

DEPARTMENT OF HEALTH CARE ACCESS AND INFORMATION

RULEMAKING FILE
(Health Care Payments Data Program
Data Use, Access, and Release)

Item 12:
FINAL STATEMENT OF REASONS



FINAL STATEMENT OF REASONS

HEALTH CARE PAYMENTS DATA PROGRAM DATA USE, ACCESS, AND RELEASE

CALIFORNIA CODE OF REGULATIONS
TITLE 22, DIVISION 7, CHAPTER 11, ARTICLE 8
SECTIONS 97380 TO 97416

November 20, 2024

I. UPDATE TO INITIAL STATEMENT OF REASONS (ISOR)

After the initial 45-day notice period for these proposed regulations, which was from June 2, 2023 through July 18, 2023, the Department of Health Care Access and Information (HCAI) made sufficiently related or nonsubstantial changes to the text of the regulations and updated its Initial Statement of Reasons to explain these changes. For these changes, HCAI provided a second comment period as required by Government Code section 11346.8(c) and Cal. Code Regs., title 1, section 44. HCAI provided 45 days for this second comment period starting on December 18, 2023, instead of the minimum 15 days, to allow interested parties time to consider the changes and provide thoughtful and complete feedback.

After the second comment period, HCAI made one additional sufficiently related change (regarding the definition of “state agency”) and several nonsubstantial changes to the proposed regulatory text from December 2023. Because of these changes, because of comments from the second comment period, and because it was unclear that HCAI updated the Initial Statement of Reasons in December, HCAI initiated a third comment period pursuant to Government Code sections 11346.8(c) and 11347.1 for (1) all the changes made to the original June 2, 2023 text and (2) the Updated Initial Statement of Reasons, dated December 18, 2023. HCAI provided notice as required by Government Code Section 11347.1(b) and Cal. Code Regs., title 1, section 44. This third comment period started on April 4, 2024 and remained open through April 19, 2024. The changes in the April 4, 2024 version of the text are either sufficiently related as defined in Cal. Code Regs., title 1, section 42; or are nonsubstantial as defined in Cal. Code Regs., title 1, section 40.

All modifications from the initial proposed text, dated June 3, 2023, of the Health Care Payments Data Program (HPD) Data Use, Access, and Release regulations, including non-substantial changes, are discussed below with statements of the specific purpose for each change from the original proposed regulatory text. Unless specifically

discussed below, the reasons/necessity statements from the Initial Statement of Reasons, dated May 22, 2023, continue to apply to these regulations. This Final Statement of Reasons supersedes and replaces the Updated Initial Statement of Reasons, dated December 18, 2023.

References to proposed regulations below are to Title 22 of the California Code of Regulations. Changes made to the originally proposed language are illustrated by ~~double strikethrough~~ and **single strikethrough and bold** for the deletions and double underline and **single underline and bold** for the additions.

1. Section 97380 Changes

Reasons for Substantive Changes to Section 97380 Text:

- **Change:** “In addition to the definitions in section ~~93700~~ 97300, the following definitions apply to this article...”
 - **Reason:** A commenter noticed this error (discussed below). HCAI had a typo in the original text and mistakenly cited to section “93700”. This was changed to reference the correct code section, “97300”—the preexisting regulation that contains definitions for the HPD in general.

- **Addition of Section 97380(d) and Deletion of Prior Section 97380(j):**
 - **Changes:**
 - **Adding Text:** “(d) ‘Custom Limited Datasets’ are datasets other than standardized limited datasets, with confidential data that do not include any of the direct personal identifiers listed in Section 164.514(e) of Title 45 of the Code of Federal Regulations.”
 - **Replacing and Deleting Text:** “~~(j) “Limited Data” means confidential data without any of the direct personal identifiers listed in Section 164.514(e) of Title 45 of the Code of Federal Regulations. This term includes standardized limited datasets.~~”
 - **Reason:** This term replaces former subsection (j) “limited data” as HCAI believed this would make the regulations clearer. These proposed regulations (Sections 97392 and 97393) were modified to now have different ways to release “custom limited datasets” versus “standardized limited datasets”. HCAI added this term, “custom limited datasets,” and replaced the term “limited data” in Section 97380 to make it clear and

easier to understand when these regulations cover non-standardized limited datasets versus standardized limited datasets.

- **Text Change:** “~~(e)~~ ‘Data Applicant(s)’ or ‘Applicant(s)’ means any individual, group of individuals, or organization that submits an application for program data under this Article.”
 - **Reason:** HCAI changed this term to explicitly include multiple individuals by adding the “(s)” and “group of individuals” to clarify that more than one individual can be applicants on the same data request.
- **Text Change:** “~~(e)~~... For applications under sections 97394 and 97398, data applicant may be used interchangeably with Principal Investigator (PI) and Co-Principal Investigator (Co-PI).”
 - **Reason:** HCAI added Principal Investigator (PI) and Co-Principal Investigator (Co-PI) as data applicants in our process. This adjustment acknowledges the potential scenario where the PI, CO-PI, and the data applicant might be fulfilled by the same individual.
- **Text Change:** “~~(t)~~ ‘State agency’ means a state agency of the State of California.”
 - **Reason:** In section 97380(t), HCAI added a definition for “state agency” as these proposed regulations have specific provisions applicable to “state agencies,” such as proposed Section 97400 which gives “state agencies” a separate way to request confidential data. The reason for this definition is to make clear that by “state agency,” the regulations mean just agencies of the State of California, instead of an agency of another state. It is anticipated that there will be interest both inside and outside of California and this definition adds clarity for other states.
- **Text Change:** “~~(u)~~ ‘Supplemental applications’ are applications related to a previously approved project.”
 - **Reason:** HCAI added this definition because HCAI added this term to these proposed regulations, and it would be cumbersome to have to define this term multiple times in later regulations. The addition of supplemental application was added to enhance the efficiency of the data request process for previously approved data requests. This definition makes clear what a “supplemental application” is and will be processed like initial data applications to modify approved data requests. For more information about this, see later sections referencing “supplemental applications.”

- **Addition of Section 97380(v):**

- **Text Change: “(v) ‘Type of Access’ means one of the following options for an individual to access program data in the enclave pursuant to an approved data application under this Article:**

(1) ‘Contributor Access’ which means the individual is able to view documents and reports generated by others, but does not have the ability to query data;

(2) ‘Analyst Access’ which means the individual has access to program data in a virtual Windows desktop, can use query tools, has access to shared project folders, and can create custom reports and data products; or

(3) ‘Research Access’ which means the same as “analyst access” except “research access” has access to greater amounts of digital storage.”

- **Reason:** In its Decision of Disapproval, the Office of Administrative Law stated it was unclear that HCAI required data applicants to state a “required access level” for individuals accessing data through the enclave, but did not outline the different access levels. Based on this HCAI added this definition. HCAI corrects this issue by replacing “required access level” with the term “type of access” and defines it here.

Regarding the definition, based on HCAI’s contract with its enclave vendor, there are three different types of access for individuals using HPD data through the enclave. For this reason, one of the application requirements for enclave access is for the data applicant to identify the “type of access” they want for each individual who access the enclave so HCAI can process the request better (see proposed sections 97392(a)(19)(C), 97393(a)(20)(C), 97394(a)(23)(C) and 97400(17)(C)). HCAI added this definition to provide clarity to the data applicant regarding what “type of access” means and to specify what information an applicant has to submit regarding this application requirement. Regarding the contract referenced above, please see the “Contributor Role HPD Work Order Authorization – 06/04/2024” document which HCAI relies on for this definition.

Reasons for Non-Substantive Changes to Section 97380 Text:

- HCAI updated the lettering in this section as new subsections were added and a section was removed.

2. Section 97382 Changes

Reasons for Substantive Changes to Section 97382 Text:

- **Splitting of Original Section 97382(b):**
 - **Text Changes:**
 - **Modifying this subsection:** “(b) Standardized Limited Datasets via the Enclave. Any individual or organization may request enclave access to standardized limited datasets by submitting an application pursuant to section 97392.”
 - **Adding this subsection:** “(c) Custom Limited Datasets via the Enclave. Any individual or organization may request enclave access to custom limited datasets by submitting an application pursuant to section 97393.”
 - **Reason:** this section and these proposed regulations were changed to add a seventh data request type, splitting the original data request type of “Limited Data via the Enclave,” to two separate data request types (1) “Standardized Limited Datasets via the Enclave” and (2) “Custom Limited Datasets via the Enclave.” This was done after receiving comments stating that it should be more streamlined to obtain standardized limited datasets through the enclave versus custom limited datasets. Since there is a statutory difference in how these datasets are treated (Health and Safety Code section 127673.83(a)), HCAI decided to have different request pathways with differing requirements that make it simpler to obtain standardized limited datasets. For specific changes regarding these data request types, see below about proposed Sections 97392 and 97393.
- **Text Change:** “(e) Direct Transmission of Standardized Limited Datasets. Any individual or organization may request direct transmission of a standardized limited dataset, ~~either in whole or in part,~~ by submitting an application pursuant to section 97396.”
 - **Reason:** Data requests will receive the entirety of the standard limited data set. This adjustment aims to streamline the data access process

by providing researchers with access to the data set, rather than segmenting it into small portions or subsets.

- **Text Change:** “(f~~e~~) Direct Transmission of Confidential Data. A researcher may request direct transmission of confidential data, other than standardized limited datasets, by submitting an application pursuant to section 97398.”
 - **Reason:** This language was added to clarify to data applicants that this data request process is not for standardized limited datasets since there is a separate way to request such datasets.

Reasons for Non-Substantive Changes to Section 97384 Text:

- The Department updated the lettering in this section as new subsections were added.

3. Section 97384 Changes

Reasons for Substantive Changes to Section 97384 Text:

- **Changes Regarding “Program Data Price”:**
 - **Changes:**
 - **Change to Heading:** “Program Data Price and Application Fees”
 - **Text Change to Section 97384(a):** “(a) The Department shall charge a price, as set by the Department’s price schedule, for program data it discloses under this Article. An individual or organization shall not receive or access program data until the program data price has been paid in full unless reduced under Section 97414.”
 - **Text Change to Section 97384(b)(2):** “The paid fee shall be applied to the total cost for the data program data price (described in subsection (a) above) if the application is approved. The application fee is non-refundable.”
 - **Reason:** In its Decision of Disapproval, the Office of Administrative Law notified HCAI that there was ambiguity in the proposed text as

the text utilizes the terms “total cost,” “fee” and “price” in various places. The Office of Administrative Law did not know whether these terms meant the same thing or had different meanings. HCAI modified this section to address this issue.

“Fee”, as in the application fee, is already described in this section and its meaning is already clear. For the term “price”, HCAI added a new subsection (a) to describe what “price” means—the price for the data. For the term “total cost”, HCAI deleted the sole reference to “cost” in these regulations which was in new section 97384(b)(2) and replaced it with “price”.

Regarding “price,” HCAI is required to create a “pricing mechanism” for confidential HPD data and has the option to do so for non-confidential data. This new subsection (a) discusses this and notes that HCAI will have a price schedule with specific prices. HCAI does not specify prices in these proposed regulations as “prices” do not have to be included in regulations and so HCAI has flexibility in setting prices.

The second sentence of subsection (a) makes it clear that data will not be provided to an approved requester until the price has been paid. This is to ensure that HCAI is paid for the data.

- **Changes Regarding “Application Fee”:**
 - **Text Changes**
 - **New subsection (b) regarding the application fee:** “**(b)** An individual or organization, except state agencies, submitting an application for program data under this Article shall pay ~~the~~ an application fee of \$100 set by the Department.”
 - **Changes to new (b)(1):** “The application fee of \$100 shall be submitted...”
 - **Reason:** HCAI added a specific amount for the application fee here because HCAI decided to have one clear application fee for all requests and not to have a separate fee schedule listing different application fees based on the request type. Also, HCAI decided on \$100 because HCAI believes this is a high enough amount that will deter uncommitted or sham applicants who would otherwise waste HCAI’s resources, but would still be reasonable for serious applicants, ensuring that only those committed to utilizing the data will proceed with their requests and that HCAI’s resources are used well.

The \$100 is also consistent with the estimated costs for HCAI to review data applications. HCAI estimates that one of its Research Data Analysts will take three to four hours of their time to complete their initial review of an application. Since the average hourly rate for this position is approximately \$31.00 an hour, the total costs to HCAI for this review is between \$93.00 to \$124.00. HCAI relied on the following documents to calculate this: (1) Duty Statement - Research Data Analyst, dated 6/2024, and (2) the CalHR Payscale, dated 8/05/2024.

Regarding the re-lettering and new changes in bold, HCAI made these changes because of the addition of the new subsection (a) regarding “program data price” as discussed above. New subsection (b) is about the “application fee.”

- **Changes Regarding Application Fees and Supplemental Applications:**

- **Text Change to section 97384(b):** “**(2)** submits its new data application or supplemental application, and no application shall be considered complete unless accompanied by the required fee.”
- **Reason:** HCAI clarified that in order to submit a supplemental application, data applicants must also pay a new application fee. The reason for this is to ensure that only those committed to utilizing data will proceed with their requests and that HCAI’s resources are used well.

This subsection was relettered because of the addition of a new subsection (a) regarding the “program data price” as discussed above.

- **Change to Reference:** “Reference: Sections **127673.8**, 127673.81, 127673.82, and 127674, Health and Safety Code.”

- **Reason:** HCAI added Health and Safety Code section 127673.8 to the references because HCAI erroneously did not list it. As this regulatory section is about “price”, that statute, like section 127673.82(f), gives HCAI authority to “establish a pricing mechanism” for certain data. Section 127673.8 is specifically for pricing for public data products and “custom reports” while section 127673.82(f) is for nonpublic data.

4. Section 97386 Changes

Reasons for Substantive Changes to Section 97386 Text:

- **Text Changes:** **“The Department will assign a request number to each application for program data submitted under this Article.** When reviewing applications ~~for program data submitted under this Article~~, the Department may do any of the following to make its decision:
 - **Reason:** In its Decision of Disapproval, the Office of Administrative Law stated that there was ambiguity for the data application requirements that asked for “request numbers” (such as proposed sections 97392(a)(1) and (5) and 97393(a)(1) and (5)). HCAI made this change to the text to explain what “request numbers” are. For each data application, HCAI will assign a number to it for tracking and reference—this is the “request number.”

5. Section 97388 Changes

Reasons for Substantive Changes to Section 97388 Text:

- **Text Change:** “(a) This section applies to all applications for program data submitted to the Department under this Article. ~~There may be specific restrictions or requirements depending on the type of data request.~~”
 - **Reason:** In its Decision of Disapproval, the Office of Administrative Law notified HCAI that the use of “specific restrictions or requirements was too vague. The California Medical Association had the same comment (see Comment 17 below). HCAI removed this sentence based on the Decision of Disapproval.
- **Text Changes to subsection (b)(5)(C) and (D):**

“(C) The applicant is requesting other entities to be able to use, control, observe, transmit or store ~~control~~ confidential data who are not necessary for applicant’s proposed use; ~~or~~

(D) The data applicant will use, control, observe, transmit or store the confidential data outside of the United States of America;...”

- **Reason:** HCAI added to and made consistent prior language about the various ways an entity will control or use HPD confidential data by adding “transmit” and “store” to the previous language that only had “control,” “observe,” and “use”. HCAI did this to make it abundantly clear that these regulatory provisions apply to transmission and storage of HPD confidential data so entities are aware that these functions must be considered here. This new language was also added to instances of the same language in later sections as discussed below.

The “or” in (b)(5)(C) was deleted because a new subsection, (b)(5)(E) was added (see below) and thus, (C) was no longer the penultimate subsection in this group.

- **Changes to subsection (b)(5) and (6):**

- **Text Changes:**

- **Addition of (b)(5)(E):** “**(E) The data security for the confidential data does not meet the standards and requirements in section 97406;**”
- **Deletion of (b)(6)(B):** “Regarding applications for the direct transmission of confidential data, ~~(A) T~~ the proposed use of the confidential data can be reasonably achieved by accessing confidential data through the enclave; or ~~(B) The data security for the confidential data does not meet the standards and requirements in section 97406; or~~”

- **Reason:** Previously, the Department revised proposed section 97406 from solely covering direct transmission to covering all confidential data releases. Erroneously, HCAI did not make corresponding changes to proposed section 97388(b) which separated out reasons for denial specifically for direct transmission and for all releases of confidential data. The new changes here fix this and make section 97388 consistent with the new provisions of section 97406.

- **Changes to subsection (c):**

- **Text Changes:**

- “(c) Discretionary Reasons for Denial. The Department ~~may~~ **shall** deny a data application, in whole or in part, if the

Department determines there is good cause to deny the application, including, but not limited to, the following:

(1) The applicant does not **substantially** comply with this Article;

(2) The applicant is required to submit data to the program and is not in **substantial** compliance with this chapter **due to circumstances under the applicant's control**; or ...”

- **Reason:** In its Decision of Disapproval, the Office of Administrative Law notified HCAI that the use of “may” in the top portion of subsection (c) was ambiguous and the Department should change it to “shall.” Based on this, the Department updated the regulation text to “shall.”

With the change from “may” to “shall”, HCAI had to make corresponding changes to some of the subparts of subsection (c)—i.e., examples of “good cause” that would result in denial. This was to make these examples less draconian—that is, HCAI did not want minor issues resulting in mandatory denials. Regarding subsection (c)(1), HCAI added “substantially” before “comply” so that an applicant that makes minor mistakes in complying with HPD data release regulations is not automatically denied. Regarding subsection (c)(2), HCAI again added language so a mandatory submitter to the HPD is not prevented from obtaining data because of minor issues or because of issues not in their control.

6. Changes to Section 97392 and Addition of Section 97393 Regarding Enclave Access to Limited Data.

- **Splitting of the Limited Data Request Provision:** Change of Scope for Section 97392 and Addition of Section 97393:
 - **Text Changes in Section 97392 from being about “Limited Data” to “Standardized Limited Datasets”:** “(a) Data Application. To request access to standardized limited datasets through the enclave...”

- **Addition of new Section 97393, “Applications for Custom Limited Datasets Through the Enclave.”**
- **Reason:** Section 97392 was modified, and Section 97393 was added as HCAI decided to split the original data request type of “Limited Data via the Enclave,” to two separate data request types: (1) “Standardized Limited Datasets via the Enclave” and (2) “Custom Limited Datasets via the Enclave.” This was done after receiving comments stating that it should be more streamlined to obtain standardized limited datasets through the enclave versus custom limited datasets. Since there is a statutory difference in how these datasets are treated (Health and Safety Code section 127673.83(a)), HCAI decided to have different request pathways with differing requirements that make it simpler to obtain standardized limited datasets. For this reason, a new section was created for “custom limited datasets” (i.e., all limited datasets that are not standardized) and the existing Section 97392 was changed to just be for “standardized limited datasets.”
- **Data Description Subsection Change Because of Splitting:** Changes to Section 97392(a)(8) (formerly (a)(5)):
 - **Text Changes:** “(85) Identification of the specific standardized limited dataset, a description of how the project meets the purposes specified by the Department for the standardized limited dataset, and the time period of the requested data. A detailed description of the requested program data to allow the Department to determine whether the data exists, or whether it can be created. This includes the time period of data requested, a list of each confidential data element desired and an explanation of why the data applicant needs each confidential data element.”
 - **Reason:** This change has to do with the splitting of the original Section 97392 to two different sections for the purpose of streamlining access to standardized limited datasets through the enclave (as discussed above). For enclave access to confidential HPD data, HPD statute allows data users to have access to either (1) to the minimum amount of confidential HPD data necessary for an approved project or (2) access to a confidential HPD dataset designed for an approved purpose. (Health and Safety Code section 127673.83(a).) The original Section 97392 required applicants to justify every confidential data element—i.e., method (1) only. Through this change, HCAI decided to utilize method (2) to streamline access to standardized limited datasets via the enclave and requires the applicant to identify the dataset it is requesting and

how its project will meet the purposes for which the dataset was designed so HCAI can evaluate whether the applicant is eligible for the standardized limited dataset. This text is very close to the similar requirement in Section 97396 for direct transmission of standardized limited datasets.

- **For reasons for the application requirements in new Section 97393(a)**, see the Initial Statement of Reasons and below. The Initial Statement of Reasons, starting on page 21 through page 33, states the reasons for following subsections of Section 97393(a): (2) to (4), (8) to (9), (11) to (13), (15) to (17) and (21).
- **For the reason for the unique mandatory reason for denial in new Section 97393(b)**, see the Initial Statement of Reasons, page 41, regarding “Section 97392(b) regarding Enclave Access to ‘Limited Data.’” New Section 97393(b) is the same language addressed in that part of the Initial Statement of Reasons.
- **Changing “data” to “datasets” in Section 97393(a), first sentence:**
 - **Text Change:** “(a) Data Application. To request access to Custom Limited Datasets through the enclave...”
 - **Reason:** HCAI changed “data” to “datasets” to match the defined term “custom limited datasets” in Section 97380.

7. Subsections (a) of Sections 97390 to 97400: Changes to Data Application Requirements

Reasons for Substantive Changes to Application Requirements in Subsections (a) of Sections 97390 through 97400:

Same Changes to All or Most Data Requests: The following discuss changes to application requirements for all or most data requests.

- **Application Submissions through HCAI's Website:** Addition in Sections 97392(a), 97393(a), 97394(a), 97396(a), 97398(a), and 97400(a):
 - **Text Change:** "... must electronically submit an application through the Department's website with all of the following:"
 - **Reason:** The reason for the change is to clarify and specify that requests must be submitted through the Department's website instead of some other electronic method, such as by email. This adjustment provides clear guidance to applicants regarding how to apply for confidential HPD data, helping to ensure consistency and to streamline the handling of requests. This is not included for non-confidential applications under Section 97390 because that process will be processed through another system.
- **Date of Application:** Deletion in subsections (a) in Sections 97392, 97394, 97396, 97398 and 97400, but retention in Section 97390(a)(1)
 - **Text Change:** "~~(1) Date of application.~~"

Reason: The "date of application" requirement was deleted because it will be automatically collected during the data submission process by the HPD confidential data request system. However, the "date of application" was retained in Section 97390 as those requests will be processed through another system.
- **New or Supplemental Application:** Additions to subsections (a) in Sections 97392, 97394, 97396, 97398 and 97400, and new Section 97393(a)(1)
 - **Text Change:** "(1) Designation as a new application or a supplemental application. If a supplemental application, the request number of the previously approved project."
 - **Reason:** This subsection asks if the application is for a new project or if the project has been previously reviewed and approved for HPD data. HCAI has a statutory duty to maintain timeliness in the processing of HPD requests. By establishing whether a project has

been previously approved for HPD, the department enhances efficiency in the review process, enabling HCAI to focus on areas that have undergone changes.

- **Prior Data Applications:** Additions to subsections (a) in Sections 97392, 97394, 97396 and 97398, and new Section 97393(a)(5)
 - **Text Change:** “(5) Whether the applicant has applied for data from the Department previously, and if applicable, the associated request number(s) and project title(s).”
 - **Reason:** This subsection requires the applicant to list any and all prior applications for HCAI data. This allows HCAI to track and manage the different potential datasets available to one data applicant and assess potential risk. This information additionally enables HCAI to better track the overall data volume that has been released by the Department.

- **Alternative Point of Contact:** Addition of new subsection (a)(6) in Sections 97392, 97394, 97396 and 97398, and new Section 97393(a)(6)
 - **Text Change:** “(6) If the point of contact for the application is different than the Data Applicant, the name, title, business address, phone number and email address of the point of contact.”
 - **Reason:** This new subsection asks for the contact information for the point of contact regarding any application questions if different from the applicant. This ensures that HCAI knows who to contact about the data request and obtains alternative methods of contact in the event that one method is ineffective. HCAI needs to ensure efficient communication to meet timeliness standards discussed in section 97410.

The Office of Administrative Law noted the Departments use of ‘email’ was too vague. HCAI’s intent is to collect the email address of the data applicants. Subsequently, HCAI added “address” after email for further clarification.

- **Project Title:** Additions of new subsections, Sections 97390(a)(9), 97392(a)(7),(97293(a)(7), 97394(a)(7), 97396(a)(7), 97398(a)(8) and 97400(a)(5)
 - **Text Change:** “Project Title.”
 - **Reason:** This section is based on the CURES regulation asking for “Project Title.” This subsection asks the applicant to give the unique

project title. The application requirement is to ensure proper identification and tracking of data projects applying for HPD data.

- **Purpose/Use of Data:** Adding new text to Sections 97392(a)(9) (formerly (a)(6)), 97394(a)(10) (formerly (a)(6)), and 97398(a)(10) (formerly (a)(7)); and regarding Section 97393(a)(9)
 - **Note:** These subsections are slightly different based on different statutory requirements, however these sections are about the same issue and the changes are the same.
 - **Text Changes**
 - **To Sections 97392(a)(9):** “(96) A description of the research or analysis purpose for the data, the anticipated use of those data, and how the purpose is consistent with program goals. This includes a description of public data products that may be created with limited data and how these products will be disclosed.”
 - **New Section 97393(a)(9):** “(9) A description of the research or analysis purpose for the data, the anticipated use of those data, and how the purpose is consistent with program goals. This includes a description of public data products that may be created with limited data and how these products will be disclosed.”
 - **To Section 97394(a)(10):** “(106) A description of the research project, the anticipated use of the data, and how project offers significant opportunities to achieve program goals. This includes a description of public data products that may be created with research identifiable data and how these products will be disclosed.”
 - **To Section 97398(a)(10):** “(107) A description of the research project, the anticipated use of the data, and how the project offers significant opportunities to achieve program goals. This includes a description of public data products that may be created with confidential data and how these products will be disclosed.”
 - **Reason:** For these subsections, HCAI added a requirement for the applicant to state the “anticipated use of the data.” HCAI added this because it enhances our comprehension of potential

privacy and security concerns.

- **Medi-Cal Data:** Adding new subsections, Sections 97392(a)(10), 97393(a)(10), 97394(a)(9), 97396(a)(9), 97398(a)(10) and 97400(a)(8):
 - **Text Change:** “If the applicant is requesting access to Medi-Cal data, how the use of the data will contribute to the project.”
- **Reason:** This subsection requires the applicant to state how the use of Medi-Cal variables will contribute to their research project. HCAI has a statutory duty to ensure applications are for the minimum amount of confidential data, as discussed in section 97388(b)(5). Requiring applicants to identify their specific need and uses for the Medi-Cal data ensures that projects are receiving the minimum required confidential data to meet the purposes directly connected with... the administration of” Medi-Cal.
- **Outside Data:** Adding new text to Sections 97392(a)(12) (formerly (a)(8)), 97394(a)(12) (formerly (a)(8)), 97396(a)(13) (formerly (a)(9)), 97398(a)(14) (formerly (a)(10)), and 97400(a)(11) (formerly (a)(9)); and regarding Section 97393(a)(12)
 - **Text Change:** “List of any data from outside the program which the data applicant wants to use or link with the confidential data and the anticipated use of those data.”
 - **Reason:** HCAI added this new language, “the anticipated use of those data” because it enhances our comprehension of potential privacy and security concerns.
- **Individual, Contractor and Third-Party Information:** Changes to text to 97392(a)(13) (formerly (a)(9)), 97394(a)(13) (formerly (a)(9)), 97396(a)(14) (formerly (a)(10)), 97398(a)(15) (formerly (a)(11)), and 97400(a)(12) (formerly (a)(10)); and regarding Section 97393(a)(13):
 - **First Change**
 - **Text Change:** “List of all ~~contractors and~~ individuals, contractors, and other third parties....”
 - **Reason for First Change:** HCAI added “other third parties” to this as there could be other organizations who are not individuals or contractors who are assisting or involved in a project who may have access to confidential data. HCAI

needs to know of all entities who will access the data to evaluate privacy and security risks.

- **Second Change**

- **Text Change:** “...who are anticipated to ~~observe, use, or control~~ use, control, observe, transmit or store confidential data and the physical location(s) from which they may work.
- **Reason for Second Change:** As discussed above, HCAI added to and made consistent prior language about the various ways an entity will control or use HPD confidential data by adding “transmit” and “store” to the previous language that only had “control,” “observe,” and “use”. HCAI did this to make it abundantly clear that these regulatory provisions apply to transmission and storage of HPD confidential data so entities are aware that these functions must be considered here.

- **Third Change**

- **Text Change:** “This includes each ~~contractor’s or individual’s, contractor’s, or other third parties’~~ name, organization, phone number, business address, email address, title, position, and role regarding the data (such as part of the data analysis team or the information technology team). This includes the data applicant.
- **Reason for Third Change:** The Department added a requirement for the contact information for these individuals, contractors and other third-parties because if there is a data breach or other urgent situation, HCAI can contact these entities and to have multiple ways to contact these entities.

- **Agreements with Contractors and Third-Parties:** Adding new subsections, Sections 97392(a)(14), 97393(a)(14), 97394(a)(14), 97396(a)(15), 97398(a)(16) and 97400(a)(13)

- **Text Change:** “If the applicant is working with a contractor or other third party, a copy of the contract(s) or agreement(s) between the collaborating entities.”
- **Reason:** This subsection asks for a copy of any contract or agreement between the data applicant and any contractors or other third parties. Contracts and agreements outline the roles and responsibilities of these entities, and, from past experience, it is

essential for HCAI to understand these relationships and what these contractors/third parties will do to properly evaluate privacy and security risks and whether these agreements are consistent with HPD requirements.

- **Signature – Changes for Multiple Applicants:** Similar Changes to Sections 97392(a)(20) (formerly (a)(13)), 97394(a)(24) (formerly (a)(16)), 97396(a)(21) (formerly (a)(16)), and 97398(a)(25) (formerly (a)(19)); and regarding Section 97393(a)(21):
 - **Note:** These subsections are slightly different based on different statutory requirements, however these sections are about the same issue and the changes are the same
 - **Text Changes**
 - **To 97392(a)(20), 97394(a)(24), and 97396(a)(21) and regarding Section 97393(a)(21):** “Signature of the data applicant(s), if an individual or individuals, or the authorized representative, and the date of signature....”
 - **Changes to 97398(a)(25):** “(~~2549~~) Signature of the data applicant(s), and the date of signature....”
 - **Reason:** Consistent with the changes to the definition of “data applicant(s)”, HCAI changed these sections to clearly indicate that there can be multiple data applicants for a data application and that all such applicants must sign the application.
- **Signature – Adding “True and Correct” Text:** Changes to Sections 97390(a)(10), 97392(a)(20), 97393(a)(21), 97394(a)(24), 97396(a)(21), 97398(a)(25), and 97400(a)(18):
 - **Text Changes:** “This signature shall certify **that** the information provided in the application **is true and correct.**”
 - **Reason:** In its Decision of Disapproval, the Office of Administrative Law stated that the signature requirement for all the proposed application sections was problematic because the text was not consistent with the description in the ISOR which had more detail. To resolve this, HCAI added the detail from the ISOR into the regulatory text. HCAI believes this makes the requirement clearer.

Same Changes to Enclave Access Data Requests: The following discuss the same changes to application requirements for enclave access data requests.

- **Security Measures:** Changes to 97392(a)(17) (formerly (a)(12)), 97394(a)(18) (formerly (a)(13)), and 97400(a)(16) (formerly (a)(13)); and regarding Section 97393(a)(17)
 - **Note:** These subsections are slightly different based on different statutory requirements, however these sections are about the same issue and the changes are the same
 - **Text Changes**
 - **To 97392(a)(17) (formerly (a)(12)) and 97394(a)(18) (formerly (a)(13)); and regarding Section 97393(a)(17):** “The security measures to protect against the unauthorized disclosure of confidential data, such as physical security for the physical location(s) where access will take place, controls limiting who can view the data, and background screening for individuals who will access the data. This includes the specific data access method for any contractors or other third parties.”
 - **To Section 97400(a)(16)(A):** If requesting confidential data through the enclave, the security measures to protect against the unauthorized disclosure of confidential data, such as physical security for the physical location(s) where access will take place, controls limiting who can view the data, ~~and~~ background screening for individuals who will access the data. ... This includes the specific data access method for any contractors or third parties; or
 - **Reason:** Inquiring about the data applicant’s intended method of data access, including any contractor or third-party involvement, is essential for implementing standard security measures. Understanding how the data will be accessed, stored, and managed allows for the establishment of appropriate security protocols to safeguard sensitive information effectively.
- **Security Plan:** Adding new subsections, Sections 97392(a)(18), 97393(a)(18), and 97394(a)(19) and new text to Section 97400(a)(16)(A):
 - **Note:** These subsections are slightly different based on different statutory requirements, however these sections are about the same issue and the changes are the same
 - **Text Changes**

- **Additions of new Sections 97392(a)(18), 97393(a)(18), and 97394(a)(19):** “The applicant’s data security plan for protecting access to the confidential data. This includes an acknowledgment of having read the data security standards and requirements in section 97406, and a description of how the data security standards and requirements in section 97406(b) will be met.”

- **Adding to Section 97400(a)(16)(A):** “If requesting confidential data through the enclave, the security measures to protect against the unauthorized disclosure of confidential data, such as physical security for the physical location(s) where access will take place, controls limiting who can view the data, ~~and~~ background screening for individuals who will access the data, the state agency’s security plan for protecting access to the confidential data, a description of how the data security standards and requirements in section 97406(b) will be met, and an acknowledgment of having read the data security standards and requirements in section 97406....”

- **Reason:** HCAI modified proposed Section 97406 to apply to all data requests when originally Section 97406 was limited to direct transmission of confidential data (regarding this change, see below). For this reason, inquiring about the applicant’s security plan, is essential for checking whether the applicant will have sufficient security for the data. Understanding how the data will be accessed, stored, and managed allows HCAI to ensure that appropriate security protocols to safeguard data are being implemented.

For new Sections 97392(a)(18), 97393(a)(18), and 97394(a)(19), HCAI deleted the word “data” because it appears in some of these subsections but not all. So to make these sections consistent, HCAI deleted “data.”

- **Enclave Use Information:** Adding new subsections, Sections 97392(a)(19), 97393(a)(20), 97394(a)(23), and 97400(a)(17)

- **Text Change:** “The following information is required for access to requested data through the enclave.

(A) The volume of data the applicant is intending to upload into the enclave.

(B) The individual responsible for uploading data to the enclave.

(C) For each individual who will access the data, the **type of access the applicant wants for the individual, required access level** and any additional software or tools **required the applicant wants available for the individual in the enclave.**

- **Reason:** HCAI needs this information about how an applicant plans to use the enclave to facilitate providing enclave access to the applicant and to determine if there are any issues or problems with how the applicant wants to use the enclave.

Subsection (A) asks for volume because the enclave has technical limitations regarding space and how much can be uploaded to the enclave at once. This information will allow HCAI to coordinate with the applicant early in the process and troubleshoot any potential technical issues.

Subsection (B) asks for the identity of the individual who will be responsible for uploading data to the enclave so HCAI knows who to contact if there are issues with an applicant uploading data.

Subsection (C) originally asked for the “required access level” for each individual who will access confidential data through the enclave. HCAI needs this information because the enclave has different types of access available for individuals and this information will allow HCAI to assess and provide the correct access to individuals. In its Decision of Disapproval, the Office of Administrative law stated “required access level” was ambiguous as there was nothing in HPD statute, current regulations, or these proposed regulations outlining what this term meant and requesters would not be familiar with this term. For this reason, HCAI changed the term to “type of access” and defined it in Section 97380(v) (the definition is discussed above).

Subsection (C) also asks for information regarding what software or tools the applicants wants each individual to have in the enclave. This is to better facilitate providing access and evaluating the requests for such software and tools. HCAI replaced the original “required” language with “the applicant wants for the individual in the enclave” to make this requirement clearer.

Same Changes to Non-Standardized Limited Dataset Requests from the Public: The following discuss the same changes to application

requirements for public requests for all data except standardized limited datasets.

- **Minimum Data:** Adding new subsections, Sections 97393(a)(19), 97394(a)(20), 97398(a)(21):
 - **Text Change:** “Detailed information explaining how the requested data is the minimum amount of confidential data required for the project.”
 - **Reason:** HCAI asks for detailed information explaining how the requested data aligns with the requirement to request the minimum amount of confidential data, in alignment with section 97388(b)(5)(B). HPD statute limits disclosure “to the minimum amount of potentially identifiable data necessary for an approved project.” This subsection is needed for this statutory limitation—that HCAI has sufficient information to analyze whether the request is only asking for the minimum amount of data necessary. With this information, HCAI can determine whether to deny, in whole or in part, a data application that asks for unnecessary data elements per proposed section 97388(b)(5) (discussed above).

Same Changes to Direct Transmission Data Requests: The following discuss the same changes to application requirements for direct transmission data requests.

- **Data Security:** Changes to Sections 97396(a)(19) (formerly (a)(14)), 97398(a)(20) (formerly (a)(15)), and 97400(a)(16)(B) (formerly (a)(13)(B)):
 - **Note:** These subsections are slightly different based on different statutory requirements, however these sections are about the same issue and the changes are the same
 - **Text Changes**
 - **To Sections 97396(a)(19), and 97398(a)(20):** “The applicant’s data security plan for protecting the confidential data, with supporting documentation. This includes an acknowledgment of having read the data security standards and requirements in section 97406, a description of how the data security standards and requirements in section 97406 will be met and the specific data access method for any contractors or other third parties.”
 - **To Section 97400(a)(16)(B):** ” If requesting direct

transmission of confidential data, the ~~data applicant's state~~ agency's security plan for protecting the confidential data, with supporting documentation. This includes an acknowledgment of having read the data security standards and requirements in section 97406, including a description of how the data security standards and requirements in section 97406 will be met, and the name, phone number, and email address of the individual who will be responsible for information security of the confidential data. This includes the specific data access method for any contractors or third parties.

- **Reason:** This section has been revised to ensure that state agencies comprehensively review all security standards. Moreover, it underscores the imperative for safe and secure environments, extending scrutiny to encompass their contracts and third-party arrangements.

Same Changes to Sections 97394 and 97398

- **Committee for the Protection of Human Subjects (CPHS)**

Documentation: Changes to Sections 97394(a)(22) (formerly (a)(15)) and 97398(a)(24) (formerly (a)(18))

- **Text Changes:** "A copy of the applicant's draft or submitted application to the Committee for the Protection of Human Subjects. (15) Documentation that the Committee for the Protection of Human Subjects has approved the project pursuant to subdivision (t) of Section 1798.24 of the Civil Code, or the data applicant's plan to seek the Committee's approval during the Department's review or after the Department conditionally approves the application pursuant to section 97410.
- **Reason:** HCAI requires this in the application to determine whether the statutory requirement has been met, or whether the applicant has a suitable plan to obtain this approval. Additionally, HCAI must confirm information submitted to CPHS is consistent with information submitted to HCAI.

Reasons for Non-Substantive Changes to Sections 97390 to 97400 Text:

- The Department updated the lettering in this section as new subsections were introduced.

8. Sections 97394(a)(10): Non-Substantive Change

Reasons for Non-Substantive Change to Section 97394(a)(10) Text:

- **Text Change:** "... and how **the** project offers significant opportunities to achieve program goals."
- **Reason:** HCAI added "the" to make this grammatically correct.

9. Sections 97396(a): Changes to Application Requirement for the Direct Transmission of Standardized Limited Datasets

Reasons for Substantive Changes to Section 97396(a) Text:

- **Deletion of "either in whole or in part" and requirement to list of data elements not requested in a standardized limited dataset**
 - **Text Changes**
 - **To Section 97396(a):** "Data Application. To request direct transmission of a standardized limited dataset, ~~either in whole or in part,~~ an individual or organization must electronically submit an application with all of the following"
 - **To Section 97396(a)(8) (formerly (a)(5)):** "... This includes an explanation of why the data applicant needs each confidential data element desired from the standardized limited dataset, ~~and a list of confidential data elements from the standardized limited dataset that the data applicant is not requesting, if any.~~"
 - **Reason:** Originally, as explained in the Initial Statement of Reasons, page 26 about this issue, HCAI did not want to directly transmit the entire standardized limited dataset if the applicant did not need all the confidential data elements. HCAI decided to change that approach as the purpose and goal of standard limited datasets is to have a file that satisfies a wide range of uses without having to

create a custom file. If the nature of the request either does not fit under one of our standard use cases and/or is of a more sensitive nature then it would go to custom or research.

- **Change regarding the requirement to describe how the applicant’s project meets the purposes specified for the standardized limited dataset and addition of program goals requirement**
 - **Text Changes**
 - **To Section 97396(a)(8) (formerly (a)(5)):** “Identification of the standardized limited dataset the data applicant wants, ~~including the time period of data, and a description of how the project meets the purposes specified by the Department for the standardized limited dataset.~~ including the time period of data, and a description of how the project meets the purposes specified by the Department for the standardized limited dataset. ...”
 - **To Section 97396(a)(9) (formerly (a)(6)):** “A description of the data use, and how the purpose is consistent with program goals. ~~how the use is consistent with the purpose of the standardized limited dataset that the Department specified.~~ .”
 - **Reason:** The Department is set to establish standardized limited datasets, incorporating potential purposes of a data project to determine eligibility for the requestor. The standard limited datasets are intended to streamline the process of accessing data while ensuring the projects aligns with specific objectives or criteria.

10. Sections 97394(b)(4) and 97398(b)(5): Changes to Unique Mandatory Reason Regarding Committee for the Protection of Human Subjects Approval

Reasons for Substantive Changes to Sections 97394(b)(4) and 97398(b)(5) Text:

- **Text Changes to 97394(b)(4) and 97398(b)(5):** ~~The Committee for the Protection of Human Subjects pursuant to subdivision (t) of Section 1798.24 of the Civil Code does not approve the research project~~ The data applicant is unable to provide documentation that the Committee for the Protection of Human Subjects has approved the project, pursuant to subdivision (t) of Section 1798.24 of the Civil Code”
 - **Reason:** These request types necessitate approval from CPHS. Failure to provide such approval to the Department would result in

the denial of the request. This stringent requirement underscores the importance of adhering to established protocols and ensuring that all necessary authorizations are obtained before proceeding with data access.

11. Section 97396(b): Addition of Specific Mandatory Reason for Denial of Application for the Direct Transmission of Standardized Limited Datasets

Reasons for Substantive Changes to Section 97396 Text:

- **Text Changes to 97396(b):** “Mandatory Reasons for Denial. In addition to section 97388, the Department shall deny an application under this section, in whole or in part, if the Department determines that:

(3) The Data Release Committee did not recommend project approval.; or

(4) The application **includes requests a standardized limited dataset that contains identifiable information for any individual or organization who furnishes, bills, or is paid for health care in the normal course of business. for identifiable provider information.**

- **Reason:** HCAI added (b)(4) to prohibit the direct transmission of standardized limited datasets which have identifiable provider information. Providers include health care facilities like hospitals and clinics and medical practitioners such as doctors and medical groups. As some comments have stated, provider information is sensitive information and could be misused or affect the privacy of individuals. For instance, information linking providers with prices could be used for anti-competitive purposes to the detriment of the public and California.

Although HCAI will review and deny improper uses, direct transmission, compared to enclave access, poses a much higher risk that data will be accidentally or purposely redirected for other uses or improperly disclosed. For this reason, HCAI added this mandatory reason for denial and applicants may still get this data through other ways in the HPD (through the enclave or via Section 97398).

HCAI will allow this data to be directly transmitted via Section 97398 because that avenue is limited only to researchers and has much more stringent requirements than Section 97396.

HCAI subsequently changed this subsection by replacing “identifiable provider information” to “identifiable information for any individual or organization who furnishes, bills, or is paid for health care in the normal course of business.” HCAI did this because “provider” is already used in in HPD statute, Health and Safety Code section 127672(a)(1)(D), and defines “provider” in a special way to only include facilities and organizations. Based on this and to make it very clear that this also includes individual health care practitioners, HCAI decided to replace the term “provider” with a more detailed description of the entities protected by this section. This new language is from the Health Insurance Portability and Accountability Act’s regulatory definition of “health care provider” in 45 C.F.R. section 160.103 (a new document relied on for this rulemaking). HCAI believes this definition captures all the entities, individual persons and organizations, that HCAI wishes to protect per the reasoning discussed above.

12. Section 97400 Changes

Reasons for Substantive Changes to Section 97400 Text:

- **Replacing “~~Data Applicant~~” or “~~Applicant~~” with “State Agency:** In this Section 97400 which is about data requests from other state agencies, HCAI replaced the terms “~~data applicant~~” or “~~applicant~~” to “state agency” in the following subsections (a)(5), (a)(7), (a)(8), (a)(13), (a)(14), (a)(15), (a)(16), (a)(17), (b)(1), and (b)(2).
 - **Reason:** HCAI made these changes to be abundantly clear that this section exclusively pertains to state agencies.

13. Section 97402 Changes

Reasons for Non-Substantive Changes to Section 97402 Text:

- **Text Changes to Section 97402(a):** “To access confidential data under Sections 97394, 97396, or 97398, it is required that the Data Release Committee recommend approval of the data applicant’s project.”
- **Text Changes to Section 97402(b):** “Once the data applicant completely submits an application under Sections 97394, 97396, or 97398, the Department shall send the Data Release Committee a copy of the application for the Committee to make its recommendation.”
 - **Reason:** The Office of Administrative Law made the Department aware of a grammatical correction that needed to be made in the text: removing the “s” from “sections”. The Department agreed with these changes as it was the proper construction of these parts and included it in the updated regulation text.

14. Section 97404 Changes

Reasons for Substantive Changes to Section 97404 Text:

- **Text Changes to Section 97404(b):** “(b) The applicant may seek the approval of the Committee for the Protection of Human Subjects before or concurrently with its data application to the Department, ~~or may wait after the Department conditionally approves the application pursuant to section 97410 to seek the Committee’s approval.~~”
 - **Reasons:** Section 97404 subsection (b) was changed as it is now required to obtain approval from CPHS before the Department can approve the data request.

Reasons for Non-Substantive Changes to Section 97404 Text:

- **Deleting Plural “S”:**
 - **Text Change:** (a) To access confidential data under Sections 97394 or 97398...”
 - **Change to Reference:** “Reference: Sections 127673.83, Health and Safety Code.”
 - **Reason:** The Office of Administrative Law made the Department aware of a grammatical correction that needed to be made in the text: removing the “s” from “sections”. The Department agreed with these changes. For the text change, this is the proper grammar, and for the reference change, this was a mistake by HCAI to include the “s”.

15. Section 97406 Changes

Reasons for Substantive Changes to Section 97406 Text:

- **Text Changes to Subsection (a)(2):** “‘FIPS 140 Validation’ means current validation by the NIST’s Cryptographic Module Validation Program ~~that a module conforms to the standards of the currently applicable Federal Information Processing Standards Publication 140.~~”

- **Reason:** After discussion with the Office of Administrative Law, HCAI decided to delete this language because it was not necessary and may cause confusion. Referencing the Cryptographic Module Validation Program appears sufficient to define this term and this is supported by the new document relied on, the “FIPS 140 Validation – the National Institute of Standards and Technology” website .
- **Change of Scope for Section 97406**
 - **Text Changes:**
 - **to Section 97406 Title:** “Data Security Standards for ~~Direct Transmission of~~ Standardized Limited Datasets and Other Confidential Data.”
 - **Addition of New Section 97406(b):** “All data applicants for confidential data must meet the following requirements:”
 - **Reason:** HCAI changed the scope of this regulation because it determined that there needed to be security requirements for access to confidential HPD data regardless of enclave or direct transmission. As discussed below, HCAI believes these basic requirements are necessary to protect confidential data. HCAI placed these new requirements here so there would be a single place to look up security requirements.
- **Addition of Section 97406(b)(1):** “(1) Anyone accessing confidential data shall receive training on information privacy and data security no less than once per year for the duration of their access to confidential data.”
 - **Reason:** Subsection (b)(1) requires applicants receive training on information privacy and data security once per year. This is a requirement from HCAI’s “Required Practices for Safeguarding Access to Confidential Data” document which is currently used for HCAI’s other confidential data programs. This is needed to ensure anyone viewing or interacting with confidential data are familiar with state and federal laws regarding the proper handling of confidential information, such as health information.
- **Addition of Section 97406(b)(2) and Deletion of prior Section 97406(d)(8) (formerly (c)(8)):**
 - **Text Changes:**

- **Addition of Section 97406(b)(2):** “(2) All software, information systems, computers, and other devices that are used to access confidential data, including through the enclave, shall have security patches applied in a reasonable time.”
- **Deletion of prior Section 97406(d)(8):** ~~“All software, information systems, computers, and other devices that process, store, or use confidential data shall have security patches applied in a reasonable time.”~~

- **Reason:** Subsection (b)(2) requires applicants to have their devices that are used to access confidential HPD data to have “security patches applied in a reasonable time.” This is a requirement from HCAI’s “Required Practices for Safeguarding Access to Confidential Data” document. This is needed so that devices have or display confidential information are not left vulnerable when a device is updated through security patches. This will minimize the risk of improper disclosure of confidential HPD data.

Subsection (d)(8) was deleted because subsection (d) is only for direct transmission of confidential data and HCAI, as discussed above, decided to apply this basic requirement to all data requests.

- **Addition of Section 97406(b)(3) and Deletion of Section 97406(d)(9) (formerly (c)(9))**

- **Text Changes:**

- **Addition of Section 97406(b)(3):** “(3) Passwords to access confidential data shall, at a minimum, have 16 characters with at least one capital letter, one small letter, one number, and one special character.”
- **Deletion of Section 97406(d)(9):** ~~“Passwords to access confidential data shall, at a minimum, have 16 characters with at least one capital letter, one small letter, one number, and one special character.”~~

- **Reason:** Subsection (b)(3) requires minimum requirements for passwords used by applicants to access confidential HPD data. The National Institute of Standards and Technology (NIST), an agency of the United States of America, states that password length has been found

to be a primary factor in characterizing password strength. Whereas NIST requires a minimum of eight (8) characters, industry experts commonly state as best practice a minimum of 16 characters is the new standard.

Subsection (d)(9) was deleted because subsection (d) is only for direct transmission of confidential data and HCAI, as discussed above, decided to apply this basic requirement to all data requests.

- **Addition of Section 97406(b)(4):** “(4) All information systems, computers, and other devices that are used to access confidential data, including through the enclave, shall have active antivirus controls. Applicants must provide the security antivirus controls in place by product name and current version.”
 - **Reason:** This subsection requires applicants utilize antivirus controls and provide HCAI with the product name and current version. This is a requirement from HCAI’s “Required Practices for Safeguarding Access to Confidential Data” document. This is needed to prevent threat actors from leveraging users’ systems in order to access or otherwise compromise the HPD solution. Active, up-to-date antivirus controls on end-user devices will reduce the chance for malicious software to be applied against HPD.
- **Change to Section 97406(d)(5):** “Unencrypted confidential data, including hard copies, shall be stored, and used within applicant’s work offices, and when unattended, shall be stored in secured areas with controlled access procedures, where it is not viewable from the outside, and is under 24-hour guard or monitored alarm.”
 - **Reason:** This standard has been updated to align with today’s security standards. By incorporating the latest practices and protocols, this update ensures that the organization remain resilient against evolving threats and vulnerabilities.
- **Change to Section 97406(d)(8) (formerly (c)(10)):** “The applicant must use signature based and non-signature based malicious code protection mechanisms at system entry and exit points. ~~Applicants shall state malicious code protection product names and current version of the products in their data applications.~~”
 - **Reason:** The change was implemented to harmonize with standard privacy and security procedures. This adjustment ensures that the organization remains compliant with established best practices governing data protection and security.

Reasons for Non-Substantive Changes to Section 97406 Text:

- The Department updated the lettering and numbering in this section as new subsections were added and some were deleted.
- The Department also recently updated this section to delete some “s” after “section” to be grammatically correct.

16. Section 97408 Changes

Reasons for Substantive Changes to Section 97408 Text:

- **Change to Section 97408(a)(1):** “Specify how the proposed project will benefit the administration of the Medi-Cal program;”
 - **Reason:** Federal law requires that Medi-Cal data “concerning applicants and recipients” is only used or disclosed for “purposes directly connected with... the administration of” Medi-Cal. This was incorporated into California law, which states, that Medi-Cal data “shall not be open to examination other than for purposes directly connected with... the administration of” Medi-Cal.” Based on the above, and communication with DHCS, Section 97408(a)(1), the Department updated the regulation text to include “administration of the” to this subsection.

17. Section 97410 Changes

Reasons for Substantive Changes to Section 97410 Text:

- **Changes to Section 97410(a)(1):**
 - **Text Changes:**
 - “(B) ~~For data applications in which a~~ **A** Data Release Committee recommendation is required for the application as stated in”

~~Section 97402 or if the Department requests input from the Committee, within 15 days of receiving input or the recommendation from the Committee; or”~~

(C) The Department requests input from the Data Release Committee for the application under Section 97836(b); or

(D) The data request includes data subject to review by the Department of Health Care Services under Section 97408; or

(E) The data request includes confidential data, which requires approval from the Committee for the Protection of Human Subjects; or

(F) If the Department has good cause to extend time.”

- **Reason:** First, HCAI deleted the time period in (B). This was done because the input or recommendation from the Data Release Committee may be complex or unclear and a certain time limit may not be a reasonable amount of time for HCAI to clarify or resolve issues raised by the Committee before having to decide on a data application. To obtain clarity or to resolve issues, HCAI may need to discuss with the Committee again and the Committee is expected to meet, at most, monthly.

Second, in its Decision of Disapproval, the Office of Administrative Law stated there was a “syntax issue” with the original subsection (a)(1)(B) because it was an “unfinished sentence” and “use[d] language incorrectly.” Based on this, and for clarity, HCAI decided to separate out the original (a)(1)(B) to subsections (a)(1)(B) and (a)(1)(C) and to correct the grammatical issue by making them complete sentences.

By adding the new subsection (a)(1)(C), this subsection had to be re-lettered.

- **Change to Section 97410(b)(2)(A):** “(A) The Department shall state in the notice the scope of the approval, the ~~fee~~ price for the data as set by the Department, and how the data will be provided to the applicant; and...”
 - **Reason:** As discussed above regarding section 97384, there was confusion on HCAI’s usage of the terms “fee” and “price” in these regulations. For clarity, “fee” was replaced with “price” here to make it clear that this is about the program data price (as described in section 97384(a)).

- **Deletion of Section 97410(c):** ~~“(c) Conditional Decision Notices. For data applications which require the approval of the Committee for the Protection of Human Subjects, the Department may issue a notice of conditional approval before the Committee makes its decision.~~

~~(1) The applicant shall provide the Department with the Committee’s decision within 10 days of receiving the decision.~~

~~(2) Within 30 days of receiving the Committee’s decision from the data applicant, the Department shall issue a final decision notice to the applicant. The Department’s final decision may be different from its notice of conditional approval.”~~

- **Reason:** Section (c) was removed because HCAI now requires data requestors to obtain approval from CPHS before HCAI approves of the project. This adjustment reflects a commitment to compliance and collaboration across state entities, ensuring all necessary regulatory protocols are followed before any actions are taken.

- **Changes to Reference:** “Reference: Sections **127673.8**, 127673.82, and 127673.83, Health and Safety Code.”

- **Reason:** HCAI added Health and Safety Code section 127673.8 to the references because HCAI erroneously did not list it. As this regulatory section mentions “price”, that statute, like section 127673.82(f), gives HCAI authority to “establish a pricing mechanism” for certain data. Section 127673.8 is specifically for pricing for public data products and “custom reports” while section 127673.82(f) is for nonpublic data.

18. Section 97412 Changes

Reasons for Substantive Changes to Section 97412 Text:

- **Change of Title to Section 97412:** “Data Use Agreements ~~for Confidential Data~~”

- **Reason:** The title was erroneous as this section also covers data use agreements for non-confidential data. The text was deleted to correct this.
- **Replacing Term “Individual” with “Person”**
 - **Text Changes:**
 - **To Section 97412(a)(1)(B):** “ (a)(1)(B) Each ~~person individual~~ who will observe, use, or control confidential data under an approved application shall execute a **confidential** data use agreement.”
 - **To Section 97412(a)(2):** “(a)(2) For non-confidential program data, **if the Department determines there is good cause for non-confidential data use agreements,** the Department ~~may~~ **shall, for good cause,** require an approved applicant or the ~~persons individuals~~ who will observe, use, or control **non-confidential** program data to execute **non-confidential** data use agreements...”
 - **To Section 97412(b):** “(b) Contents for Confidential Data Use Agreements ~~for Applicants and Individuals.~~ A **confidential** data use agreement between the Department and the applicant or ~~persons individuals~~ approved for confidential data under this Article shall have, at least, the following:”
 - **To Section 97412(b)(1):** “The applicant or ~~person individual~~ shall only observe, use, control, or store confidential data in the United States of America.”
 - **Reason:** HPD statute, Health & Safety Code section 127673.83(a), requires “each person” who receives or works with confidential HPD data to “sign a data use agreement.” Originally, the text mistakenly only required the data applicant and each “individual” who had access to the confidential data to execute a data use agreement. However, this is not consistent with HPD statute as “person” means more than individuals and includes organizations. Also, contractors can be organizational entities and individual researchers may hold confidential data with their employers. For these reasons, HCAI changed “individual” to “person” to be consistent with statute. “Person” copies statutory language and appropriately captures organizational contractors, third parties, and a researcher’s employer.
- **Adding “Confidential” or “Non-Confidential” to Distinguish Different Types of Data Use Agreements**

- **Text Changes**

- **To Section 97412(a)(1)(A):** “Each approved applicant shall execute a confidential data use agreement.”
- **To Section 97412(a)(1)(B):** “Each person ~~individual~~ who will observe, use, or control confidential data under an approved application shall execute a confidential data use agreement.”
- **To Section 97412(a)(2):** “For non-confidential program data, if the Department determines there is good cause for non-confidential data use agreements, the Department ~~may shall,~~ **for good cause**, require an approved applicant for the persons ~~individuals~~ who will observe, use, or control non-confidential program data to execute non-confidential data use agreements...”
- **To Section 97412(b):** “A confidential data use agreement between the Department and the applicant or persons ~~individuals~~ approved for confidential data under this Article shall have, at least, the following...”
- **To Section 97412(b)(2):** “The confidential data use agreement shall be governed, and construed in accordance with, the laws of the State of California and all litigation that may arise as a result of the agreement shall be litigated in the Superior Court of California, County of Sacramento.”

- **Reason:** In its Decision of Disapproval, the Office of Administrative Law believed this section was unclear because HCAI used the terms “confidential data use agreement” and also just “data use agreement.” The Office stated that there could be more than one meaning based on the different terms—whether there was one type of data use agreement, or two different types. HCAI addressed this issue by adding language to make clear that there are 2 types of data use agreements, “confidential” and “non-confidential”, which relates to the HPD data being disclosed. Specifically, HCAI added “confidential” and “non-confidential” before “data use agreement” to clarify this and to identify whether provisions apply to one or the other data use agreement.

- **For Non-Confidential Data Use Agreements, Adding More Language and Regarding Good Cause and Other Changes**

- **Text Change in section 97412(a)(2):** “For non-confidential program data, if the Department determines there is good cause for non-

confidential data use agreements, the Department ~~may shall~~, **for good cause**, require an approved applicant or the ~~persons~~ **individuals** who will observe, use, or control **non-confidential** program data to execute **non-confidential** data use agreements. **Good cause includes, but is not limited, to the following:**

(A) the applicant will receive data about individuals who are not patients or consumers and the determines that further disclosure of that data poses a safety or privacy risk to those individuals; or

(B) the applicant will receive payment data or financial data and the Department determines that further disclosure of that data would have harmful financial or anti-competitive effects.”

- **Reason:** In its Decision of Disapproval, the Office of Administrative Law stated that the original section 97412(a)(1) was problematic because the ISOR “articulate[d] specific standards” to what constitutes “good cause” that were missing in the regulatory text. The Office also noted that the word “may” made this requirement too uncertain when it would be used despite the existence of “good cause.” To resolve these issues, HCAI incorporated the examples from the ISOR into the regulatory text to give applicants more guidance and changed “may” to “shall.”
- **New Section 97412(c)**
 - **Addition of Section 971412(c): The Department shall tailor each data use agreement to ensure appropriate data use.**
 - **Reason:** This issue was raised in discussions with the Office of Administrative Law. The Department added this section regarding how each data use agreement will be tailored to notify applicants that their data use agreement will be customized based on their specific data use and what data they will receive. Customization helps address unique risks, compliance requirements, and ethical considerations, ensuring that sensitive or confidential data is used appropriately, securely, and within legal or regulatory boundaries. It also allows for clear expectations and accountability based on the specific project or research being conducted.

19. Section 97414 Changes

Reasons for Substantive Changes to Section 97414 Text:

- **Replacing Term “Fee” with “Price”**
 - **Text Changes:**
 - **To Title of Section 97414:** “~~Fee~~ Price Reduction.”
 - **To Section 97414(a)(1):** “(a) For specific data applications, the Department may reduce program data ~~fees~~ prices on the Department’s ~~fee~~ price schedule...”
 - **To Section 97414(a)(1):** “(a)(1) the financial hardship of data applicants, such as students with needs-based financial aid working toward completion of required academic milestones, or government or nonprofit organizations whose funding sources for their projects do not cover data ~~fees~~ prices...”
 - **Reason:** HPD statute indicates that HCAI must have mechanisms to reduce the cost of the data—see Health and Safety Code section 127674(f). Section 97414 is to meet this statutory requirement and creates a partial price waiver or price reduction process for entities regarding the program data price. HCAI made the change from “fee” to “price” for clarity to distinguish the “application fee” from the “program data price” which are separate things. This change is also in line with the new changes to Section 97384(a) regarding “price”.
- **Change to Section 97414(a):** “if it determines there is good cause for reduction, supported by documentation.”
 - **Reason:** HCAI requires a data applicant to demonstrate good cause for a price reduction. The data applicant must submit supporting documentation for the Department to review the applicant’s reasoning for good cause.
- **Addition of Section 97414(d):** “(d) Price reductions will be considered on a per project basis.”
 - **Reason:** Subsection (d) states that HCAI will consider price reductions on a per project basis. This was added to clarify that, to ensure fairness to different applicants, HCAI will consider reductions one project at a

time and applicants with multiple applications will not have an advantage by having many applications or projects with HCAI.

- **Addition of Section 97414(e):** “(e) Price reduction requests will be considered in the order received until available funds for price reductions are exhausted or price reductions are no longer compatible with program sustainability.”
 - **Reason:** Subsection (e) states that HCAI will consider price reductions in the order they are received until funds for price reductions are exhausted or cannot be done because of the HPD's financial status. The HPD program has a limit to the funds available for price reductions and this subsection informs applicants of this limitation so applicants are not surprised that this may be a reason for denial of a price reduction.

- **Addition of Section 97414(e):** “(f) Partial price reductions will be considered. Full price reductions may be considered for any project if supported by sufficient justification and documentation.”
 - **Reason:** Subsection (f) states that HCAI may consider partial or full price reductions. This was added to inform applicants that price reductions may cover the full price of data. This section also notifies applicants that full reductions are possible if the full reduction is supported by the applicant’s justification and documentation.

- **Changes to Reference:** “Reference: Sections 127673.8 and 127673.82 and 127674, Health and Safety Code.”
 - **Reason:** HCAI added Health and Safety Code section 127673.8 to the references because HCAI erroneously did not list it. As this regulatory section is about “price”, that statute, like section 127673.82(f), gives HCAI authority to “establish a pricing mechanism” for certain data. Section 127673.8 is specifically for pricing about public data products and “custom reports” while section 127673.82(f) is for nonpublic data.

Based on the Office of Administrative Law’s direction, HCAI removed section 127674. The Office believed that the reference to section 127674 would confuse applicants because that statute specifically uses the term “fee” instead of “price.” It was thought that including this statute would confuse the public regarding when this proposed regulation would apply.

Reasons for Non-Substantive Changes to Section 97414 Text:

- The Department updated the lettering in this section as new subsections were added.

20. Section 97416 Changes

Reasons for Substantive Changes to Section 97416 Text:

- **Changes to Section 97416(c):** “(c) Data users shall not include PII or record-level data regarding individuals who are not patients or individual consumers in their public data products if ~~such disclosure infringes on an individual’s privacy or safety.~~ the Department determines that the disclosure would be a mandatory reason for denial under section 97388(b) or if the Department determines that there is good cause to prevent the disclosure.”

- **Reason:** HCAI received several public comments regarding this subsection (c) (see below) and as a result, HCAI made the above changes. As an initial note, the public comments to Section 97416(c) focused on individual provider information, but the regulation is for any non-patient/non-consumer individual information that may enter the HPD. However, HCAI proposed this regulation mostly with individual provider data in mind.

The comments about proposed section 97416(c) have been on opposite ends of the spectrum. One commenter (SEIU California) stated that identifying individual provider information was relevant for public data products and believed that proposed section 97416(c) was too restrictive regarding the public release of this information. Other commenters (the California Association of Health Plans and the California Medical Association) stated that HCAI should be more restrictive about public release of identifiable individual provider data and to protect it like identifiable individual consumer and patient data.

Based on these comments, HCAI proposes to change section 97416(c) to add language allowing HCAI to prevent disclosure for the mandatory denial reasons in section 97388(b) or if there is other good cause to prevent disclosure.

Commenter SEIU California brought up a good point about the original text of section 97416(c) possibly being too restrictive regarding privacy. Per the California Constitution, an individual has a right to privacy but an invasion of privacy may be legally justified if it furthers legitimate and important competing interests. HCAI does not want to completely prohibit public data products with private information if there is a legitimate countervailing interest, but HCAI cannot completely ignore an individual's right of privacy. From this comment, HCAI believes it needed to change the original language about privacy.

Commenters California Association of Health Plans and California Medical Association both stated that individual provider information should be treated in the same manner as consumer/patient information. HCAI does not believe so because individual providers are different from patients/consumers. Information about individual providers, since they are licensed and do business in the State, already have information that is public and available.¹ Thus, some of their information in an HPD public data product is not as sensitive compared to individual consumers/patients. HPD statute recognizes this as HPD statute specifically protects patient/consumer information², but not individual provider information. Furthermore, there are legitimate reasons to include such information in public data products that are consistent with HPD's statutory goals.

Commenter California Association of Health Plans states that the original language in section 97416(c) is too vague and that there are no specific standards when HCAI will review public data products with individual provider information. HCAI does not believe that the terms "privacy" or "safety" are too vague, especially as the California constitutional right of privacy is well-established. In any case, this process is somewhat open because this is just the beginning of this data release program and HCAI does not know the variety of data requests and uses that will occur under this program. For this reason, HCAI needs flexibility to learn and handle these situations when they arise.

Commenter California Medical Association raises good points about potential "state provider shield laws", issues about reputational harms, and anti-competitive effects from releasing record-level or

¹ See the Department of Consumer Affairs "license search" at <https://search.dca.ca.gov/?BD=800&TP=8002>.

² Health & Safety Code sections 127671(b), and 127673.81(a).

identifiable data about individual providers. However, as noted above, HCAI does not want a blanket prohibition on record-level or identifiable individual provider data in public data products for reasons stated above. From this comment, HCAI believes it needs to broaden the circumstances in which individual provider information can be protected from disclosure to account for the everchanging health care environment. The changes to section 97416 give HCAI more leeway regarding public data products with individual provider information based on the harms noted by the Association.

Based on the above comments, HCAI proposes to change section 97416(c) to match its application denial reasons in section 97388. This accounts for Commenter SEIU California's comment about privacy as it adopts the "unreasonable risk to privacy" standard from section 97388 which is more flexible than the original language of preventing disclosure if it just "infringes" privacy. The changes also account for Commenters California Association of Health Plans and California Medical Association's comments as it broadens HCAI's ability to protect this information based on issues beyond privacy and safety. HCAI believes this balances concerns about individual providers while allowing for valuable information to be publicly released.

II. DOCUMENTS INCORPORATED BY REFERENCE (Cal. Code Regs., title 1, section 20(c)(1) and (2))

The proposed regulations incorporate the following documents by reference. These documents were directly available from HCAI for public viewing during the initial 45-day public comment period and throughout this regulatory process. Furthermore, as noted below, these documents were available on publicly-accessible websites throughout this rulemaking.

1. The Federal Information Processing Standards Publication 200, "Minimum Security Requirements for Federal Information and Information Systems," dated March 2006, are being incorporated by reference because it would be cumbersome and impractical to include this into regulatory text because this is a well-known and widely used standard and HCAI wants data applicants and public to know that HCAI is using this specific standard in these regulations. Also, this document is being incorporated by reference because incorporating this standard into text would require heavy editing that could inadvertently change the standard and because it is 9 pages long with its own numerous definitions. This document was publicly available from the following website of the United States of America throughout this rulemaking: <https://csrc.nist.gov/pubs/fips/200/final>.

2. The National Institute of Standards and Technology (NIST) Special Publication 800-53, Revision 5, “Security and Privacy Controls for Information Systems and Organizations,” dated September 2020, are being incorporated by reference because it would be cumbersome and impractical to include this document into the regulatory text since this document is over 450 pages and includes possibly hundreds of security and privacy controls. This document was publicly available from the following website of the United States of America throughout this rulemaking: <https://csrc.nist.gov/pubs/sp/800/53/r5/upd1/final>.
3. The NIST Special Publication 800-53B, “Control Baselines for Information Systems and Organizations,” dated October 2020, are being incorporated by reference because it would be cumbersome and impractical to include this document into regulatory text as the document is 71 pages and over 30 pages of tables which would be difficult to state in regulatory text. This document was publicly available from the following website of the United States of America throughout this rulemaking: <https://csrc.nist.gov/pubs/sp/800/53/b/upd1/final>.
4. Section 5 and Appendix A of the NIST Special Publication 800-88, Revision 1, “Guidelines for Media Sanitization,” dated December 2014, are being incorporated by reference because it would be cumbersome and impractical to include the 15 or so pages and tables of methods and considerations for media sanitization into the regulatory text. This document was publicly available from the following website of the United States of America throughout this rulemaking: <https://csrc.nist.gov/pubs/sp/800/88/r1/final>.
5. The California Health and Human Services Agency’s “Data De-Identification Guidelines (DDG),” version 1.0, dated September 23, 2016, are being incorporated by reference because the document contains nearly 70 pages of guidance to be used by departments and offices in the CHHS to assess data for public release. This document was publicly available from the following public website throughout this rulemaking: <https://chhsdata.github.io/dataplaybook/documents/CHHS-DDG-V1.0-092316.pdf>.

III. SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE FIRST COMMENT PERIOD OF JUNE 2, 2023 THROUGH JULY 18, 2023.

During the first comment period, HCAI received 28 comments and a public hearing was not held for this rulemaking because no one submitted a request for a public hearing.

County of Los Angeles, Department of Public Health: Comment 1 was submitted on behalf of the County of Los Angeles Department of Public Health's, Director of the Division of Medical and Dental Affairs (DMDA) Dr. Naman Shah, MD, PhD by Dr. Gayane Meschyan, PhD, MA.

Comment 1: The commenter asks HCAI to consider providing access to identifiable plan-level (i.e., payer-level) and provider-level data. The author states that deidentifying the data would result in a loss of policy potential which are important and relevant to health authorities.

Response: No changes were made in response to Comment 1. At the time of this comment, the proposed regulations did not prohibit the release of identifiable plan-level or provider-level data. HCAI narrowly modified the proposed regulations to prohibit the direct transmission of standardized limited datasets with identifiable provider information in Section 97396(b)(4), but the proposed regulations still allow this data to be released in other ways. HCAI will evaluate such requests on a case-by-case basis.

SEIU California: The following comments were submitted by Matt Lege on behalf of members of the Service Employees International Union California State Council (SEIU California).

Comment 2: The author asks HCAI to include payer and provider identifiers in standardized limited datasets since such datasets reduce administrative burdens and barriers and make it easier for applicants to obtain data.

Response: A change was made in response to Comment 2. The direct transmission of standard limited datasets now can be denied if it contains identifiable information for any individual or origination who furnishes, bills, or is paid for health care in the normal core of business.

Comment 3: The commenter asks HCAI to consider requiring asking applicants to disclose funding sources for all requests for confidential data, and not just for Medi-Cal data, in order to understand relevant funding sources and affiliations held by applicants.

Response: No changes were made in response to Comment 3. HCAI considered adding a funding disclosure requirement but believes that it is sufficient that the current regulations require applicants to disclose their use of the confidential HPD data which will disclose the beneficiaries. Also, HCAI does not believe the identity of funders is relevant because the applicant is being vetted, not their funders. HCAI will determine if the applicant will use the data appropriately and whether the applicant will sufficiently protect the data. On a case-by-case basis, HCAI has the authority to request the identity of funders if HCAI believes there is a reason for asking this information.

Comment 4: The commenter asks HCAI to consider removing the need for applicants to list the physical address from which data users will access the data

as this may lead to unnecessary disclosure of personal addresses in the current remote work environment.

Response: No changes were made in response to Comment 4. HCAI asks for “physical location” where confidential data may be used. HCAI needs this information to check if a data application can be approved and to determine what security measures are needed. For instance, whether the data will be accessed outside the United States or whether it will be accessed in a private home. Based on this information, HCAI may deny or deny in part an application or require certain security measures in a data use agreement. Also, if there is a data security incident, HCAI will need this information to properly respond to the situation. Since this information may be nonpublic or private, HCAI plans to protect this information, in part by withholding home addresses (if indicated by applicant and if justified) if there are public requests for this information.

Comment 5: The commenter asks HCAI to consider removing the requirement that an applicant requesting standardized limited datasets through the enclave must provide a detailed description of the requested program data or justification for each data element, i.e., original Section 97392(a)(5) (now Section 97393(a)(8)). The author states that this is a redundancy.

Response: Changes were made in response to Comment 5. HCAI agrees that it should be easier to obtain standardized limited datasets through the enclave and believes that HPD statute allows this. For this reason, HCAI updated the regulations by creating a separate way to specifically request enclave access to standardized limited datasets—see modifications to Section 97392. Section 97392(a)(8) now requires the applicant to give a description of how the project meets the purposes specified by the Department for the standardized limited dataset instead of justifying each data element. For more information on this, see above updates to the Initial Statement of Reasons regarding Section 97392.

Comment 6: The commenter asks HCAI to consider creating the flexibility to easily expand research projects over time without having to go through the full application process. The author recommends establishing streamlined processes for expanding the scope of a project, adding recent data, approving new linkages etc.

Response: Changes were made in response to Comment 6. HCAI updated the regulation to allow for supplemental applications. Section 97380(u) states, “Supplemental applications are application related to a previously approved project.

Comment 7: The commenter states the original version of Section 97416(c) prohibiting the public release of identifiable individual provider information if it infringes on their privacy or safety is too restrictive and would make it “very difficult” for any public data product with individual provider information to be released. Commenter asks HCAI make Section 97416(c) less restrictive.

There were also comments from others about this topic. These comments are summarized with Comment 7 as HCAI’s response takes these comments into consideration as well.

Regarding **Comment 12** below, the California Association of Health Plans (CAHP) states that Section 97416(c) is too vague and asks, to the extent possible, that HCAI protect individual provider data to the same extent as individual consumer and patient data.

Regarding **Comments 24 and 27** below, the California Medical Association (CMA) brought up similar concerns and for various reasons, asks HCAI to prohibit any non-aggregated, identifiable physician and physician group/practices information in public data products, and that if included, granular data must be de-identified. The commenter asks HCAI to consider prohibiting the disclosure of physician data that is identifiable at the individual physician level. CMA also requests that Section 97416(c) protections based on privacy and safety be expanded to cover other circumstances including for anticompetitive effects, sensitive services that may be subject to state provider shield laws and data that could harm physicians’ reputations.

Response: Changes to Section 97416(c) were made in response to Comments 7, 12, 24 and 27. See above Updates to the Initial Statement of Reasons, Part I.17, regarding Section 97416(c) changes, which addresses these comments and the changes made in response to these comments.

Ronli Levi and Hilary Seligman: Comment 8 was submitted by Ronli Levi, MPH, RD and Hilary Seligman, MD, MAS. The commenters were writing on behalf of themselves and not the University of California, San Francisco.

Comment 8: The commenters state that as researchers studying health and social policies across various domains within the California Health and Human Services Agency, including HCAI, the development of more streamlined processes for applying and accessing data across these agencies would greatly enhance their work.

Response: No changes were made in response to Comment 8. The scope of this rulemaking is only about the HPD program and HCAI cannot

regulate other departments through these proposed regulations. However, in the future, HCAI hopes to incorporate data from other departments in the HPD.

California Association of Health Plans (CAHP): Comments 9 to 12 were submitted by Anete Millers on behalf of the California Association of Health Plans.

Comment 9: The commenter asks HCAI to consider adding proprietary business intelligence (i.e., specific contracted rates, for specific provider entities, patients, and situations) to the definition of “Confidential Data” in Section 97380.

Response: No changes were made in response to Comment 9. As noted in the ISOR, the definition of "confidential data" in section 97380 is solely about data that HPD statute specifically protects—patient or consumer data (see Health & Safety Code sections 127671(b) and 127673.5). HPD statute has special requirements for requests for this type of data and for this reason, HCAI wanted to create a simple term for this data to use in these regulations. HPD statute does not protect "proprietary business intelligence" (including "specific contracted rates") or other business data and CAHP did not provide a rationale to add this data to the definition of “confidential data.”

Furthermore, HCAI does not wish to put special regulatory protections for this type of data or completely prohibit public release of granular business data because such uses are highly relevant to HPD's statutory goals for "greater transparency" and providing "public benefit for Californians and the state.”

Comment 10: The commenter asks HCAI to consider posting all completed data requests on a website for a 30-day comment period to increase feedback, accountability, and scrutiny of requests as part of the application review process.

Response: No changes were made in response to Comment 10. Section 97386 allows HCAI to do this on a case-by-case basis. HCAI does not believe a requirement for public posting/public comment is necessary or practical for all requests because of the statutory requirements for HPD data release. For the most sensitive requests, regarding research identifiable data and transmittal of confidential HPD data, requests are statutorily required to go through one or two public committees, the HPD Data Release Committee and the Committee for the Protection of Human Subjects. Thus, for these types of requests, the public already has a chance to comment on these data applications.

Comment 11: The commenter asks HCAI to consider the following when approving or denying applications:

- Intended use of data for entrepreneurial or commercial reasons,
- Request by a data submitting entity for all of its competitors' proprietary data,
- Use in subpoenas,
- Non-confidential data should not be health plan identifiable, and
- States do not always specify how the data will be used/published – aggregate or detailed level.

Response: No changes were made in response to Comment 11. HCAI appreciates this comment and plans to review each application carefully to prevent misuse of HPD data which may include the factors noted in this comment. Under section 97388, HCAI has the discretion to deny an application for good cause, which may include the factors raised by this comment.

Statutorily, HCAI can only release confidential HPD data for uses that are consistent with HPD's statutory goals, which is ultimately about improving health care in California. Every request will be reviewed carefully for compliance with this requirement. With this in mind, HCAI responds to the commenter's specific statements as follows:

1. One of these statutory HPD goals is for entities to use HPD data "to develop innovative approaches, services, and programs that may have the potential" to improve health care to individuals (HSC 127671(d)). This could possibly include commercial or entrepreneurial ventures and thus, HCAI cannot prohibit this entirely.
2. Regarding requests for competitor data, without knowing the specific data use, HCAI does not wish to have a blanket prohibition for this scenario as there may be legitimate uses of this data. Even if there are some anticompetitive effects, such uses could promote other HPD goals and benefit California.
3. Subpoenas are outside the scope of these regulations as subpoenas are court or other governmental orders and are not data requests.
4. Regarding non-confidential data and health plan identifiers, again without knowing the specific data use, HCAI does not wish to have a blanket prohibition regarding this as there are legitimate uses for this data by users outside HCAI. Also, even if there are some anticompetitive effects, the use of this data may promote other important HPD goals.

5. Regarding how data will be used or published, these are already covered by the proposed regulations. For confidential data requests, applicants are required to describe their uses and their anticipated public data products and are not allowed to deviate from these if approved (via the data use agreement). Section 97416 also reiterates HPD statutory prohibitions against publishing record-level or identifiable information about patients and consumers and also covers such information about individuals who are not patients or consumers. Regarding health plan identifiers, HCAI plans to review such uses on a case-by-case basis.

Comment 12: The commenter states that Section 97416(c) is too vague and asks, to the extent possible, that HCAI protect individual provider data to the same extent as individual consumer and patient data.

Response: Changes to Section 97416(c) were made in response to Comments 7, 12, 24 and 27. See above Updates to the Initial Statement of Reasons, Part I.17, regarding Section 97416(c) changes, which addresses these comments and the changes made in response to these comments.

California Medical Association: Comments 13 through 28 were submitted by Janice Rocco on behalf of the California Medical Association. Ms. Rocco is also a member of the HPD Advisory Committee at this time.

Comment 13: The commenter states that the regulations omitted how physician information will be managed. Thus, commenter asks HCAI to change the definition of “confidential data” in Section 97380 to include physicians. CMA states that individual physician or other health care practitioner information needs to be protected in these regulations because such identifiable information can hurt these individuals’ personal and professional reputations and provide misleading data to consumers. CMA also notes concerns about other states criminalizing certain health care services which increases the risk of civil and criminal liability to physicians and their staff. They also note that disclosure of identifiable physician data may violate state provider shield laws and could have anticompetitive effects.

Response: No changes were made in response to Comment 13. First, regarding public disclosure of identifiable health care practitioner data, as noted in the ISOR and above, HPD statute explicitly protects and prohibits the public release of identifiable or record-level patient or consumer information but does not discuss other information, such as professional information about individual providers or business information (see above comment by the California Association of Health Plans about the definition of “confidential data”). HCAI believes this was purposeful because public release of information about individual providers, regarding their professional work, may have legitimate uses especially in light of the

legislative intent for HPD to provide "greater transparency" to health care in California. Furthermore, not all identifiable or record-level data regarding individual providers, regarding their professional work, is confidential or private, or nearly as private, compared to consumer/patient information.

Regarding disclosures to qualified data applicants, requests for individual provider information will be reviewed by HCAI in its current process: once in the beginning when evaluating whether to approve a data request and release data to an applicant (see section 97388(b)), and also before the publication of a public data product that has record-level or identifiable individual provider information (section 97416(c)). HCAI believes these are sufficient to protect individual providers while allowing legitimate uses and disclosures (see proposed changes to section 97416 in response to public comments).

Regarding anticompetitive effects, HCAI will review for these issues when evaluating a data request or public data product because HCAI can only release data if consistent with HPD goals. However, as noted above, even if there are some anticompetitive effects, the release and use of this data may promote other important HPD goals and there are legitimate uses for this data (see SEIU California's comment above regarding public data products with individual provider information). For these reasons, HCAI does not wish to have a blanket prohibition regarding the release and use of identifiable individual provider data.

Comment 14: The commenter asks HCAI to delete all references to the fields of research currently required in the definition of "researcher" in Section 97380.

Response: No changes were made in response to Comment 14. HCAI believes the purpose of the HPD statutory requirement allowing direct transmission of confidential data only to "researchers" is to make sure that the person receiving the data knows how to handle and use it. HCAI believes that having the requirement that the individual have a degree "in a field that conducts research" makes it more likely that the individual can actually and appropriately use confidential data because having such a degree indicates that the individual had formal training in research.

Comment 15: The commenter supports having a non-refundable application fee and a program data fee and encourages HCAI to consider setting both fees at a reasonable level.

Response: Changes were made in response to Comment 15. HCAI did change the proposed regulations, Section 97384, to include a definitive application fee of \$100, which HCAI believes is reasonable based on its purpose (see discussion above regarding this change). Program data

fees are not stated in these regulations and will be part of a separate price schedule. In creating this price schedule for program data, one of HCAI's goals is to keep the data affordable so a wide variety of stakeholders can obtain the data while keeping in mind that the HPD program does not have a continuous funding source. HCAI has and plans to obtain public input on its price schedule, including through the two public HPD advisory committees.

Comment 16: The commenter asks HCAI to include a requirement that the review of applications must be guided by the program goals in statute and only when and to the extent necessary to confirm whether an application complies with statutory program requirements because this will create a more straightforward, fair standard.

Response: No changes were made in response to Comment 16. HPD statute only allows release of HPD data if it is consistent with the HPD's statutory goals (see HSC section 127673.83). As part of the application process, the proposed regulations require an applicant to state how their purpose is consistent with HPD goals and also require HCAI to reject an application in which a purpose is inconsistent with HPD goals (Section 97388(b)(4)). Proposed section 97386 notes the steps HCAI can take to clarify or check this requirement (among other things) and gives HCAI flexibility to do so because HCAI expects each application to be different. Since each application may be different, different actions may be necessary to confirm whether the applicant meets statutory or regulatory requirements. For this reason, HCAI does not believe there is a more specific or straightforward process at this time.

Comment 17: The commenter states the second sentence of Section 97388(a) is ambiguous and overly broad, indicating HCAI can create additional restrictions on a case-by-case basis and the author suggests making changes to this language. The commenter is also uncertain of the circumstances in which Section 97388(b)(2) applies and is concerned that this mandatory reason for denial may have broader, unintended implications inhibiting the ability to use statutorily mandated data. For this reason, the commenter urges HCAI to narrow this and to make sure that any agreements HCAI enters into to obtain more data for the HPD should not extend beyond the data obtained and not hinder existing HPD data.

Response: Changes were made related to comment 17 based on the Office of Administrative Law's Disapproval Decision. Regarding section 97388(a), HCAI removed this second sentence to alleviate ambiguity. However, proposed section 97388(c) gives HCAI discretion to deny applications for good cause, which may be about additional restrictions and requirements determined on a case-by-case basis. Section 97388(c) also provides examples when this may occur. Additionally, data use

agreements may need to include additional restrictions and requirements based on the requester, the requested data and the uses of the data.

Regarding Section 97388(b)(2), HPD may obtain data from voluntary submitters and other governmental entities. HPD statute (HSC section 127673.3(b)) also requires HCAI to supplement certain parts of the HPD with "private sources of valid and reliable data." Thus, this section is not about HPD data collected under HPD's legal mandates. To obtain this other data for HPD, HCAI may need to enter into agreements with the data sources and agree not to release that data to the public or in certain circumstances. If this mandatory reason for denial does not exist, it may dissuade data sources from providing data to the HPD to the detriment of HPD. HCAI does not believe this will have unintended consequences regarding legally mandated data because this section specifies data collected under an agreement. HCAI does not believe it can legally limit its ability, via an agreement, to disclose HPD data collected under its legal mandate, and will keep this in mind when entering into agreements for other data.

Comments 18, 19, and 20: The commenter asks HCAI to clarify sections 97394(b)(3), 97396(b)(3) and 97398(b)(4) regarding the mandatory reason for denial of the HPD Data Release Committee not recommending project approval. CMA proposes new language to ensure that applications that have not been reviewed by the Committee will not mandatorily be denied.

Response: No changes were made in response to Comments 18 to 20. The language in these sections about the Data Release Committee's project approval requirement comes directly from statute and changing it may create unintended consequences or issues of statutory interpretation. Also, regarding an application that requires the Data Release Committee's approval, the Committee may recommend against the application, but this is not necessarily the end of the application (i.e., mandatory denial). HCAI expects that in situations like this, the applicant will be afforded the chance to modify or take further action on their application and go back to the Committee. Also, with the current language, HCAI does not believe an application will be "mandatorily denied" if it is just sitting with the Committee and regardless, such an application cannot be approved per statute unless the Committee recommends approval.

Comment 21: The commenter asks HCAI to consider changing language in section 97400(b)(1) as the commenter believes it sets an excessively high and subjective standard, giving the Department overly broad authority to deny applications from other state agencies. Commenter takes issue with the "necessary" language and suggests changing this to whether the request is "inconsistent with and irrelevant to" the state agency's duties.

Response: No changes were made in response to Comment 21. HCAI does not have discretion to change the "necessity" language because it is required by HPD statute, and it is a standard from the California Information Practices Act (see, respectively, Health & Safety Code section 127673.83(d) and Civil Code section 1798.24(e)). HPD statute incorporates Civil Code section 1798.24(e) which is about releasing data to another state agency and this Civil Code section states that a state agency can disclose data:

"... to another agency if the transfer is necessary for the transferee agency to perform its constitutional or statutory duties, and the use is compatible with a purpose for which the information was collected...."

Comment 22: Regarding HPD data requests for Medi-Cal data that require the approval of the Department of Health Care Services (DHCS) (Section 97408), the commenter asks HCAI to reference the rules governing DHCS's rules, guidance, or policies containing DHCS's applicable standards to assist prospective applicant and minimize unnecessary requests and denials.

Response: No changes were made in response to Comment 22. HCAI will make information about DHCS's rules, guidance, and policies available if it has those documents. It is not appropriate to reference this information in HCAI's regulations because they are DHCS's materials and may change at DHCS's discretion.

Comment 23: The commenter asks HCAI to incorporate an expected timeframe in which DHCS or the Committee for the Protection of Human Subjects (CPHS) must complete their review of data requests and if existing law already sets such a timeframe, HCAI should reference that law these regulations.

Response: No changes were made in response to Comment 23. DHCS and CPHS are not part of HCAI and HCAI does not have control over their operations. For this reason, HCAI cannot state expected timeframes for these entities. HCAI is not aware of any current timeframes set out in existing law.

Comment 24: The commenter asks HCAI to prohibit any non-aggregated, identifiable physician and physician group/practices information in public data products, and that if included, granular data must be de-identified. Commenter states that this is to protect physician safety and privacy, because of state provider laws, and to prevent unfair reputational harms.

Response: Changes to Section 97416(c) were made in response to Comments 7, 12, 24 and 27. See above Updates to the Initial Statement of Reasons, Part I.17, regarding Section 97416(c) changes, which

addresses these comments and the changes made in response to these comments.

Comment 25: The commenter asks HCAI to consider using the defined term “confidential data” instead of reiterating the types of data that comprise that defined term in section 97416(a).

Response: No changes were made in response to Comment 25. The definition of "confidential data" in proposed section 97380(c) is solely about HPD data. Proposed section 97416 has a larger scope and includes any identifiable or record-level data which may have been created by using confidential HPD data and a data user's outside data to create public data products.

Comment 26: The commenter states that Section 97416(b) requirement that HCAI review all public data products with consumer or patient information is overly broad, and would result in an inordinate workload and inevitable bureaucratic delays in the publication of data. CMA asks HCAI to narrow this provision in light of HCAI’s limited resources.

Response: No changes were made in response to Comment 26. Commenter did not provide an alternative on how HCAI could narrow this process and, especially since this program has not started, HCAI does not believe there is better process to achieve HPD statutory purposes. HCAI believes checking every public data product with consumer/patient information is necessary now because of HPD statutory mandates to ensure the privacy, security, and confidentiality of patients and consumers. Once private information is made public, it is difficult, if not impossible, to remedy the breach, and with this regulatory process in place, HCAI does not believe it will be an inordinate amount of work or cause significant delays. HCAI will learn more about this process once this program starts and will reassess and refine it after obtaining more experience and knowledge.

Comment 27: The commenter reiterates earlier comments about prohibiting the public disclosure of identifiable provider data. Commenter goes on to state if HCAI does not completely prohibit this, that HCAI make changes to Section 97416(c) and provide a broader range of circumstances to prevent public disclosure of identifiable individual data than just infringement of privacy or safety. The commenter asks HCAI to include violating state laws and leading to anticompetitive effects as further reasons to prevent disclosure of identifiable individual physician data.

Response: Changes to Section 97416(c) were made in response to Comments 7, 12, 24 and 27. See above Updates to the Initial Statement of Reasons, Part I.17, regarding Section 97416(c) changes, which

addresses these comments and the changes made in response to these comments.

Comment 28: The commenter asks HCAI to consider ensuring that all public documents, including any proposed rulemaking documents, are published in an accessible format.

Response: HCAI appreciates this comment and initially made a mistake by not publishing the documents in an accessible format in the first public comment period from June 2, 2023 to July 18, 2023. This was an oversight, and HCAI updated its website with the regulation text ADA-accessible on August 2, 2024.

IV. SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE SECOND COMMENT PERIOD OF DECEMBER 18, 2023 THROUGH FEBRUARY 1, 2024.

After the first comment period, HCAI changed its proposed regulations. For these changes, HCAI sent out a notice in accordance with Government Code section 11346.8(c) on December 18, 2023 and initiated a 45-day comment period for the changes and for an Updated ISOR. During this second comment period, HCAI received 12 comments in writing. Additionally, HCAI received a comment during the HPD Advisory Committee Meeting on January 25, 2024 by one of the HPD Advisory Committee members.

California Medical Association: Comments 29 through 39 were submitted by Janice Rocco on behalf of the California Medical Association. Ms. Rocco is also a member of the HPD Advisory Committee at this time.

Comment 29: The commenter noted a typographical error in the first sentence of Section 97380, referring to “the definitions in section 93700.”

Response: A change was made to the regulations to correct this to “97300.”

Comment 30: The commenter reiterated Comment 13 from the first comment period.

Response: See Response to Comment 13.

Comment 31: The commenter reiterated Comment 17 regarding Section 97388(a) from the first comment period.

Response: See Response to Comment 17.

Comment 32, 33, and 34: The commenter reiterated Comments 18, 19, and 20 from the first comment period.

Response: See Response to Comments 18, 19, and 20.

Comment 35: The commenter states it supports the mandatory denial reason for direct transmission of a standardized limited dataset if the dataset has “identifiable provider information” in Section 97396(b). However, the commenter believes it is unclear whether the term “providers” in that subsection includes individual health care practitioners or not. The commenter asks HCAI to revise Section 97396(b)(4) to specifically include the statutory definition of “suppliers” as referenced in the HPD statutes, to be sure that individual health care practitioners are included in this.

Response: No changes were made in response to Comment 35. HPD statute defines provider and suppliers, and it also references the APCD-CDL. The APCD-CDL defines provider as both individuals and facilities. These regulations are written to align with the APCD-CDL while enacting statute. Providers are encompassing of individual and facility.

Comment 36: The commenter reiterated Comment 21 from the first comment period.

Response 36: See Response to Comment 21 for HCAI’s response.

Comment 37: The commenter reiterated Comment 22 from the first comment period.

Response 37: See Response to Comment 22 for HCAI’s response.

Comment 38: The commenter reiterated Comments 24, 25, 26, and 27 from the first comment period.

Response 38: See Responses to Comment 24, 25, 26, and 27 for HCAI’s responses.

Comment 39: The commenter stated it was confused whether the revised regulatory text HCAI had posted in December 2023 was part of the formal rulemaking process or not because a notice document was not on its website. Commenter noted that HCAI has removed prior rulemaking documents from its website in December 2023 and acted inconsistently from other state agencies regarding the posting of rulemaking documents. Commenter encouraged HCAI to post a notice clearly outlining the rulemaking process on its website in a manner consistent with HCAI’s sister departments.

Response 39: Changes were made to HCAI’s rulemaking process in response to Comment 39. HCAI appreciates this feedback and after the December 2023 rulemaking actions, HCAI re-posted all rulemaking documents to its website and initiated a third comment period for all the modifications to the original text and the Updated Initial Statement of Reasons on April 4, 2024. In December 2023, HCAI believes it did comply with its rulemaking obligations and notified the public of the second public comment period via email, including sending an email to CMA. Discussion of the December 2023 changes also occurred at two public meetings, respectively at the HPD Data Release Committee meeting and also at the HPD Advisory Committee meeting.

V. SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE THIRD COMMENT PERIOD OF APRIL 04, 2024 THROUGH APRIL 19, 2024

After the second comment period, HCAI again changed its proposed regulations. Also, per Comment 38, HCAI wanted to have another comment period to clarify any confusion caused by the second comment period. For these reasons, HCAI sent out notice in accordance with Government Code sections 11346.8(c) and 11347.1 on April 4, 2024 and initiated a 15-day comment period for all the changes to the original regulatory text and the Updated ISOR. HCAI received 12 comments during this comment period.

RAND Health Care Researchers: Comments 40 through 46 were submitted by Petra Rasmussen, Ph.D. and Cheryl Damberg, Ph.D. on behalf of RAND Health Care Researchers. Ms. Damberg is also a member of the HPD Advisory Committee at this time.

Comment 40: The commenter generally states that HCAI needs to work to eliminate barriers for Medi-Cal data in the HPD. Commenter is concerned with the burden on researchers of having two review processes and the potential delays to research and policymaking resulting from the requirement to receive approval from both HCAI and the Department of Health Care Services (DHCS) (i.e., Section 97408 and Section 97410(a)(1)(C)). Additionally, the commenter, from prior experience, states it takes a year to obtain approval for data from DHCS and more time to actually receive the data. Commenter states these delays are significant barriers to research and problematic for grants that researchers obtain for research.

Response 40: No changes were made in response to Comment 40. As discussed in the ISOR and in this FSOR regarding Section 97408, HCAI believes that DHCS review is required by law. It is not appropriate to reference this information in HCAI's regulations because they are DHCS's processes and may change at DHCS's discretion.

Comment 41: The commenter is concerned with the requirement in Section 97408 requiring the data project “benefit... the administration of the Medi-Cal program” Medi-Cal data. The author proposes HCAI change the rule to state the benefits of the Medi-Cal program or Medi-Cal beneficiary.

Response 41: No changes were made in response to Comment 41. See above discussion in this document regarding updates to the Initial Statement of reasons for Section 97408.

Federal law requires that Medi-Cal data “concerning applicants and recipients” is only used or disclosed for “purposes directly connected with... the administration of” Medi-Cal. This was incorporated into California law, which states, that Medi-Cal data “shall not be open to examination other than for purposes directly connected with... the administration of” Medi-Cal purposes.” Based on the above, and communication with DHCS, Section 97408(a)(1), the Department updated the regulation text to include “administration of the” to this subsection”.

Comment 42: The commenter states HCAI should have timeline requirements or deadlines for DHCS to approve HPD data requests that include Medi-Cal data.

Response 42: No changes were made in response to Comment 42. See HCAI’s response to Comment 23 which makes a similar comment. DHCS is not part of HCAI and HCAI does not have control over their operations. For this reason, HCAI cannot create deadlines or timeframes for DHCS.

Comment 43: The commenter asks HCAI to clarify in section 97404 whether approval from “the Committee for the Protection of Human Subjects” is to come from the State of California’s Committee for the Protection of Human Subjects or from the applicant’s own institutional review board.

Response 43: No changes were made in response to Comment 43. HCAI believes it is clear from statute (Health and Safety Code section 127673.83(b)(2)(B)) and the regulatory text that Section 97404 is referring to the “Committee for the Protection of Human Subjects (CPHS) for the California Health and Human Services Agency (CHHSA)” as stated in Section 1798.24(t)(1) (which is referenced by Section 127673.83(b)(2)(B)). In Section 1798.24(t)(1), CPHS is distinguished from other “institutional review boards” and HPD statute does not reference other “institutional review boards.”

Comment 44: The commenter asks HCAI to add regulations outlining the process to add data users to existing data use agreements or adding external data. Furthermore, commenter asks for regulatory text regarding requirements/restrictions for linking directly transmitted data to external data sources.

Response 44: No changes were made in response to Comment 44. HCAI believes it is more appropriate to have the process to add data users or more data in the data use agreement instead of these regulations. HCAI believes the flexibility of being able to tailor such requirements in a data use agreement based on the applicant and data use is appropriate at this time especially since this data release program is in its infancy. By maintaining flexibility and allowing room for evolution, HCAI can respond effectively to emerging challenges, and incorporate insights gleaned from practical experience.

Regarding requirements or restrictions for linking directly transmitted data to external data, HCAI wants to consider these on a case-by-case basis during the application process and via the processes that will be in data use agreements. Since data projects will be unique and since this program is just beginning, HCAI does not want to set brightline rules yet.

Comment 45: The commenter requests for clarification regarding Section 97416(c) regarding public data products and identifiable individual data regarding non-patients/non-consumers. Specifically, the commenter asks whether this section includes “individual providers” and if so, what types of providers. Also, the commenter asks whether this section applies to organizational entities and notes that public release of record-level information about individual providers may be beneficial.

Response 45: No changes were made in response to Comment 45. HCAI believes that the text of Section 97416(c) clearly applies to all individuals and includes individual providers, as the term “individuals”, is used in this section and this term is commonly used to discuss actual human beings. HCAI also agrees that public release of identifiable information about individual providers may be consistent with HPD goals and may be beneficial to California and, for this reason, Section 97416(c) does not completely prohibit the release of this information. See the discussion about Section 97416(c) in the Initial Statement of Reasons and above.

Based on the above, HCAI also believes Section 97416(c) is clear that it does not apply to organizational entities.

Comment 46: The commenter is concerned about Section 97406(c)’s use of the data security standards of NIST 800-53 as that is a standard for the federal government and RAND and other institutions use another data security standard, NIST SP 800-171. The commenter is concerned that Section 97406(c) may prevent institutions obtaining data even though they can adequately protect the data and have received confidential federal/state data in the past. In sum, RAND asks for greater flexibility in Section 97406(c).

Response 46: No changes were made in response to Comment 46. HCAI believes that Section 97406(c) has flexibility since it does not require exact compliance with NIST 800-53 but states that the data applicant must have “a level of data security for confidential data that is not less than the level required by... NIST 800-53....” Thus, RAND or another organization may comply with this requirement via other methods than NIST 800-53. Furthermore, HCAI adopted this language from its own data use agreement with the federal Centers for Medicare & Medicaid Services to obtain federal data for the HPD.

California Association of Health Plans: Comment 47 was submitted by Anete Millers on behalf of the California Association of Health Plans.

Comment 47: The commenter states a general concern that the regulations lack adequate protections for proprietary health plan data and that the regulations do not discuss such data as being confidential. Commenter notes that businesses could obtain their competitor’s contracted rates which may lead to anti-competitive activities and that the definition of “researcher” does not prevent this.

Response 47: No changes were made in response to Comment 47. It is unclear to HCAI at this time what data in the HPD is proprietary data and protected by trade secret laws or other laws (see document referenced in Footnote 15 of the Initial Statement of Reasons). The comment does not specify the data at issue or the protections for that data. Each data request will undergo thorough review and approval on an individual basis, and should protections on data stored in the HPD be identified, HCAI will assess that in considering applications.

Regarding anti-competitive effects and the definition of “researcher,” each data request will undergo thorough review and approval on an individual basis and HCAI will assess for anti-competitive issues—see the Initial Statement of Reasons’ discussion of Section 97388(c)(3). As noted in the Initial Statement of Reasons (Section II, “The Problem to be Addressed and Purpose of these Regulations), the release of pricing information may have anticompetitive effects, but may also be beneficial to California. For this reason, HCAI will carefully review and balance these when considering data applications.

Purchaser Business Group on Health: Comments 48 through 50 were submitted by Ema Hoo on behalf of the Purchaser Business Group on Health. Ms. Hoo is also a member of the HPD Advisory Committee at this time.

Comment 48: The commenter notes that the federal government now requires hospitals to annually publicly post their “plan-specific contracted rates” and fully-insured plans and self-funded employers to provide monthly updates of their

contracted provider services. From this, commenter believes that HCAI's limited datasets should have a transparency standard that is no less stringent than these federal transparency laws and should include National Provider Identification numbers and Tax Identification numbers of providers. Commenter notes that if there are safety concerns about the release of this data, HCAI can mask provider identifiers "at the procedural level."

Response 48: No changes were made in response to Comment 48. The proposed regulations do not address the contents of limited datasets and, based on the project or anticipated use, HCAI may disclose available data described by commenter to data users. Regarding public disclosure of the data described by commenter, HCAI will evaluate this based on the individual data application and will consider what is already publicly available per federal law. Also, as noted above, these regulations also have a process regarding public release of identifiable individual provider data—see Section 97416(c).

Comment 49: The commenter encourages HCAI to revisit the composition of the HPD Data Release Committee to fully reflect the stakeholders, particularly purchasers, patients and consumers, who may be the end users of such information.

Response 49: No changes were made in response to Comment 49. The selection of members of the Data Release Committee is beyond the scope of this rulemaking.

Comment 50: The commenter states that the structure of the application process and cost requirements may make it infeasible for purchasers, public interest organizations, and consumer advocacy organizations to access HPD data.

Response 50: Changes were made in response to Comment 50, Section 97384, to include a definitive application fee of \$100, which HCAI believes is reasonable based on its purpose (see discussion above regarding this change). Program data prices are not stated in these regulations and will be part of a separate price schedule. In creating this price schedule for program data, one of HCAI's goal is to keep the data affordable so a wide variety of stakeholders can obtain the data while keeping in mind that the HPD program does not have a continuous funding source. HCAI has and plans to obtain public input on its price schedule, including through the two public HPD advisory committees. Regarding cost requirements, HCAI's goal is to make the price reasonable for the entities noted by commenter.

Comment 51: The commenter states that HCAI should include "anticipated turnaround times" for review of a data user's public research findings.

Response 51: No changes were made in response to Comment 51. This appears to be a comment regarding Section 97416 regarding the review of public data products with identifiable individual information. HCAI believes checking every public data product with consumer/patient information is necessary now because of HPD statutory mandates to ensure the privacy, security, and confidentiality of patients and consumers. Once private information is made public, it is difficult, if not impossible, to remedy the breach, and with this regulatory process in place, HCAI does not believe it will be an inordinate amount of work or cause significant delays. HCAI will learn more about this process once this program starts and will reassess and refine it after obtaining more experience and knowledge.

VI. SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE THIRD COMMENT PERIOD OF SEPTEMBER 06, 2024 THROUGH SEPTEMBER 23, 2024

After the HCAI's submission to the Office of Administrative Law, HCAI again changed its proposed regulations. For this reason, HCAI sent out notice in accordance with Government Code sections 11346.8(c) and 11347.1 on September 6, 2024 and initiated a 15-day comment period for all the changes to the original regulatory text and the following documents: FIPS 140 Validation- The National Institute of Standards and Technology website accessed for print out, Contributor Role HPD Work Order Authorization – 06/04/2024, Duty Statement – Research Data Analyst – 06/2024, 45 CFR 160.103, CalHR Payscale – 08/05/2024. HCAI received 7 comments during this comment period.

California Association of Health Plans: Comments 52 through 54 were submitted by Anete Millers on behalf of the California Association of Health Plans.

Comment 52: The commenter states that HCAI should not be involved in selling health plan data to third parties as the source of their continued funding and operations. In addition, the state to leverage resources available through existing grants. However, data collection programs must be adequately funded into the future and not solely dependent on short-term sources or one-time grant funding.

Response 52: No changes were made in response to Comment 52. Section 97384 subsection (a) states that HCAI may reduce data fees on specific data applications if HCAI determines there is good cause to do so. This subsection notes that this regulation is only about price reductions for specific data applications at issue, and that it is not establishing blanket reductions. HCAI is still determining its price schedule for HPD data release, and the price schedule may have different rates for different types of applicants or data uses.

Comment 53: The commenter asks HCAI to consider the following when approving or denying applications:

- Intended use of data for entrepreneurial or commercial reasons,
- Request by a data submitting entity for all of its competitors' proprietary data,
- Use in subpoenas,
- Non-confidential data should not be health plan identifiable, and
- States do not always specify how the data will be used/published – aggregate or detailed level.

Response 53: See Response to Comment 11 for HCAI's responses.

California Medical Association: Comments 54 through 57 were submitted by Janice Rocco on behalf of the California Medical Association. Ms. Rocco is also a member of the HPD Advisory Committee at this time.

Comment 54: The commenter states it supports the inclusion of §97384(a) and the condition that the program data price must be paid in full, unless reduced in accordance with §97414, in order to receive or access the program data. However, HCAI also believes that the application should be required to be approved before the program data price is requested and paid.

Response 54: No changes were made in response to Comment 55. The data for this program cannot be released until the payment is completed. At that time the application will have gone through the full process before the data is release.

Comment 56: The commenter states that it appreciates the changes in §97396(b)(4) requiring a mandatory denial for a standardized limited dataset delivered via direct transmission containing "identifiable information for any individual or organization who furnish, bill, or are paid for health care in the normal course of business." Protecting provider identifying information is necessary to safeguard the safety and privacy of physicians and other health professionals, as well as to prevent unfair reputational harm resulting from incomplete or inaccurate data. This revision acknowledges the importance of safeguarding personally identifiable information (PII) or record-level data about physicians and other providers, by prohibiting their disclosure via direct transmission.

Response 56: No changes were made in response to Comment 56. Thank you for taking the time to share your comment with the Department.

Comment 57: The commenter states that Department should add language similar to §97396(b)(4), in §§97390, 97392, and 97393, to deny applications

requesting personally identifiable or record-level data about providers for non-research purposes. The same risks inherent in the direct transmission of providers' personally identifiable or record-level data are also present in accessing this data through the enclave. Thus, the same justifications apply to prohibiting such data from being accessed by applicants via the enclave as well as direct transmission.

Response 57: No changes were made in response to Comment 57. The Department places a high priority on data privacy. Transmitting data directly poses a higher security risk due to the lack of intermediary security measures that can be applied when data is routed through the enclave. Before any data is released into or out of the data enclave, it undergoes a thorough review by HCAI staff. This critical step is designed to safeguard privacy and ensure that all data going into the enclave and downloaded out of the enclave complies with the highest standards of confidentiality and protection. By implementing this process, the Department is committed to maintaining the integrity and security of sensitive information.

Comment 58: The commenter states that the use of non-confidential data use agreements will be crucial to affording the appropriate protections necessary for physicians and other individuals who are not patients or consumers. We read proposed subdivision (a)(2)(A), when HCAI determines there is a safety or privacy risk, it can require data use agreements in instances where an applicant will receive non-aggregated data about physicians and other licensed health professionals. Accordingly, CMA supports this revision.

Response 58: No changes were made in response to Comment 58.

VII. LOCAL MANDATE DETERMINATION

The proposed regulations do not impose any mandate on local agencies or school districts.

VIII. ALTERNATIVES THAT WOULD LESSEN ADVERSE ECONOMIC IMPACT ON SMALL BUSINESS

The proposed regulations will not impact small business because the proposed regulations create a voluntary program, and as such, will only impact entities who choose to request and obtain HPD data. Section 97414 of the proposed regulations provides a process for requesting price reductions. Small businesses with an adverse economic impact due to the price of the data, can request and receive a price reduction with sufficient justification and documentation of the economic impact.

IX. ALTERNATIVES DETERMINATION

HCAI has determined no reasonable alternatives have been identified by the Department or have otherwise been identified and brought to its attention that would be more effective in carrying out the purpose for which the action is proposed, that would be as effective and less burdensome to affected private persons than the proposed action, or that would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

X. REQUEST FOR EARLIER EFFECTIVE DATE

The Health Care Payments Database (HPD) is a research database that collects and aggregates data regarding the health care of most Californians. One of HPD's primary purposes is to provide data to researchers and analysts outside of HCAI for the benefit of California. These regulations allow HCAI to meet this primary purpose.

To allow for entities to request HPD data as soon as possible, HCAI respectfully requests that these regulations be effective at the time of filing with the Secretary of State. There is good cause for this because these regulations create a voluntary program and creates no new mandatory obligations or detriments to the public. An entity data can reasonably be able to file data requests on the first day these regulations are effective. If the normal effectiveness schedule occurs per Government Code section 11343.4(a), these regulations may not be effective until December 2024, unnecessarily delaying requests by about one and a half months.

Also, among the preliminary activities during the development of these regulations, HCAI conferred with health care stakeholders. The majority of stakeholders requested access to this data as soon as the regulations become finalized. Therefore, to support stakeholder requests, HCAI is requesting that these regulations be effective upon filing, rather than the quarterly January 1, 2025, effective date.