Secondary Analysis of Administrative Data on Substance Use Treatment CER

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The objective of this use case is for Max Researcher at Advanced Research Institute to conduct secondary analysis of administrative data on substance use treatment CER. Under a NIDA-funded study, Max Researcher wants to assess the cost-effectiveness and comparative effectiveness of extended-release naltrexone, oral naltrexone (XR-NTX or NTX), buprenorphine, and methadone treatment and psychosocial treatment only for opioid dependence among members of the Big National Payer commercial health plan, which is a HIPAA Covered Entity. Max needs to link administrative claims and encounter data from medical, behavioral health and pharmacy records.

Patient-level data on allowed behavioral, physical, and prescription drug claims are stored in an integrated national database for that health plan. Concurrent review of claims and utilization data will be used to identify beneficiaries with opioid use disorder (OUD) diagnoses. Patients will be eligible if they meet one inclusion criteria: (1) a review of claims flags the beneficiary as treated for an OUD, (2) a prescription for OUD pharmacotherapy (XR-NTX, oral NTX, buprenorphine [with an OUD diagnosis]) was filled, (3) the beneficiary was enrolled in a opioid treatment program, or (4) OUD psychosocial therapy was initiated based on procedure codes. All pharmacotherapy patients who meet selection criteria are included, as well as a random sample of OUD psychosocial therapy-only patients. Pharmaceutical and laboratory utilization patterns and charges, substance use and mental health treatment utilization and charges, and medical service utilization and charges will be included in the research database during the first 6 months following the index date.

- Max submits a protocol to his academic institution's IRB to get approval to conduct this study. The IRB determines that as a secondary analysis of de-identified data, the study qualifies as exempt from full IRB review in accordance with guidelines and regulations.
- Max executes agreements with a large national payer that include assurances she will make no attempts to re-identify individuals.
- The IRB does not require direct consent from the individuals whose data will be analyzed.

Max Researcher will need access to medical, behavioral, pharmacy, and laboratory claims data, de-identified by the national payer using the Safe Harbor method. Once Max establishes an agreement with the commercial health plan, she sends the payer's Data Center a data request for pharmacy, lab, and behavioral health claims information for beneficiaries meeting study inclusion criteria. Since the data set is de-identified, the health plan identifier is replaced with a non-meaningful unique number/code.

The payer's Data Center staff verify Max Researcher's request, protocol, credentials and agreement status. The database manager extracts, links, and de-identify data prior to releasing it to Max. The health plan uploads the linked data sets to the Claims Information System, using a secure FTP site, where Max is able to download the data to her Research Information System.

The specific data Max receives includes all procedure and diagnostic codes and claims paid for beneficiaries meeting inclusion criteria. She will receive data extracts from the Data Center's database manager exactly once a year to ensure that dates of service cannot be inferred and compromise PHI, so that she can study change in the use of medication, health and behavioral health service utilization, and costs over time.

The data will be held by Max. Max combines all of this data to examine change over time in the use opioid agonist and antagonist therapies. She will also assess impacts on the use of ambulatory, emergency and inpatient care, as well as pharmaceutical and laboratory use. She plans to publish results in peer-reviewed journals, and share the results with the commercial health plan and participating sites.

After the study ends, Max must destroy the data set; it cannot be reused or connected with a different study.

Title	Response
Description	Max Researcher wants to assess the cost-effectiveness and comparative effectiveness of four medications used to treat opioid dependence and psychosocial treatment with no medications by beneficiaries of a commercial health plan. What state and federal regulations are relevant for disclosure? Does it differ by holder of records (e.g., commercial insurer, health information exchange, state Medicaid agency, Medicaid managed care plan, CMS research data set [ResDAC]?
Primary actor /participant	Researcher (end-user) and the research information system, health plan's database manager
Support actor /participant	Health plan data manager, health plan data scientists, claims information system
Preconditions	• Claims and enrollment database with unique member identifiers that enables merging of data across different contributing service providers. • Researcher has IRB approval to conduct secondary analysis of claims data.
Post conditions	• Researcher has a combined data set available to analyze for a specific research study.

Alternatives	• Study uses State Medicaid FFS data submitted by states to Truven for inclusion in MarketScan. • Study uses State Medicaid data would require merging of data sets with data from Part 2 programs. • Study uses CMS ResDAC research data set would require merging of data sets with data from Part 2 programs. • Study does/does not include individuals under age 21 (or under age 18) who are opioid dependent. • Study uses claims and encounter data generated by Medicaid and public mental health and substance use claims and encounter data (two separate agencies). Some claims data are clearly generated from substance use treatment programs that "hold themselves out to be" substance use programs under 42 CFR Part 2 definitions. Must a DUA and permission from the substance use treatment program director (specified by Part 2) be given for patients' substance use information to be included in the research?
Considerations	• Must Max Researcher or the large national payer receive permission from a Part 2 covered substance use treatment program and have a DUA with that program to access administrative data that resides in the health plan's claims database? In a state Medicaid claims database? In a Medicaid managed care claims database? In a health information exchange's database?
Data Elements Considered	Beneficiary characteristics, claims and payment data
Purpose of the Data Collection	Clinical care, health plan operations and payment
Purpose of Data Use	Analysis under a specific IRB approved research protocol
Terms of Transfer to the Data Holders	DUA between data holder and researcher (or researcher's institution?)
Terms of Transfer to Researchers	IRB approval

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