

COVER NOTE PAGE

Project Title

Assessing Extent of Opioid Epidemic in Baltimore City

Requesting Organization

Baltimore City Law Department
C/O City Hall, Room 101
100 N. Holliday Street
Baltimore, MD 21202
Phone: (410) 396-3297

Applicant

Sara Gross, JD
Chief Solicitor at Baltimore City Law Department
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100 N. Holliday Street
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Application for Maryland Medical Care Data Base

TRACKING TABLE (For MHCC Use Only)

MHCC Data Request Number	
Application Received	
Application Approved	
Data Obtained	

INSTRUCTIONS

This form is required for all Applicants requesting MCDB data. Applicants must also complete all the attachments. The completed Application and the Data Management Plan will be used by MHCC to determine whether the request meets the criteria for data release, pursuant to COMAR 10.26.06. Incomplete applications will be returned to the Applicant, and the request will be delayed. All applications require a non-refundable application fee, payable at the time of submission. All applications must include evidence that the project has been reviewed by an Institutional Review Board that has been or will be recognized by the MHCC.

Where to submit documents:

- Completed application packages should be scanned and emailed to: mhcc.datarelease@maryland.gov
- A hard copy Application is acceptable and should be sent, with the application fee, to:
Maryland Health Care Commission
4160 Patterson Avenue,
Baltimore, MD 21215,
ATTN: MHCC Data Release
- Enclose a cover note page that includes the project title, requesting organization's name, and applicant's name.
- If an invoice is needed, send a request to: mhcc.datarelease@maryland.gov

Note to Applicants:

- Review [data availability and fees](#)
- All application attachments will be incorporated in the Approved Data Use Agreement (DUA)

Questions? Email mhcc.datarelease@maryland.gov

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PROJECT INFORMATION

Project Title			
Assessing Extent of Opioid Epidemic in Baltimore City			
Scheduled Project Start Date	October 1, 2022	Scheduled Project End Date	December 31, 2023
MHCC Staff Approved Pre-Application Number			
Project Overview: <i>Provide an abstract or brief summary (150 words) of the specific purpose and objectives of the Project.</i>			
We seek to use MCDB data to understand the trajectory of the opioid epidemic in the City of Baltimore. The objectives of this project are to estimate the number of individuals affected by the opioid epidemic as well as healthcare utilization and opioid prescribing in the City of Baltimore from 2010 to 2020.			

Applicant <i>(principal investigator, project manager, individual responsible for the research team using the data)</i>					
Name		Sara Gross, JD			
Title		Chief Solicitor			
E-Mail Address		sara.gross@baltimorecity.gov			
Telephone Number					
Organization Name		Baltimore City Law Department			
Mailing Address		C/O City Hall, Room 101, 100 N. Holliday Street			
City/Town	Baltimore	State	MD	Zip Code	21209

Requesting Organization <i>(Agency, Academic Institution, Research Organization, Company, etc.)</i>					
Organization Name		Baltimore City Law Department			
Website					
E-Mail Address					
Telephone Number		(410) 396-3297			
Mailing Address		C/O City Hall, Room 101, 100 N. Holliday Street			
City/Town	Baltimore	State	MD	Zip Code	21209

Data Custodian <i>(person responsible for receiving, organizing, storing, and archiving data)</i>					
Name		Elena Fernandez, PharmD, PhD			
Title		Manager			
E-Mail Address		elena.fernandez@monumentanalytics.com			
Telephone Number		(703) 861-6277			
Organization/Company <i>(if different from Requesting Organization)</i>		Monument Analytics			
Mailing Address		5726 Cross Country Boulevard			
City/Town	Baltimore	State	MD	Zip Code	21209
Relationship to Requesting Organization <i>(e.g., Contractor)</i>		Consultant			

Project Contact <i>(person responsible for all communications with MHCC)</i>					
Name		Elena Fernandez, PharmD, PhD			
Title		Manager			
E-Mail Address		elena.fernandez@monumentanalytics.com			
Telephone Number		(703) 861-6277			
Organization Name		Monument Analytics			
Mailing Address		5726 Cross Country Boulevard			
City/Town	Baltimore	State	MD	Zip Code	21209

ATTACHMENT A: SCOPE OF WORK

1. Project Purpose

- a. Describe the specific research question(s) you are trying to answer or problem(s) you are trying to solve with the MCDB data requested (List and number the individual questions) or describe the intended product or report that will be derived from the requested data.

We propose to use MCDB data to understand the trajectory of the opioid epidemic in the City of Baltimore. Specifically, we are interested in answering the following queries:

1. How many individuals in the City of Baltimore had Opioid Use Disorder (OUD) between 2010 and 2020?
2. What proportion of these individuals had OUD because of the opioid epidemic?
3. How many inpatient, outpatient, and emergency department visits for opioid overdoses and OUD occurred in the City of Baltimore between 2010 and 2020?
4. How much of this health care utilization was a result of the opioid epidemic?
5. What proportion of individuals with OUD received medications for addiction treatment (MAT) in the City of Baltimore between 2010 and 2020?
6. How many individuals developed complications attributable to OUD, including Hepatitis C and HIV infections, neonatal abstinence syndrome (NAS), and opioid-related accidental trauma, in the City of Baltimore between 2010 and 2020?
7. What proportion of individuals with OUD in the City of Baltimore received naloxone between 2010 and 2020?
8. What are the trends of opioid prescribing among health care providers in Baltimore City?

- b. Briefly describe the purpose(s) for which MCDB data are sought. Use quantitative indicators of public health importance where possible. For example: variation in costs of care; rates of under or over service utilization; health system performance measures, the effect of public health initiatives, health insurance, etc.

The opioid epidemic is the worst drug epidemic in our nation's history. In 2019, an estimated 49,860 people died in the U.S. from opioids, more than those who died from motor vehicle accidents, suicide, gun violence, or at the peak of the AIDS epidemic.¹ Though Maryland ranks fifth in opioid-related overdose death rates nationally, the City of Baltimore faces a higher rate of overdoses compared to other areas in Maryland. The number of opioid-related deaths in the City of Baltimore has increased since 2010, reaching 692 deaths in 2017.² More recent Baltimore City data from the State of Maryland reports 851 opioid-related deaths in 2019 and 952 opioid-related deaths in 2020.³ Combating the opioid epidemic has proven difficult for public health officials and other stakeholders for many reasons, including the multitude of contributing factors and downstream effects on individuals and communities. Estimating the burden of the opioid epidemic by epidemiologic methods can be helpful to policymakers to inform and address the needs of individuals affected by the epidemic. Efficient and informed allocation of resources will improve health and reduce long-term costs associated with combating the opioid epidemic. Useful estimates of burden of the opioid epidemic depend on robust and reliable inputs and should incorporate, whenever possible, information specific to the context in which they are applied. Therefore, data from the MCDB can provide important inputs for location-specific estimates of the opioid epidemic in the City of Baltimore over time. Our findings will provide information to stakeholders seeking to abate the opioid epidemic in the City of Baltimore. The data are sought solely for litigation purposes.

1. Centers for Disease Control and Prevention (CDC), "Drug Overdose Deaths," [https://www.cdc.gov/drugoverdose/data/statedeaths.html]
2. Baltimore City Health Department, "Baltimore City's Response to the Opioid Epidemic," [https://health.baltimorecity.gov/oid-overdose/baltimore-city-overdose-prevention-and-response-information]
3. Maryland Opioid Operational Command Center, "2020 Annual Report," [https://s3.documentcloud.org/documents/20614236/2020-annual-report-final.pdf]

- c. Explain in detail how the planned project that will use MCDB data is in the public interest and give specific examples of how the project will serve the public interest.

Monument Analytics is a health care consultancy that is working with the City of Baltimore. Monument is a decentralized, remote company that operates across the United States. At this time we are only requesting access to data from the State of Maryland. The City of Baltimore will use the MCDB data to measure the epidemiology and impact of the opioid epidemic in Baltimore City for opioid litigation purposes. This will be done by identifying the population in the MCDB data with opioid use disorder (OUD) over time and evaluating the health care utilization as captured in the MCDB data for this population. The planned project is in the public interest of the City of Baltimore and its citizens as this litigation and the findings from this analysis will provide important information to stakeholders and the resulting litigation may award abatement and/or damages funds to the City. The estimation of the opioid epidemic in Baltimore City with MCDB data may add support to the City's case for liability and subsequent abatement and/or damages. If the litigation results in abatement and/or damages funds, the City of Baltimore and its citizens will be able to fund programs based on the epidemiology of opioid epidemic in Baltimore City from this analysis to relieve the opioid epidemic in the City. If awarded funds through this litigation, the City of Baltimore public will benefit from various evidence-based programs which could include increased access to healthcare resources and treatment for OUD, including medications for addiction treatment and naloxone for overdose reversal, treatment for OUD complications, harm reduction programs, and programs aimed at preventing further harms related to the opioid epidemic.

2. Project Methodology

- a. Provide a written description of the project methodology, state the project objectives, the protocol, software and/or identify relevant study questions and analysis method to allow MHCC to understand how the MCDB Data will be used to meet project objectives or address research questions.

Project Methodology: This project will use observational epidemiologic methods with data from MCDB to produce relevant estimates of the burden of the opioid epidemic in the City of Baltimore from 2010 to 2020.

Project Objectives: The objectives of this project are to estimate the number of individuals affected by the opioid epidemic as well as subsequent and related healthcare utilization and opioid prescribing in the City of Baltimore from 2010 to 2020.

Protocol: We will conduct a descriptive, retrospective cohort analysis of individuals who were potentially affected by the opioid epidemic in the City of Baltimore between 2010 and 2020. We will include individuals 18 years of age or older with any opioid-related healthcare claims. We will exclude individuals in hospice care. We will quantify measures of the opioid epidemic including: the number of individuals with OUD; the number of individuals with opioid attributable complications, including Hepatitis C virus (HCV), HIV, or endocarditis; and healthcare utilization and costs incurred by those affected by the epidemic. Population estimates and healthcare utilization will be calculated annually and over time. We will also assess trends in opioid prescribing over time compared to external records of academic detailing.

We will use the International Classification of Diseases Clinical Modification (ICD-9 and ICD-10) codes to estimate the number of individuals and the volume of opioid-related care. To do so, we will use methods informed by the peer-reviewed literature: (1) with explicit ICD codes for OUD; and (2) when such codes are not available, by a combination of long-term opioid use with additional opioid intoxication, poisoning, or adverse effects.⁴ This latter approach is consistent with the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) criteria, which requires at least two adverse opioid events (opioid intoxications, poisonings, or adverse effects) within one year in order to fulfill diagnostic criteria for OUD. We will also characterize individuals experiencing adverse opioid events without fulfilling diagnostic criteria for OUD. ICD codes (9 and 10) for OUD and opioid-related events, where "x" signifies all subsequent sub-codes within each group, include 304.x, 305.x, V58.89, 292.89, 965.0x, E850.x, E935.x F11.1x, F11.2x, Z79.891, F11.129, F11.229, F11.122, F11.222, T40.00x, T40.10x, T40.20x, T40.30x, T40.40x, T40.605x, T40.695x. Opioid-related overdose deaths will be estimated by individuals that expired from ICD-9/10 coded opioid overdoses during the study timeframe.

We will also summarize the number of unique individuals with opioid attributable complications such as HCV, HIV, or endocarditis, and subsequent healthcare utilization. We will use ICD codes (9 and 10) such as the following, where "x" signifies all subsequent sub-codes within each group, for HCV (070.7x, 070.41, 070.44, 070.51, 070.54, B17.1x, B18.2, B19.2x), HIV (042, V08, 042.0-2, 042.9, 043.0-3, 043.9, 044.9, 079.53, B20-24), and endocarditis (421.x, 424.x, I33.x, I38, I39). We will also assess the number of unique individuals with OUD or opioid-related events during pregnancy or neonatal abstinence syndrome (NAS) and subsequent healthcare. ICD codes (9 and 10) that will be used for pregnancy are 648.3x, O99.32x, and NAS are 779.5, P96.1, where "x" signifies all subsequent sub-codes within each group.

We will use pharmacy data to assess prescription opioid use as well as treatment of OUD with medications for addiction treatment (MAT) including methadone, buprenorphine, and naltrexone. To do so, we will use both generic names as well as National Drug Codes (NDCs). We will also use covariate information on comorbid conditions, and where available, social history (e.g., alcohol, tobacco, or illicit drug use), and basic demographic information (e.g., age, race, ethnicity, and insurance status and type) to stratify and compare opioid-related healthcare utilization across different subpopulations of interest. Lastly, we will assess trends in opioid prescribing by individual providers in Baltimore City, based on National Provider Identifier, NPI, or Practitioner DEA number, over time.

Based on the amount and distribution of missing data, we will consider data imputation. Lastly, sensitivity analyses will be conducted based on the different definitions of OUD to assess the robustness of our results. Analyses will be conducted with SAS v9.4 (SAS Institute Inc., Cary, NC), STATA (version 15.1, StataCorp, College Station, TX), Microsoft Excel 2021, and R (R Core Team 2021). Protection of human subjects and data safety will be ensured as the data will only be disseminated in aggregate and no identifiable information will be reported.

Statistical software to analyze MCDB data includes:

- STATA [StataCorp. 2021. Stata Statistical Software: Release 17. College Station, TX: StataCorp LLC.]
- SAS [SAS Institute Inc 2013. SAS 9.4. Cary, NC: SAS Institute Inc.]
- R [R Core Team (2021). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL https://www.R-project.org/]

4. Watson A, Simon DM, Perattiko MB, Stringer EA. Medical Utilization Surrounding Initial Opioid-Related Diagnoses by Coding Method. *American Journal of Managed Care*. 2020;26:e64-e68.

5. Hasin DS, O'Brien CP, Auriacombe M, Borges G, Bucholz K, Budney A, Compton WM, Crowley T, Ling W, Petty NM, Schuckit M, Grant BF. DSM-5 Criteria for Substance Use Disorders: Recommendations and Rationale. *American Journal of Psychiatry*. 2013;170:834.

- b. All Applicants must obtain a review by an Institutional Review Board that has been or will be recognized by the MHCC.

Enter date submitted to IRB

Submitted: 9/30/2021
Exemption Determination: 10/11/2021

Name of the IRB

WCG IRB formerly, Western Institutional
Review Board (WIRB)

3. Publication and Dissemination

Briefly (1-3 sentences) explain any "Yes" answer.

- a. Do you anticipate that the results of your analysis will be published or made publicly available?

Yes

No

- i. If yes, how do you intend to disseminate the results of the study (e.g., publication in a professional journal, poster presentation, newsletter, web page, seminar, conference, statistical tabulation, etc.)?

A report will be developed that uses the MCDB data to calculate the harms that the opioid epidemic has inflicted on the City of Baltimore. The City may share the report with the Baltimore City Circuit Court, and the report may not be filed publicly initially, but may be subsequently released publicly.

- ii. All public displays of MCDB data, regardless of the medium, must comply with MCDB's cell size suppression policy, as set forth in the Data Use Agreement. Describe how you will ensure that any public display will suppress every cell containing s less than 11 observations and suppress percentages or other mathematical formulas that result in the display of every cell with less than 11 observations.

Any results will be reported as aggregates. If any cell size is less than 11 in aggregated results, cells will be listed as "Suppressed" in the final report.

- iii. Identify the lowest geographical level of analysis of data you will present for publication or presentation (e.g., state level, city/town level, zip code level, etc.). Will maps be presented? What methods will be used to ensure that individuals cannot be identified?

The lowest geographical level of analysis will be the City zip code level. Individuals will be de-identified prior to analysis and results will only be presented in aggregate form. Project products will protect Personal Health Information (PHI) by further aggregating data across specific groups across Baltimore City.

- b. If you answer "yes" to any of the following questions, describe the types of products, software, services, or tools and the corresponding fees will for such products, software, services, or tools.

- i. Will the MCDB data be used for consulting purposes? Yes No

- ii. Will report(s), website(s) or a statistical tabulation(s) using MCDB data be shared or sold? Yes No

A report will be developed that uses the MCDB data to calculate the harms that the opioid epidemic has inflicted on the City of Baltimore. The City may share the report with the Baltimore City Circuit Court, and the report may be publicly filed. The report of aggregated, non-identifiable data filed with the court may be available to the public. No underlying data will be publicly shared.

iii. Will a software product using MCDB data be shared or sold? Yes No

iv. Will MCDB data be used as input to develop a product (i.e., severity index tool, a risk adjustment tool, a reference tool, etc.)? Yes No

v. Will MCDB data be sold or shared in any format not noted above? Yes No

If yes, in what format and who are the purchaser of the data?

vi. Will the project result in disclosing MCDB data, or any data derived or extracted from such data, in any paper, report, website, a statistical tabulation, seminar, or another setting that is not disseminated to the public? Yes No

A report will be developed that uses the MCDB data to calculate the harms that the opioid epidemic has inflicted on the City of Baltimore. The City may share the report with the Baltimore City Circuit Court, and the report may not be filed publicly initially, but may be subsequently released publicly.

vii. Will the results from the project be used for price transparency? Yes No

viii. Will health care providers be individually identified? Yes No. Describe your protocol for informing health care providers prior to publication of this data/report.

ATTACHMENT B: MCDB DATASET REQUESTED

MHCC collects privately insured data (claims and membership), known as the Medical Care Data Base (MCDB), on a quarterly basis from life and health insurance carriers, health maintenance organizations (HMOs), third party administrators (TPAs), and pharmacy benefits managers (PBMs) that are licensed to do business in Maryland. The MCDB data that is available for release contains eligibility and professional, institutional, and pharmacy claims. Starting in 2015, the Medical Care Data Base (MCDB) excludes private plan data for self-insured ERISA due to the Gobeille v. Liberty Mutual Supreme Court ruling.

The data which is refreshed and updated annually contains only privately fully-insured and self-insured non-ERISA health insurance plans for Maryland and non-Maryland residents. The MCDB encompasses about 90-95% of the privately fully insured market and 25% - 30% of the self-insured market (post-Gobeille, primarily non-ERISA). To determine the years for which data are available check on the [MHCC website](#). That site also contains information about the most current MCDB Release Version and a full list of elements in the release including the release record layouts, data dictionaries, and supporting documentation.

1. Which MCDB files are you requesting? Provide a brief justification (1-3 sentences) for each one.

Dataset	Year(s)
<input checked="" type="checkbox"/> Institutional Claims	2010 - 2020.
The MCDB institution claims are needed to report estimates of opioid-related hospitalizations and clinical services rendered in inpatient, outpatient, and emergency department treatment settings in the City of Baltimore.	
<input checked="" type="checkbox"/> Professional Claims	2010 - 2020.
The MCDB professional claims are needed to report estimates of individuals with OUD and attributable complications from ICD 9/10 diagnosis codes in the City of Baltimore.	
<input checked="" type="checkbox"/> Pharmacy Claims	2010 - 2020.
The MCDB pharmacy claims are needed to report estimates of (1) medication for addiction treatment (MAT) and naloxone dispensing for individuals with OUD, and (2) opioid prescribing among health care providers in Baltimore City.	
<input checked="" type="checkbox"/> Member Eligibility	2010 - 2020.
The MCDB member eligibility dataset is needed to report demographic characteristics of individuals who experienced opioid overdoses or have OUD in the City of Baltimore.	

ATTACHMENT C: ADDITIONAL DATA SOURCES AND LINKAGE

1. Medicaid Data

Applications for access to Medicaid Managed Care data for studies comparing the privately insured to Medicaid Managed Care patients can be submitted but require a separate approval from the Maryland Medicaid Administration. The fields available on the Medicaid MCO data sets have been aligned with MCDB fields to the extent possible.

- a. Indicate whether you are seeking Medicaid data: Yes No
- b. Do you intend to merge or link MCBD data with Medicaid data? Yes No
If yes, provide a brief justification.

Medicaid Managed Care (MCO) data will be merged to MCBD data. No individuals will be followed over time. Individuals will be de-identified prior to analysis and results will only be presented in aggregate form. Project products will protect Personal Health Information (PHI) by further aggregating data across specific groups across Baltimore City.

- c. 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 Maryland Medicaid Data, please describe, in the space below, why your use of the Data meets this requirement.

Provision of healthcare services for OUD falls disproportionately on Medicaid compared to other payers.⁶ Our use of Maryland Medicaid data meets restrictions because the higher proportion of enrollees with OUD is directly connected to the administration of the Medicaid program. Estimates from the Maryland Medicaid data are needed to accurately reflect the burden of the opioid epidemic and subsequent healthcare utilization in the City of Baltimore.

6. The Medicaid and CHIP Payment and Access Commission. Report to Congress on Medicaid and CHIP June 2017. "Medicaid and the Opioid Epidemic." [<https://www.macpac.gov/wp-content/uploads/2017/06/Medicaid-and-the-Opioid-Epidemic.pdf>]

2. Other Linkages

Data linkage involves combining MCDB data with other data to create a more extensive database for analysis.

1. Do you intend to merge or link MCBD Data with other data? Yes No

If Yes:

- a. What are the files to be linked?

- b. Why is this linkage needed?

- c. Which MCDB data elements will be linked to the data elements in the external file?

- d. What methodology or algorithm will be used to create this match? If you intend to create a unique algorithm, describe how it will link each dataset.

e. What variables from each of the source files will be included in the final linked analytic file?

2. Explain why the linkages are needed.

N/A

3. Describe the specific steps the Organization will take to prevent the identification of individuals in the linked files.

N/A