

**Commonwealth of Massachusetts
Center for Health Information & Analysis (CHIA)
Non-Government Application for MA APCD Limited Data Set**

This form is required by all Applicants, except Government Agencies as defined in 957 CMR 5.02. All Applicants must also complete the Data Management Plan, attached to this Application. The Application and the Data Management Plan must be signed by an authorized signatory of the organization. This Application and the Data Management Plan will be used by CHIA to determine if your organization may receive CHIA data. Please be sure the documents are completed fully and accurately. You may wish to consult the Evaluation Guide that CHIA will use to review your documents. Prior to receiving CHIA Data, the organization must execute the Data Use Agreement. You may wish to review that document as you complete these forms. This application should be completed by the Primary Investigator, and must be signed by a party with authority to bind the organization seeking CHIA Data for the purposes described herein.

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

All attachments must be uploaded to IRBNet with your Application. All applications documents can be found on the CHIA website in Word and/or PDF format.

I. GENERAL INFORMATION

APPLICANT INFORMATION	
Applicant Name: (Primary Investigator)	Dr. Jane O'Brien
Title:	Chief Medical Officer
Organization:	Franciscan Children's, -A pediatric specialty children's hospital providing medical, mental health, and educational services for children with medical and behavioral complexity and special health care needs
Project Title:	Healthcare Resource Use and Spending for Children with Medical Complexity
Mailing Address:	30 Warren St. Brighton, MA 02135
Telephone Number:	617-254-3800 ex. 5811
Email Address:	jobrien@fhfc.org
Names of Co-Investigators:	Jay Berry, Helene Dumas, Matt Hall
Email Addresses of Co-Investigators:	jberry@fhfc.org, hdumas@fhfc.org, matt.hall@childrenshospitals.org
Original Data Applicant Submission Date:	September 13, 2016
Dates Data Application Revised:	2011-2015
Project Objectives (240 character limit):	To assess predictors of healthcare use across the care continuum for children with medical complexity residing in Massachusetts
Project Research Questions (if applicable) or Business Use Case(s):	1. 1. Which children with medical complexity have

	<p>the highest likelihood of use of certain health services (e.g., hospitalization, readmission, ED visit?)</p> <p>2. Which children with medical complexity have the highest likelihood of not using certain health services (e.g. primary or dental care?)</p> <p>3. Are the child’s outpatient/community healthcare concentrated within a few primary care practices or evenly dispersed among them all?</p>
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II. PUBLIC INTEREST & PROJECT SUMMARY

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

Children with medical complexity, although small in population size, have a substantial impact on the pediatric health care system. These children account for nearly one-third of all healthcare spending on children. Considered to be the most chronically-ill and medically-fragile of all children, it is in the public’s interest to learn as much about the healthcare experiences of these children in order to design the most optimal system of healthcare for them.

2. Has an Institutional Review Board (IRB) reviewed your project?

- Yes, a copy of the approval letter and protocol must be **attached** to this Application
- No, this project is not human subject research and does not require IRB review.

3. If your project has not been reviewed by an IRB, please **attach** a brief (1-2 page) description of your project including the methodology, objectives, and research questions.

III. DATA FILES REQUESTED

1. Please indicate the MA APCD databases from which you seek data, the year(s) of data requested, and your justification for requesting each file. Please refer to the MA APCD Release 5.0 Data Specifications for details of the file contents.

MA ALL-PAYER CLAIMS DATABASE FILES	Year(s) Of Data Requested Current Yrs. Available <input checked="" type="checkbox"/> 2011 <input checked="" type="checkbox"/> 2012 <input checked="" type="checkbox"/> 2013 <input checked="" type="checkbox"/> 2014 <input checked="" type="checkbox"/> 2015
<input checked="" type="checkbox"/> Medical Claims	<p>Please describe how your research objectives require Medical Claims data:</p> <p>We will use the medical claims data to assess every healthcare encounter for the children that occurred across the continuum during the study period, including outpatient, inpatient, home, community, therapy, rehabilitation, etc.</p>

<input checked="" type="checkbox"/> Pharmacy Claims	<p>Please describe how your research objectives require Pharmacy Claims data: We will use pharmacy claims to help identify and describe the cohort of children with medical complexity assessed during the study. For cohort inclusion, the children must use at least one chronic medication. To describe the cohort, we will count the total number of dispensed medications, as well as the number of medical classes.</p>
<input checked="" type="checkbox"/> Dental Claims	<p>Please describe how your research objectives require Dental Claims data: We will use dental claims to assess which children with medical complexity did not receive dental care during the study period.</p>
<input checked="" type="checkbox"/> Member Eligibility	<p>Please describe how your research objectives require Member Eligibility data: Some children with medical complexity, especially those using Medicaid, may not have continuous enrollment in their health insurance plan or program during the study period. This information is critical to understand as we take steps to ensure that we are not undercounting or underrepresenting health service use experienced by these children.</p>
<input checked="" type="checkbox"/> Provider	<p>Please describe how your research objectives require Provider data: The provider file will be necessary to assess the concentration of children with medical complexity receiving health services by provider and practice. Recent literature reports that many primary care providers are reluctant to offer primary care for children with medical complexity while others embrace caring for these children. We will use NPI to assess the provider and clinic volume of children with medical complexity across primary care practices.</p>
<input checked="" type="checkbox"/> Product	<p>Please describe how your research objectives require Product data: The product file is needed to distinguish type of insurance product (e.g., fee-for-service vs. managed care) for each beneficiary in the study.</p>

IV. GEOGRAPHIC DETAIL

Please choose one of the following geographic options for MA residents. *For releases with 5 digit zip code, CHIA will apply a substance abuse filter which will remove all claims that include a substance abuse diagnosis.*

<input type="checkbox"/> 3 Digit Zip Code (MA) (standard)	<input checked="" type="checkbox"/> 5 Digit Zip Code (MA)***
<p>***Please provide justification for requesting 5 digit zip code. Refer to specifics in your methodology: Due to the absence of race/ethnicity in the limited data set, 5-digit ZIP code will be linked to Census data for the purposes of obtaining area-based demographic attributes.</p>	

V. DATE DETAIL

Please choose one option from the following options for dates:

<input type="checkbox"/> Year (YYYY) (Standard)	<input type="checkbox"/> Month (YYYYMM) ***	<input checked="" type="checkbox"/> Day (YYYYMMDD) *** [for selected data elements only]
<p>*** If requested, please provide justification for requesting Month or Day. Refer to specifics in your methodology:</p> <p>Day data are requested to assess the temporal relationship of health services. For example, we intend to measure hospital readmissions, emergency department visits, and primary care visits following an index (i.e., antecedent) hospitalization</p>		

VI. NATIONAL PROVIDER IDENTIFIER (NPI)

Please choose one of the following options for National Provider Identifier(s):

<input type="checkbox"/> Encrypted National Provider Identifier(s) (standard)	<input checked="" type="checkbox"/> Unencrypted National Provider Identifier(s)***
<p>*** If requested please, provide justification for requesting unencrypted National Provider Identifier(s). Refer to specifics in your methodology:</p> <p>We will use unencrypted NPI for the purposes of linking with CMS NPI registry of AMA physician Masterfile for provider analysis. This will enable an assessment of how many children with medical complexity use a particular practice for the receipt of primary care.</p>	

VII. MEDICAID DATA

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 to the administration of the Medicaid program. If you are requesting Medicaid data from Level 2 or above, please describe, in the space below, why your use of the data meets this requirement. Requests for 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.

Most children with medical complexity use Medicaid as their primary or secondary form of insurance due to the enormous expenditures families must undertake with regard to medical care, medical supplies, and home care, among other aspects. The MassHealth administration has prioritized this population of children to consider for existing and developing population health initiatives striving to optimize the health and well-being of the children.

VIII. DATA LINKAGE AND FURTHER DATA ABSTRACTION

Note: Data linkage involves combining CHIA Data with other databases to create one extensive database for analysis. Data linkage is typically used to link multiple events or characteristics that refer to a single person in CHIA Data within one database.

1. Do you intend to link or merge CHIA Data to other datasets?

- Yes
- No linkage or merger with any other database will occur

2. If yes, please indicate below the types of database to which CHIA Data be linked. [Check all that apply]

- Individual Patient Level Data (e.g. disease registries, death data)

- Individual Provider Level Data (e.g., American Medical Association Physician Masterfile)
- Individual Facility Level Data level (e.g., American Hospital Association data)
- Aggregate Data (e.g., Census data)

- Other (please describe): Feudtner’s Pediatric Complex Chronic Conditions Classification System Version 2 and AHRQ’s Chronic Condition Indicator will be used for purposes of grouping data into larger standardized categories that facilitate stratifying data by age and analyzing resource utilization.

3. If yes, describe the data base(s) to which the CHIA Data will be linked, which CHIA data elements will be linked; and the purpose for the linkage(s):

Feudtner’s Pediatric Complex Chronic Conditions Classification System Version 2 and AHRQ’s Chronic Condition Indicator will be used for purposes of grouping data into larger standardized categories that facilitate stratifying data by age and analyzing resource utilization. We will also link to census data. Furthermore, we will link to NPI data with the CMS NPI registry of AMA physician Masterfile for provider analysis.

4. If yes, for each proposed linkage above, please describe your method or selected algorithm (e.g., deterministic or probabilistic) for linking each dataset. If you intend to develop a unique algorithm, please describe how it will link each dataset.

Deterministic for all datasets being linked

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

Grouping the into the two classification systems will serve to reduce the risk of re-identification by reducing the granularity of diagnosis codes analyzed. The CCS grouper reduces the approximately 14,000 diagnosis codes to 12 major categories and 75 subcategories and the AHRQ CCI grouper reduces the diagnosis codes to approximately 485 groups. Aggregation and cell suppression will be used to reduce any risks associated with using census data and individual provider level data.

XI. PUBLICATION / DISSEMINATION / RE-RELEASE

1. Describe your plans to publish or otherwise disclose CHIA Data, or any data derived or extracted from such CHIA Data, in any paper, report, website, statistical tabulation, seminar, conference, or other setting. All publication of CHIA Data must comply with CHIA’s cell size suppression policy, as set forth in the Data Use Agreement. Please explain how you will ensure that any publications will not display a cell less than 11, and no percentages or other mathematical formulas will be used if they result in the display of a cell less than 11.

We will share all project findings with CHIA and will seek a variety of opportunities to present the findings. Venues for presentation will include the Academic Pediatrics Association Complex Care Special Interest Group, the 2017 Pediatric Academic Societies meeting, and the 2017 AcademyHealth Research Meeting. Local presentations on the methods and findings will be given to primary care fellows and faculty in the Harvard Pediatric Health Services Research Fellowship Program at Boston Children’s Hospital, as well as the Harvard Center for Primary Care Innovation. Dr. Hall will leverage the Children’s Hospital Association’s extensive networking expertise that includes conferences, forums, and webinars to promote and disseminate the findings to clinicians, families, government relations personnel, quality and safety leaders, researchers, and executives across the association’s 220 member hospitals. We will review every cell of every table used in manuscripts, presentations, reports, and other dissemination products ahead of public submission to ensure that no percentages or other mathematical formulas will be used if they result in the display of a cell less than 11.

2. Do you anticipate that the results of your analysis will be published and/or publically available to any interested party? Please describe how an interested party will obtain your analysis and, if applicable, the amount of the fee, that the third party must pay.

The results of our analysis will be published in peer reviewed journals but other than that, the results will not be publically available. Should a special circumstance arise that might generate the discussion of such possibility, then we would recommend that the party submit their own independent application to obtain and analyze the APCD.

3. Will you use CHIA Data for consulting purposes?

- Yes
- No

4. Will you be selling standard report products using CHIA Data?

- Yes
- No

5. Will you be selling a software product using CHIA Data?

- Yes
- No

6. Will you be reselling CHIA Data in any format?

- Yes
- No

If yes, in what format will you be reselling CHIA Data (e.g., as a standalone product, incorporated with a software product, with a subscription, etc.)?

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

8. If you have answered “yes” to questions 4, 5, or 6, what is the fee you will charge for such products, services or studies?

X. APPLICANT QUALIFICATIONS

1. Describe your qualifications (and the qualifications of your co-investigators) to perform the research described.

Our team has extensive experience identifying children with medical complexity (CMC), assessing their coexisting conditions, and studying their health care utilization and health outcomes in large administrative datasets, including Medicaid claims data. We have used several different ICD-9-CM diagnosis coding schemes to identify CMC,^{8,17,70} including Feudtner’s Complex Chronic Conditions and the AHRQ Chronic Condition Indicator schemes. We have experience studying use of primary care³, hospital care^{7,8}, and emergency department care¹² in CMC. We also have experience deriving different types of regression models (hierarchical^{7,8,11} and tree⁷¹) to predict health outcomes and health care utilization of CMC. Our work has been published in peer-reviewed journals, including *Journal of the American Medical Association*, *Health Affairs*, and *Pediatrics*. Members of our team have received national recognition for their health services research using large, administrative healthcare claims databases.

2. **Attach** résumés or curricula vitae of the Applicant/principal investigator, and co-investigators. (These attachments will not be posted on the internet.)

XI. USE OF AGENTS AND/OR CONTRACTORS

Please note: by signing this Application, the Organization assumes all responsibility for the use, security and maintenance of the CHIA Data by its agents, including but not limited to contractors.

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

Company Name:	Children’s Hospital Association
Contact Person:	Matthew Hall, PhD
Title:	Senior Statistician
Address:	6803 W 64th St, Mission, KS 66202
Telephone Number:	(913) 262-1436
E-mail Address:	Matthew.hall@childrenshospitals.org
Organization Website:	https://www.childrenshospitals.org/

1. Will the agent have access to the CHIA Data at a location other than your location, your off-site server and/or your database?

- Yes, a separate Data Management Plan must be completed by each agent who will store CHIA Data
- No

2. Describe the tasks and products assigned to this agent for this project; their qualifications for completing the tasks; and the Organization’s oversight of the agent, including how the Organization will ensure the security of the CHIA Data to which the agent has access.

Matt Hall, PhD, will be an external agent working on this project. Dr. Hall is Principal Biostatistician at Children’s Hospital Association (CHA). He will be tasked with performing all of the statistical analyses required to achieve the specific aims of the project. Dr. Hall will have access to the raw data, analytic files, and output with cell sizes <11.

Dr. Hall has expertise in statistical analysis specifically with regard to conducting studies using large datasets containing detailed hospitalization data. Dr. Hall leads multiple collaborative hospital research groups of physician investigators in order to perform a variety of pediatric hospital clinical epidemiologic and health services research on various topics, including drug use, efficacy, and safety. He is also the lead statistician on CHA’s whole system measures project where he has worked to develop pediatric specific measures (13 over the past two years) following the Institute for Healthcare Improvement model. Dr. Hall’s familiarity with large datasets and statistical analysis make him perfectly qualified to use and analyze the All Payer Claims Database.

As a specialty children’s hospital, Franciscan Children’s is a covered entity under HIPAA. Dr. Hall will be a research contractor at Franciscan that will be supervised by research staff Dr. Jay Berry. As a research contractor, he will be held to the same binding policies, procedures, rules, and regulations of Franciscan.

As such, Dr. Hall will have to comply with HIPAA, HITECH, and all other IT regulations and any current and future regulations promulgated under HIPAA or HITECH. He will also agree to comply with all relevant state and local laws governing the privacy and security of patient health or personal information. As necessary, Dr. Hall will sign a Business Associate Agreement further defining his protection of confidential health information. Dr Hall will agree not to use or further disclose any PHI or Individually Identifiable Health Information, other than as permitted by HIPAA requirements and contractual agreements. Furthermore, Dr. Hall shall not violate any law, rule, regulation, order, judgment, injunction, decree or other restriction of any court or governmental authority of which he is subject, or by which any material property or asset of which he is bound or affected.

Dr. Hall will access CHIA data on the Franciscan server through a secure VPN administered and governed by Franciscan. The server will be accessed through a password protected, encrypted computer with up-to-date virus/malware/spyware protective software. SonicWall and Barracuda will be used to continuously track access and analysis of the data with notification to the research team should anyone other than Dr. Hall access it. Upon completion of the project, an exit interview will occur with Dr. Hall with termination of his password-protected access to the Franciscan server and review of his work computer to ensure that no physical CHIA data reside on it. Should Dr. Hall discontinue the work and another Children’s Hospital Association statistician pick it up, then Dr. O’Brien (PI) will notify the DUA holder of the staff change by email and/or phone.

XII. FEE INFORMATION

Please consult the fee schedules for MA APCD Data and select from the following options:

- Researcher
- Others (Single Use)

Are you requesting a fee waiver?



- Yes
- No

If yes, please refer to the Application Fee Remittance Form and submit a letter stating the basis for your request (if required). 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.

By submitting this Application, the Data Applicant attests that it is aware of its data use, privacy and security obligations imposed by state and federal law *and* is compliant with such use, privacy and security standards. The Data Applicant further agrees and understands that it is solely responsible for any breaches or unauthorized access, disclosure or use of any CHIA Data provided in connection with an approved Application, including, but not limited to, any breach or unauthorized access, disclosure or use by its agents.

Applicants requesting data from CHIA will be provided with data following the execution of a Data Use Agreement that requires the Data Applicant to adhere to processes and procedures aimed at preventing unauthorized access, disclosure or use of data.

By my signature below, I attest to: (1) the accuracy of the information provided herein; (2) that the requested data is the minimum necessary to accomplish the purposes described herein; (3) the Data Applicant will meet the data privacy and security requirements describe in this Application and supporting documents, and will ensure that any third party with access to the data meets the data use, privacy and security requirements; and (4) my authority to bind the organization seeking CHIA Data for the purposes described herein.

Signature: (Authorized Agent)	
Printed Name :	Alex DeNucci
Title:	Chief Financial Officer
Signature: (Applicant/Primary Investigator)	
Name:	Dr. Jane O'Brien
Title:	Chief Medical Officer
Original Data Request Submission Date:	September 9, 2016
Dates Data Request Revised:	n/a

Attachments. Please indicate below which documents have been attached to the Application and uploaded to IRBNet:

- 1. IRB approval letter or summary of project (if applicable)
- 2. Resumes of Applicant and co-investigators
- 3. Data Management Plan (for each institution that will store CHIA Data)