# Agenda IV: HPD Data Access and Release Regulations

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# Anticipated Data Access & Release Timeline



**2022**

**2023**

**2024**

## DRC Planning
Perform initial planning, recruit and select members, schedule and conduct first meeting.

## DRC Ramp-Up
Conduct regular meetings. Onboarding and orientation. Provide input on policies and procedures.

## DRC Application Review
Review and make recommendations on data requests.

## Data Access Regulations
Complete all aspects of the data access and release regulations process.

## Data Enclave Implementation
Build Enclave, create and house datasets, establish workflows, user testing, HCAI approval.

## Access
Design, develop, and implement data request process. Begin intake and processing of data use requests, onboard approved users, collect fees, authorize data access/release.

*DRC: Data Release Committee*

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# HCAI Administrative Rulemaking Activities

- Develop regulations language

- **Workshop regulations concept**

- Finalize draft regulations text and prepare regulations supporting documents

- Public Comment Period

- Development of final rulemaking package for Office of Administrative Law (OAL)

- OAL review and approval

- Effective Jan 2024

# Data Release Program Governance Layers

**Goals**
► Included in statute, adopted by the Committees, and committed to by program leadership

**Policies**
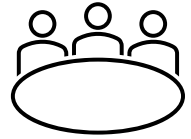► Rules and directives that support the goals

**Processes**
► Checklists and steps, for people and systems, to implement the policies

**Criteria**
► Rules and standards applied during processes, in support of policies and goals

**Procedures**
► Activities that support processes, apply criteria, and improve over time

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# DRC - How it Supports the Program

| Goals | Policies | Processes | Criteria | Procedures |
|---|---|---|---|---|
| Supports program goals: | Helps HCAI develop policies on: | Helps HCAI develop and execute processes to: | Helps HCAI develop criteria to determine: | Helps HCAI improve procedures to: |

**Goals** — Supports program goals:
- Patient privacy
- Appropriate users
- Appropriate uses
- Consistent review
- Inform policymakers

**Policies** — Helps HCAI develop policies on:
- Access to data with direct identifiers
- Direct data transmission
- Data use agreements
- Appropriate use cases and requestor experience

**Processes** — Helps HCAI develop and execute processes to:
- Review a request
- Communicate with requestors
- Inform the public on how data is being used
- Establish precedents for approving and rejecting requests

**Criteria** — Helps HCAI develop criteria to determine:
- If a request is approved
- Alignment with program goals
- Requestor eligibility for direct data transmission
- If a use case informs policymakers

**Procedures** — Helps HCAI improve procedures to:
- Share request information with the Committee
- Evaluate data requests against HPD program goals
- Evaluate a requestor's system security

# HPD Data Use, Access, & Release Regulations

- ✓ Definitions/Key Terms
- ✓ Eligibility for Program Data
- ✓ Review of Data Applications
- ✓ General Reasons to Deny Data Applications
- ✓ Data Release Committee

- ✓ Committee for the Protection of Human Subjects (CPHS)
- ✓ Special Requirements for Medi-Cal Information
- ✓ Decisions on Data Applications
- ✓ Data Use Agreements
- ✓ Restrictions for Public Data Products

*These sections of the rule will directly impact DRC operations*

# Key Terms

- Confidential Data includes Personally Identifiable Information (PII) and/or record-level patient information.

- Limited Data is confidential data *without* direct personal identifiers.

- Research Identifiable Data is confidential data that *includes* direct personal identifiers.

- Standardized Limited Datasets will be developed by the Department and include confidential data *without* direct personal identifiers.

# Eligibility for Program Data

| Type of Program Data | Access Method | Eligibility | PII/PHI | Record Level Data | Requires DRC Review |
|---|---|---|---|---|---|
| Non-Confidential Data | Both | Any Entity | No (no record level data) | No | No* |
| Limited Data | Enclave | Any Entity | Indirect Identifiers | Yes | No* |
| Research Identifiable Data | Enclave | Any Entity | Direct and Indirect Identifiers | Yes | Yes |
| Standardized Limited Datasets | Direct File Transfer | Any Entity | Indirect Identifiers | Yes | Yes |
| Confidential Data | Direct File Transfer | Researchers | Direct and Indirect Identifiers | Yes | Yes |
| State Agency Requests | Both | State Agencies | Direct and Indirect Identifiers | Yes | No* |

*HCAI can request DRC review of these applications.*

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# Review of Data Applications

- To assist in the review of applications, HCAI may seek:

  - Additional information from the applicant

  - Input from the Data Release Committee, even if not required

  - Input from the public, California regulatory and other state agencies, the Advisory Committee, or HPD data sources.

# General Reasons to Deny Data Applications

- State or federal law prohibits the disclosure

- The agreement through which HCAI obtained the data prohibits disclosure, e.g., DHCS, CDPH, CMS DUA, etc.

- Disclosure would create unreasonable patient privacy or safety risks

- The proposed use is inconsistent with HPD program goals

- The data would be used in making determinations regarding patient care or treatment, individual eligibility or coverage decisions, or similar purposes.

# HPD Program Goals

1. Provide public benefit for Californians and the state while protecting individual privacy.

2. Increase transparency about health care costs, utilization, quality, and equity.

3. Inform policy decisions on topics including the provision of quality health care, improving public health, reducing disparities, advancing health coverage, reducing health care costs, and oversight of the health care system and health care companies.

4. Support the development of approaches, services and programs that deliver health care that is cost effective, responsive to the needs of Californians, and recognizes the diversity of California and the impacts of social determinants of health.

5. Support a sustainable health care system and more equitable access to affordable and quality health care for all.

# Data Release Committee

- The DRC must review and recommend approval of requests that include Standardized Limited Datasets and Research Identifiable Data.

- The Department will refer complete applications for Standardized Limited Datasets and Research Identifiable Data to the DRC for review and recommendation.

- The DRC will consider applications at public meetings and may require the applicant to attend to respond to questions.

- After meetings, the DRC will issue written recommendations regarding approval.

# DHCS and CPHS Roles

**DHCS**

- Applicants seeking confidential Medi-Cal data must describe:
    - How the project will benefit Medi-Cal
    - Project funding sources
    - Whether the project will develop a commercial product.
- Applications that include Medi-Cal data are subject to review and approval by DHCS.

**CPHS**

- Applications requesting Research Identifiable Data must be reviewed and approved by the Committee for the Protection of Human Subjects (CPHS).
- Applicants may seek CPHS approval before, during, or after HCAI/DRC review.

# Decisions on Data Applications

- Timeliness: HCAI must notify applicants of decisions within 60 days of submission unless:
  - The applicant agrees to a longer time period
  - The request is subject to DHCS and/or CPHS review
  - HCAI has good cause.
- Options:
  - Denied – The notice must include the reasons for denial
  - Approved – The notice will include data use/access fee information, method of access, and a Data Use Agreement
  - Conditional – HCAI may issue a conditional approval pending DHCS/CPHS approval.

# Data Use Agreements

- Execution of a Data Use Agreement is required prior to applicants obtaining or accessing confidential data.

- For non-confidential data, HCAI may require applicants to execute a Data Use Agreement.

# Restrictions for Public Data Products

- Public Data Products are created by data users for publication, presentation, or other public release or disclosure.


- Public Data Products:
  - Cannot include PHI or record level patient information
  - Contents are limited to aggregated and de-identified data
  - Data users must submit drafts to HCAI for compliance review
  - Public data products cannot be released without written HCAI approval.

# Discussion Questions

- What are your reactions to the draft HPD data access and release regulations? How do you see these affecting the DRC's work?

- What questions or additional discussion items should HCAI address at future DRC meetings?