A Study Manual for:

The PACE Study

Post Affordable Care Act: Evaluation of Community Health Centers

AHRQ R01HS024270
NCT 02657499

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A partnership between:
Oregon Health & Science University
OCHIN, Inc.

This manual of procedures provides an overview of the PACE project, and is meant to serve as a resource to facilitate the replication of this study in other settings. An overview of the study describes the project aims, as well as information about the study team, funding, and data sources. Further sections describe the regulatory aspects of the study, major project decisions, and the analyses conducted.

Funding
This work was supported by the Agency for Healthcare Research and Quality grant number R01HS024270, and was funded September 2015 through September 2017.

Table 1. Study Staff.

Name	Project Role	Institution
Jennifer DeVoe, MD, DPhil	Principal Investigator	OHSU
Heather Angier, PhD, MPH	Co-Project Director, Co-Investigator	OHSU
Nathalie Huguet, PhD	Co-Project Director, Co-Investigator	OHSU
Miguel Marino, PhD	Co-Investigator, Biostatistician	OHSU
Lewis Raynor, PhD, MS, MPH	Co-Investigator	OCHIN
Megan Hoopes, MPH	Data Analyst - Site PI (Year 2- NCE)	OCHIN
Heather Holderness, MPH	Project Manager	OHSU
Nate Warren, MPH	Project Manager	OCHIN
Jean O'Malley, MPH	Data Analyst	OHSU
Rachel Springer, MS	Data Analyst	OHSU
Steele Valenzuela, MS	Data Analyst	OHSU
David Ezekiel-Herrera, MS	Data Analyst	OHSU
Teresa Schmidt, MS	Data Analyst	OCHIN
Pedro Rivera-Ortega	Data Programmer Year 1	OCHIN
Allison O'Neil	Data Analyst Year 1	OCHIN
Carlyn Hood	Project Manager Year 1	OCHIN
Kaleb Keaton	Project Manager Year 1	OHSU

ClinicalTrials.gov Protocol Submission
ClinicalTrials.gov Identifier: NCT02657499

Specific Aims
Aim 1. Compare pre-post health insurance status, primary care, mental health, and dental visits, and receipt of preventive services, as well as changes in payer mix among ADVANCE CHCs in states that did and did not expand Medicaid. *Hypothesis 1a*: CHCs in expansion states will experience an increase in overall visits and visits paid by Medicaid, relative to non-expansion states. *Hypothesis 1b*: The percentage of Medicaid visits in CHCs' overall payer mix will increase more significantly in expansion-states relative to non-expansion states.

Aim 2. Examine pre-post utilization of CHC services (including receipt of preventive services) by newly insured compared to already insured and uninsured patients. *Hypothesis 2*: Newly insured patients will have a significant increase in overall CHC visits compared to (a) already insured and (b) uninsured patients.

Aim 3: Measure pre-post changes in overall utilization of healthcare services and Oregon Medicaid expenditures among newly insured compared to already insured patients.

Hypothesis 3a: There will be an increase in utilization of CHC services and a decrease in use of services external to the CHCs (*e.g.,* emergency department) for newly insured patients, but these utilization rates will remain the same for already insured patients. *Hypothesis 3b*: There will be an initial increase, then plateau, in overall Medicaid expenditures among newly insured relative to already insured patients.

Data Sources

ADVANCE EHR Data. We used electronic health record (EHR) data from the Accelerating Data Value Across a National Community Health Center Network (ADVANCE) clinical data research network (CDRN) data warehouse. The ADVANCE CDRN is a unique 'community laboratory' for research with underrepresented populations that includes patients receiving care in safety net clinics. The ADVANCE CDRN data warehouse includes *integrated* longitudinal EHR data from several organizations. Data from two ADVANCE partners, OCHIN and Health Choice Network (HCN), were used in the PACE study. From the ADVANCE CDRN, we included CHC members 'live' on their EHR as of January 1, 2013: 225 primary care CHCs in 10 states that expanded Medicaid as of 1/1/2014 (California, Hawaii, Maryland, Minnesota, New Mexico, Ohio, Oregon, Rhode Island, Washington, and Wisconsin) and 134 primary care CHCs in 6 non-expansion states (Florida, Kansas, Missouri, North Carolina, Texas, Montana). We included Wisconsin as an expansion state because although they did not expand Medicaid to 138% FPL they opened enrollment to adults with eligibility criteria of 100% FPL and therefore behaved more like an expansion state. Montana did not expand Medicaid until after our study period (expanded 1/1/2016), which included a one-year pre- (1/1/13-12/31/13) and a two-year post-period (1/1/2014-12/31/2015). Analyses included >4 million ambulatory visits among patients aged 19-64 (expansion states: 2.6 million visits from 499,719 patients; non-expansion states: 1.5 million visits from 370,600 patients).

Linkage between EHR and Medicaid administrative data. Oregon Medicaid administrative data was linked to OCHIN Oregon clinics in the ADVANCE CDRN to assess the receipt of healthcare services outside the Oregon CHCs and all healthcare expenditures.

Study Population and Study Period

The overall study population was adults ages 19-64 throughout the study period, 2012-2015. Included patients had ≥1 ambulatory visit at an eligible facility in the study period. Included facilities provided adult primary care and were 'live' on OCHIN's or HCN's EHR system by the start of the study period (1/1/2012). EHR data were extracted on all eligible patients, encounters, and facilities.

Overall, study analyses included >4 million ambulatory visits among patients aged 19-64 (expansion states: 2.6 million visits from 499,719 patients; non-expansion states: 1.5 million visits from 370,600 patients).

We examined differences in utilization among patients newly gaining Medicaid coverage (***newly insured)***, as compared to utilization among individuals who are already insured by Medicaid (***already insured***) and those who remain uninsured (***uninsured***). Additionally, in subpopulation analyses restricted to the state of Oregon (an expansion state), we link EHR data from Oregon CHC clinics to Oregon's Medicaid administrative claims data to investigate post-expansion overall healthcare utilization and Medicaid expenditures among the newly insured as compared to the already insured. Inclusion and exclusion criteria were modified for some analyses; see below for details on specific paper analyses.

Table 2. Study population stratified by expansion status and state

2014 Expansion status	State	N facilities	N patients
Expansion	California	48	163,686
Expansion	Hawaii	2	10,075
Expansion	Maryland	24	15,297
Expansion	Minnesota	4	12,725
Expansion	New Mexico	25	63,488
Expansion	Nevada	3	2,326
Expansion	Ohio	15	55,537
Expansion	Oregon	121	261,166
Expansion	Rhode Island	59	38,946
Expansion	Washington	6	24,585
Non-expansion	Alaska*	1	3,820
Non-expansion	Florida	169	412,138
Non-expansion	Indiana**	10	16,200
Non-expansion	Kansas	9	8,047
Non-expansion	Missouri	3	16,461
Non-expansion	Montana	6	13,155
Non-expansion	North Carolina	21	39,726
Non-expansion	Texas	5	11,383
Non-expansion	Wisconsin***	8	20,593

*Alaska expanded Medicaid to 138% FPL on 9/1/2015 and was excluded from some analyses; **Indiana expanded Medicaid to 138% FPL on 2/1/2015 and was excluded from some analyses; ***Wisconsin expanded Medicaid from 0% to 100% on 1/1/2014 and therefore more closely resembled an ACA expansion state. Wisconsin was considered an expansion state in analyses.

Stakeholder Engagement

The project team engaged a Patient Investigator (Kaye Dickerson) and a Clinician Investigator (Dr. Andrew Suchocki, MD) throughout the duration of the project. These stakeholders advised the project team during the data analysis, manuscript development, and dissemination phases of the project. Their involvement was facilitated through ongoing training about the research process, collaboration with research team about data analyses challenges, data interpretation,

and manuscript development, and dissemination of research aims through presentations and blogging.

Data Analyses

Medicaid Expansion Produces Long-Term Impact on Insurance Coverage Rates in Community Health Centers

Full Citation	Huguet, N., Hoopes, M. J., Angier, H., Marino, M., Holderness, H., & DeVoe, J. E. (2017) **Medicaid Expansion Produces Long-Term Impact on Insurance Coverage Rates in Community Health Centers.** *J Prim Care Community Health*. 8(4):206-212.
Objective	Assess change in insurance coverage rates pre- and post-ACA in Medicaid expansion and non-expansion states for community health center patients.
Study Population	N=875,571 patients; Inclusion: ages 19-64 with ≥ 1 visit between 2012 and 2015. Setting: 412 primary care CHCs in 9 expansion and 4 non-expansion states.
Exclusion Criteria	Pregnant women
Independent Variables	Whether state had taken Medicaid expansion as of January 1, 2014.
Dependent Variables	**Health care delivery:** rates of billed encounters (all, primary care, new patient, established patient), receipt of preventive services (preventive medicine visits, immunizations, medications ordered). 1. **Insurance type:** uninsured, Medicaid-insured, privately-insured.
Covariates	Clinic-level: distributions of sex, age, race/ethnicity, primary language, federal poverty level. State-level: marketplace type, 2013 minimum wage, 2013 uninsured rate, 2013 unemployment rate.
Analysis Plan	Post- versus pre-expansion rate ratios within expansion group; difference-in-difference ratios (comparing post- versus pre-period changes between expansion states vs non-expansion states); and second year post- (2015) versus first year post-ACA (2014) rate ratios within expansion group.
Data Set Name	OCHIN: e:\sasroot\PPDA\P_Huguet_24mo
Code Location	OCHIN SAS server

Oregon Medicaid Expenditures After the 2014 Affordable Care Act Medicaid Expansion: Over-time Differences Among New, Returning, and Continuously Insured Enrollees

Full Citation	Springer, R., Marino, M., O'Malley, J. P., Lindner, S., Huguet, N., & DeVoe, J. E. (2018). **Oregon Medicaid Expenditures After the 2014 Affordable Care Act Medicaid Expansion: Over-time Differences Among New, Returning, and Continuously Insured Enrollees.** *Med Care, 56*(5), 394-402.
Objective	To assess health care expenditures among Medicaid enrollees in the 24 months after Oregon's 2014 Medicaid expansions and examine whether expenditure patterns were different among the newly, returning, and continuously insured.
Study Population	Oregon adult Medicaid beneficiaries insured continuously from 2014 to 2015 who were either newly, returning, or continuously insured.
Exclusion Criteria	Our study population included adults aged 19-64 insured by Oregon Medicaid continuously from January 2014 through December 2015. We excluded patients without coverage on 1/1/2014 and those with coverage gaps during the study period. We excluded patients with dual Medicaid and Medicare eligibility and whose 2014-2015 eligibility did not depend on FPL (e.g. pregnant women). Of 622,513 adults aged 19-64 with any 2014 Medicaid enrollment, 230,602 (37%) remained in our sample.
Independent Variables	Insurance group, time, and their interaction terms, mean monthly expenditures.
Dependent Variables	standardized expenditures for inpatient care, prescription drugs, and total outpatient care in addition to subdivisions of outpatient: outpatient claims were classified as either emergency department, dental, mental and behavioral health, primary care evaluation, management, and procedures, specialist evaluation, management, and procedures, and primary care/specialist imaging or tests based on a hierarchical system involving procedure code, provider type, provider specialty, place of service, and associated costs.
Covariates	The patient's age, sex, racial and ethnic background, rural setting, and comorbidity level as assessed by the enhanced Charlson comorbidity index score.
Analysis Plan	Retrospective cohort study using inverse-propensity weights to adjust for differences between groups. We summarized enrollee

	utilization outcomes as mean monthly expenditures, running a separate (two-part) hurdle model for each type.
Data Set Name	NPAT, INPATIENT_Q42015, OUTPAT, OUTPATIENT_2015Q4, RX , RX_Q42015, SAMPLE, SAMPLE_with_weights FY_2015_FR_AND_CN_Table 5, Nov 2013 Fee Schedule – Excel, January 2014 Behavioral Health Fee Schedule, January 2014 Mental Health Fee Schedule – Excel
Code Location	Box at OHSU

Medicaid Coverage Accuracy in Electronic Health Records

Full Citation	Marino, M., H. Angier, S. Valenzuela, M. Hoopes, M. Killerby, B. E. Blackburn, N. Huguet, J. Heintzman, B. Hatch, J. P. O' Malley and J. E. DeVoe (2018). **Medicaid Coverage Accuracy in Electronic Health Records**. *Prev Med Reports* **11**: 297–304.
Objective	To evaluate the validity of EHR data for monitoring longitudinal Medicaid coverage and assess variation by patient demographics, visit types, and clinic characteristics.
Study Population	Oregon Medicaid patients aged 18-64 years with a Medicaid ID or Medicaid insurance recorded in the OCHIN EHR ≥1 billed health care visit (excluding dental) from 184 Oregon CHCs in the OCHIN network linked to state Medicaid records during the study time period (1/1/2013–12/31/2014). N=135,514.
Exclusion Criteria	Patients with no Medicaid record on EHR who also did not have a Medicaid ID.
Independent Variables	Insurance cohort: (1) continuously Medicaid (Medicaid recorded at all visits); (2) continuously not Medicaid (Medicaid not recorded at any visit (patients could have Medicare, private, VA/Military, worker's compensation, or no coverage); (3) Gained Medicaid: Medicaid not recorded for all visits in 2013 and Medicaid recorded at all visits in 2014; and (4) Discontinuously Medicaid: Any combination of visit coverage that did not follow the definitions above.
Dependent Variables	The primary outcome was agreement between EHR and Medicaid data in assigning patients to one of the four cohorts.
Covariates	Patient demographics (sex, age, race, ethnicity, language, household income represented as % FPL, urban/rural, number of common chronic conditions, and number of encounters), visit and provider types, and clinic-specific (department type and customers of OCHIN's billing service) characteristics. We included the following common chronic conditions assessed

	from diagnostic codes in the EHR: hypertension, diabetes, coronary artery disease, lipid disorder, and asthma/chronic obstructive pulmonary disorder.
Analysis Plan	Visit-level: agreement, prevalence-adjusted bias-adjusted kappa (PABAK), sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). Patient-level: 4x4 cross-tabulation, of insurance cohorts; two-stage logistic regression.
Data Set Name	PPDA Projects → InsuranceValidation → Data → CLEAN → patients.csv, patient_pre.csv, patient_post.csv, patient_ch.csv, encs_pre.csv, encs_post.csv, agree_no_final.csv Code is included under: PPDA Projects → InsuranceValidation → Final Code
Code Location	Box at OHSU

In Low-Income Latino Patients, Post-Affordable Care Act Insurance Disparities May Be Reduced Even More than Broader National Estimates: Evidence from Oregon

Full Citation	Heintzman, J., S. R. Bailey, J. DeVoe, S. Cowburn, T. Kapka, T. V. Duong and M. Marino (2017). **In Low-Income Latino Patients, Post-Affordable Care Act Insurance Disparities May Be Reduced Even More than Broader National Estimates: Evidence from Oregon.** *J Racial Ethn Health Disparities* **4**(3): 329-336.
Objective	To evaluate the association of Hispanic/Latino ethnicity and Spanish language preference with insurance status among a cohort of patients accessing community health centers (CHCs) in Oregon; prior to ACA implementation (2013) and 1-year post-ACA (2014). To determine if disparities in insurance coverage existed by race/ethnicity and language preference prior to ACA. If so, were such disparities mitigated by ACA implementation.
Study Population	N=49,392; Adults aged 21-79 in Oregon community health centers (CHCs) who had low income (<100% FPL), and at least 1 primary care encounter at a study clinic in 2009-2013, had to have at least 1 face to face primary care encounter.
Exclusion Criteria	
Independent Variables	Race/ethnicity, preferred language
Dependent Variables	Insurance status: Medicaid, Medicare, private insurance, uninsured.

	Categorized patients into the Medicaid and Medicare categories if patient had one or more encounters with these insurances.
Covariates	Age at beginning of study, sex, total number of primary care office visits in study period.
Analysis Plan	Chi-square for patient demographics; ANOVA to compare patient demographics by insurance group; GEE to account for correlation of patients nested with CHCs; DID/GEE to assess changes in odds of uninsured from pre-to post-ACA between Hispanic/Latino/Spanish, Hispanic/Latino/English, and non-Hispanic White cohorts.
Data Set Name	PPDA Projects → PACE → HeintzmanACA → 2014data.xls, heintzman_k_post_aca_comparison.xls Code is included under: PPDA Projects → PACE → Heintzman ACA → Code
Code Location	Box at OHSU

Medicaid's Impact on Chronic Disease Biomarkers: A Cohort Study of Community Health Center Patients.

Full Citation	Hatch, B., M. Marino, M. Killerby, H. Angier, S. R. Bailey, J. Heintzman, J. P. O' Malley and J. E. DeVoe (2017). **Medicaid's Impact on Chronic Disease Biomarkers: A Cohort Study of Community Health Center Patients.** *J Gen Intern Med* **32**(8): 940-947.
Objective	To assess changes in biomarkers of chronic disease among community health center (CHC) patients who gained Medicaid coverage with the Oregon Medicaid expansion (2008–2011).
Study Population	OCHIN Medicaid patients within 3 chronic disease cohorts: patients with diabetes (N=608); patients with hypertension patients (N=1244); patients with hyperlipidemia patients (N=546). Patients gained Medicaid coverage between 2008-2011: Patients aged 1-+64 years; Non-pregnant, non-deceased; Uncontrolled biomarker result in EHR within 6 months before/after gained Medicaid coverage.
Exclusion Criteria	Pregnant women
Independent Variables	Insurance status, time, “spline” (slope change at 6 months) interactions between time and insurance and spline and insurance.
Dependent Variables	Biomarkers: 1. HbA1c

	2. Systolic blood pressure 3. Diastolic blood pressure 4. Lipids
Covariates	federal poverty level, comorbidities
Analysis Plan	Time to event assessing time from uncontrolled baseline measurement to follow up controlled measurement; Longitudinal analysis modeling the mean biomarker value over time; Logistic regression to estimate the odds of having a disease-specific medication ordered during study.
Data Set Name	PPDA Projects → PACE → CARDIACBiomarker → Data → all the files in there Code is under: PPDA Projects → PACE → CARDIACBiomarker → Rcode
Code Location	Box at OHSU

Uninsured Primary Care Visit Disparities Under the Affordable Care Act

Full Citation	Angier, H., M. Hoopes, M. Marino, N. Huguet, E. A. Jacobs, J. Heintzman, H. Holderness, C. M. Hood and J. E. DeVoe (2017). **Uninsured Primary Care Visit Disparities Under the Affordable Care Act.** *Ann Fam Med* **15**(5): 434-442.
Objective	To assess changes in insurance coverage at community health center (CHC) visits after the Patient Protection and Affordable Care Act (ACA) Medicaid expansion by race and ethnicity
Study Population	1. N=870,319 2. 359 CHCs 3. CHC patients aged 19-64 years 4. Expansion states as of 1-1-14: California, 5. Hawaii, Maryland, Minnesota, New Mexico, Ohio, Oregon, Rhode Island, Washington, and Wisconsin 6. Non-expansion states as of 1-1-14: Florida, Kansas, Missouri, North Carolina, Texas, Montana
Exclusion Criteria	Pregnant women
Independent Variables	Expansion status (Medicaid expansion vs. non-expansion)
Dependent Variables	Health insurance type at each visit (Medicaid-insured, uninsured, privately-insured)
Covariates	
Analysis Plan	1. Difference-in-difference (DID) 2. Difference-in-difference-in-difference (DDD) 3. GEE models
Data Set Name	HA_disp_analysis_long.sas7bdat HA_disp_monthly_analysis_set.sas7bdat
Code Location	OCHIN archive server

A Cohort Study of Public Health Insurance Coverage Loss among Oregon Adolescents

Full Citation	Angier, H., C. J. Tillotson, L. S. Wallace, M. Marino, J. P. O' Malley, A. Sumic, L. Baker, C. Nelson, N. Huguet, A. Suchocki, H. Holderness and J. E. DeVoe (2018). **A Cohort Study of Public Health Insurance Coverage Loss among Oregon Adolescents**. *J Health Dispar Res 11(1).*
Objective	The purpose of this study was to identify the sociodemographics of adolescents transitioning to young adulthood who lost public health insurance which could inform future health policies for this vulnerable population.
Study Population	Oregon adolescents (17-19 years of age) with public coverage [January 1, 2011-December 31, 2013 (n=51,988).
Exclusion Criteria	Missing information on urban/rural residency status (n=4,025) and/or family income (n=973).
Independent Variables	Sociodemographic characteristics: age, sex, race, ethnicity, language, percentage of federal poverty level based on family income and size, history of a healthcare visit to a community health center included in the OCHIN network during the study period (2011-2013), and urbanicity.
Dependent Variables	OHP Coverage
Covariates	
Analysis Plan	Time to Event: to determine association of coverage loss with sociodemographic characteristics.
Data Set Name	analysis_nogaps_01202016.sas7bdat dmapochin13_nogaps_01202016.sas7bdat Code is under: R:\Active projects\IMPACCT\Reports\Data analysis and results\Teen Transition\Carrie\SAS Code and Programs\5d_MV Models nogaps 01112016.sas
Code Location	OCHIN archive server

A New Role for Primary Care Teams in the United States After "Obamacare": Track and Improve Health Insurance Coverage Rates.

Full Citation	DeVoe, J. E., H. Angier, M. Hoopes and R. Gold (2016). **A New Role for Primary Care Teams in the United States After "Obamacare": Track and Improve Health Insurance Coverage Rates.** *Family Medicine and Community Health* ***4****(4): 63-67(65).*
Objective	Describe efforts to longitudinally track health insurance rates using data from the electronic health record (EHR) of a primary care network and to use these data to support practice-based insurance outreach and assistance.

Study Population	OCHIN member clinics and patients.
Exclusion Criteria	Not an OCHIN member clinic or patient.
Independent Variables	NA
Dependent Variables	Insurance coverage in EHR.
Covariates	NA
Analysis Plan	NA
Data Set Name	NA
Code Location	NA

The Impact of the Affordable Care Act Medicaid expansion on visit rates for a patient population with diabetes or pre-diabetes in safety net health centers

Full Citation	Huguet, N., R. Springer, M. Marino, H. Angier, M. Hoopes, H. Holderness and J. E. DeVoe. (2018) **The Impact of the Affordable Care Act Medicaid expansion on visit rates for a patient population with diabetes or pre-diabetes in safety net health centers**. *J Am Board Fam Med. 31(6):905-916*
Objective	To compare clinic-level uninsured, Medicaid-insured, and privately insured visit rates within and between expansion and non-expansion states prior to and after the ACA Medicaid expansion among the three cohorts of patient populations; and, to assess whether there was a change in clinic-level overall, primary care, preventive care visits, and diabetes screening rates in expansion versus non-expansion states from pre- to post-ACA Medicaid expansion.
Study Population	198 primary care community health centers: Non-pregnant patients aged 19-64 with ≥1 ambulatory visit between 01/01/2012-12/31/2015 (n=483,912 in expansion states; n=388,466 in non-expansion states).
Exclusion Criteria	Pregnant women
Independent Variables	Expansion status
Dependent Variables	1. Insurance coverage 2. Healthcare services
Covariates	Health insurance status, sociodemographic variables, urban/rural, state-level factors.
Analysis Plan	• Rate Ratios • Difference in Difference • GEE/Poison models with sandwich variance estimators • Clustered models by CHC

	• Exchangeable covariance structure • Sensitivity analysis
Data Set Name	STATES, ELIGIBLE FACILITIES, ENCOUNTERS_AV1215_pipe, PAT_CONSORT_08312016, FAC_URBRUR
Code Location	BOX at OHSU

Prescription Opioid Use Patterns, Use Disorder Diagnoses, and Addiction Treatment Receipt after the 2014 Medicaid Expansion

Full Citation	Springer, R., M. Marino, S. Bailey, H. Angier, J. O'Malley, M. Hoopes, S. Lindner, J. DeVoe and N. Huguet. **Prescription Opioid Use Patterns, Use Disorder Diagnoses, and Addiction Treatment Receipt after the 2014 Medicaid Expansion.** Resubmitted 12/18 to Addiction.
Objective	To examine rates of opioid prescribing, Opioid Use Disorder (OUD) prevalence, and OUD treatment among Oregon Medicaid enrollees after the ACA Medicaid expansion; and to understand how insurance history and dose type are related to OUD diagnosis rates, as well as whether patients with OUD in the expansion population (of new enrollees and those 'returning' after coverage gaps) had different MAT participation rates than those previously continuously enrolled.
Study Population	Adults aged 19+64; continuously insured by Oregon Medicaid 1/2014-12/31/2015. N=225,295.
Exclusion Criteria	Patients with coverage gaps during study period; dual eligibles; hospice care; cancer diagnosis other than non-melanoma skin cancer.
Independent Variables	1. Insurance group 2. Episode type
Dependent Variables	1. Opioid filled prescription 2. Documented diagnosis of OUD 3. Chronic opioid use 4. Receipt of medication assisted treatment
Covariates	Age, sex, race, urban/rural, co-morbidities, zip code, federal poverty level, employment, and number of episodes
Analysis Plan	1. Inverse propensity weighting 2. Absolute standardized mean difference 3. Prevalences 4. Logistic regression 5. Cox proportional hazard 6. Multinomial logistic regression
Data Set Name	OUTPAT, OUTPATIENT_2015Q4, RX , RX_Q42015, SAMPLE_FLAGGED_FOR_EXPORT

	hospice_providers, mat_codes, opioid_ndcs_2016
Code Location	Box at OHSU

Following uninsured patients through Medicaid Expansion: healthcare utilization and diagnosed conditions

Full Citation	Huguet, N., S. Valenzuela, M. Marino, H. Angier, B. Hatch, M. Hoopes and J. E. DeVoe. **Following uninsured patients through Medicaid Expansion: healthcare utilization and diagnosed conditions.** *Submitted Ann Fam Med 11/18.*
Objective	Assess healthcare utilization and diagnosed health conditions among a cohort of community health center patients who were uninsured pre-ACA and follow them 24 months post-Affordable Care Act (ACA).
Study Population	All non-pregnant patients without insurance pre-ACA, aged 19-64 during the study period, with ≥1 ambulatory visit pre-ACA from 300 primary care CHCs 'live' on their EHR system as of 1/1/2012 in 11 states. N=138,246.
Exclusion Criteria	Pregnant women, insurance coverage prior to ACA.
Independent Variables	1. Insurance group
Dependent Variables	1. Healthcare utilization 2. Health conditions
Covariates	Age, sex, language, race/ethnicity, federal poverty level, and clinic location
Analysis Plan	1. Adjusted predicted probability 2. Mixed effects ordinal logistic regression 3. Random effects to account for clustering visits
Data Set Name	PAT_CONSORT_08312016 encounters_AV1215_pipe FAC_URBRUR STATES PPDA_RUCA_CHARLSON PPDA_PREEXISTING_CONDITIONS Code is under: PPDA Projects -> Who_Remains_Uninsured -> draft4.Rmd
Code Location	Box at OHSU

Utilization of Community Health Centers in Medicaid Expansion and Non-expansion States, 2013-2014.

Full Citation	Hoopes, M. J., H. Angier, R. Gold, S. R. Bailey, N. Huguet, M. Marino and J. E. DeVoe (2016). **Utilization of Community Health Centers in Medicaid Expansion and Non-expansion States, 2013-2014.** *J Ambul Care Manage 39(4): 290-298.*
Objective	Assess CHC utilization a full year before and after the implementation of Affordable Care Act (ACA) Medicaid expansions (24 months) and describes changes in visit type before and after implementation.
Study Population	Adults 19-64 years, billed visits in pre expansion (1/1/13-12/31/13) and post expansion (1/1/14-12/31/14) OCHIN member clinics. N=401,988 patients.
Exclusion Criteria	Pregnant women
Independent Variables	Expansion status
Dependent Variables	1. Insurance status 2. Visit type
Covariates	Sex, age, race/ethnicity, urban/rural, federal poverty level, minimum wage, unemployment, insurance exchange type.
Analysis Plan	1. GEE 2. Poisson models
Data Set Name	OCHIN: e:\sasroot\CATCHUP\ACA 12 month
Code Location	OCHIN SAS server

Effect of Gaining Insurance Coverage on Smoking Cessation in Community Health Centers: A Cohort Study.

Full Citation	Bailey, S. R., M. J. Hoopes, M. Marino, J. Heintzman, J. P. O'Malley, B. Hatch, H. Angier, S. P. Fortmann and J. E. DeVoe (2016). **Effect of Gaining Insurance Coverage on Smoking Cessation in Community Health Centers: A Cohort Study.** *J Gen Intern Med* ***31****(10): 1198-1205.*
Objective	To determine if uninsured community health center (CHC) patients who gained Medicaid coverage experienced greater primary care utilization, receive more cessation medication orders, and achieve higher quit rates, compared to continuously uninsured smokers.
Study Population	CHC patients aged 19–64 years who gained Oregon Medicaid coverage between 2008 and 2011 after being uninsured for ≥ 6 months and who maintained this insurance for ≥ 6 months. Cohort of 'current every day smoker' or 'current some day smoker.'

Exclusion Criteria	Non-smoking, pregnant, non-living, private insurance, Medicare insurance.
Independent Variables	Insurance Status
Dependent Variables	1. 'Quit' smoking status (yes/no) 2. Smoking cessation medication ordered (yes/no)
Covariates	Usual source of care after in follow up period.
Analysis Plan	1. Propensity score matching 2. Between group differences 3. GEE for clustering
Data Set Name	Smoking_model_set_PSmatches.sas7bdat
Code Location	OCHIN archive server

Observational Study of Racial/Ethnic Disparities in Health Insurance and Differences in Visit Type for a Population of Patients with Diabetes after Medicaid Expansion.

Full Citation	Angier, H., D. Ezekiel-Herrera, M. Marino, M. Hoopes, E. A. Jacobs, J. E. DeVoe and N. Huguet (In press). **Observational Study of Racial/Ethnic Disparities in Health Insurance and Differences in Visit Type for a Population of Patients with Diabetes after Medicaid Expansion**. *J Health Care Poor Underserved.*
Objective	To understand the impact of the Affordable Care Act (ACA) Medicaid expansion on racial/ethnic health insurance disparities and differences in visit type for a population of patients with diabetes, by assessing changes pre- versus post-ACA in expansion compared with non-expansion states.
Study Population	Adults aged 19-64, diabetes diagnosis any time during study period, CHCs in ADVANCE network with EHRs live as of January 2013.
Exclusion Criteria	Pregnant women
Independent Variables	Expansion status
Dependent Variables	1. Health insurance status 2. Healthcare visit types a. Total b. Type
Covariates	Sex, age, FPL, Charlson comorbidity index score, state-level factors
Analysis Plan	1. Incidence rates 2. GEE Poisson models 3. Difference in Difference

Data Set Name	Analytic Data: PPDA Projects → PACE → Diabetes Disparities → Analytic Data Code: PPDA Projects → PACE → Diabetes Disparities → Code
Code Location	Box at OHSU

Assessing the prevalence of pre-existing conditions among community health center patients.

Full Citation	Huguet, N., H. Angier, M. J. Hoopes, M. Marino, J. Heintzman, T. Schmidt and J. E. DeVoe. **Assessing the prevalence of pre-existing conditions among community health center patients.** Medical Care. Submitted 9/18
Objective	To assess the prevalence of pre-existing conditions pre- versus post-Affordable Care Act (ACA) for community health center (CHC) patients who gained insurance
Study Population	386 CHCs in 19 states; 78,059 non-pregnant patients aged 19-64 uninsured at their last visit pre-ACA.
Exclusion Criteria	Pregnant women
Independent Variables	Medicaid expansion state status
Dependent Variables	Prevalence and types of pre-existing conditions by insurance status and race/ethnicity.
Covariates	
Analysis Plan	1. Prevalence 2. Within-group prevalence 3. GEE
Data Set Name	OCHIN: e:\sasroot\PPDA\Huguet_preexist cond paper
Code Location	OCHIN SAS server

Manuscripts:

1. Huguet N, Hoopes MJ, Angier H, Marino M, Holderness H, DeVoe JE. Medicaid Expansion Produces Long-Term Impact on Insurance Coverage Rates in Community Health Centers. J Prim Care Community Health. 2017;8(4):206-212. PMC5665709.

2. Angier H, Hoopes M, Marino M, Huguet N, Jacobs EA, Heintzman J, et al. Uninsured Primary Care Visit Disparities Under the Affordable Care Act. Annals of Family Medicine. 2017;15(5):434-42. PMC5593726.

3. Hoopes MJ, Angier H, Gold R, Bailey SR, Huguet N, Marino M, et al. Utilization of Community Health Centers in Medicaid Expansion and Nonexpansion States, 2013-2014. The Journal of Ambulatory Care Management. 2016;39(4):290-8. PMC4942402.

4. Springer R, Marino M, O'Malley JP, Lindner S, Huguet N, DeVoe JE. Oregon Medicaid Expenditures After the 2014 Affordable Care Act Medicaid Expansion: Over-time Differences Among New, Returning, and Continuously Insured Enrollees. Med Care. 2018;56(5):394-402. PMC5893375.

5. Marino M, Angier H, Valenzuela S, Hoopes M, Killerby M, Blackburn BE, et al. Medicaid Coverage Accuracy in Electronic Health Records. Prev Med Reports. 2018;11:297–304. PMC6082971.

6. Hatch B, Marino M, Killerby M, Angier H, Bailey SR, Heintzman J, et al. Medicaid's Impact on Chronic Disease Biomarkers: A Cohort Study of Community Health Center Patients. Journal of General Internal Medicine. 2017;32(8):940-7. PMC5515790.

7. Huguet N, Springer R, Marino M, Angier H, Hoopes M, Holderness H, et al. The impact of the Affordable Care Act Medicaid expansion on visit rates for diabetes in safety net health centers. Journal of the American Board of Family Medicine. 2018;31(6):905-16. PMID30413546

8. Angier H, Ezekiel-Herrera D, Marino M, Hoopes M, Jacobs EA, DeVoe JE, et al. Observational Study of Racial/Ethnic Disparities in Health Insurance and Differences in Visit Type for a Population of Patients with Diabetes after Medicaid Expansion. J Health Care Poor Underserved. In Press.

9. Angier H, Tillotson CJ, Wallace LS, Marino M, O' Malley JP, Sumic A, et al. A Cohort Study of Public Health Insurance Coverage Loss among Oregon Adolescents. J Health Dispar Res. 2018;11(1): 74-84.

10. Bailey SR, Hoopes MJ, Marino M, Heintzman J, O'Malley JP, Hatch B, et al. Effect of Gaining Insurance Coverage on Smoking Cessation in Community Health Centers: A Cohort Study. J Gen Intern Med. 2016;31(10):1198-205. PMC5023615.

11. DeVoe JE, Angier H, Hoopes M, Gold R. A New Role for Primary Care Teams in the United States After “Obamacare:” Track and Improve Health Insurance Coverage Rates. Family Medicine and Community Health. 2016;4(4):63-7(5). PMC5617364.

12. Heintzman J, Bailey SR, DeVoe J, Cowburn S, Kapka T, Duong TV, et al. In Low-Income Latino Patients, Post-Affordable Care Act Insurance Disparities May Be Reduced Even More than Broader

National Estimates: Evidence from Oregon. J Racial Ethn Health Disparities. 2017;4(3):329-36. PMC5075278.

Submitted Manuscripts:

Springer R, Marino M, Bailey S, et al. Prescription Opioid Use Patterns, Use Disorder Diagnoses, and Addiction Treatment Receipt after the 2014 Medicaid Expansion. Addiction. Revised and Resubmitted 11/2018.

Huguet N, Valenzuela S, Marino M, et al. Following uninsured patients through Medicaid Expansion: healthcare utilization and diagnosed conditions. Annals of Family Medicine. Revised and Resubmitted 11/2018.

Huguet N, Angier H, Hoopes MJ, et al. Assessing the prevalence of pre-existing conditions among community health center patients. Medical Care. Submitted 9/2018.

Bailey SR, Marino M, Ezekiel-Herrera D, et al. Tobacco Cessation in Affordable Care Act Medicaid Expansion States versus Non-Expansion States. Nicotine & Tobacco Research. Submitted 12/2018.

Presentations:

Valenzuela S, Huguet N, Springer R, Ezekiel-Herrera D, O' Malley JP, Marino M. Navigating Large-Scale Forest Plots Using R and Shiny. Poster Presentation presented at American Statistical Society Conference on Statistical Practice; Feb 15-17, 2018, 2017; Portland, OR.

Springer R, Raynor L, Marino M, et al. Effects of Medicaid Expansion on Oregon Medicaid Patient Expenditures from 2014-2015. Oral Presentation on Completed Research presented at 45th annual meeting of the North American Primary Care Research Group; Nov 17-21, 2017; Montreal, Canada.

Springer R, Marino M, Bailey SR, et al. Opioid Medication Expenditures in Oregon Medicaid Enrollees after the ACA Expansion. Poster presentation presented at AcademyHealth Annual Research Meeting; June 24-26, 2018; Seattle, WA.

Springer R, Marino M, Bailey S, et al. Opioid Prescription Expenditures by Oregon Medicaid Enrollees after the 2014 Medicaid Expansion. Oral presentation presented at 46th Annual Meeting of the North American Primary Care Research Group; Nov, 2018; Chicago, IL.

Marino M. Assessing the Impact of Health Policy Changes in Primary Care. Joint Statistical Meeting J, Vancouver, Canada. Assessing the Impact of Health Policy Changes in Primary Care. Oral presnetation presented at Joint Statistical Meeting; July 28-August 2, 2018; Vancouver, Canada.

Marino M, Valenzuela S, Raynor L, et al. Validation of Medicaid Coverage in Electronic Health Records to Monitor Health Reform. WNAR Conference; June 27, 2017, 2017.

Marino M, Valenzuela S, Hoopes M, DeVoe JE. A Two-Stage Logistic Regression Model to Identify Covariates that are Predictive of Agreement Between Insurance Sources. Oral Presentation presented at 10th International Chinese Statistical Association International Conference; Dec. 19-22, 2016; Shanghai, P. R. China.

Marino M, Killerby M, Hatch B, et al. Change in chronic disease biomarkers over time: The role of Medicaid Expansion. Oral Presentation presented at 44th annual meeting of the North American Primary Care Research Group; 2016; Colorado Springs, CO.

Marino M, Killerby M, Angier H, et al. Using Electronic Health Records for Accurate Adult Medicaid Coverage Continuity. 44th annual meeting of the North American Primary Care Research Group; 2016; Colorado Springs, CO.

Marino M, Huguet N, Springer R, Angier H, Hoopes M, DeVoe JE. Studying the Impact of the Affordable Care Act Using Electronic Health Records. Oral Presentation presented at 12th International Conference on Health Policy Statistics; Jan 10-12, 2018, 2018; Charleston, SC.

Marino M, Angier H, Valenzuela S, et al. The Impact of the Affordable Care Act on Diabetes Biomarker Control. Oral Presentation presented at AcademyHealth Annual Research Meeting; June 24-26, 2018, 2018; Seattle, WA.

Marino M, Angier H, Springer R, et al. The Affordable Care Act - Effects of Medicaid on Diabetes Biomarker Control. Oral Presentation on Completed Research presented at 45th annual meeting of the North American Primary Care Research Group; Nov 17-21, 2017; Montreal, Canada.

Marino M, Angier H, Hoopes M, et al. Combining Historical Data and Propensity Score Methods in Observational Studies to Improve Internal Validity. Poster Presentation presented at American Statistical Association Conference on Statistical Practice; Feb 15-17, 2018, 2017; Portland, OR.

Marino M. Using Electronic Health Records for Observational Cancer Studies. Invited Speaker presented at OHSU Knight Cancer Biostatistics Symposium; May, 2018, 2018; Portland, OR.

Krollenbrock A, Baker D, Crosland K, et al. Developing a multi-level model for patient engagement in a Practice-based Research Network. 8th International Conference on Patient- and Family- Centered Care; June 2018, 2017; Baltimore, MD.

Huguet N, Valenzuela S, Marino M, et al. Who remained uninsured after Medicaid expansion? Oral Presentation on Completed Research presented at 45th annual meeting of the North American Primary Care Research Group; Nov 17-21, 2017; Montreal, Canada.

Hoopes M, Schmidt T, Winters K, et al. Prevalence and Characteristics of Cancer Survivors in Outpatient Safety Net Clinics. Poster Presentation presented at AcademyHealth Annual Research Meeting; June 24-26, 2018, 2018; Seattle, WA.

Hoopes M, Angier H, Suchocki A, Dickerson K, DeVoe JE. Impacts of the Affordable Care Act Insurance Expansions on Community Health Centers: Current and Future Directions. OCHIN Learning Forum; April 14-16, 2016; Portland, OR.

Hoopes M, Angier H, Gold R, et al. Impact of the First Year of Affordable Care Act Insurance Expansions on Community Health Center Encounters. 43rd annual meeting of the North American Primary Care Research Group; October 24-28, 2015; Cancun, Mexico.

Holderness H, O'Malley JP, Marino M, et al. Initial Source of Outpatient Services after Implementation of the Affordable Care Act Medicaid Expansion in Oregon. Poster presentation presented at OHSU Research Week; 2018, 2018; Portland, OR.

Holderness H, O'Malley JP, Marino M, et al. Initial Source of Outpatient Services after Implementation of the Affordable Care Act Medicaid Expansion in Oregon. Poster Presentation presented at AcademyHealth Annual Research Meeting; 2018; Seattle, WA.

Holderness H, O' Malley JP, Huguet N, et al. Site of First Primary Care Visit by Medicaid Enrollees after Implementation of the Affordable Care Act Medicaid Expansion. Oral Presentation presented at 46th Annual Meeting of the North American Primary Care Research Group; Nov 9-13, 2018, 2018; Chicago, IL.

Hatch B, Tillotson C, Hoopes M, et al. Clinic factors associated with receipt of needed preventive services. 44th annual meeting of the North American Primary Care Research Group; 2016; Colorado Springs, CO.

Ezekiel-Herrera D, Angier H, Springer R, et al. Modeling and Interpreting Three-Way Interactions for Disparities Research. Poster Presentation presented at American Statistical Association Conference on Statistical Practice; Feb 15-17, 2018, Rejected 2017; Portland, OR.

DeVoe JE. Using Electronic Health Record Data from Community Health Centers to measure Utilization One Year Before and After Affordable Care Act Insurance Expansions in the United States. 3rd International Primary Health Care Reform Conference; March 17, 2016; Brisbane, Australia.

DeVoe JE. Innovation and Discovery in Primary Care: Creating 21st Century Laboratories and Classrooms for Improving Health. Society for Teachers of Family Medicine Annual Spring Conference; May 2, 2016; Minneapolis, MN.

DeVoe JE. Health Policy Roundtable: U.S. Healthcare System in Transition. Health Policy Roundtable, Australian Commonwealth Department of Health; March 22, 2016; Canberra, Australia.

DeVoe JE. Healthcare Policy Seminar Series: U.S. Healthcare System in Transition: Before and After Obamacare. Healthcare Policy Seminar series, Australian Commonwealth Department of Health; March 22, 2016; Canberra, Australia.

Angier H, Huguet N, Hoopes M, et al. Prevalence and Type of Pre-existing Conditions Before and After the Affordable Care Act among Vulnerable Populations. Oral Presentation on Completed Research presented at 46th Annual Meeting of the North American Primary Care Research Group; Nov 9-13, 2018, 2018; Chicago, IL.

Angier H, Hoopes M, Marino M, Heintzman J, Huguet N, DeVoe JE. Impact of the Affordable Care Act on Racial and Ethnic Disparities in Medicaid Expansion vs. Non-Expansion States. 44th annual meeting of the North American Primary Care Research Group; 2016; Colorado Springs, CO.

Institutional Review Board (IRB)

A separate *Regulatory Binder* containing all IRB and other regulatory documents is maintained by the OHSU Project Manager. Refer to this binder for more details about regulatory documents.

Approval
See Appendix 1

Protocol
See Appendix 2

Data Use Agreements and Amendments

Table 3. Data Use Agreements

Parties	Document	Purpose	Execution
OCHIN and OHSU	DUA	Allows OCHIN to share limited data set with OHSU	4-6-16
OCHIN and HCN	DUA	Allows OCHIN to share HCN data found in the ADVANCE CDM with OCHIN as a limited data set	6-3-16
OCHIN and OHSU	DUA Amendment	Adds Community Vital Signs data to original DUA	5-22-17
OCHIN and Oregon	DAA	Allows OCHIN to use state-owned Medicaid data	6-20-16

See Appendix 3 for full agreements.

Table 4. Decision Log

Study	Influence	Date of Decision	Decision Context	Decision
PACE	Insurance Validation Paper (Miguel)	03/29/16	PPD Meeting	Will exclude Medicare/Medicaid dual eligibles (since we cannot determine who they are in the ADVANCE data).
PACE	Insurance Validation Paper (Miguel)	03/29/16	PPD Meeting	Will exclude visits coded as being paid by another public payor – these don't provide information about Medicaid coverage.
PACE	Data Methods	01/12/16	PPD Meeting	Data Pull will include all states, however down the road if there are complications based on a state's data they will be excluded.
PACE	Bio Marker Paper (Miguel)	02/23/16	PPD Meeting	Analysts will use Oregon Medicaid administrative data to create insurance cohorts to validate ADVANCE visit based insurance groups.
PPD	Definitions	03/15/16	PPD Meeting	Patient state and clinic state will be given, classified as expansion vs non expansion. Patient state will be state at the patient's most recent encounter, not historical state at date of encounter.
PPD	Data Methods	03/25/16	Journal Club	Currently, the methods used within the "Propensity score weighting with multilevel data" article by Li, Zaslavsky and Landrum will be applied to all papers.
PPD	Data Methods	04/01/16	Allison/ Jean/ Megan	Base data pull: Clinic inclusion criteria OCHIN: dept type=primary care, public health, or medical specialty specified as internal med, peds, or women's health. School-based health centers (SBHCs) included. Health Choice network: site type=CHC, peds, SBHC, or hospital specified as outpatient clinic. Exclude based on facility names including radiology, mental, behavioral, substance, dental, pharmacy, or lab. Facility type categorized into: primary care, public health, pediatrics, women's health, mobile, specialty, and SBHC.

PPD	Data Methods	04/01/16	Allison/ Jean/ Megan	Base data pull: the following algorithm was used to assign go-live dates to HCN facilities: - PM golive = earliest encounter date per facility that is >=1/1/2003 (earliest actual go-live date for an HCN facility is in 2003) - Identify earliest vitals date that is >=1/1/2003 --> if earliest vitals date is >= PM golive date then EHR golive=earliest vitals date; else if earliest vitals date < PM golive then EHR golive=PM golive; else if no vitals date, then EHR golive = null.
PPDA	Data Methods	04/25/16	Analyst Meeting	Blood glucose and HbA1c both in consideration for diagnosis of diabetes (included in Nichols algorithm).
PPDA	Data Methods	05/02/16	Email	'Encounters' in the OCHIN system can include non-face-to-face contacts such as telephone visits, mychart updates, etc. In past studies, we have typically considered 'visits' to be the face-to-face and in-clinic subset of 'Encounters', though this definition has varied across studies/analyses. At times 'encounter' and 'visit' has been used interchangeably.
PPDA	Data Methods	05/02/16	Email	Other Ambulatory Visit (OA): Includes other non-overnight ambulatory encounters such as dental visits, hospice visits, home health visits, skilled nursing visits, other non-hospital visits, as well as telemedicine, telephone and email consultations. May also include "lab only" visits (when a lab is ordered outside of a patient visit), "pharmacy only" (e.g., when a patient has a refill ordered without a face-to-face visit), "imaging only", etc.
PPDA	Data Methods	05/02/16	Email	Ambulatory Visit (AV): Includes visits at outpatient clinics, physician offices, same day/ambulatory surgery centers, urgent care facilities, and other same-day ambulatory hospital encounters, but excludes emergency department encounters. Not limited to medical visits (e.g., includes mental/behavioral health visits).
PPDA	Data Methods	05/02/16	Email	If additional encounter details, such as provider type, facility type, level of service, etc., are used in the inclusion/exclusion criteria, they should be clearly specified in the outlines (i.e. "OB qualifying encounter types": face-to-face with x diagnoses, y procedures, provider type(s), etc.).

PPDA	Data Documentation	05/09/16	Analyst Meeting	High-level patient inclusion/exclusion criteria for each paper will be tracked in columns in Manuscript Tracker; more detailed documentation (e.g., 'readme' and data dictionaries) will be provided with each study dataset and included as an attachment in the manuscript tracker.
PPDA	Data inclusion	06/06/16	Analyst Meeting	Residents of states that are not included in study (but were seen at eligible facilities in one of our 19 states) will be excluded.
PPDA	Data Methods	06/13/16	Analyst Meeting	There may be data errors in the provider_type variable in the encounters file (i.e., an AV visit may have dentist listed as provider type – which one is correct?) – safer to use AV count based on ADVANCE data team's large amount of work on this categorization.
PPDA	Data Definition		Email	PACE: Pre=2013, Post=2017/PREVENTD: Pre=2012, Post=2020
PPDA	Data inclusion	06/16/16	Manuscript Meeting	Keep continually insured, uninsured in pre and mix of all insured visits, track how many visits were paid by Medicaid (will be able to isolate based on persons insurance status), throw out public insurance/Medicare patients. Patient with continual private insurance in periods will be continuously insured.
PPDA	Data inclusion	06/16/16	Manuscript Meeting	Biomarker change could change based on preexisting condition in Medicare group, Patients with Medicare record will be excluded (all papers).
PPDA	Data analysis	8/18/16	Manuscript Meeting	Include WI as an expansion state in all analyses.
PPDA	Data Methods	06/14/17	Manuscript meeting	HCN data for "smoking" not specific enough; using tobacco-only analysis instead of separating out type of Tobacco use (unless able to code further).
PPDA	Data Methods	06/14/17	Manuscript meeting	Collect pre-AND post- Charlson Comorbidity Index score (using problem list)
PPDA	Data analysis	1/4/18	PPDA Manuscript Meeting	ADVANCE data from 2017 to be pulled February 2018.
PPDA	Data analysis	2/14/18	Other	Refer to as "Enhanced Charlson Comorbidity Index" and cite: Charlson ME, Charlson RE, Marinopoulos SS, Briggs WM, Hollenberg JP. The Charlson Comorbidity Index is adapted to predict costs of chronic disease in primary care patients. J Clin Epidemiol. 2008; 61:1234-40.

OREGON HEALTH & SCIENCE UNIVERSITY

IRB MEMO

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Appendix 1. IRB Approval

APPROVAL OF SUBMISSION

May 1, 2017

Dear Investigator:

On 5/1/2017, the IRB reviewed the following submission:

IRB ID:	IRB00011858	MOD or CR ID:	MOD00007213
Type of Review:	**Expedited-Minor Modification**		
Title of Study:	Impacts of the Affordable Care Act		
Title of modification	Protocol Update		
Principal Investigator:	Jennifer Devoe		
Funding:	Name: DHHS CDCP, PPQ #: 1007159, Funding Source: U18 DP006116; Name: DHHS NIH Natl Cancer Inst, PPQ #: 1007752, Funding Source: pending; Name: DHHS Agency for Hlth Care Policy & Rsch, PPQ #: 1006693, Funding Source: R01HS024270		
IND, IDE, or HDE:	None		

The IRB granted final approval on 5/1/2017. The study is approved until 3/30/2018.

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

1) Protocol Title

Impacts of the Affordable Care Act

2) Objectives

The purpose of this study is to understand the impacts of the Affordable Care Act (ACA) in a safety net population. We will assess the following in states that expanded Medicaid compared to those that did not or among states that expanded Medicaid:

- Pre-post rates of health insurance status and payer mix
- Pre-post access to healthcare (i.e., visits, provider workforce, receipt of recommended healthcare services, receipt of chronic disease specific care and outcomes; receipt of preventive care, appropriate care for specialized populations such as cancer survivors and patients with multimorbidity/complex healthcare needs)
- Pre-post healthcare expenditures
- Pre-post changes in health disparities (e.g., low-income, racial and ethnic minorities, rural versus urban)

We will look at differences in access to healthcare, expenditures, and disparities among those who gained coverage in the post-period, those who already had coverage, those with intermittent coverage, and those who remained uninsured. We will also try to understand how aggregated measures of social determinants of health constructed from community-level geocoded data (i.e., fast food availability, parks, income distribution, and racial/ethnic breakdown) from publicly available sources, such as the US Census Bureau, change the impact of disparities, access, and receipt of healthcare in relation to gaining or not gaining health insurance.

We propose to investigate how complex, and early-onset diseases affect the receipt of healthcare services later in life. Some of these analyses will focus on sub-group populations including patients with a history of cancer and those with multiple or complex chronic conditions. To accomplish these analyses, we will examine data from patients of all ages as many childhood cancers have a high likelihood of survival, and it is important to identify these patients as they are likely to have additional healthcare needs throughout their lifespan.

3) Background

Health insurance facilitates access to care and reduces unmet healthcare needs,[1-4] yet 47 million Americans had no coverage in 2012.[5] The ACA, the largest healthcare-related legislation in the United States (US) since Medicare's establishment in 1966, was enacted with the goal of expanding coverage to all citizens and legal residents.[6] The ACA increases opportunities to gain health insurance, including expansions in Medicaid coverage to individuals earning ≤ 138% of the federal poverty level (FPL) and the establishment of health insurance marketplaces. In 2012, the Supreme Court ruled that states were not legally required to implement Medicaid

expansions, and those opting out could not be penalized.[7] As of December 2014, 27 states (and D.C.) implemented the expansion;[8] the number of states is increasing. Many persons directly affected by these expansions are seen at community health centers (CHCs), which comprise much of our nation's healthcare 'safety net' and serve a rapidly increasing number of patients;[9] in 2012, 36% of CHC patients were uninsured.[10] The effect of the ACA on health insurance coverage and access to health care services is unknown, thus it is imperative to assess its impact.

4) Study Design

Secondary data analysis.

We will use electronic health record (EHR) data from the Accelerating Data Value Across a National Community Health Center Network (ADVANCE) clinical data research network (CDRN) data warehouse and Oregon Medicaid administrative data.

The ADVANCE CDRN is a unique 'community laboratory' for research with underrepresented populations that includes patients receiving care in safety net clinics. The ADVANCE CDRN data warehouse includes *integrated* longitudinal outpatient EHR data from several organizations, including OCHIN, Health Choice Network, Fenway Health, and Legacy Health.

Oregon Medicaid administrative data will be linked to OCHIN Oregon clinics in the ADVANCE CDRN to assess the receipt of healthcare services outside the ADVANCE network clinics and all healthcare expenditures.

Additionally, we will partner with the state cancer registries of one or more states to complete probabilistic linkage between our patient population and reported cancer cases. It is currently unknown how well personal cancer history and related data are documented in the outpatient EHR (i.e., data contained in the ADVANCE CDRN), thus our ability to identify and characterize cancer survivors may be incomplete. A linkage with one or more state cancer registries will supplement the CDRN data by comprehensively identifying cancer survivors in our cohort. This will allow us to test and validate our EHR-based algorithms, and to evaluate post-cancer care services provided by community health centers and the impact of insurance coverage for this population.

5) Study Population

a) Number of Subjects

Approximately 2.3 million total possible subjects. All analyses will contain a subset of these subjects.

b) Vulnerable Populations

Children ages 0-18 will be included for methods development and analyses related to childhood cancer and long-term care for cancer survivors. There is little literature about childhood cancers in vulnerable populations (e.g., economically marginalized, uninsured, or Medicaid insured) and associated disparities. Furthermore, adults with a history of childhood or adolescent cancer may require special follow-up care and screening

throughout their adult lives, thus we wish to have access to their EHR records from earlier ages where available.

c) Setting

This research will be conducted in collaboration with OCHIN. OCHIN requests the OHSU IRB serve as the IRB of record for this study.

d) Recruitment Methods and Consent Process

All patients with data in the ADVANCE CDRN may be included in this study. Subsets may include only OCHIN EHR data, only Oregon OCHIN EHR data, only persons with certain diseases or conditions (*e.g.,* cancer, diabetes, obesity), etc. For analysis of expenditures, Oregon OCHIN clinics from the ADVANCE CDRN will be linked to Oregon Medicaid administrative data using Medicaid identification number; subjects found in both datasets will be included. Similarly, for cancer registry linkage analyses only patients identified in both datasets will be included in analyses.

The ADVANCE data was collected under a waiver of authorization as the data warehouse poses very little risk to patients, and it was not practical to consent the number of patients included in the dataset.

6) Procedures

Secondary data analysis will be conducted.

7) Data and Specimens

a) Sharing of Results with Subjects

Results will not be directly shared with subjects.

b) Data and Specimen Banking

No specimens are being collected. Data is not being banked for future research.

8) Data Analysis

We will summarize baseline measures using descriptive statistics and data visualization methods (*e.g.*, histograms, scatter plots) to characterize baseline data across clinic and state groups. We will estimate the differences in access and receipt of recommended health care. We will also assess health care expenditures. Our primary methodological approach will utilize difference-in-differences (DID) methodology. The DID approach has been frequently used by health economists and health services researchers to account for potential secular effects and changing policies that would affect both expansion and non-expansion states over time, while adjusting for potential confounders.[11-16]

We will implement state random effects in clinic-level analyses and both clinic and state random effects in patient-level analyses to control for correlation of observations nested in clusters (*e.g.,* individuals nested in clinics which are nested in states). We recognize that the assumption for random effects may not be met and we will also assess the robustness of our

assumptions by running models that treat clinics and states as fixed effects. We will formally test the validity of the random effects using the standard Hausman test,[17] as well as assessing overall qualitative differences that may arise between the random and fixed effects models.

We will use GLMM models,[18] which offer flexible regression modeling to accommodate different sources of correlations (serial, intra-clinic, and intra-state), categorical and continuous covariates, and fixed and time-dependent covariates. These methods offer a wide range of parametric distributions to model the dependent variables, including logistic regression (binary data), beta regression (percent data), Poisson regression (count data), and Gaussian regression (normally distributed data). The distribution of the outcomes of interest will be examined before selecting an analysis model; specific models will be refined through an iterative process.

Potential variables included in the analyses	**Description**
Age	Categories
Sex	Male/female, other
Race	White, American Indian/Alaskan Native, Asian, Black, Native Hawaiian/Pacific Islander, Other
Ethnicity	Hispanic/non-Hispanic
Household Income	Federal poverty level; overall income; % FPL
Language Preference	English, Spanish, other, etc.
Clinic Information	Rural/urban; panel size; panel demographics; provider characteristics
Medicaid Expansion Status	ACA Medicaid expansion state/non-expansion state; date of expansion
Visits	Frequency and type of visits
Healthcare Need	Special need because of a chronic condition
Insurance	Coverage status and type at visit; changes in status and type over time; % covered over time
Continuity of Care	% of visits at the same site and with same provider; Continuity of Care Index
Service Utilization	Number and types of all billed encounters overall and yearly; all services received; disease specific services received; preventive services received; amount of time services are delayed
Expenditures	Categories; overall
Health outcomes	Biomarkers such as HbA1c, blood pressure, body mass index, cholesterol measurements, etc
Diagnoses	Number and type of chronic and acute conditions
Community Vital Signs	Community markers of social determinants of health (e.g., fast food availability, parks, income distribution, racial/ethnic breakdown, healthy food availability, income distribution, homeownership)
Cancer registry elements	Date of diagnosis, primary type, stage, sequence, histology, behavior, grade, insurance at diagnosis, family history, treatment, vital status, date of death

9) Privacy, Confidentiality and Data Security

We will obtain EHR data for patients included in the ADVANCE CDRN data warehouse. Data has already been transferred to the ADVANCE data warehouse from OCHIN, HCN, Fenway Health, and Legacy Health. The ADVANCE data are stored securely at OCHIN. All of the protections currently in place for the ADVANCE data warehouse will apply to this study. We will request the Oregon Medicaid administrative data from the Oregon Health Authority and collect it under a Data Authorization Agreement. The data transferred from OCHIN to OHSU will be de-identified and shared under a Data Use Agreement. The dataset will be de-identified by assigning each patient a unique subject identification that is not based on any personal identifiers. All data will be stored on secure servers and password protected computers. All data will be computerized and managed on HIPAA-compliant computers. All data work will be done on password-protected, HIPAA-compliant computers. All data will be stored and backed up on password-protected secure servers. All reports will describe results in aggregate form only.

For cancer registry linkage activities, we will access personal identifiers sufficient for completing probabilistic matching; direct identifiers will be stripped from all datasets and replaced with anonymized patient identifiers at the completion of linkage and for the duration of analyses. Data access and linkage procedures will be governed by Data Access Agreements between each relevant state agency and OCHIN. Any data transferred from OCHIN to OHSU will fall under the same protocol as outline in the Data Use Agreement between these two institutions.

10) Risks and Benefits

a) Risks to Subjects

There is a small risk of a loss of confidentiality.

b) Potential Benefits to Subjects

There is no direct benefit to the subject for taking part in this study.

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DATA USE AGREEMENT

This Data Use Agreement ("Agreement") with respect to a Limited Data Set is entered into by and between OCHIN Inc. ("OCHIN") and Oregon Health & Science University (OHSU) on behalf of OHSU Department of Family Medicine ("Data Recipient").

RECITALS

OCHIN and Data Recipient desire to set forth the terms and conditions under which OCHIN will disclose to Data Recipient certain Protected Health Information in the form of a Limited Data Set, as defined below, for the research described in this Agreement.

In consideration of the mutual promises below, and OCHIN's disclosure of the Limited Data Set to Data Recipient under this Agreement, the parties agree as follows:

ARTICLE I
DEFINITIONS

As used in this Agreement:

1.1 "HIPAA" means, collectively, the Health Insurance Portability and Accountability Act of 1996 and regulations thereunder, as amended from time to time.

1.2 "Limited Data Set" means the information described in Exhibit A constituting a "limited data set" as generally defined in the Privacy Rule at 45 C.F.R. §164.514(e). Under the Privacy Rule, a limited data set contains Protected Health Information, can include specific identifiers, and must exclude others. A limited data set must **exclude** the following direct identifiers of an individual and his or her relatives, employer(s), and household members: names; postal address information (except town or city, state and zip code which are permitted); telephone numbers; fax numbers; electronic mail addresses; Social Security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; license plate numbers and other vehicle identifiers and serial numbers; device identifiers and serial numbers; URLs; Internet Protocol (IP) address numbers; biometric identifiers including finger and voice prints; and full-face photographic and any comparable images. In the event of any conflict between this definition and the definition of a limited data set in HIPAA, the HIPAA definition will govern.

1.3 "Privacy Rule" means the Standards for Privacy of Individually Identifiable Health Information (45 C.F.R., Parts 160 and 164, Subparts A and E).

1.4 The following terms shall have the meanings given to them in HIPAA: "Breach," "Unsecured PHI," "Covered Entity," "Individual," "Protected Health Information," "Minimum Necessary," and "Required by Law."

ARTICLE II

DISCLOSURE

2.1. OCHIN intends to disclose to Data Recipient the Limited Data Set for the purposes of the research study entitled **"Post Affordable Care Act: Evaluation of Community Health Centers (PACE)"** which study is more specifically described in Exhibit A (the "Study").

2.2 The Data Recipient represents that to the extent the Data Recipient requests that OCHIN disclose Protected Health Information to the Data Recipient as described in Section 2.1 and Exhibit A, such a request is only for the Minimum Necessary Protected Health Information for the accomplishment of the Data Recipient's purpose.

2.3 The Data Recipient shall provide OCHIN with the results of its Study as soon as practical.

ARTICLE III
DATA RECIPIENT'S OBLIGATIONS

3.1. Unless specifically stated otherwise in this Agreement, Data Recipient's obligations with respect to the Limited Data Set apply to the whole and to any part of the Limited Data Set, including any Protected Health Information contained in the Limited Data Set.

3.2. Data Recipient shall not use or disclose the Limited Data Set for any purpose other than the Study or as Required by Law. In addition, Data Recipient shall not use or disclose the Limited Data Set in any manner that would violate the Privacy Rule or any other HIPAA provision if done by a Covered Entity.

3.3. Data Recipient shall not disclose the Limited Data Set to any employee, other individual, or entity other than those employees, agents, or subcontractors specified in Exhibit A who are permitted to use or receive the Limited Data Set for the purposes of the Study ("Data Sub Recipients").

3.4. Except as specified in Exhibit A, Data Recipient may not subcontract its performance obligations, or assign its rights, under this Agreement without the express written consent of OCHIN. Data Recipient shall ensure that any Data Sub Recipients, other than Data Recipient's employees, to whom it provides the Limited Data Set agree in writing to the same terms and conditions regarding the Limited Data Set that apply to Data Recipient under this Agreement.

3.5. Data Recipient must use appropriate safeguards to prevent the use or disclosure of the Limited Data Set in any manner not permitted by this Agreement.

3.6. Data Recipient must not identify or contact (or attempt to do so), either directly or through another person, any Individual in the Limited Data Set.

3.7. Data Recipient shall ensure that any agents to whom it provides the Limited Data Set agree to the same restrictions and conditions that apply to the Data Recipient with respect to such information.

3.8. Data Recipient agrees to mitigate, to the extent feasible, any harmful effect that is known

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or becomes known to Data Recipient that arises from a use or disclosure of the Limited Data Set by Data Recipient or its employees or agents in violation of this Agreement or HIPAA.

3.9. Data Recipient must notify OCHIN within twenty-four (24) hours by phone, and in writing within five (5) business days, after Data Recipient becomes aware of any use or disclosure not authorized by this Agreement and any actual or suspected breach of Data Recipient's security. Data Recipient shall notify OCHIN within 5 days following the discovery of a suspected or actual Breach of Unsecured PHI. The Breach notice shall include the identification of each individual whose Unsecured PHI has been, or is reasonably believed by the Data Recipient to have been, accessed, acquired, or disclosed during the Breach, and any other information available that OCHIN will need to notify the affected individual(s). Data Recipient shall be responsible for payment of costs and will indemnify OCHIN for any reasonable expenses OCHIN incurs in complying with the Breach notification requirements where the Data Recipient or the Data Recipient's subcontractors or agents cause the Breach.

3.10. Data Recipient acknowledges that Data Recipient has no ownership rights in the Limited Data Set.

3.11. Within ten (10) business days of a written request by OCHIN, Data Recipient shall allow OCHIN to conduct a reasonable inspection of Data Recipient's facilities, systems, books, records, agreements, and policies and procedures relating to the use or disclosure of the Limited Data Set for the purpose of determining Data Recipient's compliance with this Agreement. Any failure of OCHIN to inspect or to detect or notify Data Recipient of an unsatisfactory practice does not constitute acceptance of the practice by OCHIN or a waiver of any remedy or right OCHIN has under this Agreement or applicable law.

3.12. Data Recipient shall comply with state laws to the extent that they are more protective than HIPAA of the Individual's privacy and security of the information contained in the Limited Data Set.

ARTICLE IV
AMENDMENT AND TERMINATION

4.1 When OCHIN reasonably concludes that an amendment to this Agreement is necessary to comply with applicable law, OCHIN shall notify Data Recipient in writing of the proposed modification(s) ("Legally-Required Modifications"). Data Recipient shall be deemed to have accepted the Legally Required Modifications on the 30th day after it receives such notice unless, within that time period, Data Recipient delivers a written rejection of them to OCHIN. Data Recipient's rejection of a Legally Required Modification is grounds for termination of this Agreement by OCHIN on thirty (30) days written notice.

4.2. The following violations shall constitute cause for immediate termination by OCH1N of this Agreement:

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4.2.1. A violation by Data Recipient of HIPAA as well as any other state or federal laws and regulations related to the use or disclosure of Protected Health Information or any information contained in the Limited Data Set;

4.2.2. Any breach of privacy or security by Data Recipient that is not properly disclosed to OCHIN pursuant to Section 3.8 and cured to the satisfaction of OCHIN;

4.2.3 Any use of data that is inconsistent with the authorized purposes described in this Agreement; and

4.2.4 Any violation of any provision of this Agreement, as determined by OCHIN.

At its sole discretion, OCHIN may give Data Recipient thirty (30) days to cure any such violations or breaches described in this Section 4.2.

4.3. On termination of this Agreement for any reason, Data Recipient shall return or destroy the Limited Data Set unless return or destruction is not feasible and Data Recipient explains why, in writing, to the address provided in this Agreement.

4.3.1. If Required by Law, Data Recipient may retain the portions of the Limited Data Set for the time specified as necessary to comply with the law.

4.3.2. Data Recipient's obligations under this Agreement shall continue until Data Recipient destroys the Limited Data Set or returns the Limited Data Set to OCHIN; provided however, that on termination of this Agreement, Data Recipient shall not further use or disclose the Limited Data Set except as Required by Law.

4.3.3. If Data Recipient elects to destroy the Limited Data Set, Data Recipient shall certify in writing to OCHIN that the Limited Data Set has been destroyed.

4.4. At the expense of the Data Recipient, OCHIN shall have the right to cure any breach of the Data Recipient's obligations under this Agreement. OCHIN shall give the Data Recipient notice of its election to cure any such breach and the Data Recipient shall cooperate fully in the efforts by OCHIN to cure the Data Recipient's breach. All requests for payment for such services by OCHIN shall be paid within thirty (30) days.

4.5. This Agreement shall commence on 1/16/16 and shall continue in full force and effect for an initial period of one (1) year(s) (the "Initial Term") and shall automatically renew for consecutive one (1) year periods (each a "Subsequent Term"), provided however that either party may terminate this Agreement by providing the other with not less than ninety (90) days notice prior to the commencement of any Subsequent Term.

ARTICLE V
MISCELLANEOUS

5.1. Exhibit A is part of this Agreement and may be modified by the parties at any time pursuant to a writing executed by both parties or as specified in Section 4.1 above. In the event of a conflict between the provisions of Exhibit A and the provisions of Articles I through V of this Agreement, the latter shall govern.

5.2. Any ambiguity in this Agreement relating to the use and disclosure of the Limited Data Set by Data Recipient shall be resolved in favor of a meaning that further protects the privacy and security of the information.

5.3. All written notices required or permitted under this Agreement may be delivered personally, by courier, electronic facsimile (with a confirmation by registered or certified mail placed in the mail no later than the following day), or registered or certified mail, postage prepaid, directed to a party as indicated below:

If to OCHIN:	Data Recipient:
OCHIN Inc. 1881 SW Naito Parkway Portland, OR 97201 Attention: Abby Sears Chief Executive Officer Facsimile No.: (503) 943-2501	OHSU Department of Family Medicine 3181 SW Sam Jackson Park Road Mail Code: FM Portland, OR 97239 Attention: Jen DeVoe, MD, DPhil Facsimile No.: (503) 943-2500 Email: devoej@ohsu.edu

Notice delivered personally or by courier or transmitted by electronic facsimile will be deemed to have been given on receipt (as evidenced, in the case of facsimile, by confirmation of transmission). Notice delivered by registered or certified mail will be deemed given on the 3rd day after mailing to the address above. The above addresses may be changed by giving written notice as described in this section.

5.4. Data Recipient's obligations under Articles III and IV and Sections 5.7, 5.9 and 5.11 of this Agreement shall survive the termination of this Agreement.

5.5. If any provision of this Agreement is determined by a court of competent jurisdiction to be invalid, void, or unenforceable, the remaining provisions shall continue in full force and effect.

5.6. This Agreement shall be governed by the laws of the State of Oregon.

5.7. The Data Recipient shall indemnify, defend, and hold OCHIN harmless from and against any actual legal or administrative action, claim, liability, penalty, fine, assessment, lawsuit, litigation, or other loss, expense, or damage, including without limitation any reasonable attorneys' fees and costs that OCHIN may incur directly or indirectly resulting from any actions or omissions of Data Recipient, its agents or subcontractors, including failure to perform its obligations under this Agreement.

5.8. OCHIN shall indemnify, defend, and hold Data Recipient harmless from and against any actual legal or administrative action, claim, liability, penalty, fine, assessment, lawsuit, litigation, or other loss, expense, or damage, including without limitation any reasonable attorneys' fees and costs that Data Recipient may incur directly or indirectly resulting from any actions or omissions of OCHIN, its agents or subcontractors, including failure to perform its obligations under this Agreement.

5.9. Data Recipient shall obtain and maintain during the term of this Agreement liability insurance covering claims based on a violation of HIPAA or any applicable state law or regulation concerning the privacy of patient information and claims based on its obligations pursuant to this Agreement in an amount not less than $1,500,000 per claim. Such insurance shall be in a form of occurrence based coverage. A certificate evidencing the policy shall be provided to OCHIN upon written request. Data Recipient shall provide OCHIN at least thirty (30) days' advance notice of cancellation or material modification to said policies.

5.10. This Agreement, including all Attachments and Exhibits which are deemed incorporated by this reference, is the entire Agreement between the parties, and no other agreements, oral or written, have been entered into with respect to the subject matter of this Agreement. This Agreement specifically supersedes and replaces all prior agreements between the parties on the subject matter of this Agreement whether oral or written.

5.11. Data Recipient shall not assign its rights, duties or obligations under this Agreement (including by merger, consolidation, or acquisition) without the prior written consent of OCHIN. OCHIN may assign this Agreement to any affiliate, subsidiary, parent or related entity of OCHIN.

5.12. No term or provision of this Agreement shall be deemed waived and no breach excused unless waiver or excuse of breach is in writing and signed by the party against whom such waiver or excuse is claimed.

IN WITNESS WHEREOF, the parties have executed this Agreement effective as of: _____

OCHIN, Inc.	
By:	By: Deborah Golden-Eppelein
Name: Abby Sears	Name: Deborah Golden-Eppelein
Title: Chief Executive Officer	Title: Associate Vice President, Office of Proposal & Award Management
Date: 4-6-16	Date March 28, 2016:

EXHIBIT A to the Data Use Agreement for Research

By and Between OCHIN Inc. and Oregon Health & Science University (OHSU)
on behalf of the OHSU Department of Family Medicine
Dated 1/ 15/ 2016

1. **Description of the Study, including description of the project goals and objectives and the relationship of the Study to the interests of OCHIN members:**

This study, *Post Affordable Care Act: Evaluation of Community Health Centers,* proposes to examine the impact of the Affordable Care Act (ACA) Medicaid expansion on patients utilizing community health centers (CHCs). The Supreme Court ruling, which determined that states were not legally required to implement the ACA Medicaid expansion, created a 'natural policy experiment.' We will use electronic health data from the national ADVANCE clinical data research network (CDRN), which has patient-level data in expansion and non-expansion states, to measure pre-post expansion health care utilization, receipt of services, and Medicaid expenditures.

The specific aims of this proposal are: 1) Compare pre-post health insurance status, primary care, mental health, and dental visits, and receipt of preventive services, as well as changes in payer mix among CHCs in states that did and did not expand Medicaid; 2) Examine pre-post utilization of CHC services (including receipt of preventive services) by newly insured compared to already insured and uninsured patients; and 3) measure pre-post changes in overall utilization of healthcare services and Oregon Medicaid expenditures among newly insured compared to already insured patients.

The research will be informed by an Expert Advisory Group of local and national experts who will meet quarterly, including: Kristin "Kay" Dickerson, a CHC patient and founding member of OCHIN's patient engagement panel; Merwyn "Mitch" Greenlick, PhD, a health services researcher and state legislator; Jeanene Smith, MD, MPH, a Principal at Health Management Associates; Amit Shah, MD, the medical director of CareOregon, an Oregon-based, non-profit, Medicaid health plan; and Marni Kuyl, MS, RN, Washington County (Oregon's second largest county) Health and Human Services Director. This study will have national relevance, as it measures how Medicaid expansion impacts access and changes in receipt of health care services among vulnerable populations.

2. **Limited Data Set.** The Limited Data Set will contain the following variables and/or variables that have been derived from these variables (such as counts, means, etc.) ("Data Elements"):

DATA ELEMENTS– LIMITED DATA SET

DATA ELEMENTS:

The data included in the datasets will fall into several classes as shown in the table below. Some examples of each class of data are shown but do not comprise an exhaustive list of possible variables to be included in the dataset.

ADVANCE Tables	Examples include, but are not limited to:
Demographics	Patient id, sex, date of birth, race, ethnicity, primary language, annual income, FPL, primary payor, state of residence, sites
Enrollment	Patient id, site id, enrollment start date, enrollment end date
Encounter	Encounter id, patient id, admit date, provider id, facility location, encounter type, facility id, admitting source, primary payor, site id
Diagnosis	Diagnosis id, patient id, encounter id, encounter type, admit date, provider id, diagnosis, diagnosis type, diagnosis source, site id
Procedures	Procedures id, patient id, encounter id, encounter type, provider id, procedure date, procedure code, procedure type, procedure source, site id

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Vital	Vital id, patient id, encounter id, measure date, measure time, vital source, height, weight, diastolic blood pressure, systolic blood pressure, original bmi, blood pressure position, smoking, tobacco, tobacco type, site id
Dispensing	Dispensing id, patient id, prescribing id, dispense date, national drug code, dispense supply, dispense amount, site id
Lab Result CM	Lab result cm id, patient id, encounter id, lab name, specimen source, lab LOINC, result location, lab procedure, lab procedure type, lab order date, result date, result quality, result number, result modifier, result unit, norm range low, norm range high, norm modifier high, abnormal result indicator, site id
Condition	Condition id, patient id, encounter id, report date, onset date, resolve date, condition status, condition, condition type, condition source, site id
Prescribing	Prescribing id, patient id, encounter id, rx provider id, rx order date, rx start date, rx end date, rx quantity, rx refills, rx days supply, rx frequency, rx basis, rx norm concept identifier, site id
Death	Patient id, death date, death date imputed, death source, death match confidence, site id
Death cause	Patient id, death cause, death cause code, death cause type, death cause confidence, site id

3. **Time Period.** The Limited Data Set includes Data Elements for the following time period: 1/1/2012 to 12/31/2017

4. **OCHIN Members.** Data Elements from the following OCHIN members are included in this Limited Data Set:

AH FEATHER RIVER HC	COMMUNITY HEALTHNET	INCLINE MEDICAL	METROPOLITAN COMMUNITY HEALTH
ALLIANCE MEDICAL CENTER	COWLITZ FAMILY HEALTH CENTER	ONE COMMUNITY HEALTH	MOLINA MEDICAL MANAGEMENT
AXIS MEDICAL CENTER	CROOK COUNTY	THE NATIONAL COLLEGE OF NATURAL MEDICINE	MONTEREY COUNTY HEALTH DEPT
BASTYR UNIVERSITY	OHSU	JEFFERSON COUNTY HEALTH DEPT	CLINICA ROMERO
BENTON HEALTH SERVICES	DESCHUTES COUNTY HEALTH DEPT	KODIAK COMMUNITY HEALTH CENTER	NORTHERN HEALTH CENTERS
CARE ALLIANCE	DUNES FAMILY HEALTH	LAGUNA BEACH COMMUNITY CLINIC	MOSAIC MEDICAL
CARING HEALTH CENTERS	OUTREACH COMMUNITY HEALTH CENTER	LINCOLN COUNTY HHS	MULTNOMAH COUNTY HEALTH DEPT
CHC OF CAPE COD	EL CENTRO DE CORAZON	LYNN COMMUNITY HEALTH CENTER	COASTAL FAMILY HEALTH CENTER

CLACKAMAS COUNTY PHD	FREE CLINIC OF CLEVELAND	MERCY CARE	QUEENSCARE HEALTH CENTERS
COMMUNITY HEALTH ALLIANCE-CHAP	GREATER ROSLINDALE MEDICAL AND DENTAL CENTER	CITY OF HOUSTON	MT HOOD WOMEN'S HEALTH PC
NEIGHBORHOOD FAMILY PRACTICE	WESTERN UNIVERSITY	UNIVERSITY WESTERN STATES	WATERFALL COMMUNITY HEALTH CENTER
NORTH TAHOE FAMILY CARE	ROANOKE CHOWAN COMM HLTH CTR	ARCW MEDICAL CENTER	INTL COMMUNITY HEALTH CTR
PLACER COUNTY MEDICAL CLINIC	SANTA CRUZ COUNTY	PACIFIC UNIVERSITY	
MOLINA MEDICAL GROUP	THE UROLOGY CLINIC, PC	WALLACE MEDICAL CONCERN	
SKY LAKES MEDICAL CENTER	TRUCKEE TAHOE MEDICAL GROUP	PROGRESSIVE COMMUNITY HLTH CTR	
SOUTHSIDE COMMUNITY HEALTH	VIRGINIA GARCIA MEMORIAL HC	SOUTH BOSTON CHC	
CENTRAL NEIGHBORHOOD HEALTH FOUNDATION	THE PUBLIC HEALTH FOUNDATION OF COLUMBIA COUNTY		

5. **Permitted Uses.** Data Recipient may only use the Limited Data Set and any Protected Health Information contained in the Limited Data Set for the Study as follows:

The study will use individual-level clinical data to evaluate the provision of health care services across community health centers facilities in the Advance common data model (CDM). There will be no individual, regional or provider identifiers other than those allowed for a Limited Data Set. The CDM has deidentified data by replacing the original identifiers on sensitive or confidential fields with arbitrary pseudo-identifiers, the "crosswalk" tables that contain these mappings are by design not part of the CDM, and access to these tables is limited to authorized ADVANCE staff.

6. **Permitted Disclosures.** Data Recipient may only disclose the Limited Data Set and any Protected Health Information contained in the Limited Data Set to the following Data SubRecipients, including Data Recipient's employees, to use or receive in the course of assisting Data Recipient in the performance of the Study described in the Agreement as follows:

Disclosures are permitted for the Principal Investigator, co-investigators and data analysts to conduct data analysis to address the specific aims of the study.

Additionally, the Data Recipient may disclose to OCHIN Inc. the limited data set and any protected health

information contained in the limited data set for the purposes of data analysis, data management, and quality assurance.

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AMENDMENT #1 TO EXHIBIT A

OF THE DATA USE AGREEMENT FOR RESEARCH BY

AND BETWEEN HEALTH CHOICE NETWORK OF FLORIDA INC. AND OCHIN INC.

Health Choice Network of Florida Inc. (hereinafter "HCN") and OCHIN Inc. (hereinafter "OCHIN") are parties to a January 1, 2015 Data Use Agreement (hereinafter "DUA") that became effective on or about April 3, 2015. HCN and OCHIN, as part of the DUA, executed Exhibit 1 to the DUA on or about April 10, 2015. In the DUA and Exhibit 1 to the DUA, HCN and OCHIN agreed to various roles and responsibilities as they apply to the ADVANCE study and three research cohorts to ADVANCE. HCN and OCHIN wish to expand their roles as responsibilities as it applies to ADVANCE as follows:

1. Replacing the opening sentence of Paragraph 1(c) to read "Support the planning and implementation of all ADVANCE research cohorts. Provide preliminary data to assess the feasibility of conducting future research, inform and prepare or assist in preparation for the design of the research and conducting the actual research for all ADVANCE research studies."

2. Replacing Paragraph 3 subsection (2) to read "(2) addressing the aims of all ADVANCE studies."

Other than stated above, the DUA and Exhibit 1 to the DUA remain in full force and effect. This Amendment #1 will be effective as of the date of the final signature.

HEALTH CHOICE NETWORK OF FLORIDA INC.

By: _____

Name: Blanca M. Ollet

Title: Chief Operating Officer

Dated: 6-3-16

OCHIN INC.

By: _____

Name: Abby Sears

Title: CEO

Dated: 6-3-16

AMENDMENT TO EXHIBIT A
OF THE DATA USE AGREEMENT FOR RESEARCH BY AND BETWEEN
OCHIN, INC. AND OHSU DEPARTMENT OF FAMILY MEDICINE FOR THE STUDY
***Post Affordable Care Act: Evaluation of Community Health Centers* (PACE)**

OCHIN, Inc. ("OCHIN") and OHSU Department of Family Medicine ("Data Recipient") are parties to a Data Use Agreement executed on April 6, 2016, in which OCHIN and Data Recipient set forth the terms and conditions under which OCHIN will disclose to Data Recipient certain Protected Health Information for the study *Post Affordable Care Act: Evaluation of Community Health Centers* (PACE).

OCHIN and Data Recipient agree to amend Exhibit A of the aforementioned Data Use Agreement as follows:

Add the following to the Data Elements Table listed in Paragraph 2: Limited Data Set.

ADVANCE Tables	Examples include, but are not limited to:
Environmental*	Employment status, Neighborhood Socioeconomic Composition, Neighborhood Resources

*This class contains information about the patient's environment and social determinants of health. The data comes from publicly available community data sources (including but not limited to the USDA, USDA Food Atlas, and Census/American Community Survey). Geographic identifiers (address, zip code, census tract) will not be included in this domain.

This Amendment does not modify any other portion of the Data Use Agreement, which shall remain in full force and effect. This Amendment will be fully executed upon signing by both parties.

OCHIN, Inc.

Signature: [signature]
Name: Abigail Sears
Title: CEO
Date: May 22, 2017

OHSU Department of Family Medicine

Signature: [signature]
Name: Deborah Golden-Eppelein
Title: Associate Vice President
Office of Proposal & Award Mgmt.
Date: 6/12/17

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DIVISION OF MEDICAL ASSISTANCE PROGRAMS
Health Programs Analysis & Measurement Section
John A. Kitzhaber, MD, Governor

Oregon Health Authority

500 Summer Street NE, E35
Salem, OR 97301-1077
VOICE: 503-945-6429
FAX: 503-373-7689
TTY 503-378-6791
www.oregon.gov/OHA

January 15, 2015

The following pages contain a *Research Application* and an *Information Access Agreement* that must be completed to grant access to the data you requested. You must complete the application areas designated by **bold** text.

The completed application should be returned to:

Oregon Health Authority
ATTN: Office of Health Analytics
Health Programs Analysis and Measurement Unit
500 Summer Street NE, E-35
Salem, OR 97301-1077

Direct inquiries to:

Office of Health Analytics
Health Programs Analysis and Measurement Unit
Saundra Mitchell (503) 945-6593

When your request was received a data request number was assigned. After the application and completed agreement have been received, the application will be reviewed and the requestor will be notified of its disposition. The Requestor shall send two original completed and signed agreements with the HPAMU assigned tracking number to the Office of Health Analytics HPAMU authorized representative named above. The HPAMU authorized representative will appropriate responsible signees signature, and return one original to the Requestor.

NOTE:
The purpose of your request must support the administration of the Oregon Health Plan, and this must be outlined clearly in the application. For requests initiated or authorized as public health surveillance, please complete the supplemental public health disclosure, in addition.

For projects that are primarily research, you must submit your *IRB* application accompanied by the signed, dated approval. If you have any question about what constitutes research, please contact the Manager of Health Programs Analysis and Measurement Unit.

RESEARCH APPLICATION

Please use this template to fill in your information

Applicant Name: OCHIN, Inc.
Applicant Address: 1881 SW Naito Parkway, Portland, OR 97201
Applicant Contact Name: Jennifer DeVoe, MD, DPhil, 503-943-2618, devoej@ohsu.edu

1. **Describe the general purpose of study.**
   The purpose of the "*Long-term Trends in Health Insurance Coverage and Access to Health Care Services* " study is to understand trends in health insurance coverage and access to health care services over time in a safety net population. This will include investigating health insurance coverage patterns and differences in health insurance coverage reported in OCHIN versus the Oregon Health Plan [(OHP) Oregon's Medicaid Program]. We will look at health care services patients receive and how health insurance coverage impacts these services. Additionally, we will look at how health insurance patterns and health care services change as state and federal policies are implemented (for example, the Affordable Care Act, or Coordinated Care Organizations) in Oregon as well as the other states with OCHIN clinics. We will also compare the use of electronic health record tools to keep patients insured.

2. **Describe the specific details of the request:**

   a. **Detail the purpose of request, state the research or evaluation question(s), hypotheses to be tested:**

   This study will 1) examine the relationship between health insurance coverage and receipt of health care services, alone and in relation to policy change, 2) track changes in health insurance patterns and health care services, alone and in relation to policy change, 3) assess differences between OCHIN and DMAP data, and 4) evaluate the use of electronic health record tools to keep patients insured.

   b. **Specify the data elements/information that is requested from DMAP, which enrollment and claims data elements for specific date periods:**

   This is a secondary data analysis study only. Potential subjects will be from four OHSU IRB-approved research studies for which there already exist individual Data Access Agreements with OHA DMAP [IMPACCT (OHSU IRB#00009244, OHA Request #2653), FAMILY (OHSU IRB#00006727, OHA Request #2398), AMRIC (OSHU IRB#00007327, OHA Request #2545), and CATCH UP (OHSU IRB# IRB00009862; OHA Request #3455)].

   To meet the aims of this study, we will utilize all Claims data (inpatient/long-term care, outpatient, and pharmacy claims); Eligibility/Enrollment data (including demographic variables); and Provider Information data (including but not limited to

provider ID and provider type) for the period 1/1/2002-6/30/2019, for all children (ages 0-20) and adults (ages 18 and older).

We would like to utilize data currently being received under the auspices of the four studies mentioned above. In addition, we are now requesting some additional data to fill in the gaps in the existing DMAP data for the timeframe of the "Long-term Trends in Health Insurance Coverage and Access to Health Care Services" study.

Specific additional data we are now requesting include:

- Inpatient claims, 2002-2010, ages 0-20
- Eligibility/enrollment, outpatient claims, and pharmacy claims, 2002-2010, ages 19-20
- All files, 2002-2004, ages 18+
- All files, 2013-6/30/2019, all ages
- Language and ethnicity demographic elements for all years, all patients
- Primary care home data for CCO patients, all applicable years

We request receipt of the data currently available, with the remainder provided separately when it becomes available and on a schedule mutually agreed upon by OCHIN Inc. and Oregon Health Authority, Division of Medical Assistance Programs (DMAP).

c. Details of how DMAP data will be used for said purpose:
Our analyses will include: 1) descriptive examinations of the data, including demographics, characterization of variations and patterns of insurance coverage, and receipt of health care alone and in relation to policy changes. Insurance coverage may be displayed on maps to visualize areas where uninsurance rates are higher; 2) analyses of how factors are associated with outcomes of interest; 3) examination of various lag times for gain / loss of insurance coverage and changes in utilization patterns; 4) identification of potential confounders; and 5) evaluation of the impact of insurance coverage status change / no change on utilization of preventive services, adjusted for potential confounders. We will also assess the interaction between insurance status and continuity of coverage.

d. Provide the names and contact information for lead or principle investigators and any others who have access to data information we provide:

Jennifer DeVoe, MD, DPhil	OCHIN	devoej@ohsu.edu
Heather Angier, MPH	OHSU	angierh@ohsu.edu
Stuart Cowburn, MPH	OCHIN	cowburns@ochin.org
Rose Harding, BA	OHSU	hardingr@ohsu.edu

Brigit Hatch, MD, MPH	OHSU	adamusb@ohsu.edu
Megan Hoopes, MPH	OCHIN	hoopesm@ochin.org
Jean O'Malley, MPH	OHSU	omalleyj@ohsu.edu
Aleksandra Sumic, MPH	OCHIN	sumica@ochin.org
Carrie Tillotson, MPH	OHSU	tillotso@ohsu.edu
Miguel Marino, PhD	OHSU	marinom@ohsu.edu
Eve Dexter, MS	OHSU	dextere@ohsu.edu
Christine Nelson, PhD, RN	OCHIN	nelsonc@ochin.org
Thuy Le, MPH	OCHIN	let@ochin.org
Jon Puro, MA	OCHIN	puroj@ochin.org
Nathalie Huguet, PhD	OHSU	huguetn@ohsu.edu
John Heintzman, MD	OHSU	heintzma@ohsu.edu
Steffani Bailey, PhD	OHSU	bailstef@ohsu.edu
Rachel Gold, PhD	Kaiser Permanente CHR/OCHIN	Rachel.Gold@kpchr.org
Charles Gallia, PhD	State of Oregon	Charles.A.Gallia@state.or.us
Sonja Likumahuwa, MID, MPH	OHSU	likumahu@ohsu.edu
Erika Cottrell, PhD	OHSU	cottrele@ohsu.edu

e. Specifics on how the purpose helps DMAP administer the Medicaid program: and,

The proposed project could result in expanded understanding of health services DMAP covered children and adults receive at Community Health Centers (CHCs) and how health insurance coverage impacts these services, alone and in relation to policy changes. In addition, this project could result in better understanding of how the use of electronic health record tools to keep patients insured affects continuity of coverage. These tools have potential for widespread adoption in CHCs providing care

to DMAP covered children and adults. Increased continuity of coverage could improve the quality of evidence-based care provided to the CHC patients and reduce administrative burden associated with "churning".

f. **Timeframe of study.** 1/1/2002 to 06/30/2019

NOTE: Access to DMAP's data will only be granted if the purpose supports the administration of the Oregon Health Plan. The request must detail how the data supports the administration of the Oregon Health Plan. Purpose statement must also support each specific data element requested.

3. **Detail the administrative, technical, and physical safeguards Requestor will use to protect the data set.** Specifically, in order to ensure that client privacy is protected and meets DHS' Health Insurance Portability and Accountability Act Of 1996, (HIPAA) privacy policies, review and agree to abide by the OHA administrative policies including:

Administrative, Technical and Physical Safeguards Policy	OHA-100-005
Client Privacy Rights Policy	OHA-100-002
De-identification of Client Information and Use of Limited Data Sets Policy	OHA-100-007
Enforcement, Sanctions and Penalties for Violations of Individual Privacy Policy	OHA-100-009
General Privacy Policy	OHA-100-001
Minimum Necessary Information Policy	OHA-100-004
Uses and Disclosures of Client or Participant Information Policy	OHA-100-003
Uses and Disclosures for Research Purposes and Waivers Policy	OHA-100-006

(See http://www.oha.state.or.us/policy/admin/privacylist.htm). Ensure that the description meets Title II, Subtitle F of the Health Insurance Portability and Accountability Act of 1996, 42USC 1320d et.seq, and, when applicable, the Substance Abuse and Mental Health confidentiality regulations outlined in Part II of the Department of Health and Human Services, Public Health Service, 42CFR Part 2; ORSs 179.505, 192.535, 192.547.

4. **Provide a detailed description of health information safety and privacy protocols.** Under the current business associates agreement between OCHIN and DMAP, DMAP will provide OCHIN with a file containing the requested data.

All data exchanges will be done using standard security processes with password-controlled Secured File Transfer Protocol (SFTP) access. Access will be given only to study personnel. All reports will describe results in aggregate form only.

OHSU will receive the data once the following identifiers are removed: OHP and OCHIN ID numbers, names, full addresses, and phone numbers. IRB approval has been obtained from this research at OHSU. OCHIN has requested OHSU be the IRB of record for this study.

(Agreement / Request # 3524)

INFORMATION ACCESS AGREEMENT

This agreement is between the Oregon Health Authority, Division of Medical Assistance Programs (DMAP),

and **OCHIN, Inc.**
1881 SW Naito Parkway, Portland, OR 97201
Jennifer DeVoe, MD, DPhil, 503-943-2618, devoej@ohsu.edu OCHIN, Inc.,
here forward known as "Requestor" has requested access to DMAP's:

Claims data (inpatient/long-term care, outpatient, and pharmacy claims); Eligibility/Enrollment data (including demographic variables); Provider Information data (including but not limited to provider ID and provider type) for the period 1/1/2002-6/30/2019, for all children (ages 0-20) and adults (ages 18 and older).

Requestor of information related to Fee-for-Service medications will agree to use it specifically and exclusively as stated in the Information Access Agreement and in the attached Research Application. Additionally, as a condition of use and for an extension of the agreement, the requestor will provide DMAP a documentation of how this information was used to meet the terms of this agreement, upon request.

Requestor warrants and agrees:

1. The confidentiality of all data sources used for the purposes stated above will be protected as mandated by state and federal laws and regulations, including HIPAA privacy regulations; and that all information related to personal facts and circumstances of DMAP will be treated as privileged communications and will be held confidential;

2. Any data provided by DMAP will not be physically moved or electronically transmitted unless written authorization is received from DMAP; if the above stated purpose or security protocols outlined above includes electronic transmission or physical movement of data, this Agreement serves as such written authorization for only above-stated purpose and specifications;

3. That the facts and statements made above in any research protocol, study, or project plan submitted to DMAP for each purpose are complete and accurate;

4. That the data will not be used for any other purposes other than those stated above unless upon mutually agreed between Requestor and DMAP with written authorization by authorized DMAP representative;

5. That any information related to behavioral health patient records will be treated with the federal and state standards for confidentiality as defined in Part II of the Department of Health and Human Services, Public Health Service, 42CFR Part 2; and ORS 179.505;

6. That no findings, listing, or information derived from the file(s) and data will be released or disclosed to other parties with or without identifiers, if such findings, listing, reports, or information contain any combination of data elements that might allow the deduction of a beneficiary's identification, without first obtaining written authorization from the appropriate DMAP representative (see DMAP signatory below);

7. That access will be limited to individuals directly involved and identified that are necessary to achieve the purposes stated above, and that access will be limited to the minimum amount of data necessary to achieve the purpose stated above, and that any breach of security or violations to this agreement will be reported to DMAP as soon as you are aware of the violation;

8. That the Requestor has in place appropriate administrative, technical, and physical safeguards so that DMAP data will be protected to prevent unauthorized use, and that authorized DMAP representative will be granted access to premises where above-stated data are kept for the purpose of inspecting security arrangements to confirm that the Requestor is in compliance with security requirements;

9. That data will be destroyed and an attestation shall be provided to that effect or the data will be returned not later than 60-days after completion of the project as specified above, unless written agreement between Requestor and appropriate DMAP representative. Requestor will notify DMAP within 30-days of completion of project date once above stated purpose has been accomplished, if completed before above-stated completion date. Requestor will submit, on Requestor's letterhead, confirmation that no copy, data, nor parts thereof have been retained, and that the data has been destroyed or has been returned. Said letter (and returned data) should be sent to DMAP's address on first page of the Agreement. The data agreement must be reviewed and resubmitted no less than annually if research project extends beyond one year. The ability of the Requestor to use the data under this agreement is valid for one year and must be extended in writing;

10. That DMAP will be consulted in the analysis of the data and interpretation of the results, and be allowed reasonable time to review for accuracy any reports or published articles from this study prior to release.

This agreement addresses the conditions under which State of Oregon, Oregon Health Authority, Division of Medical Assistance Programs (DMAP) will disclose, and the Requestor will obtain and use the DMAP data specified above. It supersedes any and all other prior agreements with respect to use of the specified data above. The terms of the Agreement can only be changed by a written modification to this Agreement, or by the parties adopting a new agreement.

Requestor agrees that DMAP retains all ownership rights to the data file(s) referred to in this agreement, and that the Requestor does not obtain any right, title, or interest in any of the data furnished by DMAP.

By signing this Agreement, the Requestor agrees to abide by all provisions set out in this Agreement.

SIGNATURES:

2/16/15

(Organization) Authorized Signature, title
Date

2/4/15

Authorized Signature, Jon C. Collins, PhD
OHA, Manager Health Programs Analysis and Measurement

Date

DATA ACCESS AGREEMENT AMENDMENT FORM

CONTACT INFORMATION
(Please use this template to fill in your information)

Date: May 31, 2016

Request #3524

Principal Investigator: Jennifer DeVoe, MD, DPhil

Enter changes here and state page number and section of the agreement you are amending.

We are adding two studies to this DAA on page 2 (section 2b): Post Affordable Care Act Evaluation of Community Health Centers (PACE) and Assessing Community Cancer care after insurance ExpansionS (ACCESS). Both protocols have been approved by the OHSU IRB (see attached protocols and notices of IRB approval).

Below are additional changes to the agreement:

P. 3, under section 2c, Details of how DMAP data will be used for said purpose, we added:
Bullet point 8) Compare pre-post ACA receipt of cancer care prevention and screening among vulnerable community health center patients in Medicaid expansion versus non-expansion states (ACCESS).

P. 4, we added three new staff who have access to the data (see Personnel Changes form) and updated the Co-Investigator to Lewis Raynor, PhD, MS, MPH.

P. 5, under section f, Timeframe of study, we are amending the timeframe end date to 3/31/21.

Reason for the Amendment:

Two new studies have been funded that fall under the general purpose of this DAA, "Long-term Trends in Health Insurance Coverage and Access to Health Care Services".

Directors Approval J C Collins **Date** 6/20/16

Jon C. Collins, PhD
Director of Office of Health Analytics