

Agenda VI: HPD Data Use Agreement

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HPD and Data Use Agreements (DUAs)

- General purpose of a DUA
 - DUAs are enforceable contracts between data providers and data users
 - The primary goal of the DUA is to make sure confidential data is protected
 - DUAs establishes the rights, limitations, and obligations data users have regarding confidential data, including how they can use data and further distribute it
 - DUAs also establish procedures and remedies for violations of use
- HPD Statute requires that “each person who accesses or obtains nonpublic personal data shall sign a data use agreement”
 - Approved data applicants and any persons who will access confidential data are required to execute a DUA before accessing confidential data.

Examples of Health Care Data DUAs

- DHCS Data Use Agreement
 - https://www.dhcs.ca.gov/dataandstats/data/Documents/DRC%20Applications/Public_HealthDUA2019.doc
- CMS Data Use Agreement
 - <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/Data-Use-Agreement.pdf>
- AHRQ Data Use Agreement
 - <https://hcup-us.ahrq.gov/team/StateDUA.jsp>

DUA Key Areas

- Data Ownership
 - Once disclosed, who owns the data and any derived data
 - Possible provisions for HCAI to obtain and use the user's research, data products, or publications (for some data requests, this is required)
- Data Use
 - For HPD, this will be determined through the application process and then incorporated into the DUA
 - No use will be allowed beyond what was approved through the application process
 - Per HPD statute, DUA to reiterate that only aggregate and de-identified patient/consumer data can be released publicly
- Data Security
 - There are proposed data security standards in the data release regulations which will be incorporated along with the user's security plan/measures

DUA Key Areas (cont.)

- Recordkeeping/Audit
 - Requiring Data User to have records on data use
 - Provisions that allow HCAI or the State to check compliance with the DUA or legal requirements
- Data Breach Procedures
 - Notice/Reporting requirements to HCAI and others
 - Actions to be taken after breach
- Contract Remedies and Liability
 - Indemnification to HCAI for any damages/losses/litigation against HCAI because of User's acts or omissions
 - Liquidated Damages
 - Termination provisions

Enforcement for DUA Violations

Violation of the terms of a Data Use Agreement may result in:

- Termination of the DUA and a requirement to immediately return or destroy all data
- HCAI lawsuit for breach of contract for damages, or to prevent violations of the DUA
- Liquidated damages to HCAI

HPD Approach to DUAs

- HCAI plans to have a base DUA template with different attachments for different types of HPD data disclosures (enclave v. direct transmission, requestor v. personnel)
 - For unique circumstances, HCAI may customize DUAs based on the data usage or other factors
- HCAI plans to allow some changes to a data user's project, such as the adding/replacement of personnel, through amendments to the DUA
 - Major changes, such as adding data or a data use, or replacing the project lead, will require the user to go through the application process

DUA – Questions for the Committee

- What would make a better DUA?
- Any provisions that could discourage use of the data?
- What are your experiences with DUAs?