

**Commonwealth of Massachusetts
Center for Health Information & Analysis (CHIA)
Non-Government Agency Application for Data**

This application is to be used by all applicants, except Government Agencies, as defined in 957 CMR 5.02.

NOTE: *In order for your application to be processed, you must submit the required application fee. Please consult the fee schedules for APCD and Case Mix data for the appropriate fee amount. A remittance form with instructions for submitting the application fee is available on the CHIA website.*

I. GENERAL INFORMATION

APPLICANT INFORMATION	
Applicant Name:	Dan Gildea
Title:	President
Organization:	JEN Associates, Inc.
Project Title:	Quality of Care in Recipients of Injectable Antipsychotics and Other Treatments for Schizophrenia
Date of Application:	June 12, 2014
Project Objectives (240 character limit)	Describe/evaluate resource utilization patterns and medication use of schizophrenia patients in MA; Analyze differences in resource and medication use by payer and health plan type; Evaluate quality of care across payer and health plan type and patient subgroups
Project Research Questions (if applicable)	1. What are the patterns of utilization and cost in people diagnosed with schizophrenia? 2. What is the exact prevalent schizophrenia population in each of the years 2010-2012? 3. What are the days, visits, episodes and costs of treatment? 4. What comorbidities are present and what are their treatments and costs?

I. PROJECT SUMMARY

Briefly describe the purpose of your project and how you will use the requested CHIA data to accomplish your purpose.

Describe the purpose of your project

JEN Associates will investigate services related to the quality of care in recipients of injectable antipsychotics and other treatments for schizophrenia. The primary goals of the study are to:

1. Describe/evaluate resource utilization patterns and medication use of schizophrenia patients in Massachusetts. Potential patient subgroups include schizophrenia-only, schizophrenia and schizo-affective, schizophrenia and other mental health, schizophrenia and substance use disorder, or by treatment groups. Service categories include:
 - a. Acute inpatient
 - b. Long-term institutional (nursing facility, ICF)
 - c. Outpatient and community mental health service utilization
 - d. Pharmacy, e.g., psychotropic vs non

- e. Other
- 2. Analyze differences in resource and medication use by payer and health plan type.
- 3. Evaluate quality of care across payer and health plan type and patient subgroups (described above).
The following measures will be included:
 - a. Rates of hospital admission for mental health conditions by payer/plan/patient subgroup
 - b. Rates of 7-day and 30-day readmission for mental health conditions by payer/plan/patient subgroup
 - c. Rates of hospital admission, 7-day and 30-day readmissions for mental health conditions for persons who use injectable antipsychotics versus those who use oral antipsychotics versus no antipsychotics
 - d. Rates of follow-up after hospitalization for mental illness
 - e. Rates of adherence to antipsychotic medications
 - f. Rates of screening and monitoring for diabetes
 - g. Rates of monitoring for cardiovascular diseases.

Describe how you will use the requested CHIA data to accomplish your purpose

Since the APCD contains the records of almost four million state residents, the schizophrenia population should be on the order of 30,000. Annual incidence may amount to 2,000. The exact number of patients with schizophrenia and the treatments they receive will be the subject of this study. The study will focus on the patients covered by commercial payers, which are estimated to be 8,000. JEN Associates will be responsible for the analysis and has extensive experience working with the APCD.

This study will initially consist of descriptive univariate analyses, with simple significance testing via chi-square and t-tests. More complex investigations, using matched cohorts and multivariate regression models, will take place in the second year of this study, depending on interest and available population size.

This study will first of all determine the exact prevalent schizophrenic population in each of the years 2010-2012. Detecting members of the prevalent population will be accomplished by examining the primary ICD-9 diagnoses in the claims records. A single primary schizophrenia diagnosis in a hospital claim will be sufficient to include a patient in the study population, as well as two physician claims. Drug coding in the APCD pharmacy file will reveal drug treatments.

Service utilization and costs are available through the APCD's medical claims files. Days, visits, and episodes of treatments and their costs will be summarized in Excel spreadsheets, broken down by treatment received. Similarly, the presence, treatment and costs of comorbidities can be determined using diagnosis and procedure codes in the claims files. The comorbidity status of each patient will be summarized using a form of the traditional Charlson comorbidity index, as well as the JEN Serious Mental Illness index. Both of these estimate risk for further intensive medical treatment. As appropriate, these analyses will also be broken down by subpopulation, with particular emphasis on low-income urban residents.

The study of health utilization for privately insured individuals with schizophrenia includes analyses of co-occurring medical conditions and risk factors that increase the likelihood of adverse events such as hospitalization and emergency room visits. Substance use disorders (SUD) are common among the schizophrenia population and are a key risk factor in predicting these adverse events and understanding the patterns of service utilization. As part of the study, JEN also plans to apply a nationally recognized risk indicator, the JSMI Risk index, to risk adjust the study population. This JSMI Risk index uses a variety

of chronic conditions, including SUD, as part of its formula. Therefore, diagnostic information about substance use is critical to our analysis.

We have prepared a full summary of the data elements we are requesting in the Data Specification Workbook. In summary, we seek medical and pharmacy claims and eligibility data for individuals with primary diagnosis in the range 295.0 to 295.9. We are not requesting any Dental Claims. We are requesting Pharmacy claims, specifically psychotropic versus non-psychotropic medications. The Product file contains data relevant to analyzing differences in resource and medication use by payer and health plan type. The Provider file data is essential for our analysis of the quality of care across payer and health plan type and patient subgroups. The Medical file will provide the claims we need to understand utilization and quality care.

Please refer to the table below for the analytic uses and justification of the different groups of variables:

Quality of Care Measures	The detail and data quality of the APCD claims files are sufficient to construct a population profile for quality of care measures, broken down by treatment received or subpopulation. JEN has developed algorithms for determining the HEDIS quality of care measures identified above. These address clinical issues related to treatment adherence and continuity of care.
Incident Population	These analyses will be extended to the identified incident population, assuming it is of substantial size. We will separate incident, i.e., new schizophrenic cases, from the established prevalent cases. As a preliminary analysis, the study will examine the 2010-2012 population, assuming that anyone without a previous schizophrenic diagnosis in 2010 is a new diagnosis. Service use, treatment, and costs for this population will be tracked through the end of 2012.
Early Treatment	The identified incident population will be useful for studying the effects of early treatment. In addition to the analyses conducted in the prevalent population, the incident population will also be compared on the basis of treatment received during and in the months after the first schizophrenic episode.
Long-acting injectable vs oral treatments	It will be a simple mathematical task to construct patient populations aggregated according to type of treatment received. As a supplementary analysis with greater statistical power, the study will rerun the above comparative analyses with patient data summarized into three treatment groups: recipients of long-acting injectable antipsychotics, daily oral treatments along, and long-acting injectables with oral supplementation.

II. FILES REQUESTED

Please indicate the databases from which you seek data, the Level(s) and Year(s) of data sought.

ALL PAYER CLAIMS DATABASE	Level 1 ¹ or 2 ²	Single or Multiple Use	Year(s) Of Data Requested Current Yrs. Available 2009 - 2012
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¹ Level 1 Data: De-identified data containing information that does not identify an individual patient and with respect to which there is no reasonable basis to believe the data can be used to identify an individual patient. This data is de-identified using standards and methods required by HIPAA.

² Level 2 (and above) Data: Includes those data elements that pose a risk of re-identification of an individual patient.

X Medical Claims	<input type="checkbox"/> Level 1 ³ <input checked="" type="checkbox"/> Level 2	Single	X 2010 X 2011 X 2012
X Pharmacy Claims	X Level 2	Single	X 2010 X2011 X 2012
<input type="checkbox"/> Dental Claims X Member Eligibility X Provider X Product	<input type="checkbox"/> Level 2 X Level 2 X Level 2 X Level 2	Select... Single Single Single	X 2010 X 2011 X 2012

CASEMIX	Level 1 - 6	Fiscal Years Requested
Inpatient Discharge	<input type="checkbox"/> Level 1 – No Identifiable Data Elements <input type="checkbox"/> Level 2 – Unique Physician Number (UPN) <input type="checkbox"/> Level 3 – Unique Health Information Number (UHIN) <input type="checkbox"/> Level 4 – UHIN and UPN <input checked="" type="checkbox"/> Level 5 – Date(s) of Admission; Discharge; Significant Procedures <input type="checkbox"/> Level 6 – Date of Birth; Medical Record Number; Billing Number	1998-2013 Available (limited data 1989-1997)
Outpatient Observation	<input type="checkbox"/> Level 1 – No Identifiable Data Elements <input type="checkbox"/> Level 2 – Unique Physician Number (UPN) <input type="checkbox"/> Level 3 – Unique Health Information Number (UHIN) <input type="checkbox"/> Level 4 – UHIN and UPN <input checked="" type="checkbox"/> Level 5 – Date(s) of Admission; Discharge; Significant Procedures <input type="checkbox"/> Level 6 – Date of Birth; Medical Record Number; Billing Number	2002-2012 Available (2013 available 8/1/14)
Emergency Department	<input type="checkbox"/> Level 1 – No Identifiable Data Elements <input type="checkbox"/> Level 2 – Unique Physician Number (UPN) <input type="checkbox"/> Level 3 – Unique Health Information Number (UHIN) <input type="checkbox"/> Level 4 – UHIN and UPN; Stated Reason for Visit <input checked="" type="checkbox"/> Level 5 – Date(s) of Admission; Discharge; Significant Procedures <input type="checkbox"/> Level 6 – Date of Birth; Medical Record Number; Billing Number	2000-2012 Available (2013 available 9/1/14)

³ Please note that Level 1 APCD data is not available as of 4/30/2014. This is scheduled to be available later in 2014.

III. FEE INFORMATION

Please consult the fee schedules for APCD (Administrative Bulletin 13-11) and Case Mix data (Administrative Bulletin 13-09) and select from the following options:

APCD Applicants Only

- Academic Researcher
- Others (Single Use)
- Others (Multiple Use)

Case Mix Applicants Only

- Single Use
- Limited Multiple Use
- Multiple Use

Are you requesting a fee waiver?

- Yes
- No

If yes, please submit a letter stating the basis for your request. Please refer to the fee schedule for qualifications for receiving a fee waiver. If you are requesting a waiver based on the financial hardship provision, please provide documentation of your financial situation. Please note that non-profit status alone isn't sufficient to qualify for a fee waiver.

IV. REQUESTED DATA ELEMENTS [APCD Only]

State and federal privacy laws limit the use of individually identifiable data to the minimum amount of data needed to accomplish a specific project objective. Please use the APCD Data Specification Workbook to identify which data elements you would like to request and attach this document to your application.

V. MEDICAID DATA [APCD Only]

Please indicate here whether you are seeking Medicaid Data:

- Yes
- No

Federal law (42 USC 1396a(a)7) restricts the use of individually identifiable data of Medicaid recipients to uses that are directly connected with the administration of the Medicaid program. If you are requesting Medicaid data from Level 2 or above, please describe in detail why your use of the data meets this requirement. Applications requesting Medicaid data will be forwarded to MassHealth for a determination as to whether the proposed use of the data is directly connected to the administration of the Medicaid program. MassHealth may impose additional requirements on applicants for Medicaid data as necessary to ensure compliance with federal laws and regulations regarding Medicaid.

VI. REQUESTS PURSUANT TO 957 CMR 5.04

If you are a payer, provider, provider organization or researcher seeking access to Level 1 (de-identified) data, please describe how you will use such data for the purposes of lowering total medical expenses, coordinating care, benchmarking, quality analysis or other administrative research purposes. Please provide this information below.

VII. FILTERS

If you are requesting APCD elements from Level 2 or above, describe any filters you are requesting to use in order to limit your request to the minimum set of records necessary to complete your project. (For example, you may only need individuals whose age is less than 21, claims for hospital services only, or only claims from small group projects.)

APCD FILE	DATA ELEMENT(S) FOR WHICH FILTERS ARE REQUESTED	RANGE OF VALUES REQUESTED
Medical Claims	Limit selection to all patients with the primary diagnosis of schizophrenia	Only 295.0 – 295.99
Pharmacy Claims		
Dental Claims		
Membership Eligibility		
Provider		
Product	Limit to the 16 carriers (excluding MassHealth (3156)) who cover the majority of claims, plus 11541 (Health Safety Net), 7221 (UMR, Inc.), 11347 (Horizon Blue Cross/Blue Seld of NJ), 7397 (Blue Cross/Blue Shield of Alabama), 7268 (Humana Insurance Company), 7473 (Zenith American Solutions), 7421 (Health Smart Benefit Solutions)	

VIII. PURPOSE AND INTENDED USE

1. Please explain why completing your project is in the public interest.

Schizophrenia affects approximately two millions adults in the United States. It is responsible for \$28 billion in annual health care costs, owing in part to its early age of onset (third decade or younger), chronic course, and severe disability. Currently, there is no cure for schizophrenia, only treatment. Medication non-adherence among persons with schizophrenia is a significant cause of relapse and worse functional outcomes. Despite the fact that antipsychotic medications reduce the risk of relapse, medication non-adherence is common (40-50%) and dose omission gaps non-trivial (18.7% of days). In

the United States, costs for hospital readmissions associated with relapse for treated persons with schizophrenia have been estimated to be nearly \$2 billion annually.

There are few studies specifically evaluating patient interventions to improve adherence in patients with schizophrenia. The determinants of non-adherence are complex and likely not only include patient factors (e.g. previous hospitalizations), but also drug-related factors (e.g. number of drugs) and system factors (e.g. insurance). The healthcare utilization patterns of people with schizophrenia are also not well known.

These issues become particularly important with the current implementation of the Affordable Care Act, since there will be an increase in schizophrenic patients entering the pool of patients covered by health insurance. The more we can understand how best to meet the needs of this often neglected population, the better equipped we will be make quality improvement activities more impactful.

2. **Attach** a brief (1-2 pages) description of your research methodology. (This description will not be posted on the internet.)
3. Has your project received approval from your organization's Institutional Review Board (IRB)? Please note that CHIA will not review your application until IRB documentation has been received (if applicable).
 - Yes, and a copy of the approval letter is attached to this application.
 - No, the New England IRB reviewed the project and determined that the project is exempt from IRB review. A copy of the exemption letter is attached.**
 - No, this project is not subject to IRB review.
 - No, my organization does not have an IRB.

IX. APPLICANT QUALIFICATIONS

1. Describe your qualifications to perform the research described or accomplish the intended use of CHIA data.

JEN Associates, Inc. is a national leader in providing data-driven health care analyses based on interdisciplinary models of applied research. Its founder and president, Dan Gilden, will be the principal investigator of this study. He is a recognized expert in the use of Medicare, Medicaid and other health data for research with diverse applications such as medical research, public policy planning, public health surveillance, epidemiology, and private sector litigation support. Under his direction, JEN Associates has assembled a team of system designers, programmers and analysts who have gained a national reputation in the management and interpretation of large health care Medicare and Medicaid claims databases. Dan has worked with collaborators from academia, government, and industry on projects in multiple areas of research, including analysis of patterns of disease, treatment effectiveness and outcomes, the actuarial analysis of Medicare and Medicaid data and population dynamics, and policy development. Dan serves as the lead Principal Investigator for the research consortium awarded under JEN's Medicare/Medicaid Research and Demonstration contract (MRAD) awarded by CMS. This consortium includes partners at Harvard, Duke, University of Massachusetts, University of Pennsylvania, University of North Carolina, University of Alabama, and the Albert Einstein Center for Urban Healthcare.

2. Attach résumés or curricula vitae of the applicant/principal investigator, key contributors, and of all individuals who will have access to the data. (These attachments will not be posted on the internet.)

X. DATA LINKAGE AND FURTHER DATA ABSTRACTION

1. Does your project require linking the CHIA Data to another dataset?

Yes

No

2. If yes, will the CHIA Data be linked to other patient level data or with aggregate data (e.g. Census data)?

Patient Level Data

Aggregate Data

3. If yes, please identify all linkages proposed and explain the reasons(s) that the linkage is necessary to accomplish the purpose of the project. Please be specific in describing vvhich data elements will be linked to outside datasets and how this will be accomplished.

4. If yes, please identify the specific steps you will take to prevent the identification of individual patients in the linked dataset.

XI. PUBLICATION / DISSEMINATION / RE-RELEASE

1. Describe your plans to publish or otherwise disclose CHIA Data, or any data derived or extracted from such data, in any paper, report, website, statistical tabulation, seminar, conference, or other setting.

The research will be disseminated through peer-reviewed manuscripts and presentations at national high impact meetings. For the current proposal, we anticipate submitting findings to the US Psychiatric Congress, American Public Health Association Annual Meeting, ISPOR, American Psychiatry Annual Meetings, and other national and international meetings. We believe the manuscripts to be generated as a result of the proposed work will be well received by top tier mental health journals. We believe that our work will be of interest to CMS, payers, and state Medicaid Directors, as well. Toward that goal, JEN Associates has a long-standing track record of widely available policy briefs of research. In order to protect confidential health information, no tables with cell sizes less than 11 will be produced

2. Will the results of your analysis be publicly available to any interested party? Please describe how an interested party will obtain your analysis and, if applicable, the amount of the fee.

The analysis be publicly available to all interested parties through the means described above. There will be no fees for receiving the results, although the conferences will likely charge for admission.

3. Will you use the data for consulting purposes?

Yes

No

4. Will you be selling standard report products using the data?
 Yes
 No

5. Will you be selling a software product using the data?
 Yes
 No

6. If you have answered "yes" to questions 3, 4 or 5, please describe the types of products, services or studies.

The analyses will be conducted under a consultant contract; we will not be using the data for further consulting purposes.

XII. USE OF AGENTS AND/OR CONTRACTORS

Third-Party Vendors. Provide the following information for all agents and contractors who will work with the CHIA Data.

No third party vendors.

Company Name:	
Contact Person:	
Title:	
Address:	
Telephone Number:	
E-mail Address:	
Organization Website:	

7. Will the agent/contractor have access to the data at a location other than your location or in an off-site server and/or database?
 Yes
 No

8. Describe the tasks and products assigned to this agent or contractor for this project.

n/a

9. Describe the qualifications of this agent or contractor to perform such tasks or deliver such products.

n/a

10. Describe your oversight and monitoring of the activity and actions of this agent or subcontractor.

n/a but please see the data security and integrity section below.