

**DEPARTMENT OF HEALTH CARE ACCESS AND INFORMATION
HEALTH CARE PAYMENTS DATA PROGRAM
DATA COLLECTION REGULATIONS**

INITIAL STATEMENT OF REASONS

**CALIFORNIA CODE OF REGULATIONS
TITLE 22, DIVISION 7, CHAPTER 11**

7/1/2025

I. BACKGROUND

Pursuant to Health and Safety Code (HSC) sections 127671 to 127674.1, HCAI established the Health Care Payments Data Program (HPD) to collect health care data from health plans, health insurers, government agencies, and other entities. The HPD is what is known as an “all-payer claims database,” or “APCD,” something which 22 states have created in some form. For more background on the HPD, please see the *Health Care Payments Data Program: Report to the Legislature*,¹ dated March 9, 2020 (referred to as “HPD Legislative Report”). The HPD Legislative Report was created to advise the State of California on how to implement the HPD.

HPD statute states that HCAI is to “substantially complete” the development of the HPD System no later than July 1, 2023. This was accomplished with the release of HPD’s first public report in June 2023, known as the HPD Snapshot.² Existing law also required HCAI to adopt emergency regulations by December 31, 2021, that outlined who must submit data, what data must be submitted, the format and content of data submissions, timelines and frequency of data submissions, and methods of data collection. Emergency regulations for HPD data collection were adopted on December 20, 2021, and data collection began in 2022 for the collection of data files including member eligibility, medical claims, pharmacy claims, and provider data. The emergency regulations were certified on November 17, 2023, to permanently adopt the HPD regulations, clarify specific regulation sections, and update documents incorporated by reference. On March 25, 2025, the HPD regulations were updated again to collect non-claims payment (NCP) data as part of the required HPD data collection efforts as well as to update and clarify specific regulation sections.

¹ Health Care Payments Data Program: Report to the Legislature, dated March 9, 2020 (<https://hcai.ca.gov/wp-content/uploads/2020/12/HPD-Legislative-Report-20200306.pdf>).

² HPD Snapshot (<https://hcai.ca.gov/visualizations/healthcare-payments-data-hpd-snapshot/>).

II. THE PROBLEM TO BE ADDRESSED

Now that the HPD is established and data collection has been ongoing since 2022, HCAI must ensure its regulations are maintained and updated regularly and as needed to be consistent with the national standards proposed by the APCD Council, University of New Hampshire, and National Association of Health Data Organizations (NAHDO) for collecting HPD data, as required under HSC section 127673(b)(1). This proposed rulemaking seeks to update and clarify specific regulation sections and update documents incorporated by reference.

As stated in HSC section 127671(b), the HPD was created because health care data is reported and collected through many disparate systems making it difficult to assess California's health care system. This creates substantial barriers to improving health care in California. As such, the HPD's purpose is to collect and centralize health care data from various sources and process the data in a way that can be used by the state and public to learn and seek improvements in health care while protecting patient privacy.³

To address this problem, the HPD was created by statute to collect health care data from entities that make payments for health care (i.e., government health plans and commercial health plans and insurers). The December 2021 emergency regulations were promulgated to initiate HPD's first stage of data collection and identified mandatory data submitters, specified data to be collected, created a process for data submission, and set a timeline for data collection. The certification of the emergency regulations in November 2023 permanently adopted the HPD Data Collection regulations, updated and clarified specific regulations, and expanded on data collection requirements. To further expand on the required data collection efforts of the HPD, the regulations were updated in March 2025 to establish requirements and implementation for the collection of NCP data. This proposed rulemaking seeks to update and clarify specific regulation sections and update documents incorporated by reference to ensure the HPD Data Collection regulations are maintained and updated regularly so HCAI receives the most accurate and comprehensive data for HPD.

III. BENEFITS OF THIS REGULATORY ACTION

The purpose of this proposed rulemaking is to update and clarify specific regulation sections and update documents incorporated by reference. Updating documents incorporated by reference and clarifying specific regulation sections will ensure that HCAI receives the most accurate and comprehensive data for HPD. It is necessary to update and clarify specific regulation sections to ensure health plans are following the most-up-date requirements when submitting comprehensive data to the HPD. Furthermore, updating documents incorporated by reference will ensure HCAI is

³ Health & Safety Code sections 127671(b) and (c), and 127673.5(a).

continuing to meet the national all-payer claims database standards it is required to consider in the development of the HPD regulations (HSC section 127673(e)(4)).

By collecting, aggregating, and processing this health care data, the HPD will continue to fulfill its statutory purposes to provide greater transparency about California's health care system to the state and the public, which will inform health care policy decisions.⁴ Using this data, California will learn more about its health care system which will hopefully lead to improvements in public health, reduction of health disparities, advancement of health coverage, reduction of health care costs, and better oversight of the health system and health care companies. Furthermore, regarding another statutory purpose for the HPD, it is hoped that the public and government agencies will use HPD data to "develop innovative approaches, services, and programs that may have the potential"⁵ to improve health care for Californians.

IV. THE PURPOSE AND NECESSITY OF EACH REGULATION

The following states the purpose and necessity of each proposed regulatory provision.

a. Article 1. Chapter Definitions

i. Section 97300(a) "APCD-CDL™"

HCAI proposes to incorporate by reference the latest version of the APCD-CDL™, Version 4.0.1, released February 2025. Since the regulations were updated in March 2025, a new version of the APCD-CDL™ was released, and HCAI seeks to have a transition period to the new version in this rulemaking.

The APCD-CDL™ is a national standard developed by the University of New Hampshire and the National Association of Health Data Organizations (NAHDO) to harmonize health care data collection across states and reduce the burden of data submission. The APCD-CDL™ was developed specifically for efforts like the HPD and was based on standards used by health care entities for financial transactions. HPD statute indirectly references the APCD-CDL™ under HSC section 127673(b)(1) and requires that HCAI collect data consistent with it. The APCD-CDL™ is maintained and updated on a biennial cycle by the APCD Council, and corrections are made as needed.

In the development of the HPD regulations, HCAI was required to consider national, regional, and other all-payer claims databases' standards (HSC section 127673(e)(4)). The APCD-CDL™ is the only national standard available for state health care databases. Furthermore, it was adopted into regulations in November 2023 on the recommendation of the HPD Legislative Report:

⁴ Health & Safety Code section 127671(b).

⁵ Health & Safety Code section 127671(d).

“Discussions with the likely submitters to the HPD Program indicate a preference for the emerging APCD-CDL™ standard. Payers that operate in multiple states especially appreciate the prospect of a standard format that can be used to support multiple APCD systems. [The Department of Health Care Services] has also indicated a preference for providing data in this format.” (HPD Legislative Report, page 31).

The APCD-CDL™ Version 2.1 was first adopted in the emergency regulations in December 2021 to specify the contents that data submitters must submit to the HPD. The APCD Council released Version 3.0.1 of the APCD-CDL™ on April 1, 2023, which was incorporated by reference in the certification of the emergency regulations on November 17, 2023. The certificate of compliance established February 17, 2024, as the date for health plans to transition from Version 2.1 to Version 3.0.1 for data submission.

Following the transition date, Version 2.1 of the APCD-CDL™ was no longer relevant for HPD reporting requirements. As such, this version was removed from the definition of “APCD-CDL™”, with Version 3.0.1 being the main version of the layout for data submission in the March 2025 regulations update. To collect NCP data (which are HPD’s Annual Payment Files, Pharmacy Rebate Files, and Capitation Files), the March 2025 regulations update also incorporated by reference the NCP Data Layout™: A Data Layout for Non-Claims Payments, Version 1.0, released April 2024. The NCP Data Layout™ was developed by the APCD Council, NAHDO, and University of New Hampshire as the national standard for collecting NCP data.

During the March 2025 regulations update to establish requirements for collecting NCP data, the APCD Council updated and released APCD-CDL™ Version 4.0.1 in February 2025. Version 4.0.1 of the APCD-CDL™ incorporated the NCP Data Layout™ Version 1.0 and updated various file contents throughout for clarity and consistency. Accordingly for this rulemaking, HCAI proposes to incorporate by reference Version 4.0.1 and to have a transition period from Version 3.0.1/the NCP Data Layout™ to Version 4.0.1. Additionally, HCAI proposes this transition because Version 4.0.1 makes minor changes for clarity and consistency as noted in the 2024 APCD-CDL™ Maintenance Process Change Log⁶.

This new definition in this rulemaking is the same approach and regulatory language used when the program transitioned from APCD-CDL™ Version 2.1 to Version 3.0.1 on November 17, 2023 (OAL Matter Number 2023-1013-03).

Although this rulemaking proposes to use two different versions of the APCD-CDL™, HCAI seeks to use one term for the different versions of the APCD-CDL™. HCAI plans to completely transition to a new version of the APCD-CDL™ on February 17, 2026, so

⁶ Available at <https://www.nahdo.org/sites/default/files/Resources/Data%20Layouts/APCD-CDLv4%20changelog.pdf> (last accessed June 26, 2025). A redline version of the APCD-CDL™ Version 4.0.1 is available at <https://www.nahdo.org/sites/default/files/Resources/Data%20Layouts/APCD-CDL%E2%84%A2%20v4%20-%20REDLINE.pdf> (last accessed June 26, 2025).

for any point in time, only one version of the APCD-CDL™ will apply to HPD data submitters. Having a specific date for the transition, rather than having the transition occur on a reporting month, was chosen because the HPD System can only accept one data file specification format at a time.

Because of these circumstances, HCAI believes using one definition of “APCD-CDL™” will be simpler and will prevent confusion and repetition of language. Data submitters will only need to look at this one definition to determine which APCD-CDL™ version to use. Having two different versions of the APCD-CDL™ means that Section 97300(a) needs to be separated into two paragraphs, which will in turn create two subsections for clarity and ease of reading.

Proposed regulations under Section 97300(a) provide a transition period between the old and new versions of the APCD-CDL™ and state that all data submissions or resubmissions must use Version 4.0.1 beginning February 17, 2026. Because HPD data submitters will have already been submitting NCP data using the NCP Data Layout™ Version 1.0 since September 1, 2025, and because there are only minor changes from Version 3.0.1 to Version 4.0.1, HCAI believes this transition period is sufficient time for submitters to adjust to the new version. Additionally, HCAI sent a survey on May 7, 2025, to current HPD data submitters to gather feedback about this proposed change. HCAI did not receive any concerns about this timeframe.

February 17, 2026, was chosen as the start date for the new version of the APCD-CDL™ because HPD data beginning calendar year 2026 will be under Version 4.0.1 (as January 2026 data is due in early March 2026) so that it is easier to track when the change occurred. February 16, 2026, is the end date to use Version 3.0.1 to give submitters the ability to submit and resubmit data for December 2025. As previously discussed, the HPD System can only process data from one version of the APCD-CDL™ at a time, so having the transition period be at the beginning of the calendar year will help with making the transition as simple as possible.

For related issues to this transition, see discussion below regarding changes to Sections 97300(c), 97300(m), and 97341.

ii. Section 97300(b) “Data Portal”

HCAI proposes updating the definition of “data portal” to make it clearer and because of other changes to these regulations regarding the data portal (see changes to Section 97340 and the Data Submission Guide below).

The term was originally adopted in November 2023 to mean the “secure data submission mechanism” plans and submitters use to register and submit data files to the system. The term “secure data submission mechanism” is a reference to HCAI contractor’s Claims Data Manager (CDM), the secure website through which submitters can register and send data to HCAI. The definition is being changed from “secure data

submission mechanism” to “secure website” to make this definition clearer and to clarify that there are actually two ways to submit data to the program (discussed below).

The definition is also changed from “through which...data files *are* submitted to the system” to “through which... data files *can be* submitted to the system.” This change is to reflect that there are actually two ways to submit data to the program and that data submission is not solely through the data portal. The different ways to submit data are more thoroughly discussed below regarding Section 97340 and changes to the Data Submission Guide.

iii. Section 97300(c) “Data Submission Guide”

HCAI proposes to incorporate by reference the new version of the Health Care Payments Data Program: Data Submission Guide (DSG) Version 4.0, dated August 11, 2025. The Data Submission Guide was updated because of the new APCD-CDL™ Version 4.0.1. HCAI proposes to have two versions of the DSG incorporated by reference, Version 3.0 and new Version 4.0, and a transition period from Version 3.0 to Version 4.0 in this rulemaking.

As with Section 97300(a), this new definition for “Data Submission Guide” is the same approach and regulatory language used when the program transitioned from DSG Version 1.0 to Version 2.0 on November 17, 2023 (OAL Matter Number 2023-1013-03). It also the same approach HCAI described above for the definition of APCD-CDL™.

Section 97300(c) needs to be separated into two paragraphs, creating two subsections for clarity and ease of reading since HCAI is proposing to incorporate by reference two different versions of the DSG. Like Version 3.0, Version 4.0 has requirements and instructions for submitter registration and offers additional details for data requirements from the APCD-CDL™. See below regarding the changes from DSG Version 3.0 to DSG Version 4.0.

HCAI seeks to use one term for the two different versions of the DSG and proposes a transition date of February 17, 2026, for the same reasons as the new definition of “APCD-CDL™” discussed above.

iv. Section 97300(m) “NCP Data Layout™”

HCAI proposes updating the definition of “NCP Data Layout™” to add the end date of February 16, 2026, as the last day plans will use the NCP Data Layout™ for data file submissions and resubmissions. As discussed above, the NCP Data Layout™ was incorporated by reference in the March 2025 regulations update along with APCD-CDL™ Version 3.0.1. During the update, the APCD Council released APCD-CDL™ Version 4.0.1 in February 2025 which incorporated the file contents of the NCP Data Layout™. Because HCAI is proposing to transition between versions of the APCD-CDL™ in this proposed rulemaking, HCAI is also proposing to add an end date for use of the NCP Data Layout™ because it will no longer be required once plans begin using

Version 4.0.1 of the APCD-CDL™. This date aligns with the transition between versions of the APCD-CDL™. See above for further discussion on why this date was chosen.

b. Article 3. General Provisions

i. Section 97314. Qualified Health Plans.

Since Section 97314 currently references submission of data only through the data portal, HCAI proposes to change this section so it is consistent with the fact that data can be submitted outside the data portal. To do this, HCAI proposes replacing the reference to “data portal” to “Program”. For more information about the ways plans can submit data to HPD, see the discussion for the changes to Section 97300(b), and Section 97340.

c. Article 4. Data Portal Registration

i. Section 97331. Submitter Registration Requirement.

Since Sections 97331(a) and (b) currently reference submission of data only through the data portal, HCAI proposes to change these subsections so they are consistent with the fact that data can be submitted outside the data portal. To do this, HCAI proposes replacing the current language from “to submit data through the data portal” to “as a data submitter”. For more information about the ways plans can submit data to HPD, see the discussion for the changes to Section 97300(b), and Section 97340.

ii. Section 97332. Registration Process.

In this rulemaking, HCAI proposes to add new requirements for usage of the data portal outlined in the DSG (see below regarding changes to the DSG). Because of these changes, HCAI proposes adding language to subsection (a)(1) of Section 97332 to clearly notify plans and delegated submitters about these new requirements in the DSG. This is necessary for clarity and continuity purposes. HCAI is also proposing to add this new language to Section 97340(a)(1) to continue the pattern already established in regulations of citing when and how the DSG is used. For example, Sections 97342 and 97344 specify when the DSG must be used for submitting monthly and annual data files and Section 97332 specify that the DSG’s registration instructions must be followed.

d. Article 5. Data File Submission

i. Section 97340. Data Submission Methods.

Since Section 97340 currently states the only way to submit data is through the data portal, HCAI proposes updating Section 97340 to reflect the fact that plans can submit data to HPD outside of the data portal. There are actually two methods to electronically submit data files to HPD: (1) through the data portal, and (2) outside the data portal.

For this reason, HCAI proposes to generalize Section 97340 and state that plans must “electronically submit data files to the Program” in new subsection (a). Additionally, HCAI proposes to update the section title from “Data Submission Method” to “Data Submission Methods” since there is more than one way to electronically submit data files to the HPD.

New Section 97340(b) states that plans and delegated submitters must follow the DSG’s data submission instructions and requirements. Specifics about how a submitter can electronically submit data are now in the new DSG Version 4.0 (changes discussed below). HCAI also proposes new requirements for electronic data submission, such as encryption, which are detailed in the new DSG. This subsection (b) also notes that when submitting files through the data portal, submitters are required to follow the DSG’s new data portal requirements.

Section 97340(b) is necessary to clearly notify plans and delegated submitters that specifics about data submission as well as the new requirements for data submission and data portal use are detailed in the DSG. This is also necessary for continuity purposes. HCAI is proposing to add new Section 97340(b) to continue the pattern already established in regulations of citing when and how the DSG is used. For example, Sections 97342 and 97344 specify when the DSG must be used for submitting monthly and annual data files, and Section 97332 specifies that the DSG must be used for registrations.

ii. Section 97341. Data Submission Due Dates.

The change to this section, as detailed below, is the same approach and regulatory language used when program transitioned from APCD-CDL™ Version 2.1 to Version 3.0.1 on November 17, 2023 (OAL Matter Number 2023-1013-03).

HCAI proposes updating Section 97341(a) to add a new starting time period for submission of January 2026 monthly data files. Normally, Section 97341(a) provides a deadline to submit monthly data files but does not state when a submitter can start submitting data. Theoretically, a submitter could submit its monthly data files the day after a report month. The new language prevents this for the report month of January 2026 and requires a submitter to wait until February 17, 2026, to start submitting files for January 2026. The deadline to file is the same.

HCAI proposes this to match the transition to the new version of the APCD-CDL™ on February 17, 2026 (discussed above in Section 97300(a)). As discussed above, the transition must occur on a particular date rather than on a reporting month because the HPD System can only use one version of the APCD-CDL™ at a time. HCAI is adding this requirement for January 2026 to ensure all submitters file their January 2026 monthly data using the new version of the APCD-CDL™ so there is consistency for all January 2026 monthly files.

iii. Section 97342. Data File Contents.

HCAI proposes updating Sections 97342(a) and (b) to add the end date of February 16, 2026, for using the NCP Data Layout™ for data file submissions and resubmissions. Although Section 97300(m) already states this, adding the new language in Sections 97342(a) and (b) will provide clarity because requirements for use of the NCP Data Layout™ are in Section 97342. As discussed above, because HCAI is proposing to transition between versions of the APCD-CDL™ in this proposed rulemaking, HCAI is also proposing to end usage of the NCP Data Layout™ as it will no longer be required once plans begin using Version 4.0.1 of the APCD-CDL™. This date aligns with the transition between versions of the APCD-CDL™. See Section 97300(a) for further discussion about the transition.

iv. Section 97344. Data File Technical Requirements.

HCAI proposes updating Section 97344 to add the end date of February 16, 2026, for using the NCP Data Layout™ for data file submissions and resubmissions. Although Section 97300(m) already states this, adding the new language in this section will provide clarity because requirements for use of the NCP Data Layout™ are in Section 97344. As discussed above, because HCAI is proposing to transition between versions of the APCD-CDL™ in this proposed rulemaking, HCAI is also proposing to add an end date for use of the NCP Data Layout™ as it will no longer be required once plans begin using Version 4.0.1 of the APCD-CDL™. This date aligns with the transition between versions of the APCD-CDL™. See Section 97300(a) for further discussion about the transition.

v. Section 97346. Submission Completion.

Since Section 97346 currently references submission of data only through the data portal, HCAI proposes to change this section so it is consistent with the fact that data can be submitted outside the data portal. To do this, HCAI proposes replacing the reference to “data portal” to “Program”. For more information about the ways plans can submit data to HPD, see the discussion for the changes to Section 97300(b), and Section 97340.

e. Article 5.5 Special Rules for Program Opening and Historical Data Submission

i. Section 97350. Preparation for Historical Data Submission.

HCAI proposes updating the references in this section from Sections 97351(b) and (c) to 97351(a)(2) and (a)(3) to accurately cross-reference the sections. This is necessary because of the renumbering of Section 97351 in this rulemaking. See Section 97351 for further discussion on the changes being made.

ii. Section 97351. Historical Data Files.

HCAI proposes updating Section 97351 for the likely situation of plans not having the required historical data available for submission. Section 97351 is also being reorganized for clarity purposes and ease of reading. As such, current Sections 97351(a), (b), and (c) are renumbered to Sections 97351(a)(1), (2), and (3), respectively.

Section 97351 currently requires plans to submit historical data (i.e., data starting from June 29, 2017). As explained in prior rulemakings, this is based on HPD law (HSC section 127673(h)(1)). However, HCAI believes this absolute requirement is impractical and unfair to plans, especially in regards to NCP data since the regulatory requirement to submit historical NCP data was only approved on March 25, 2025 (OAL Matter Number 2025-0210-01). Depending on a plan's record retention policies and practices, it is reasonable that plans may not have historical data going back to June 29, 2017, especially historical NCP data.

Plans and submitters also previously communicated that the historical data might not be accessible from HCAI's survey of plans in January 2024 during the prior rulemaking to collect NCP data.⁷ Of the 11 responses received, 6 respondents stated that they did not have the historical data available for the timeframe dating back to June 29, 2017. The explanations for why the historical data was not available included the plans' retention policies, challenges with reporting back to 2017, availability of the data being dependent on the plan's third-party administrators, the data not being available due to system migrations and acquisitions, and one plan not collecting monthly Capitation Files.

HPD law seems to recognize this issue regarding historical data and gives HCAI leeway in collecting historical data. HPD law states that HCAI "shall seek [historical] data." (HSC section 127673(h).) "Seek" means "to ask for", or "to try to acquire or gain".⁸

Based on the above, HCAI is proposing to add language in Section 97351(a) that plans must only submit historical data "to the extent plans have [historical] data."

New Section 97351(b) specifies process for plans that do not have the required historical data to submit. Plans that do not have the historical data will need to submit a report to HCAI through email at least 30 days before the due date describing the data they do not have, the time period for which they do not have the data, and why they do not have the data. This reporting process is necessary to give HCAI information when reviewing historical data submissions for completeness/accuracy and keeping track of outstanding historical data submissions. The information is also necessary for HCAI to establish that it meets the requirements of HPD law to seek historical data and relevant information for future data users who may use historical data. HCAI requires an

⁷ Health Care Payments Data Program: Non-Claims Payment Data Collection Survey.

⁸ "Seek." Merriam-Webster.com Dictionary, Merriam-Webster, <https://www.merriam-webster.com/dictionary/seek>. Accessed 30 Jun. 2025.

explanation of why a plan does not have data to determine whether it is reasonable for the plan not to submit the data.

Currently, some plans are communicating with HCAI that they do not have the historical files that are required to be submitted. HCAI is communicating on a case-by-case basis to notify plans to submit in writing explaining why they do not have the data, to be notated in the data reporting. Adding this process in the regulations will provide all plans with the same, consistent communication on procedures to follow if they do not have the historical data to submit. This process is different from variance requests under Section 97370 because variances are temporary and are for regular data reporting. HCAI may also deny variance requests, which does not make sense if a plan simply does not have historical data to submit.

f. Article 6. Data Acceptance Correction

i. Section 97360. Data Acceptance.

Since Section 97360(a) currently references submission of data only through the data portal, HCAI proposes to change this section so it is consistent with the fact that data can be submitted outside the data portal. To do this, HCAI proposes replacing the reference to “data portal” to “Program”. For more information about the ways plans can submit data to HPD, see the discussion for the changes to Section 97300(b) and Section 97340.

Additionally, HCAI proposes updating Section 97360(a)’s reference to the “file intake specifications” in the DSG to the more general term “requirements.” This is necessary because of the changes made to the DSG. In the current regulations, submitters are required to meet the file intake specifications outlined in Section 5 of the DSG Version 3.0. However, the DSG is being updated to Version 4.0 in this proposed rulemaking with more requirements for data acceptance than just “file intake specifications”, such as methods for data submission and encryption (see below regarding these changes to the DSG). For this reason, HCAI is proposing to update the referencing term to more broadly and accurately refer to the requirements detailed in the DSG that submitters must follow for HCAI to accept their data submissions.

g. Article 7. Variances

i. Section 97370. Requesting a Variance.

HCAI proposes updating Section 97370(a)’s reference to the “file intake specifications” in the DSG to the more general term “requirements.” This is necessary because of the changes made to the DSG. In the current regulations, submitters are required to meet the file intake specifications outlined in Section 5 of the DSG Version 3.0. However, the DSG is being updated to Version 4.0 in this proposed rulemaking with more requirements for data acceptance than just “file intake specifications”, such as methods for data submission and encryption (see below regarding these changes to the DSG).

For this reason, HCAI is proposing to update the referencing term to more broadly and accurately refer to the requirements detailed in the DSG that submitters must follow for HCAI to accept their data submissions.

h. Data Submission Guide, Version 4.0

This discusses Version 4.0 of the DSG, dated August 11, 2025, which HCAI proposes to replace prior versions of the DSG (as discussed above regarding the definition of “Data Submission Guide”) and to incorporate by reference as part of this regulatory action. Below identifies the changes that are being made to Version 4.0 from Version 3.0.

This rulemaking includes a redline version of DSG Version 4.0, which shows changes from Version 3.0. New additions to Version 4.0 are underlined and deletions from the previous Version 3.0 are struck through. The underlining and struck through language will be removed in the final version of DSG Version 4.0.

Cover Page and footers of all pages: The date of the DSG was revised to August 11, 2025. The version number was revised from Version 3.0 to Version 4.0.

“Document Change Log”: HCAI added an additional row to the change log to detail changes made to Version 4.0 from Version 3.0. This enables the submitter to focus on updates to the DSG.

Part 1 of DSG, “Introduction”: The introduction is changed to replace references to the APCD-CDL™ Version 3.0.1 to Version 4.0.1. It is also changed to delete references to the NCP Data Layout™ since that document is now incorporated into the APCD-CDL™ Version 4.0.1. This change includes the removal of file types per the respective data layouts, due to the inclusion of all file types into the APCD-CDL™.

The Introduction also states that DSG Version 4.0 is to be used for data submissions and resubmissions after February 17, 2026. This allows users to clearly understand the time frame for which this version of the DSG is applicable.

Part 2.2 of DSG, “Submitter Registration”: HCAI added additional registration requirements for submitters who submit data outside the data portal via secure file transfer protocol (SFTP). Submitters utilizing SFTP to submit data will need to provide contacts in their organization for SFTP submissions.

One such contact is the “SFTP technical contact” who is responsible for technical requirements for SFTP submissions. The other contact is if the submitter has a separate person who facilitates communications between the SFTP technical contact and HCAI or its contractor. Part 2.2 describes these roles and requests the contact’s first and last name, title, phone, email, and address. This information is needed to identify appropriate points of contact to facilitate the SFTP data submission process for a

submitter and allows for efficient communication in the event of any problems, so as not to delay the submission process.

HCAI also added the requirement that registering submitters must create a password upon approval of their registration. This is to more accurately reflect the registration process and put submitters on notice of this requirement. The use of a password for the data portal is required to maintain the security of the data portal and prevent unauthorized access.

Part 5 of DSG, “Data Portal Requirements”: HCAI changed Part 5 from “File Intake Specifications” to “Data Portal Requirements” and moved the information from former Part 5 to Part 6.2, which is discussed in more detail below. HCAI added requirements for the proper use of the data portal by plans and submitters after these requirements were suggested by HCAI’s data portal contractor. HCAI and its data portal contractor believe these requirements are basic requirements and are needed to keep the data portal secure and to protect the interests of HCAI and its data portal contractor. Having these in the DSG will provide clear notice to plans and submitters about these requirements.

The first requirement is that plans and submitters must “not infringe any intellectual property right that HCAI or HCAI’s data portal contractor has in the data portal.” This is to notify plans and submitters that the data portal is protected by intellectual property rights and to protect HCAI and HCAI’s data portal contractor’s property from misuse.

The second requirement is that plans and submitters must “protect and keep confidential their passwords to the data portal.” This is a basic requirement to protect the security of the data portal and prevent misuse of the data portal.

The third requirement is that plans and submitters must “not use and prevent the use of the data portal by its staff for purposes other than to comply with HPD requirements or other legal requirements.” This is another basic requirement to prevent misuse of the data portal and provides notice to plans and submitters that they must take steps to prevent misuse from their staff.

The fourth requirement is that plans and submitters must:

“Immediately notify HCAI or HCAI’s data portal contractor if the plan or submitter believes the data portal is not functioning properly for it to submit data, or that the data portal’s security has been compromised, including, but not limited to, if the plan or delegated submitter’s password was disclosed to or used by unauthorized entities.”

This requirement is needed so that HCAI or its data portal contractor can immediately address problems with the data portal’s functionality which may delay or hinder data submissions or timely respond to security issues.

The fifth requirement is that plans and submitters must:

“Immediately notify HCAI or HCAI’s data portal contractor if the plan or submitter obtains access to another entity’s data or data about patients, consumers, or providers in the data portal.”

Plans and submitters should not have access to another entity’s data in the data portal. However, if this occurs, it would be a major security issue and HCAI or its data portal contractor would need to take immediate action to stop this access and take other steps to correct the problem. This requirement is to make sure plans and submitters notify HCAI or its contractor immediately so the problem is timely addressed.

The sixth requirement is that plans and submitters must “assist HCAI or HCAI’s data portal contractor in investigating and resolving data portal failures or security issues.” This is to make sure that plans and submitters cooperate with HCAI or its contractors in addressing security or other issues with the data portal as the plan or submitter may have important information needed by HCAI or its contractor to resolve issues.

Part 6 of DSG, “File Submissions”: HCAI created this new section to consolidate all the requirements to the file submission process. A new addition, Part 6.1 “Data Submission and Encryption Requirements”, was added and the previous Part 5 of DSG Version 3.0, “File Intake Specifications” was moved to Part 6.2 (“File Intake Specifications”). All other subparts of Part 5 of DSG Version 3.0 were renumbered accordingly in Version 4.0.

Part 6.1 of DSG, “Data Submission and Encryption Requirements”: HCAI added new data file submission requirements, including encryption in this subpart.

As described above regarding changes to Section 97300(b) and Section 97340, prior regulatory language indicated that there was only one way to submit data to the HPD—through the data portal. However, this was inaccurate as submitters were allowed to submit data outside of the data portal via SFTP. Part 6.1 clarifies and fixes this and states submitters are allowed to submit data either (1) through the data portal, or (2) outside the data portal via SFTP.

SFTP is the data transfer standard identified as an alternative to submission through the data portal, due to its security standards, availability, and wide use. It is currently being used by HCAI’s data portal contractor and has been used with success in the past with data submitters.

The rest of Part 6.1 has requirements for encryption and sending data files. These requirements are here to make it clear to submitters on what is needed to send files.

Part 6.1 goes on to require submitters to encrypt the data files submitted to HPD regardless of the submission method and requires the use of the OpenPGP encryption standard for this. Generally, encryption is a required step for data submission to ensure

that the highly confidential and sensitive medical data being transmitted to HPD is protected from unauthorized access during transmission and that even if obtained by other entities, the data files cannot be used. OpenPGP encryption allows for the secure exchange of data between two parties using a public and private key pair to encrypt sensitive data. OpenPGP encryption standard was selected because it is utilized by HCAI's data portal contractor, is a widely utilized industry standard, and submitters can meet the OpenPGP encryption standard without incurring any additional cost. In the unlikely event that submitters do not already have access to OpenPGP encryption software, it is publicly available for download at <https://openpgp.org>, which is referenced in Part 6.1 of the Data Submission Guide version 4.0 for the convenience of submitters. Therefore, using OpenPGP is the most effective and least burdensome method of providing this sensitive data securely to HPD.

Part 6.1 goes on to give essential instructions to submitters on how to use the OpenPGP standard and requires the creation of an OpenPGP key pair and that the public PGP key must be exchanged with HCAI's data portal contractor. Part 6.1 goes on to require that submitters encrypt using their public PGP key and to identify HCAI's data portal contractor as the recipient of the file. Finally, Part 6.1 notes that submitters must sign the encryption with their private PGP key with the submitter identified as the sender of the file.

For SFTP data submissions, Part 6.1 also gives essential instructions about the SFTP process, specifically requiring submitters to create a "Secure Shell" (SSH) key pair and exchanging their public SSH key pair with HCAI's data portal contractor.

Lastly, Part 6.1 notifies submitters that failure to comply with the encryption or data submission requirements will result in their data files being rejected. This is to make it clear the consequences for non-compliance.

Part 6.2 of DSG, "File Intake Specifications": This was previously Part 5 of the DSG Version 3.0.

The only change to Part 6.2 is to add a new reason for rejection—for files that "have data about non-California residents." Per HPD statute, HPD can only collect data on California residents (HSC section 127671.1(b)), and this is reflected in Section 97342(a)(1) regarding the Member Eligibility File. This is to make it clear to submitters that their files may be rejected for having non-California resident data, which HPD cannot collect. Also, if non-resident data is collected, it is difficult, costly, and time-consuming to make changes to the HPD System to remove this information and thus, the best way to fix this issue is to have the submitter resubmit data without the improper data.

Part 6.3 of DSG, "File Header": This was previously Part 5.1 of DSG Version 3.0. HCAI updated notes in the CDLHD010 data element from "3.0.1" to "4.0.1" to reflect the correct version of the APCD-CDL™ in use.

Part 6.4 of DSG, “File Trailer”: This was previously Part 5.2 of DSG Version 3.0. HCAI updated notes for the CDLTR007 data element that pointed to data elements CDLAP015, CDLPR010, and CDLMA012 as references to CDLAP016, CDLPR011, and CDLDC019. The referenced fields were changed in the notes for this field in APCD-CDL™ Version 4.0.1, and the changes were made in DSG Version 4.0 to reflect the update.

Part 6.5 of DSG, “Member Eligibility File”: This was previously Part 5.3 of DSG Version 3.0. There were no further changes to this section.

Part 6.6 of DSG, “Medical Claims File”: This was previously Part 5.4 of DSG Version 3.0. There were no further changes to this section.

Part 6.7 of DSG, “Pharmacy Claims File”: This was previously Part 5.5 of DSG Version 3.0. HCAI updated the name for the CDLPC030 data element from “Compound Drug name or Compound Drug ingredient List” to “Drug name or Compound Drug ingredient List”. APCD-CDL™ Version 4.0.1 renamed this data element as “Drug name or Compound Drug ingredient List”, so the DSG was updated to reflect the same. The content of the Notes column for the CDLPC030 data element was removed as it was redundant to what is listed in APCD-CDL™ Version 4.0.1.

Part 6.8 of DSG, “Dental Claims File”: This was previously Part 5.6 of DSG Version 3.0. There were no further changes to this section.

Part 6.9 of DSG, “Provider File”: This was previously Part 5.7 of DSG Version 3.0. There were no further changes to this section.

Part 6.10 of DSG, “Annual Payment File”: This was previously Part 5.8 of DSG Version 3.0. HCAI updated the table header for this part from “NCP Data Layout™ Data Element” to “APCD-CDL™ Data Element”. This change was made because the NCP Data Layout™ was incorporated into the new APCD-CDL™ Version 4.0.1. For the same reason, HCAI removed notes that referenced the NCP Data Layout™ from the following data elements: CDLAP006, CDLAP012, and CDLAP013. Lastly, HCAI updated the notes for the CDLAP014 data element to include a new category ‘C’, and the notes for CDLAP015 data element to include new subcategories ‘C5’ and ‘C6’. These subcategories were added in APCD-CDL™ Version 4.0.1, and the DSG was updated accordingly.

Part 6.11 of DSG, “Pharmacy Rebate File”: This was previously Part 5.9 of DSG Version 3.0. HCAI updated the table header for this part from “NCP Data Layout™ Data Element” to “APCD-CDL™ Data Element”. This change was made because the NCP Data Layout™ was incorporated into the new APCD-CDL™ Version 4.0.1. HCAI also removed a note referencing the NCP Data Layout™ from the CDLPR008 data element for the same reason.

Part 6.12 of DSG, “Capitation File”: This was previously Part 5.10 of DSG Version 3.0. HCAI updated the table header for this part from “NCP Data Layout™ Data Element” to “APCD-CDL™ Data Element”. This change was made because the NCP Data Layout™ was incorporated into the new APCD-CDL™ Version 4.0.1. HCAI also removed a note referencing the NCP Data Layout™ from the CDLCF018 data element for the same reason.

V. TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDY, REPORTS, OR DOCUMENTS RELIED UPON

HCAI relies on the Health Care Payments Data Program: Report to the Legislature, dated March 9, 2020 (referred to as “HPD Legislative Report” above), prepared by the Office of Statewide Health Planning and Development (HCAI’s former name). HCAI was required to prepare this report for the California Legislature based on input from a review committee composed of health care stakeholders and experts about how HPD should be implemented. (See Assembly Bill 1810, section 23 (2017-2018); and HSC section 127672(d) (2019) [requiring HCAI to create the legislative report for HPD]).

HCAI relies on the 2024 APCD-CDL™ Maintenance Process Change Log prepared by the APCD Council. This document outlines all the changes that were made from the APCD-CDL™ Version 3.0.1 and the NCP Data Layout™ to Version 4.0.1. The change log helped HCAI determine the impact of the transition between the versions for HPD data submitters.

HCAI relies on the Redline Version of the APCD-CDL™ Version 4.0.1 prepared by the APCD Council. This document outlines all the changes that were made from the APCD-CDL™ Version 3.0.1 and the NCP Data Layout™ to Version 4.0.1. The redline version helped HCAI determine the impact of the transition between the versions for HPD data submitters.

HCAI relies on the Health Care Payments Data Program: APCD-CDL™ Version 4.0.1 Transition Economic Impact Survey, prepared by HCAI and sent to health plans and submitters on May 7, 2025. The survey was conducted to estimate the economic impact of health plans and submitters for complying with the transition from APCD-CDL™ Version 3.0.1 to Version 4.0.1. The results helped inform the economic impact analysis of these regulations.

HCAI relies on the Health Care Payments Data Program: Non-Claims Payment Data Collection Survey, prepared by HCAI and sent to health plans and submitters on January 23, 2024. The survey was conducted to learn about the business processes for submitting NCP data files to HPD. The results helped inform in the development of these regulations.

HCAI relies on the Merriam-Webster dictionary definition of “seek” in the issue regarding collecting historical data under HSC section 127673(h).

VI. REASONABLE ALTERNATIVES

No other reasonable alternatives were presented to, or considered by, HCAI that would be either more effective in carrying out the purpose of which these regulatory actions as proposed or would be effective and less burdensome. Alternatives to specific regulatory sections, when considered, are discussed above in Part IV of this Initial Statement of Reasons.

VII. ECONOMIC IMPACT ASSESSMENT/ANALYSIS

HCAI believes this regulation is a minor reporting requirement for health and dental plans, health insurers, and other mandatory HPD data submitters based on a survey provided to mandatory data submitters. During the development of these regulations, HCAI conducted a survey on May 7, 2025, with all currently registered plans and submitters to better understand the one-time cost, ongoing system costs, and types of jobs created, or eliminated to comply with these requirements. Survey results were provided by three respondents who represented one dental plan and 10 registered health plan submitters.

One question asked whether jobs would be eliminated due to the requirements of the regulations. All respondents stated that no jobs would be eliminated due to the requirements of the regulations.

Another question asked whether jobs would need to be created due to the requirements of the regulations. Two respondents stated no jobs would need to be created, while one respondent representing nine health plan submitters stated that approximately one to three jobs would need to be created due to the requirements of the regulations. Although one respondent stated that approximately one to three jobs would need to be created due to the requirements of the regulations, HCAI believes this will likely not have a significant economic impact on the state. The UC Berkeley Labor Center reported that approximately 2.65 million Californians were employed in a range of health care sectors in 2023.⁹ HCAI believes the creation of approximately one to three jobs due to the requirements of these regulations will likely not have a significant impact on the state when comparing this number to the approximately 2.65 million Californians employed in the health care sector.

Based on the above reasoning, HCAI concludes that this regulatory action will:

1. Likely not create jobs within the state;
2. Likely not eliminate jobs within the state;
3. Not create new businesses within the state;
4. Not eliminate existing businesses within the state;

⁹ "California Health Care Employment by District and County 2023," UC Berkeley Labor Center, <https://laborcenter.berkeley.edu/california-health-care-employment-by-district-and-county-2023/>. Accessed July 1, 2025.

5. Not affect the expansion of businesses currently doing businesses in the state; and
6. Not have any anticipated benefits to worker safety or the state's environment.

This regulatory action would benefit the health and welfare of California residents. The benefits of this proposed regulatory action are further detailed in the benefits section of this document.

VIII. FACTS SUPPORTING FINDING NO SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS

HCAI has determined that there will be no significant adverse economic impact on any businesses in California. To understand what potential economic impacts there may be to HPD data submitters, HCAI administered a survey to all currently registered plans and submitters on May 7, 2025. The survey assessed the one-time and ongoing costs for complying with these regulations, whether jobs would be created or eliminated, and the types of jobs needed to comply with the regulation requirements. A total of three organizations representing one dental plan and 10 registered health plan submitters responded to the survey.

The total covered lives served by these health and dental plans and insurers range from approximately 12,000 to 8 million. The two health plan submitters who responded to the survey are two of the HPD's largest health plan submitters. One of these submitters indicated that the estimated one-time cost for complying with the regulations would be between \$25,001 and \$75,000 and estimated ongoing annual costs would be between \$37,501 and \$50,000. The other submitter indicated that the estimated one-time cost for complying with the regulations would be between \$55,556 and \$111,111 and estimated ongoing annual costs would be between \$11,111 and \$72,222. The one dental plan that responded indicated an estimated one-time cost of complying with the regulations would be \$25,000 or less and estimated ongoing annual costs would be \$12,500 or less.

Based on the results of the survey, HCAI estimates the total one-time cost for all submitters implementing the requirements of these regulations to be approximately \$1,060,612. HCAI also estimates the total ongoing annual costs for all submitters implementing the requirements of these regulations to be approximately \$666,680. The total statewide cost to comply with this regulatory action for initial start-up costs and the first year of annual costs will be approximately \$1,727,280.

The results of the survey conclude that there is an economic impact on registered plans and submitters. However, the impact will not eliminate jobs. One respondent concluded that the requirements of these regulations will likely create an estimated one to three jobs. This supports HCAI's position that this regulatory action does not have any significant adverse economic impact on businesses required to comply with these regulations.