

DEPARTMENT OF HEALTH CARE ACCESS AND INFORMATION

RULEMAKING FILE

(Health Care Payments Data Program)

Item 9:

FINAL STATEMENT OF REASONS

**FINAL STATEMENT OF REASONS**  
CALIFORNIA CODE OF REGULATIONS  
TITLE 22, DIVISION 7, CHAPTER 11:  
HEALTH CARE PAYMENTS DATA PROGRAM (HPD)

March 25, 2025

**I. BACKGROUND AND MODIFICATION TO INITIAL STATEMENT OF REASONS**

On August 2, 2024, through September 17, 2024, the Department of Health Care Access and Information (HCAI) gave notice of proposed regulations for the Health Care Payments Data (HPD) Non-Claims Payment (NCP) Data Collection. This proposed rulemaking is to collect NCP data as part of the required HPD data collection efforts under Health and Safety Code (HSC) section 127673(b) and update and clarify specific regulation sections. In response to public comments received during the initial 45-day comment period, HCAI made modifications to the regulation text which were substantially related to the original proposed text, as well as one non-substantial correction to a citation reference. HCAI also revised the Data Submission Guide Version 3.0, which is incorporated by reference, to include new requirements for NCP file testing and registration. These revisions were made available during a 15-day public comment period between November 6, 2024, and November 22, 2024. These revisions are outlined below under Section 1. Subsequent to these events, HCAI was also notified of changes to the Data Submission Guide Version 3.0 which HCAI had not explained in the Initial Statement of Reasons—HCAI explains these non-substantial changes in Section 1.

Furthermore, while preparing the final text of the proposed regulations, HCAI noted the following non-substantial typos:

- § 97300(a)(2) – The term, “APCD Council”, was inadvertently inserted into the proposed and modified regulatory texts of this section. Current subsection 97300(a)(2) does not include this term. The order in which the two organizations, the “University of New Hampshire” and the “National Association of Health Data Organizations (NAHDO),” were named were also inadvertently switched between the proposed and modified regulatory texts and the original regulatory text. Also in this subsection, in the proposed and modified texts, it was indicated that “NAHDO” was being newly added, but it was pre-existing language.
- § 97300(b) – The term, “system”, was inadvertently capitalized in the proposed and modified regulatory texts of this section. Current subsection 97300(b) does not have this term capitalized. The system, capitalized and not capitalized, means the Health Care Payments Data System.

- New § 97300(n) – A semicolon was inadvertently replaced by a comma between the words, “plan,” and “and,” in the modified regulatory text of this section. The current version of this section has a semicolon in between the two words.
- New § 97350(b) – An underline was inadvertently added to (c) in the modified regulatory text, which is being renumbered to new subsection (b).
- Old § 97351(a) – A comma was inadvertently added after “2017” in the modified regulatory text.
- New §97351(a) – A comma was inadvertently added after “2017” in the modified regulatory text.

HCAI subsequently was notified of the following mistakes regarding the Data Submission Guide Version 3.0 (dated October 28, 2024). The following discusses these mistakes and changes, if any, to the final text because of these mistakes. As background, HCAI published two versions of the new Data Submission Guide Version 3.0 (dated October 28, 2024) for the public in this rulemaking. There was the “amended” Version 3.0 which showed the deletions and additions from Version 2.0 and there was the “final” Version 3.0 which just showed the final language.

- Data Submission Guide Version 2.0, Section 2, first sentence, stated there were two registration processes: “one for plans, and one for plans and delegated submitters”. The “final” Version 3.0 changed this language to “one for plans, and one for submitters”. However, HCAI mistakenly did not explain this change in the Initial Statement of Reasons and did not indicate this change in the “amended” Version 3.0. For this reason, Section 2 of Version 3.0 will revert to the language in Version 2.0.
- HCAI mistakenly had different language in the “amended” and “final” Version 3.0 documents in Section 4.1. The “final” Data Submission Guide Version 3.0, Section 4.1, first sentence, states “plans and delegated submitters.” The “amended” Version 3.0, HCAI mistakenly states “plans and registered submitters.” This was erroneous as it should have been “delegated submitters” instead of “registered submitters”. This is consistent with the requirement in 97350(c) which states “Before plans submit historical data files under Section 97351(b) or (c), plans and delegated submitters shall comply with the registration testing requirements in Section 4 of the Data Submission Guide”. Both terms are defined in pre-existing regulation, §97300. For this reason, the language from the “final” Data Submission Guide Version 3.0, Section 4.1, will be retained.
- Regarding the Data Submission Guide Version 3.0, Section 5.1, data element “CDLHD005” and Section 5.2, data element “CDLTR005; Version 3.0 added language naming each data file type from the old and new §97342 in the “Notes” boxes compared to Version 2.0. However, the “amended” Version 3.0 only indicated that the new NCP data files (i.e., the Annual Payments, Pharmacy Rebates, and Capitation Files) were new to these data elements. This was a

mistake as all the data files from §97342 were being added to the “Notes” boxes. As this addition just provided information regarding pre-existing requirements, HCAI is keeping all the new language.

- Regarding the Data Submission Guide Version 3.0, Section 5.1, data elements “CDLHD006” and “CDLHD007” and Section 5.2, data element “CDLTR006”; HCAI added the date format in the “Notes” boxes in Version 3.0. However, the “amended” Version 3.0 did not indicate that these were changes from Version 2.0. As this addition just provided information regarding pre-existing requirements, HCAI is keeping the new language.
- Regarding the Data Submission Guide Version 3.0, Section 5.2, data element “CDLTR007”, HCAI altered and added language in the “Notes” box compared to Version 2.0. However, “amended” Version 3.0 did not fully indicate all the changes and only indicated that the references to the new non-claims payment data files were new. As this addition just provided information regarding pre-existing requirements, HCAI is keeping the new language.
- Regarding the Data Submission Guide Version 3.0, Section 5.2, data element “CDLTR008”, HCAI added language in the “Notes” box compared to Version 2.0. However, “amended” Version 3.0 did not indicate that the language was new. As this addition just provided information regarding pre-existing requirements, HCAI is keeping the new language.

The mistakes and typos have been corrected in the final text. HCAI believes the mistakes and typos are non-substantial, as the insertion of these typos and the mistakes do not alter new or pre-existing requirements and obligations of the regulation sections.

## **1. THE PURPOSE AND NECESSITY OF REVISIONS TO PROPOSED REGULATIONS**

### **§ 97300 (c). Definitions**

HCAI revised the publication date of the Data Submission Guide Version 3.0 from July 17, 2023, to October 28, 2024, because of the changes HCAI made after receiving comments during the initial 45-day comment period (see Documents Incorporated by Reference below).

### **§ 97300 (r). Definitions**

HCAI did not delete “(q)” when relettering the subsection to “(r)”. This corrects this typographical error.

### **§ 97305 (b). Voluntary Participation in the Program**

HCAI revised this subsection to correct an error to ~~strikeout~~ the reference to Section 97300 (s) and replace it with Section 97300 (t) because of the relettering of Section

97300.

### **§ 97350 (a) and (c). Preparation for Historical Data Submission**

HCAI revised subsection (a) back to the original language regarding “registered submitters.” Originally, HCAI did not believe testing for NCP data collection was necessary and thus, this subsection was narrowed to be just about dental plans, which still had obligations to test. However, HCAI revised this rulemaking to require testing for NCP data (subsection (c)). Because of this revision, it is now necessary to revert this subsection to be about all registered submitters since all registered submitters may be required to do testing for NCP data. These changes were in response to comments received during the initial 45-day comment period (see Comment #2).

In the August 2, 2024, rulemaking revisions, HCAI completely changed subsection (c). HCAI originally did not believe it was necessary to provide a testing period for submitters to test historical NCP data submission because submitters were already experienced in submitting data to the HPD and based on the survey conducted in January 2024, as discussed in the Initial Statement of Reasons. One question asked in the survey was about the feasibility of providing annual historical data files by Quarter 3 of 2025. A majority of respondents replied that they would be able to provide annual historical files by Quarter 3 of 2025, leading HCAI to select the last day of July 2025 as the due date for submitting annual historical files. However, HCAI now believes a more robust testing period is needed and changed subsection (c) to require testing. This decision was made in response to a comment received during the 45-day comment period (see Comment #2). HCAI believes adding a testing requirement is necessary to assist submitters to successfully comply with NCP data collection. Reinstating the testing period also aligns with prior implementation of HPD data submissions. HCAI also added a special registration requirement specifically for NCP file submission because annual registration which begins in January 2025 will occur before the proposed regulations will take effect. It is necessary to add a special registration requirement to allow for a pathway for plans and submitters to update registration of NCP file testing and to account for mapping of plan to submitter relationships. The new testing and registration requirements for NCP files were added to the Data Submission Guide (DSG) Version 3.0 as this document describes the requirements for plans and submitters to comply with HPD program. For more about the new testing and registration requirements, see the section, “Documents Incorporated by Reference”, regarding changes to the Data Submission Guide (DSG) below.

### **§ 97351 (b) and (c). Historical Data Files**

HCAI revised the dates of these two subsections in response to initial 45-day public comment received (see Comment # 4). Subsection (b) relating to the Capitation File was changed from a reporting period ending on July 31, 2025, to July 31, 2026. The Capitation File due date was changed from September 1, 2025, to September 1, 2026. Subsection (c) relating to Annual Payment File and Pharmacy Rebate File was changed from a reporting period ending on December 31, 2023, to December 31, 2024. The

Annual Payment File and Pharmacy Rebate File due date was changed from July 31, 2025, to July 31, 2026.

HCAI chose the original deadlines based on the survey conducted in January 2024, as discussed in the Initial Statement of Reasons. One question asked in the survey was about the feasibility of providing annual and monthly historical data files by Quarter 3 of 2025. A majority of respondents replied that they would be able to provide annual and monthly historical files by Quarter 3 of 2025, leading HCAI to select the last day of July 2025 as the due date for submitting the historical files. However, HCAI now finds it necessary to give more time to submitters so they will be successful in submitting production ready files to HCAI. This was determined from public comments received regarding providing additional time for submitters to successfully submit production ready files. Postponing data collection of historical files by one year will give submitters a total of 10 additional months to prepare for NCP data collection through the testing process. This will allow submitters to work with HCAI to address any potential concerns or difficulties with NCP data collection prior to submitting historical data files.

### **§ 97352 (b). Initiation of Monthly Data File Reporting**

In response to initial public comment (see Comment #3), HCAI revised the start of monthly Capitation File reporting from August 2025 to August 2026. Because of this, HCAI also revised the due date for this monthly data file from October 1, 2025, to October 1, 2026. HCAI originally believed the August 2025 start date and October 1, 2025, due date was a reasonable amount of time for submitters to prepare for the monthly file submissions based on results from the January 2024 survey, as discussed in the Initial Statement of Reasons. However, HCAI now finds it necessary to make these revisions to allow submitters adequate time to prepare and submit production ready Capitation Files. HCAI also believes this revision provides a reasonable amount of time for submitters to prepare for this submission after these regulations become effective. This was determined in response to public comments received regarding providing additional time for monthly data file reporting. Postponing data collection of monthly files by one year will add 10 months to the testing period which will allow submitters to work with HCAI to address any potential concerns or difficulties with monthly data file reporting.

### **§ 97353. Initiation of Annual Data File Reporting**

HCAI revised the beginning of the regular annual reporting of the Annual Payment File and Pharmacy Rebate File from 2024 to 2025. Because of this, HCAI also revised the due date for these annual files from September 30, 2025, to September 30, 2026. The changes were made in response to initial public comment (see Comment #3). HCAI originally believed the 2024 reporting date and September 30, 2025, due date was a reasonable amount of time for submitters to prepare for the annual file submissions based on results from the January 2024 survey, as discussed in the Initial Statement of Reasons. However, HCAI now believes this change is necessary to provide adequate time between the adoption of these regulations and the time in which submitters must successfully submit production ready data files. This was determined from public

comments received regarding providing additional time for submitters to successfully submit production ready files. Postponing data collection of annual files by one year will add 10 months to the testing period which will allow submitters to work with HCAI to address any potential concerns or difficulties with annual data file reporting.

### **Documents Incorporated by Reference**

Revisions were made to the Data Submission Guide (DSG) Version 3.0 in response to comments received during the initial 45-day public comment period. Below is the summary of changes made to this document and the necessity for each:

- Title page and footers – HCAI revised the publication date from July 14, 2024, to October 28, 2024. This change was made to reflect the date of revisions made to the DSG.
- Table of Contents – HCAI struck out Section 4 “KEY UPDATES IN THIS VERSION INTENTIONALLY OMITTED” and replaced with “SPECIAL REGISTRATION AND TESTING REQUIREMENTS FOR HISTORICAL NCP DATA FILES”. This change was made to reflect the addition of new content to this section.
- Document Change Log – The version was kept the same as 3.0, but the date was changed to October 28, 2024, to reflect the new revision date. The same information from June 14, 2024, was kept while adding two items: 1) added new section 4 which describes requirements for registration, and 2) testing for historical NCP Data Files. Also, a change was made to correct a grammatical error to the file names.
- New Section 4 – Special Registration and Testing Requirements for Historical NCP Data Files – In response to the comments left during the 45-day comment period, HCAI added this section to create special registration and testing requirements before entities can submit historical NCP data files. As discussed above, HCAI believes testing is necessary to ensure that submitters submit data correctly.
  - This new Section 4 starts with a definition of “NCP Data Files” to make clear this is only about the new files being added through this rulemaking.
  - New Subsection 4.1 requires Plans and Delegated Submitters to update their HPD registrations or newly register before testing for historical NCP Data File Submission. HCAI needs this information to identify and track the entities who are required to test and to know what types of NCP Data Files each entity needs to test. Normally, Plans and Delegated Submitters must register with HPD every year between January and February identifying the entities that will submit data and what data they will submit. Since in the year 2025, entities will not be required to submit NCP Data Files (as HCAI proposes to start NCP Data File submission in 2026), these

entities will not register information about NCP Data Files during the normal HPD registration cycle. However, since testing is to start in 2025 (discussed below), HCAI needs this information in 2025, thus these special registration requirements are needed. Subsection 4.1's subparts have directives for Plans and Submitters submitting NCP Data Files to either update their 2025 registrations or to register as NCP Data File submitters if not already registered. These requirements refer to the pre-existing registration requirements in the DSG, Section 2.

- New Subsection 4.2 requires registered submitters (after registering under Section 4.1) to test regarding whatever historical NCP Data Files they will submit. HCAI believes testing is needed because of the comments it received about submission deadlines being too soon and the new NCP Data Layout being unfamiliar to submitters. Through required testing, HCAI believes it can take early steps to help submitters, establish a more structured framework for collaboration between submitters and HCAI regarding NCP Data Files and make sure that submitters are ready to submit files by the submission deadlines.
  - To make sure that entities start testing early, the first part of Subsection 4.2 requires entities to submit their first test files by September 1, 2025. This is needed to make sure that entities begin the testing process early enough so that they will meet the testing and data submission deadlines.
  - The second part of Subsection 4.2 requires entities to successfully complete testing by June 30, 2026. This deadline is a month before the start of NCP Data File submission (see proposed Section 97351(c)) and HCAI believes that if entities are able to successfully complete testing by this date, they will have a reasonable amount of time to submit their first NCP Data Files.
  - The second part of Subsection 4.2 also defines what “successfully complete testing” means—that it is a file that was not rejected by HCAI and refers to the reasons for rejection that are pre-existing in DSG section 5. This is to provide clarity to testers on what needs to be done for them to complete testing.

HCAI also neglected to explain several additions the Data Submission Guide (DSG) from Version 2.0 to Version 3.0 in the Initial Statement of Reasons. Below are explanations for these non-substantial additions:

- New language in the “Notes” boxes for Section 5.1, data element “CDLHD005” and for Section 5.2, data element “CDLTR005” – Version 3.0 added language naming each data file type from the old and new §97342 in these “Notes” boxes compared to Version 2.0. HCAI added this language to clarify and make sure

data submitters knew that the new non-claims payment data files were included for this data element.

- Date Format specified in the “Notes” boxes for Section 5.1, data elements “CDLHD006” and “CDLHD007”; and Section 5.2, data element “CDLTR006” - HCAI added the date format in these “Notes” boxes in Version 3.0 for clarity as different data formats could be used.
- Altered and new language in the “Notes” box for Section 5.2, data element “CDLTR007”
  - Version 2.0 just stated, “Required for claims files.” Version 3.0 added language to this stating it was for both the old “claims” files and the new “non-claims” files. As this rulemaking is adding NCP data files, this had to be updated to include files beyond claims files. HCAI also specifically listed each type of data file to clarify and make sure data submitters knew what data files this was referring to.
  - Version 3.0 also added new language, “Control total for each file (CDLMC125, CDLPC037, CDLDC060, CDLAP015, CDLPR010, CDLMA012).” HCAI added this for clarity to specify which fields should be used to produce the control total for each file.
  - Version 3.0 also added new language, “Do not code decimal point or provide any punctuation.” HCAI added this for clarity purposes to ensure submitters understood that a decimal point must not be included.
- New language in the “Notes” box for Section 5.2, data element “CDLTR008” - HCAI added new language, “Total number of records submitted in the file, excluding header and trailer records.” HCAI added this for clarity purposes to ensure that submitters calculated the total number of records correctly.

## **2. NEWLY ADDED TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDY, REPORTS, OR DOCUMENTS RELIED UPON**

In response to comments received during the initial 45-day public comment period (see Comments #1 and 6), HCAI added to the rulemaking file the “Non-Claims Payment and Alternative Payment Model Classification Frameworks”. This document was made available for the duration of the 15-day comment period and continues to be made available on HCAI website.

## **II. LOCAL MANDATE**

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

### III. SUMMARY AND RESPONSES TO COMMENTS RECEIVED DURING 45-DAY COMMENT PERIOD

The following organizations submitted written comments during the 45-day public comment period from August 2, 2024, to September 17, 2024: AHIP (Formerly America’s Health Insurance Plans) and California Association of Health Plans (CAHP). Comments received on the proposed regulations are summarized below with similar comments grouped together where appropriate.

#### Comment 1: § 97300. Definitions, § 97342. Data File Contents, and § 97344. Data File Technical Requirements

- HCAI received comments from AHIP and CAHP to adopt the Health Care Payment Learning & Action Network's (LAN) Alternative Payment Model (APM) classification framework for data reporting under this regulatory action, rather than the NCP Data Layout™ which follows the Expanded Non-Claims Payment Framework (Expanded Framework). AHIP and CAHP state the LAN reporting structure for Alternative Payment Models (APMs) is widely used across the health care industry and easily understood by plans, providers and consumers.
- HCAI response: No action taken. As stated in the initial statement of reasons (ISOR), HCAI is statutorily required to “consider national, regional, and other all-payer claims databases” standards. The NCP Layout™ was developed by the All-Payer Claims Database (APCD) Council and the National Association of Health Data Organizations with the University of New Hampshire and is the only national standard of this type of data for use by state APCDs. The NCP Layout™ was developed specifically to support uniform, efficient, and accurate NCP data collection for state APCDs. Also, HCAI has adopted the APCD-CDL™ as its standard for HPD’s current data collection. The NCP Layout™ will be incorporated into the APCD-CDL™ through the biennial data maintenance process in 2025 which further supports the decision of HCAI to adopt the NCP Layout™ as a data collection standard. In addition, the Office of Health Care Affordability (OHCA) within HCAI developed the Expanded Framework which is also incorporated within the NCP Layout™ to capture payment categories and subcategories for Annual Payment and Capitation files. The Expanded Framework categories are similar to the Health Care Payment Learning & Action Network (HCP-LAN) as described in the “Non-Claims Payment and Alternative Payment Model Classification Frameworks document, a new document relied upon for this rulemaking, and which was added as part of the 15-day comment period for this regulatory action. This document shows the relationship between the HCP-LAN payment categories and the Expanded Framework payment categories.

#### Comment 2: § 97300. Definitions, § 97342. Data File Contents, and § 97344. Data File Technical Requirements

- AHIP commented that there are challenges for submitters to report data in the proposed NCP Data Layout™ which follows the Expanded Framework, including significant time and resources needed to report in new format and difficulty categorizing Capitation and Full Risk Payments (LAN Category 4) into multiple subcategories required in the NCP Data Layout™ specifications.
- HCAI response: In response to this comment, HCAI proposes adding a testing period and postponing data collection by one year as part of the 15-day notice for this regulatory action. Health plans and/or their delegated submitters will have a total of 10 months to prepare for NCP data collection through the testing process. This allows time for each individual health plan to work with HCAI to address any concerns or difficulties with NCP data collection. In comparison to the initial opening of the HPD program, health and dental plans and their delegated submitters were given three months to test APCD-CDL™ data files before submitting production ready files. HCAI believes providing this additional testing period for NCP data collection addresses both the time and resource concerns to submit data conforming with the new NCP Data Layout™.

Comment 3: § 97352. Initiation of Monthly Data File Reporting and § 97353. Initiation of Annual Data File Reporting

- HCAI received comments from both AHIP and CAHP regarding the following: to proceed incrementally rather than requiring reporting under each granular subcategory of the Expanded Framework at the outset of implementation; submitters needing appropriate length of time to update their process and remediate or make changes to current data submissions; and to provide a runway for implementation and/or delaying the start of implementation. Specifically, both AHIP and CAHP requested starting implementation in 2027 and further collaboration and consultation in 2028 and 2029 to address inconsistencies or problems with reporting.
- HCAI response: In response to this comment, HCAI proposes adding a 10-month testing period and postponing data collection by one year as part of the 15-day notice comment period for this regulatory action. As stated in Comment 2 above, this allows for health plans and their delegated submitters to work directly with HCAI during the testing period on specific concerns that may arise. HCAI believes this is sufficient time to address both commenters' concerns and establish a more structured framework for collaboration between health plans and HCAI during the implementation of this new NCP Layout™. HCAI rejects the portion of the comment which requests the use of the HCP-LAN framework as described in response to Comment 1 above.

Comment 4: § 97351. Historical Data Files

- HCAI received comments from both AHIP and CAHP to remove section 97351 Historical Data Files in its entirety due to unavailability of data going back to

2017. Both commenters state that data warehouses only maintain a limited number of months of data. AHIP and CAHP also state that since 2017, many health plans have modified and/or adopted new data systems entirely, or acquired additional companies and merged data systems, making their ability to submit these historical data files nearly impossible. Further, AHIP and CAHP question the reliability or comparability of historical data compared to today's investments.

HCAI response: No action taken. As described in Health and Safety Code section 127673, HCAI is legally required to seek data for the three years prior to the effective date of the statute. The effective date of the statute was June 29, 2020, and thus three years prior is June 29, 2017. HCAI further explains this requirement in the ISOR. If historical files are not available for the period of time being requested by HCAI, health plans are encouraged to work with the HCAI and initiate the data variance process as specified in the California Code of Regulations, Title 22, Division 7, Chapter 11, Article 7 – Variances. This is the mechanism used for all HPD plans and delegated submitters if the entity is unable to submit data files that meet the DSG.

#### Comment 5: Public Reporting.

- HCAI received comments from AHIP and CAHP with concerns relating to public reporting of NCP data. Specifically, it was stated that the proposed regulations would require payers to publicly report investments in value-based arrangements, risking exposure of plans' broad strategic approaches to value-based care. Additionally, AHIP and CAHP are concerned this information would be reported without additional context for the nuances agreed upon by payers and providers around value-based care investments. It was also stated by CAHP that public reporting of non-claims data is anti-competitive for plans and threatens exposure of investments in value-based arrangements and approaches to value-based care.
- HCAI Response: No action taken. This regulatory action is related to data collection and not the release of data. Health and Safety Code section 127673 (b) states "mandatory submitters shall, and voluntary submitters may, provide health care data, including claim and encounter, member enrollment, provider and supplier information, nonclaims-based payments, premiums, and pharmacy rebate data...". This regulatory action is to set the requirements for collecting non-claims payments, capitation, and pharmacy rebates as required by statute.

#### Comment 6: Focus on consistency of reporting

- HCAI received comment from CAHP recommending placing a continued focus on consistency across reporting with Office of Health Care Affordability (OHCA) within HCAI.

- HCAI response: No action taken. Ensuring uniform data collection and providing consistent guidance for data submission is of high importance to HCAI. Health plans and submitters are required to submit separate files to both HPD and OHCA and although the data submitted to each program have similarities, each is for a different set of use cases. OHCA will collect aggregated NCP totals and will eventually include NCP subtotals for primary care and behavioral health spend. OHCA will collect data for a payer’s full line of business. In contrast, HPD will collect detailed contract-level, National Drug Code-level, and member-level NCP data in three file formats. This level of granularity for HPD NCP data is required so that HPD can link the NCP data to the member-level claims and encounter data already being received from plans. HPD will collect data for a payer’s commercial and Medicare Advantage lines of business. OHCA and HPD are taking a unified approach by using the same payment categories and subcategories, codes and descriptions in the Expanded Framework. As detailed in HCAI’s response to Comment 1, the Expanded Framework categories crosswalk to the Health Care Payment Learning & Action Network (HCP-LAN) as described in the “Non-Claims Payment and Alternative Payment Model Classification Frameworks” document which is incorporated by reference as part of the 15-day comment period for this regulatory action. This document shows the relationship between the HCP-LAN categories and the Expanded Framework.

Comment 7: Definition of pharmacy rebate in the NCP Data Layout™

- HCAI received a comment from CAHP regarding the pharmacy rebates definition in the NCP Data Layout™ and the OHCA definitions as found in the Total Health Care Expenditures (THCE) Data Submissions Guide (DSG), with the addition of “for drugs identified using NDC labeler and product codes”. HCAI HPD reporting is more granular by drug.
- HCAI response: No action taken. The NDC labeler and product code for NCP Data Layout™ data collection matches with the pre-existing APCD-CDL™ pharmacy claims file which is part of HPD data collection. This enables HCAI to understand the rebates and discounts provided to health plans members, given that the goal of the HPD system is to collect information to provide greater transparency regarding health care costs, utilization, quality and equity as stated in Health and Safety Code section 127371 (b). OHCA’s collection method of pharmacy rebates are at an aggregated level, therefore NDC labelers and product codes are not relevant.

Comment 8: Small consistencies matter regarding pharmacy rebate reporting

- HCAI received a comment from CAHP stating that the pharmacy rebates reporting in the NCP Data Layout™ “may be negative,” while in OHCA’s THCE reporting, it must be positive (NAHDO NCP layout p. 14).
- HCAI response: No action taken. This comment is referring to data element CDLPR011 “Total Paid Amount” on page 14 of the NCP Layout™. Included in the

description of this data element is the following: “Total all payments made during the reporting/performance period. Round to the nearest dollar (e.g. \$1,000.25 converts to 1000. If the value for this field is zero, report as “0”, not as null). This field may contain a negative value”. It is important to recognize this is a calculation of all payments and thus there may be instances where the total reflects a negative number indicating rebates being returned. OHCA’s THCE reporting is a different use case and therefore comparison of the totals being negative or positive is not relevant.

#### Comment 9: Inability to find Data Submission Guide (DSG) version 3.0

- HCAI received a comment from CAHP regarding the inability to find the DSG version 3.0.
- HCAI response: No action taken. The final version DSG version 3.0, as well as the amended DSG 3.0 indicating proposed changes to the document, were made available on the HCAI website at the start of the 45-day public comment period and are still posted and available for review. It can be found on both the HCAI Laws & Regulations page, <https://hcai.ca.gov/about/laws-regulations/>, and the HPD homepage, <https://hcai.ca.gov/data/cost-transparency/healthcare-payments/>. Further, HCAI announced notice of proposed regulations and 45-day public comment period to all current HPD submitters and all individuals who subscribe to HPD news on August 2, 2024, which includes links to proposed regulations and documents incorporated by reference. Lastly, HCAI reached out to the commenter via email on September 25, 2024, to share where the direct link and URL for where the document can be found.

#### **IV. SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE 15-DAY COMMENT PERIOD**

The following organizations/individuals submitted written comments during the public comment period from November 6, 2024, to November 22, 2024: California Long-Term Care Ombudsman Association, Veradigm, Painted Brain, and a member of the public. Comments received on the proposed modified regulations are summarized below.

#### Comment 1: Links do not work in 15-day notification email

- HCAI received a comment from California Long-Term Care Ombudsman Association stating that the links to the documents in the 15-day public comment email notice do not work.
- HCAI response: No action taken. Upon rechecking links, all links to documents work. Commenter was advised of this and was also advised to check downloads folder or discussing with their IT department.

#### Comment 2: Asked for a link and website update

- HCAI received a comment from Painted Brain requesting link to "Section 35101 of California Code of Regulations, Title 2 (Administration), Division 8 (Miscellaneous Conflict of Interest Codes), Chapter 14: Office of Statewide Health Planning and Development — Conflict of Interest Code. Filed with Secretary of State April 12, 2023, effective May 12, 2023."
- HCAI response: No action taken. This request is irrelevant to the revisions made to the rulemaking record as part of the 15-day comment period. HCAI reported the request to the department's web team to add appropriate link to Section 35101.

Comment 3: User wanted to know if Ambulatory Surgical Centers will be affected by NCP data collection

- HCAI received a comment from Veradigm asking whether Ambulatory Surgical Centers are subject to proposed regulations.
- HCAI response: No action taken. Ambulatory Surgery Centers are not mandatory submitters to the HPD and therefore not subject to the proposed regulations. This information was provided to the commenter.

Comment 4: User requests hold for further consideration of data gathering

- HCAI received a comment from a member of the public stating that there are data elements that are unnecessary and redundant. The commenter also stated that the submission guide is not going to produce a clear picture of actual cost because there should be two individual guides. In addition, the commentor states that data should not be combined because it doesn't include Data Element for Military and Veteran beneficiaries who receive medical and aren't managed. The commenter requests the regulatory action be put on hold pending further review and inclusion. The commentor also stated failure not to add all medical secondary insurance will result in further miscommunication between systems and cyber-attacks.
- HCAI response: No action taken. This request is irrelevant to the revisions made to the rulemaking record as part of the 15-day comment period.

**V. ALTERNATIVE THAT WOULD LESSEN THE ADVERSE ECONOMIC IMPACT TO SMALL BUSINESS**

HCAI determined there is no adverse economic impact to small business, therefore there are no alternatives proposed.

**VI. ALTERNATIVES DETERMINATION**

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.

## **VII. DOCUMENTS INCORPORATED BY REFERENCE**

The proposed regulations have the following documents incorporated by reference. These documents were disclosed with the Initial Statement of Reasons and were available for public viewing during the 45-day public comment period or 15-day public comment period.

- The *Health Care Payments Data Program: Data Submission Guide (DSG) Version 3.0* dated October 28, 2024, is being incorporated by reference in section 97300 (c). HCAI is seeking to incorporate this document by reference as it would be burdensome and impractical to list the hundreds of specifications made in the document in regulation text.
- The *NCP Data Layout™: A Data Layout for Non-Claims Payments, Version 1.0* is being incorporated by reference and is defined as *NCP Data Layout™* in section 97300 (m). HCAI is seeking to incorporate this document by reference as it would be burdensome and impractical to state the data elements in the *NCP Data Layout™* with their corresponding descriptions, codes, and sources in regulation text.

## **VIII. REQUEST FOR EFFECTIVE DATE ON FILING**

HCAI requests that this regulatory proposal be made effective upon filing with the Secretary of State. This request is based on the following good cause.

The proposed regulatory text includes registration, testing, and submission instructions for the collection of NCP data files. This is new data for the HPD program but from entities currently submitting data to HPD program. In order to provide health plans and insurers adequate time to register, prepare NCP data files for testing, engage with HCAI during the testing period, and to ensure timely statutorily required reporting on this new data source, HCAI respectfully requests these regulations become effective upon filing with the Secretary of State instead of during the quarterly adoption period. An effective date upon filing with the Secretary of State does not cause undue harm to health plans and insurers but allows these entities additional time and notice to comply with the regulations.