio-Selective
33-30	33	30	Alpha-Beta Blockers
			CALCIUM CHANNEL BLOCKERS
34-00	34	00	Calcium Channel Blockers
			ANTIARRHYTHMICS
35-10	35	10	Antiarrhythmics Type I-A
35-20	35	20	Antiarrhythmics Type I-B
35-30	35	30	Antiarrhythmics Type I-C
35-40	35	40	Antiarrhythmics Type III
35-50	35	50	Antiarrhythmics - Misc
			ANTIHYPERTENSIVES
36-10	36	10	ACE Inhibitors
36-15	36	15	Angiotensin I Receptor Antagonists
36-17	36	17	Direct Renin Inhibitors
36-20	36	20	Antiadrenergic Antihypertensives
36-25	36	25	Selective Aldosteron Receptor Antagonists (SARAs)
36-30	36	30	Agents for Pheochromocytoma
36-40	36	40	Vasodilators
36-60	36	60	Antihypertensives - Misc
36-99	36	99	Antihypertensive Combinations
			DIURETICS
37-10	37	10	Carbonic Anhydrase Inhibitors
37-20	37	20	Loop Diuretics
37-40	37	40	Osmotic Diuretics
37-50	37	50	Potassium Sparing Diuretics

37-60	37	60	Thiazides and Thiazide-Like Diuretics
37-90	37	90	Diuretics - Miscellaneous
37-99	37	99	Diuretic Combinations
			VASOPRESSORS
38-00	38	00	Vasopressors
38-70	38	70	Neurogenic Orthostatic Hypotension (NOH) - Agents
38-90	38	90	Anaphylaxis Therapy Agents
			ANTIHYPERLIPIDEMICS
39-10	39	10	Bile Acid Sequestrants
39-20	39	20	Fibric Acid Derivatives
39-30	39	30	Intestinal Cholesterol Absorption Inhibitors
39-35	39	35	Proprotein Convertase Subtilisin/Kexin Type 9 Inhibitors
39-40	39	40	HMG CoA Reductase Inhibitors
39-45	39	45	Nicotinic Acid Derivatives
39-48	39	48	Microsomal Triglyceride Transfer Protein (MTP) Inhibitors
39-50	39	50	Antihyperlipidemics - Misc
39-99	39	99	Antihyperlipidemics - Combinations
			CARDIOVASCULAR AGENTS - MISC
40-10	40	10	Peripheral Vasodilators
40-12	40	12	Pulmonary Hypertension - Prostacyclin Receptor Agonist
40-13	40	13	Pulmonary Hypertension - Sol Guanylate Cyclase Stimulator
40-14	40	14	Pulmonary Hypertension - Phosphodiesterase Inhibitors
40-16	40	16	Pulmonary Hypertension - Endothelin Receptor Antagonists
40-17	40	17	Prostaglandin Vasodilators
40-18	40	18	Vasoactive Natriuretic Peptides
40-20	40	20	Cardioplegic Solutions
40-30	40	30	Impotence Agents
40-50	40	50	Septal Agents
40-70	40	70	Sinus Node Inhibitors
40-99	40	99	Cardiovascular Agents Misc. - Combinations
			ANTIHISTAMINES
41-10	41	10	Alkylamines
41-20	41	20	Ethanolamines
41-30	41	30	Ethylenediamines
41-40	41	40	Phenothiazines
41-45	41	45	Piperazines
41-50	41	50	Piperidines
41-55	41	55	Non-Sedating

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

Staff Reviewer: Mary Ann Evans

Agreement Number: 4951

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**			
IRB accredited? (Write accrediting agency in notes)			**X**	

Task	Yes	No	N/A	Notes
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?				
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 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**			

Task	Yes	No	N/A	Notes
Adequately described filters and algorithms for including and excluding claim lines (provide rationale and list strengths and weaknesses of algorithms in notes)?	X			
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.)	X			
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?				
If project requires linkage to another data source, does PI propose adequate steps to prevent re-identification in 5.2d?				
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			
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	

Task	Yes	No	N/A	Notes
Does question 4.1 correspond with files selected and number of years input in row c of payment table?				
Is cost calculated correctly?				
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?	**X**			
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 receiving 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: ___4951_____

Staff Review Checklist

Staff Name: Mary Ann Evans

1. Data Source(s) Requested:

	APAC	

2. Application materials included:

Application	Y
Payment	N
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: