

View xForm - Project Application v6

This form is for new projects that have not been previously approved by CPHS.

Data entry

New Submission Study Personnel

NEW CONTACT INSTRUCTIONS

April 2025 cycle.

A DSL from HCAI is attached.

03/12/2025 • Sussan Atifeh • Internal

Summary:

This application submitted by HCAI and is specifically asking for a "Waiver of Informed Consent" to collect and maintain healthcare data for the Health Care Payments Database (HPD) as a data depository, as allowed by California law. It's not for secondary research or any other purpose at this time.

Source of Data: The database gathers data from key sources, including:

- Centers for Medicare & Medicaid Services (CMS) (Medicare data, submitted quarterly).
- California Department of Health Care Services (DHCS) (Medi-Cal data, submitted monthly).
- California Department of Public Health (CDPH) (vital statistics, submitted quarterly).
- Commercial health plans and insurers (monthly submissions).

•HCAI clarified that the HPD program has no anticipated end date.

.

03/12/2025 • Sussan Atifeh • Internal

Dear Researchers: Please address the three minor comments left in the application and resubmit the application. In each page, please scroll down to see the entire page.

Thank you.

03/12/2025 • Sussan Atifeh • *Not* Internal • Resolved

Dear Researchers:

The reviewers of this project requested that you please attach a copy of the data base management polices and procedures to this application. You can attach the requested document in the "Procedures" section of the application.

This project will be scheduled to be discussed in the CPHS April 25, 2025, Full board Meeting.

Also, please see the new comments left by CPHS staff to adjust the application for a full board review (instead of an expedited review).

Thanks,

03/25/2025 • Sussan Atifeh • Not Internal

If personnel are not found by their email address while trying to complete the following questions, you can add them in the system with the link below. Click on the "New Contact Form" and complete it. Within a few minutes of completing the form, you will receive an email notifying you of the availability of the new contact. You should then be able to add them in the subsequent questions.

New Contact Form

PRINCIPAL INVESTIGATOR (PI)

Enter the Principal Investigator's email address.

Dionne Evans-Dean, MHA

Email: dionne.evans-dean@hcai.ca.gov

Business: (916) 326-3937

Choose the institution with which the PI is affiliated (not the location at which the research is being conducted).

Department of Health Care Access and Information (HCAI)

Enter the city in which the PI's institution is located.

Sacramento

Enter the state in which the PI's institution is located.

Start typing in the state name to select the name from the list.

California

Attach a copy of the PI's Curriculum Vitae.

CV for Dionne Evans-Dean PI Curriculum Vitae

CO-PRINCIPAL INVESTIGATOR (CO-PI)

Enter the Co-PI's email address by clicking on the "Add Contact" button.

If there are multiple co-principal investigators, repeat this action for all Co-PIs. If there are no Co-PIs for this project, skip this question.

No answer provided.

ADMINISTRATIVE CONTACT

Enter the email address(es) for the administrative contact(s). If you are the administrative contact, enter your email address, and enter anyone else you want listed as an administrative contact.

Anthony Tapney, MBA

Email: anthony.tapney@hcai.ca.gov **Business:** (916) 326-3932

RESPONSIBLE OFFICIAL (RO)

Enter the RO's email address.

*The RO **cannot** be the same person as the PI or Co-PI. The RO must have supervisory authority, in the administrative structure of the institution, over the PI.*

Michael Valle, MPA, MA

Email: michael.valle@hcai.ca.gov **Business:** (916) 326-3954

OTHER RESEARCH STAFF

Enter the email address for any other research staff by clicking the "Add Contact" button.

Repeat this action for all other research staff not previously provided on this screen that should receive notifications about this project. If there are no additional research staff, skip this question.

Jasmine Neeley

Email: jasmine.neeley@hcai.ca.gov **Business:** (916) 326-3816

Amandeep Singh

Email: Amandeep.singh@oshpd.ca.gov **Phone:**

Manpreet Singh

Email: Manpreet.Singh@hcai.ca.gov **Business:** (916) 326-3978

Chris Crettol

Email: chris.crettol@hcai.ca.gov **Business:** (916) 326-3996

Alyssa Borders, PhD

Email: Alyssa.Borders@hcai.ca.gov **Business:** N/A

Justin Tonooka, MPH

Email: Justin.Tonooka@hcai.ca.gov **Business:** (916) 326-3805

Anna Dito, BA

Email: anna.dito@hcai.ca.gov **Business:** (916) 326-3991

Anna Kriuchkova, MS

Email: anna.kriuchkova@hcai.ca.gov **Business:** (916) 326-3902

Benson Zheng, BA

Email: benson.zheng@hcai.ca.gov **Business:** (916) 326-3993

Suzanne Hermreck, MS

Email: suzanne.hermreck@hcai.ca.gov **Business:** (916) 326-3841

Check for PI same as RO (internal only question) *(Internal)*

False

Project Information

SUBMITTER

Application completed by:

Chris Craig

Email: Chris.Craig@hcai.ca.gov **Business:** (916) 326-3634

PREVIOUSLY APPROVED EXEMPTION

Is there a previously-approved exemption from CPHS for this project?

No

PROJECT TITLE

Enter the project title (please capitalize each word in your title).

Health Care Payments Data (HPD) System Operations

PROJECT SITE

Indicate the primary site at which the research will be conducted.

Department of Health Care Access and Information (HCAI)

STUDY PROCEDURES

Indicate the study procedures involved in this research. Check all that apply.

none

TYPE OF RESEARCH REQUEST

Indicate which of the following applies to this research. Check all that apply.

*Death Data Only refers to health-related studies requesting existing mortality data from **within** the California Human Health Services Agency (CHHSA)*

*SB-13 (Information Practices Act) refers to health-related studies requesting existing data from **outside** the CHHSA (e.g. California Department of Corrections and Rehabilitation [CDCR], California Department of Education [CDE], etc.) **OR** studies requesting data **within** the CHHSA that are not state funded or involving state staff.*

Common Rule/Human Subjects refers to health-related studies that involve direct or indirect interaction with human subjects (e.g. recruitment, interviews, etc.)

*Common Rule Only refers to health-related studies requesting existing data from **within** the CHHSA (e.g. Office of Statewide Health Planning and Development [OSHPD], California Department of Public Health [CDPH], etc)*

Common rule only

PROJECT TYPE DETAILS

Indicate which, if any, apply to this research. Check all that apply.

If the research does not involve any of following, choose "None of the above."

Minimal Risk

Informed Consent Waiver

VULNERABLE POPULATIONS

Indicate which vulnerable populations, if any, will be involved with this research. Check all that apply.

If vulnerable populations are not part of the research, choose "Not applicable."

Note regarding minors: in the United States, a minor is under 18 years of age. If research is conducted outside the United States, a minor is under the age of majority in the countries where research is to be conducted.

Not applicable

FUNDING

Is this research funded?

Yes

Indicate the funding source for this project.

State funded

Federally funded

Locally funded

Privately funded

University funded

Enter name of state-funded source.

General Fund

Enter name of federally-funded source.

CMS Enhanced Federal Financial Participation

EXPEDITED REVIEW CONSIDERATION

Please check the criteria below that you think your project meets to qualify for an expedited review. If none of these expedited criteria are appropriate for your project, choose 'not applicable'; your protocol will be reviewed by the full committee. Note that CPHS will make the final determination of whether the project meets the criteria for expedited review.

Your response in this section should mirror your answer in the "Type of Research Request" section. Please edit. Thanks.

03/12/2025 • Sussan Atifeh • Not Internal • Resolved

Since the reviewers requested this project to be scheduled for discussion in the CPHS April 25, 2025, full board meeting, please select "Not Applicable" option in this section. Thanks.

03/25/2025 • Sussan Atifeh • Not Internal

Protected Health Information/Personally Identifiable Data (PHI/PID) is defined as information in any format that identifies the individual, including demographic information collected from an individual that can reasonably be used to identify the individual. Additionally, PHI is information created or received by a healthcare provider, health plan, employer, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual, including any of the 18 HIPAA identifiers.

Note: Please be aware that individual participants may be identifiable by combining other items in the data even when none of the 18 HIPAA identifiers are present. Thus, a study may still contain PID even after removing or never acquiring the identifiers, and the investigator may still need to provide complete answers for the data security questions in the protocol.

***The Departments within the California Health and Human Services Agency (CHHSA) are: Aging, Alcohol and Drug Programs, Child Support Services, Community Services and Development, Developmental Services, Emergency Medical Services Authority, Health Care Services, Mental Health, Public Health, Rehabilitation, Social Services and Statewide Health Planning and Development.*

Not applicable

ANTICIPATED PROJECT START DATE

Projects cannot begin before they have been reviewed. The earliest possible start date is always the date of the next public meeting at which the project will be heard.

Since the April meeting was postponed to April 25, would you please change this date to 4/25/2025 or a date following 4/25/25 within a few weeks?

Thank you.

03/25/2025 • Sussan Atifeh • *Not Internal*

For a list of public meeting dates, see the CPHS website

05/01/2025

ANTICIPATED PROJECT END DATE

INTERNAL NOTE:

HCAI clarified that the HPD program has no anticipated end date. The program's authorizing statute instructs HCAI to collect data starting June 29, 2017, and maintain at least three years of data. The law does not specify an upper limit.

For the purposes of this CPHS application, HCAI has suggested a project end date of Dec. 31, 2040, since the end date field is required for form submission, but the HPD program is expected to be permanent.

03/12/2025 • Sussan Atifeh • Internal

12/31/2040

Project Details

PURPOSE

Include a brief statement, less than 500 words, describing the research project. Be sure to address the background for the project, including relevant literature, the major research questions to be addressed, and the expected end product (e.g., article, report or other publications). Include the location(s) where the project will take place. The summary should be understandable to the general public.

The Health Care Payments Database (HPD) is California's All Payer Claims Database or APCD. The HPD is a research database comprised of healthcare administrative data: claims and encounters generated by transactions among payers and providers on behalf of insured individuals. The HPD collects claim and encounter data as submitted from California payers.

The information from the HPD System is intended to support greater health care cost transparency and will be used to inform policy decisions regarding the provision of quality health care, and to reduce health care costs and disparities. It is also intended for the information to be used to develop innovative approaches, services, and programs that may have the potential to deliver health care that is both cost effective and responsive to the needs of all Californians.

To maximize its utility and value for California policymakers, researchers, and others interested in improving California's healthcare system, HCAI intends for the HPD to be as comprehensive and complete as possible by increasing the quality, volume, and variety of data collected over time.

MAJOR RESEARCH QUESTION

What is the major research question to be addressed in this project?

Legislative Intent for the HPD System:

Assembly Bill 80 (AB 80) (Chapter 12, Statutes of 2020) requires the Department of Health Care Access and Information (HCAI) to create and administer a statewide Health Care Payments Data Program (HPD), often referred to as an All-Payer Claims Database or APCD.

Per California Health and Safety Code (HSC) Section 127671.1, HCAI is required to establish and administer the HPD system to collect health care data from health care plans, health insurers, government agencies and others. The data in the HPD system is intended to support greater health care cost transparency and will be used to inform policy decisions regarding the provision of quality health care, and to reduce health care costs and disparities. The information is also to be used to develop innovative approaches, services, and programs that may have the potential to deliver health care that is both cost effective and responsive to the needs of all Californians.

Disclaimer for this Application:

This form is designed to ask questions specific to a research protocol, but HCAI is using this form to request a waiver of consent for a research repository (the HPD database). For questions that are not answerable by a research repository, to avoid creating confusion, HCAI has chosen to reframe the question or abstain from answering. In these situations, we have included the following statement for clarity:

"HCAI believes this question is not applicable. The Department is requesting a waiver of the consent requirement for the collection, storage, and maintenance of the HPD database in accordance with California statute. This request does not involve data use for secondary research purposes."

STUDY PROCEDURES

Describe in detail all procedures for this research. Do not attach grant applications or similar documents. Information in this application must be sufficient to fully explain the procedures without such documents

As required by law, the HPD database collects and aggregates administrative data from health care payers including the federal Centers for Medicare & Medicaid Services (CMS); the California Department of Health Care Services (DHCS, or "Medi-Cal"); and commercial health plans and insurers. The data is collected from a variety of submitters, transformed into the HPD data model, and stored in the HPD system. The administrative data collected by HPD were created for health care operations not research. However, they have immense value to secondary research and analytics, which is why many states leverage mandatory reporting to create APCD systems.

The HPD program works with submitters to help ensure the best available data makes it into the HPD database. These activities include the following key components:

- Frequent and proactive communication with submitters
- Guidelines and requirements for data submissions, formalized in the California Code of Regulations (CCR), Title 22, Division 7, Chapter 11, Articles 1-7
- Timely validation checks and communication to submitters about data that do not pass initial quality checks
- Evaluation of accepted data for variation in quality over time
- Acceptance and incorporation of replacement data, when appropriate, to address data quality concerns
- Ongoing maintenance of all collected data within a multi-module research repository, including but not limited to deduplication of records; matching and reconciliation of identity records; applying schemas and metadata to submitted records; and applying/enforcing administrative, physical, and technical safeguards for all data interactions

For security reasons, certain operational details may not be made public-- particularly with respect to information security and privacy procedures.

With respect to the question below, "Indicate any of the following CHHSA department(s)' involvement in providing research staff, funding and/or patients from State mental hospitals for this project," the HPD database does contain inpatient records for behavioral health services. Although HCAI has not analyzed whether any such records are definitively attributed to a State mental hospital, the Department receives a large volume of behavioral health data from the Department of Health Care Services. For this reason, we are indicating "DHCS" for that question. These records are not specifically targeted for collection, storage, and maintenance due to population characteristics; rather, they are incidentally among all Medi-Cal records collected from DHCS.

Please upload here any tables or charts related to your study procedures and any materials (such as surveys or interview questions) that will be presented to participants.

No answer provided.

RECORDING

Will audio or video recording occur?

No

DECEPTION

Will deception be used in this study?

No

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY (CHHSA) DEPARTMENTS LIST

Indicate any of the following CHHSA department(s)' involvement in providing research staff, funding and/or patients from State mental hospitals for this project.

Update on 3/13/25:

HCAI response to the comment below:

With respect to the question below, "Indicate any of the following CHHSA department(s)' involvement in providing research staff, funding and/or patients from State mental hospitals for this project," the HPD database does contain inpatient records for behavioral health services. Although HCAI has not analyzed whether any such records are definitively attributed to a State mental hospital, the Department receives a large volume of behavioral health data from the Department of Health Care Services. For this reason, we are indicating "DHCS" for that question. These records are not specifically targeted for collection, storage, and maintenance due to population characteristics; rather, they are incidentally among all Medi-Cal records collected from DHCS.

You selected "DHCS, CDPH, and HCAI" in this section. Are these departments providing research staff, funding and/or patients from State mental hospitals for this project? if yes, please explain briefly in the "Procedures" section of the application to clarify about the role of each department in this project. if no, please update the section accordingly. If they only provide funding for this project, please confirm it in the Procedures section of the application.

Thanks.

.

03/12/2025 • Sussan Atifeh • *Not* Internal • Resolved

DHCS: Department of Health Care Services

Study Population

POPULATION DESCRIPTION

Provide a full description of how human subjects will be involved in the research. Address characteristics of subjects such as: age; sex; ethnicity; and number of participants. Include requested participant number.

The HPD program is statutorily mandated to collect health care data on all California residents to the extent feasible beginning June 29, 2018--three years prior to the effective date of enabling statute--with no anticipated end date. The only selection criterion is that an individual must be a California resident during the period of data submission to HCAI. There is no limitation or restriction on data collection based on personal characteristics.

The HPD database collects data at various intervals depending on the submitter. Most submitters, including all mandatory and voluntary submitters, provide data to the HPD program once per month. These submissions include all persons who were known to have a California address of residence for at least one day during the month being reported. HCAI receives Medicare data from CMS once per quarter. HCAI also receives quarterly vital statistics from the California Department of Public Health (CDPH). The data from CMS and CDPH is likewise limited to individuals with a California address during the period being reported.

The HPD system includes services and eligibility records for approximately 80%-90% of all California residents with medical coverage in one or more health care plans for each reporting year. Using comparison data, the HPD system includes:

- Member information for 82% of California's total population and 89% of California's insured population
- Approximately 90% of state-wide emergency department visits
- Approximately 85% of inpatient admissions
- Approximately 76-89% of office visits

In addition, nearly all of California's providers are represented in the HPD system, including over 83,000 individual physicians.

Because the HPD database collects, stores, and maintains data on all California residents to the extent feasible, the database contains data from vulnerable populations (including minors, prisoners, pregnant women, neonates, individuals with impaired decision-making abilities, and economically or educationally disadvantaged persons). The inclusion of these vulnerable populations in HPD is incidental as part of the broader California population; they are not specifically targeted for collection, storage, and maintenance of data.

RATIONALE

What is the rationale for studying the requested group(s) of participants?

HCAI is required by state law to collect, store, and maintain information in the HPD database. The broad basis for the HPD database is described in HSC, Division 107, Part 2, Chapter 8.5, "Health Care Payments Data Program." Per Section 127671:

---(begin block quote)

a) The Legislature finds and declares that California has a substantial public interest in the price, cost, utilization, equity, and quality of health care services. California is a major purchaser of health coverage through the Public Employees' Retirement System, the State Department of Health Care Services, the Department of General Services, the Department of Corrections and Rehabilitation, the California Health Benefit Exchange, and other entities acting on behalf of a state purchaser. California also provides major tax expenditures through the tax exclusion of employer-sponsored coverage and tax deductibility of coverage purchased by individuals, as well as tax deductibility of excess health care costs for individuals and families.

(b) It is the intent of the Legislature in enacting this chapter to establish a system to collect information regarding health care costs, utilization, quality, and equity. Health care data is reported and collected through many disparate systems. Creating a process to aggregate and use this data will provide greater transparency regarding health care costs, utilization, quality, and equity, and the information may be used to inform policy decisions regarding the provision of quality health care, improving public health, reducing disparities, advancing health coverage, reducing health care costs, oversight of the health care system and health care companies, and providing public benefit for Californians and the state, while preserving consumer privacy.

(c) It is the intent of the Legislature to improve data transparency to achieve a sustainable health care system with more equitable access to affordable and quality health care for all.

(d) It is the intent of the Legislature in enacting this chapter to encourage state agencies, researchers, health care service plans, health insurers, providers, suppliers, and other stakeholders to use this data to develop innovative approaches, services, and programs that may have the potential to deliver health care that is both cost effective and responsive to the needs of enrollees, including recognizing the diversity of California and the impact of social determinants of health.

---(end block quote)

Many states throughout the country recognize that APCDs are increasingly essential resources because health care cost transparency enables development of informed policies to realize meaningful and lasting

improvements to health care delivery and outcomes. APCDs contribute to a comprehensive understanding of cost, quality, utilization, and many aspects of population health across payer types and settings of care (e.g., hospitals, outpatient clinics, EDs, medical offices). Other data sources provide important information but have limitations. For example, hospital discharge data are limited to facility-provided inpatient and outpatient procedures and do not include information on actual payments, disease registries are limited to specific health conditions, and health plan-specific databases are limited to a single payer. An APCD builds upon and complements these datasets, enabling a deeper understanding of the health care system and support for the policy solutions that will reduce costs, improve quality, and improve access to care.

States use APCDs to meet a variety of needs. In many states, APCDs support public reporting that highlights geographic variation in health care cost, quality, and utilization; prevalence of and costs to treat chronic disease; and other public health related measures. States generate analytic datasets, reports, and other information products to support research, public health, and health care operations, among many other uses. Custom analyses are generated on an ad hoc basis to address emerging health care policy issues as well. Several states have created health care pricing tools that provide average (or median) paid amounts for specific procedures, some of them on a named provider basis.

STUDY DURATION

Estimate the probable duration of the entire study. This estimate should include the total time each subject is to be involved and the duration of each data collection about the subject.

E.G., This is a two-year study. Participants will be interviewed three times per year; each interview will last approximately two hours. Total approximate time commitment for participants is 12 hours.

The HPD program has no anticipated end date. The program's authorizing statute instructs HCAI to collect data starting June 29, 2017, and maintain at least three years of data. The law does not specify an upper limit.

For the purposes of this CPHS application, HCAI has suggested a project end date of Dec. 31, 2040, since the end date field is required for form submission, but the HPD program is expected to be permanent.

Risks and Benefits

RISK DESCRIPTION

Provide a description of possible risks to participants: physical, psychological, social, economic, loss of data security, and/or loss of confidentiality. Describe and justify whether the research is minimal risk or greater than minimal risk.

The primary risk resulting from the collection, storage, and maintenance of HPD data is the possibility of a breach of confidentiality for individuals whose information is stored in the database. HCAI believes the risk is minimal. The Department employs a broad array of administrative, physical, and technical safeguards to mitigate the possibility of unauthorized disclosure of HPD data. Such controls are mandated for state agencies by California law, as further defined in the State Administrative Manual (SAM) and specified in the Statewide Information Management Manual (SIMM). HCAI is subject to independent audits and assessments of the Department's information security controls.

Specific details regarding HCAI's active threat detection and risk mitigation approach on this topic are considered confidential and nonpublic for information security purposes.

INTERNATIONAL RESEARCH

Will this research occur outside of the United States or U.S. territories?

Check with client to see if they consider territories to be outside the U.S. or not, as this can vary between institutions.

No

BENEFITS

Describe the benefits, if any, to the subjects or to society that will be realized as a result of this project. Discuss the benefits that may accrue directly to the subjects as well as to society. If there is no direct benefit anticipated for the subjects, state that clearly.

The primary benefit of the HPD database is to enable secondary research that serves California's substantial public interest in the price, cost, utilization, equity, and quality of health care services performed for California residents. In gathering, integrating, and organizing information about how health plans and insurers pay for care, the HPD system offers an unprecedented opportunity to address health care costs and drive improvement in California's health care system.

California's goal for the HPD database is to facilitate secondary research purposes, with input from (and considering the requests of) stakeholders, to examine the most pressing and important issues of health policy--today and well into the future. Key priorities beginning in 2025 include health equity, hospital sector spending, and enhanced pharmaceutical sector spending. These priorities are expected to change over time as California's health system evolves.

In general, the HPD database will enable secondary research that supports the following public benefits:

- Visibility on how California spends \$300 billion on health care annually
- Comparisons among Medicare, Medi-Cal, and commercial health plans and insurers
- Clarity as to which elements of California's health care system are most likely to drive costs
- Targeted interventions for low-quality and/or high-cost health care
- Cost, utilization, and quality measures that can be compared across payers and regions
- Analyses that help address rising costs and improve health system performance

These efforts would be impracticable, if not impossible, without the HPD database to collect, normalize, sanitize, reconcile, and align inputs from throughout the state.

Administrative Safeguards

PERSONALLY IDENTIFIABLE DATA (PID) INSTRUCTIONS

Protected Health Information/Personally Identifiable Data (PHI/PID) is defined as information in any format that identifies the individual, including demographic information collected from an individual that can reasonably be used to identify the individual. Additionally, PHI is information created or received by a healthcare provider, health plan, employer, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual, including any of the 18 HIPAA identifiers.

Note: Please be aware that individual participants may be identifiable by combining other items in the data even when none of the 18 HIPAA identifiers are present. Thus, a study may still contain PID even after removing or never acquiring the identifiers, and the investigator may still need to provide complete answers for the data security questions in the protocol.

If the researcher demonstrates that he or she is unable to comply with any of the requirements below, he or she may request an exception from these requirements. The researcher should indicate any measures that will be taken to address this requirement. The exception request should be made in the text box of the corresponding requirement. An exception will only be granted if the researcher can demonstrate that adequate alternative measures have been taken to minimize risks so as to justify the exception.

HIPAA IDENTIFIERS

Please identify which HIPAA Identifiers you plan to request as part of your submission.

Name

Address (all geographic subdivisions smaller than state, including street address, city county, and zip code)

All elements (except years) of dates related to an individual (including birthdate, admission date, discharge date, date of death, and exact age if over 89)

Social Security Number

Medical record number

Health plan beneficiary number

TRAINING PROCEDURES

Describe the procedures for training all research staff who have access to PID on privacy and security. Indicate if staff are required to sign a confidentiality statement related to general use, security, and privacy.

All personnel who operate the HPD database are required to complete security and privacy awareness training at least once per year. The training process includes explicit acknowledgment of acceptable use and confidentiality requirements.

STAFF VETTING PROCEDURES

Describe procedures, either background check or thorough reference check, for vetting staff who will have access to PID.

All HCAI contractors that are expected to interact with sensitive or confidential data on behalf of the Department are required to conduct background checks for employees and subcontractors who will be granted access to such data. HCAI is in the process of implementing background checks for State employees consistent with statutory requirements set forth in HSC §127011.

SUPPORT LETTER

Obtain and submit a department support/data release letter.

Would you please also attach a copy of DUA with CMS in this section and name it as "DUA with CMS" so it can be recognized by its name?

I'm referring to the DUA # RSCH-2020-55668
(AGREEMENT FOR USE OF CENTERS FOR MEDICARE &
MEDICAID SERVICES (CMS)
DATA CONTAINING INDIVIDUAL IDENTIFIERS)

Please do not delete the document you already attached in this section.

Thanks.

03/12/2025 • Sussan Atifeh • Not Internal • Resolved

This is a statement from the state agency or department you are receiving data from. It must be on that agency's/department's letterhead and should include both

1) *that the release of the desired data is legal and*

2) *that the entity is willing to release the desired data to you, the researcher. If you are not receiving data, this letter should indicate that you are supported.*

***For VSAC requests, if you do not have a Departmental Letter of Support (LOS)/Data Release, you may upload a copy of the Data Request Form (application) from the department to secure a review for the upcoming cycle. The protocol will not be approved until the LOS is uploaded to the protocol.*

Please also review the CPHS Statement for Birth and Death Data.

CMS Data Use Agreement RSCH-2020-55668

HPD Enabling Statute.pdf

Department Letter of Support

Department Letter of Support

PREVENTING RE-USE AND UNAUTHORIZED ACCESS

Explain how you will ensure that data will not be reused or provided to any unauthorized person or entity.

Unauthorized means that the person or entity does not have a need to access the data for purposes of the research project approved by CPHS.

Access to the HPD database is limited through role-based access controls (RBAC) that are in place for each HPD system module. The HPD database's collection, storage, and maintenance functions are separated into different teams. Elevated privileges are limited within each functional area to specific team members. User activities, including interactions with data, are logged. Multiple administrative and technical safeguards are in place around all data movement within the HPD database, with a bias toward data NOT moving between modules unless specifically authorized. HCAI enforces the principle of least privilege and minimum necessary, consistent with State of California requirements. Specific details on this topic are considered confidential and nonpublic for information security purposes.

CONFIDENTIALITY OF PUBLISHED DATA

Indicate whether information will be published that could possibly be used to identify an individual subject.

HCAI believes this question is not applicable. The Department is requesting a waiver of the consent requirement for the collection, storage, and maintenance of the HPD database in accordance with California statute. This request does not involve data use for secondary research purposes. Collection, storage, and maintenance does not involve publication of data.

DATA REQUEST JUSTIFICATION

Provide adequate justifications for the quantity of the data, the years and the variables being requested. Have you requested no more than the minimum necessary data to perform the research?

The HPD statute describes the various types of information HCAI must (required), should (encouraged), and may (optional) collect in the HPD database, as well as the data sources for each. In general, the HPD database is required to collect data on all Californians to the extent feasible and permissible.

The HPD database employs the All-Payer Claims Database Common Data Layout (APCD-CDL(tm)) to collect records from all statutorily mandated submitters. This format was recommended through stakeholder engagement with the HPD Advisory Committee (also enacted in statute) and ratified in CCR Title 22, Division 7, Chapter 11, Articles 1-7.

Mandatory submitters to the HPD database include all health plans, health insurers, and public self-insured plans with at least 40,000 members who are California residents. HCAI is also instructed by law to collect Medi-Cal data from DHCS (also in the APCD-CDL(tm) format); Medicare data from CMS (in a proprietary format but reasonably equivalent to the APCD-CDL(tm)); "any data collected by [HCAI] from providers and suppliers," to the extent possible (HSC 127673(i)); and data from various sources to supplement the development of master person, provider, and payer indices (HSC 127673.3(b)).

Finally, the HPD statute requires HCAI to "ensure that the [HPD database] can map to other datasets, including public health datasets on morbidity and mortality, and data regarding the social determinants of health" (HSC 127672.8).

All data collection methodologies and data scopes in use at the time of this application were selected following extensive stakeholder engagement and in consultation with the HPD Advisory Committee. HCAI will continue to operate through California's public regulations process for any future changes to the HPD database's collection practices.

LIMITATIONS TO DATA ACCESS

Indicate if access to data is limited only to those with a need to know for purposes of implementing or evaluating the research.

Yes, access to HPD data is limited through role-based access controls (RBAC) that are in place for each HPD system module. The HPD database's collection, storage, and maintenance functions are separated into different teams. Elevated privileges are limited within each functional area to specific team members. HCAI enforces the principle of least privilege and minimum necessary, consistent with State of California requirements. Specific details on this topic are considered confidential and nonpublic for information security purposes.

UNIQUE IDENTIFIERS

If applicable, justify why unique identifiers, other than social security numbers, cannot be used.

HCAI believes this question is not applicable. The Department is requesting a waiver of the consent requirement for the collection, storage, and maintenance of the HPD database in accordance with California statute. This request does not involve data use for secondary research purposes.

PROTECTION AGAINST SMALL CELL SIZES AND ASSOCIATED PROBLEMS

Describe appropriate and sufficient methods to protect the identity of individual subjects when small cells or small numbers and/or data linkage to another data set are involved in the research project.

HCAI believes this question is not applicable. The Department is requesting a waiver of the consent requirement for the collection, storage, and maintenance of the HPD database in accordance with California statute. This request does not involve data use for secondary research purposes.

LINKAGES

Will the data set be linked with any other data sets?

No

DESTRUCTION OF PID VERIFICATION

Indicate that you will provide CPHS with a letter certifying that PID has been destroyed and/or returned to the data source once research is concluded.

Yes

DATA SECURITY LETTER

Upload a certification/statement from the Chief Information Officer, Privacy Officer, Security Officer or equivalent position of the researcher's institution that CPHS Data Security Standards are met.

- *Data security letters cannot be signed by the Principal Investigator or Responsible Official.*
- *The data security letter must be on your institution's letterhead.*
- *Example of data security letter*

Data Security Letter for HPD Operations Data Security Letter

Deleted Attachments: 1 (Most Recent: HCAI CPHS Security Letter.docx on 03/03/2025 4:31 PM ET)

Physical Safeguards

DATA PROTECTION

Indicate that research records and physical samples will be protected through the use of locked cabinets and locked rooms; PID in paper form will not be left unattended unless locked in a file cabinet, file room, desk, or office.

Yes

DATA DESTRUCTION

Will data/samples will be destroyed or returned as soon as it is no longer needed for the research project.

Yes

RETAINED DATA

Will the retained data/samples have personal identifiers or be de-identified?

data will contain personal identifiers

DESTRUCTION METHODS

Describe how you will ensure the PID in paper form is disposed of through confidential means, such as cross cut shredding or pulverizing.

HCAI believes this question is not applicable. The collection, storage, and maintenance of the HPD database does not allow or involve printing, faxing, or mailing of data. HCAI employs a wide variety of administrative, physical, and technical safeguards to secure the HPD database against unauthorized use. The California Department of Technology approved HCAI's implementation of the HPD database following detailed oversight during the Project Approval Lifecycle as well as through Independent Verification and Validation of the system. Specific details on this topic are considered confidential and nonpublic for information security purposes.

FAXING

Describe how you will ensure that faxes with PID are not left unattended and fax machines are in secure areas.

N/A

MAILING

Indicate whether mailings of PID are sealed and secured from inappropriate viewing; and whether mailings of 500 or more individually identifiable records of PID in a single package, and all mailings of PID to vendors/contractors/co-researchers, are sent using a tracked mailing method, which includes verification of delivery and receipt, such as UPS, U.S. Express Mail, or Federal Express, or by bonded courier.

N/A

ELECTRONIC STORAGE

State whether PID in paper or electronic form, e.g., stored on laptop computers and portable electronic storage media (e.g., USB drives and CDs), will ever be left unattended in cars or other unsecured locations.

All computing environments involved in the collection, storage, and maintenance of the HPD database are subject to administrative, physical, and technical safeguards, including but not limited to strong data encryption, data loss prevention capabilities, and secure physical storage. The California Department of Technology approved HCAI's implementation of the HPD database following detailed oversight during the Project Approval Lifecycle as well as through Independent Verification and Validation of the system. Specific details on this topic are considered confidential and nonpublic for information security purposes.

PHYSICAL STORAGE

Describe whether facilities, which store PID in paper or electronic form, have controlled access procedures, and 24 hour guard or monitored alarm service.

HPD data are not stored in paper form. All data centers involved in the collection, storage, and maintenance of HPD data are secure facilities with controlled access procedures. Specific details on this topic are considered confidential and nonpublic for information security purposes.

SERVER SECURITY

Provide a description of whether all servers containing unencrypted PID are housed in a secure room with controlled access procedures.

N/A; all HPD data are encrypted.

STORING IDENTIFIERS

Indicate whether identifiers will be stored separately from analysis data.

HCAI believes this question is not applicable. The Department is requesting a waiver of the consent requirement for the collection, storage, and maintenance of the HPD database in accordance with California statute. This request does not involve data use for secondary research purposes. Specific details regarding the HPD database's logical model are considered confidential and nonpublic for information security purposes.

DISK STORAGE

State whether all disks with PID will be destroyed.

HCAI generally follows California State requirements for media destruction specified in National Institute of Standards and Technology Special Publication 800-88, "Guidelines for Media Sanitization." Specific details on this topic are considered confidential and nonpublic for information security purposes.

Electronic Safeguard

COMPUTER ACCESS OVERVIEW

State whether all computer access will be protected through the use of encryption, passwords, and other protections.

All computing environments involved in the collection, storage, and maintenance of the HPD database are subject to administrative, physical, and technical safeguards, including but not limited to strong data encryption, data loss prevention capabilities, and secure physical storage. The California Department of Technology approved HCAI's implementation of the HPD database following detailed oversight during the Project Approval Lifecycle as well as through Independent Verification and Validation of the system. Specific details on this topic are considered confidential and nonpublic for information security purposes.

FIPS 140-2 COMPLIANCE: WORKSTATIONS

Indicate whether all workstations that contain PID have full disc encryption that uses FIPS 140-2 compliant software. If not, explain why not and what encryption will be used.

All computing environments involved in the collection, storage, and maintenance of the HPD database use FIPS 140-2 compliant software. Specific details may not be made public, per Government Code 7929.210(a).

FIPS 140-2 COMPLIANCE: LAPTOPS

Indicate if all laptops that contain PID have full disc encryption that uses FIPS 140-2 compliant software. If not, explain why not and what encryption will be used.

All computing environments involved in the collection, storage, and maintenance of the HPD database use FIPS 140-2 compliant software. Specific details may not be made public, per Government Code 7929.210(a).

FIPS 140-2 COMPLIANCE: REMOVABLE MEDIA DEVICES

Indicate if PID on removable media devices (e.g. USB thumb drives, CD/DVD, smartphones, backup recordings) are encrypted with software that is FIPS 140-2 compliant.

HCAI does not permit the use of removable media devices with HPD data. Notwithstanding, the HCAI network does not permit removable media devices unless they are pre-approved and are FIPS 140-2 compliant. Specific details may not be made public, per Government Code 7929.210(a).

SECURITY PATCHES

Indicate if all workstations, laptops and other systems that process and/or store PID have security patches applied in a reasonable time frame.

All computing environments involved in the collection, storage, and maintenance of the HPD database are routinely patched. Specific details may not be made public, per Government Code 7929.210(a).

PASSWORD CONTROLS

Indicate if sufficiently strong password controls are in place to protect PID stored on workstations, laptops, servers, and removable media.

All computing environments involved in the collection, storage, and maintenance of the HPD database use passwords that meet a minimum length and complexity requirement. Specific details may not be made public, per Government Code 7929.210(a).

ELECTRONIC SECURITY CONTROLS

Indicate if sufficient system security controls are in place for automatic screen timeout, automated audit trails, intrusion detection, anti-virus, and periodic system security/log reviews.

All the listed electronic security controls are in place. Specific details may not be made public, per Government Code 7929.210(a).

FIPS 140-2 COMPLIANCE: ELECTRONIC TRANSMISSION

Explain whether all transmissions of electronic PID outside the secure internal network (e.g., emails, website access, and file transfer) are encrypted using software which is compliant with FIPS 140-2.

HCAI believes this question is not applicable. The collection, storage, and maintenance, of HPD data does not permit transmission outside the secure internal network. Notwithstanding, all data transmissions within the HPD database are encrypted. Specific details may not be made public, per Government Code 7929.210(a).

INTERNET ACCESSIBILITY

Note if PID in an electronic form will be accessible to the internet.

The HPD database is a modular system that includes some cloud-based applications, but there is no access to the open internet. The California Department of Technology approved HCAI's implementation of the HPD database following detailed oversight during the Project Approval Lifecycle as well as through Independent Verification and Validation of the system. Specific details may not be made public, per Government Code 7929.210(a).

DISPOSING OF PID

When disposing of electronic PID, indicate whether sufficiently secure wiping, degaussing, or physical destruction will be used.

HCAI generally follows California State requirements for media destruction specified in National Institute of Standards and Technology Special Publication 800-88, "Guidelines for Media Sanitization." Specific details may not be made public, per Government Code 7929.210(a).

Conflict of Interest Information

CONFLICT OF INTEREST (COI) INSTRUCTIONS

A COI is defined as any financial or other relationships of the researcher(s) or the institution that could be perceived as affecting the objective conduct of the research, including the interpretation and publication of the findings. Researchers must disclose any COI, including perceived COI.

Financial relationships to be disclosed include but are not limited to the following:

- **Present or anticipated ownership of stock, stock options, or other financial obligations of the source of funding.**
- **Receipt or expectation of payment of any sort in connection with papers, symposia, consulting, editing, etc. from the source of funding.**
- **The sale or licensing or anticipated sale or licensing of medical or other products or intellectual property, such as patents, copyrights, or trade secrets to the source of funding or other entities.**
- **Any past, present or anticipated receipt of money or other valuable consideration from the source of research funding by the researcher(s), the family of the researcher(s), the research institution, or by an institution in which the researcher(s) or the family of the researcher(s) has an interest as owner, creditor, or officer.**

DISCLOSURES

Does any member of the study team, members' spouses, or members' dependent children have any significant financial interests related to the work to be conducted as part of the above-referenced project?

No

Informed Consent Waiver

INFORMED CONSENT WAIVER

Are you requesting a waiver or alteration of informed consent?

Yes

Provide a rationale as to why the research could not practicably be conducted without the waiver or alteration.

HCAI is requesting a waiver for the Healthcare Payments Data (HPD) database from the Common Rule consent requirements specified at 45 CFR 46.116(a). HCAI is NOT requesting an exemption for HPD generally, or from the secondary research projects that may occur using the HPD database.

Per the Common Rule at 45 CFR 46.116 and 45 CFR 46.117, CPHS may waive the documentation requirements for consent for the storage, maintenance, and secondary research use of identifiable private information. This type of waiver is permitted for research involving public benefit and service programs conducted by or subject to the approval of state or local officials, so long as individuals were not asked to provide broad consent and refused to do so. In order to apply this waiver, CPHS must find and document that the HPD database is:

"...subject to the approval of state...government officials and is designed to study, evaluate, or otherwise examine:

- (A) Public benefit or service programs;
- (B) Procedures for obtaining benefits or services under those programs;
- (C) Possible changes in or alternatives to those programs or procedures; or
- (D) Possible changes in methods or levels of payment for benefits or services under those programs" (45 CFR 46.116(e)(3)(i))

In addition, CPHS must find the HPD database could not practicably be carried out without the requested waiver.

HCAI believes all the listed Common Rule criteria are satisfied with respect to the HPD database.

First, the HPD database is subject to the approval of state government officials. The authority for the database was established through California's public legislative process. The database was created under the approval from state government officials at HCAI, with mandatory oversight from the California Health and Human Services Agency (CalHHS) as well as the California Department of Technology (CDT). HCAI operates and maintains the HPD database, which is subject to ongoing technical compliance requirements set forth in the State Administrative Manual and further elaborated in the Statewide Information Management Manual. CDT assesses HCAI compliance with these controls through a variety of state-standard methods.

Second, the HPD database is designed to study, evaluate, and examine public

benefit and service programs. The HPD database was established following a legislative finding that "California has a substantial public interest in the price, cost, utilization, equity and quality of health care services" (HSC 127671(a)). The Legislature's intent in establishing the HPD database was to "[provide] public benefit for Californians and the state, while preserving consumer privacy" (HSC 127671(b)), with a stated goal to "improve data transparency to achieve a sustainable health care system with more equitable access to affordable and quality health care for all" (HSC 127671(c)). In order to achieve these legislative intents, HCAI "shall collect data on all California residents to the extent feasible and permissible subject to the state constitutional right to privacy and any other applicable state or federal law" (HSC 127671.1(b)). More than half of all human subject data stored and maintained in the HPD database is received from public benefit programs (namely Medicare and Medicaid). The Centers for Medicare & Medicaid Services (CMS) implicitly acknowledged the public benefit nature of the HPD program in approving the program for Medicaid Federal Financial Participation, and by authorizing the release of Medicare data to HPD following CMS Institutional Review Board approval. CMS may only take these actions when the applicant has demonstrated a clear improvement to the public benefit for program participants, i.e. Medicaid or Medicare enrollees. The Medicare data release was subject to the Health Insurance Portability and Accountability Act (HIPAA) research exception process, which is reasonably similar to the Common Rule's waiver requirements. Furthermore, HCAI is required by law to use HPD data for the creation of new public knowledge that benefits as many Californians as possible. This intent is reflected throughout the enabling statute. See, e.g., HSC 127673.5(a)(1): "The purpose of the system is to learn about and seek to improve public health, population health, social determinants of health, and the health care system, not about individual patients"; HSC 127673.8(a): "The department shall use the program data to produce publicly available information, including data products, summaries, analyses, studies, and other reports, to support the goals of the program"; HSC 127673.81(d): "Program data shall not be used for determinations regarding individual patient care or treatment and shall not be used for any individual eligibility or coverage decisions or similar purposes"; and HSC 127673(m): "The program performs public health activities described in subdivision (b) of Section 164.512 of Title 45 of the Code of Federal Regulations. The information collected in accordance with this chapter is necessary to carry out projects with public health purposes."

Third, collection, storage, and maintenance of HPD data cannot practicably be carried out without the requested Common Rule waiver. The HPD statute mandates approximately 40 health organizations to submit data to the HPD database. Collectively, these submitters cover approximately 25 million lives at any given time. It is not practicable to obtain consent across so many organizations for that large a population. CMS accepted this argument with regard to Medicare data alone, which comprises less than 25% of HPD data. In addition, HCAI believes the statutory intent for the HPD database would be jeopardized if consent is required for data collection, storage, and maintenance. The purpose of the database is to collect and aggregate information on as many California residents as possible. Gaps in data collection would diminish the HPD database's ability to support the research goals set forth in law. It would be especially harmful to statutory intent if

gaps in data collection were concentrated to a specific geographic area or subpopulation, which could introduce unintended biases to research outcomes, public reports, and policymaking--thereby hindering the State's goal of improving equity and reducing disparities for the overall population.

Finally, no individual has been asked and subsequently refused to provide broad consent for the storage and maintenance of HPD data. Therefore, CPHS is not prohibited from granting HCAI a waiver for the Common Rule's consent documentation requirements.

It is HCAI's position that consent for the existence of the HPD database was obtained through California's constitutional processes for public governance and discourse. The enabling statute was the result of a public and democratic process, including public committees on the statutory language and opportunity for public comment on the resulting regulations. Detailed program information is publicly available on the HCAI website. The requested waiver will allow HCAI to continue to collect, store, and maintain HPD data to support vital public benefit research in compliance with the Common Rule and the CalHHS Federalwide Assurance.

Provide a detailed account of the plans and measures that will be in place to protect the rights and welfare of the subjects.

From March 2019 to February 2020 HCAI convened a Review Committee comprised of health care system stakeholders and experts who advised HCAI on the establishment, implementation, sustainability, and ongoing administration of the Health Care Payments Database. The Review Committee unanimously approved 36 recommendations that were included in an HCAI report to the Legislature, released March 9, 2020. HCAI has used these recommendations as guideposts in the development of the HPD program. They include principles that help protect the rights and welfare of Californians, such as:

- Use a national standard data collection format that is maintained through a public process
- Have legislation and regulation that clearly authorizes submitters to send health care data that includes personal information
- Exclude any lines of business not required to meet the legislative intent for the program
- Maximize the usefulness of the data, and ensure those uses are to the benefit of California
- Maintain a governance structure--including public committees--that inform program policies and use of the data
- Protect individual privacy in compliance with applicable federal and state laws
- Ensure the system is used to learn about the health care system and populations, not about individual patients
- Make only aggregate, deidentified information publicly accessible

HCAI continues to engage with HPD stakeholders, other state agencies, and with the public on the collection of data. At the time of this application, two public committees provide input to the HPD program: The HPD Advisory Committee, and the HPD Data Release Committee. Each body is required by

statute to include at least one member who represents consumers' interests. HPD data is prohibited from being used for purposes related to patient care, treatment, eligibility, coverage, or similar decisions.

The HPD database itself is protected and hardened by a broad array of administrative, physical, and technical safeguards alluded to previously in this application. Although HCAI is not able to disclose detailed information security and privacy controls in a public document, the Department employs a considerable degree of rigor to protect the system against unauthorized use or disclosure of data. Multiple security and privacy teams coordinate activities to keep the HPD database safe. Security measures are assessed by the Centers for Medicare & Medicaid Services; the California Department of Technology; and the California Military Department.

Many additional safeguards are in place to provide protections for secondary research uses of HPD data. However, since this application is limited to a waiver from consent for collection, storage, and maintenance of data, those protections are not fully enumerated herein. In brief:

- Requests to use HPD data for secondary research purposes must comply with law, regulation, and legally binding data use agreements
- All requests must pass an HCAI-internal review that considers the proposed project's scientific legitimacy, data security, privacy, and risk factors
- In addition, each request may be subjected to review and approval by multiple bodies, such as the Committee for the Protection of Human Subjects; the HPD Data Release Committee; and the Department of Health Care Services (for projects involving Medi-Cal data)
- The majority of secondary research projects supported by the HPD database will use HCAI's secure HPD Enclave, which isolates project-specific data to a secure computing environment and includes administrative mechanisms to prevent misuse or unauthorized exfiltration of data

HIPAA Determination

HIPAA INSTRUCTIONS

To determine if this project is covered by HIPAA, answer the following questions.

COVERED ENTITY

Will health information be obtained from a covered entity, known as a clearinghouse, such as Blue Cross, that processes or facilitates processing health data from another entity, including but not limited to state databases?

Yes

HEALTHCARE PROVISIONS

Will the study involve the provision of healthcare by a covered entity, such as the UCD Medical Center?

No

OTHER HIPAA CRITERIA

Will the study involve other HIPAA criteria not listed above?

No

HIPAA WAIVER

Are you requesting a waiver or alteration of HIPAA authorization?

If you have already received a waiver/alteration from another IRB choose 'waiver/alteration approved by another IRB'. You do not need to apply for a waiver or alteration as the HIPAA waiver or alteration of authorization is only required from one IRB.

Waiver/alteration approved by another IRB that reviewed this project.

HIPAA AUTHORIZATION FORM

Upload a copy of the HIPAA Authorization form(s) or the documentation of the approval of a waiver/alteration from another IRB.

CPHS HIPAA Authorization package.pdf HIPAA Documents

Cover Letter and PI Signature for PI Submission

BUDGET

Does this project have a budget?

Yes

Attach a copy of your project budget here

HPD Long-Term Funding Budget Proposal Project Budget

COVER LETTER

Attach a copy of your project cover letter.

Cover letter must have the requesting institution's letterhead.

CPHS Cover Letter for HPD Consent Waiver.pdf Cover Letter

In order for the PI to review and sign this form, you will need to click "Next" and on the next page, click "Submit." At that point the PI will receive notification that will need to review the application and if they request changes, they will return the form to you and you will receive an email notification.

Copyright ©2000-2025 Tech Software. All Rights Reserved.
2025.4.8097.0/Release/5f5a7b9 | GCWBWS1 | 2025-04-08 21:40:58Z

Powered By  IRBManager