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NOTICE OF PROPOSED RULEMAKING

CALIFORNIA CODE OF REGULATIONS TITLE 22, DIVISION 7, CHAPTER 11, ARTICLE 1 TO 7, SECTIONS 97300-97370: HEALTH CARE PAYMENTS DATA PROGRAM

The Department of Health Care Access and Information (Department) proposes to adopt regulations to collect Non-Claims Payment (NCP) data for the Health Care Payments Data Program (HPD) after considering all comments, objections, and recommendations regarding the proposed action.

I. PUBLIC HEARING

The Department has not scheduled a public hearing on this proposed action. However, the Department will hold a hearing if it receives a written request for a public hearing from any interested person or their authorized representative no later than 15 days before the close of the written comment period.

II. WRITTEN PUBLIC COMMENT PERIOD AND CONTACT PERSON

Any interested person, or their authorized representative, may submit written comments relevant to the proposed regulatory action. All comments must be received by the Department by 5:00 PM on September 17, 2024. Inquiries and written comments regarding the proposed action should be addressed to the primary contact person named below. Comments delivered by email are suggested. Comments may also be hand delivered or mailed.

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Department of Health Care Access and Information
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Inquiries and comments may also be directed to the backup contact person at the same mailing address:

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III. AUTHORITY AND REFERENCE

California Health and Safety Code (HSC) section 127673(f) authorizes the Department to adopt these proposed regulations. The specific code sections that are being implemented, interpreted, or made specific are HSC sections 127671, 127671.1, 127673, 127673.1, 127673.4.

IV. INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

a. Summary of Existing Laws and Effect of the Proposed Regulations

Existing law required the Department to establish the HPD by HSC sections 127671 to 127674.1. The purpose of the HPD is to collect health care data from health care plans, health insurers, government agencies, and others, and to use this data to provide greater transparency regarding health care costs, utilization, quality, and equity to improve health care in California.

As part of the requirements under HSC section 127673(e), the Department promulgated emergency regulations for the collection of HPD data on December 20, 2021, and data collection began in 2022 for the collection of core claims 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.

This proposed rulemaking is to adopt HPD regulations to collect NCP data as part of the required HPD data collection efforts under HSC section 127673(b) and update and clarify specific regulation sections.

The proposed regulations will further expand on the required data collection efforts of the HPD and will permanently establish requirements and implementation for the collection of NCP data. HCAI also proposes to update and modify parts of the existing regulations because of updates made to documents incorporated by reference and to provide clarity and differentiate between data currently being collected and NCP data. Changes include:

- Removing outdated parts of the definition “APCD-CDL™” and, accordingly, the outdated parts of the HPD Data Submission Guide (HSC sections 97300(a) and (c));
- Adopting definitions applicable for NCP data collection (HSC section 97300(m));
- Removing outdated guidance and clarifying the method for submitting data files (HSC section 97340);

- Adopting a new section to specify due dates for the submission of monthly and annual data files (HSC section 97341);
- Adopting specifications and requirements for the submission of NCP data file contents (HSC sections 97342 and 97344);
- Updating current and adopting new requirements for the preparation of historical data submission (HSC section 97350);
- Adopting requirements for the submission of historical NCP data files (HSC section 97351);
- Removing outdated and adopting new requirements for the initiation of monthly data file reporting (HSC section 97352); and
- Adopting requirements for the initiation of annual data file reporting (HSC section 97353).

b. Policy Statement Overview

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

As required by statute, the HPD's purpose is to collect health care data from the entities that make payments for health care (i.e. commercial health plans and health insurers, and government health plans). The December 2021 emergency regulations were promulgated to initiate HPD 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.

In November 2023, the Department was issued a Certificate of Compliance for the HPD Program Data Collections regulations by the Office of Administrative Law. The Certificate of Compliance makes permanent the December 2021 HPD Program emergency regulations that established procedures for health care data collection and submission.

Regarding benefits, this rulemaking will allow HPD to continue collecting health care data to help inform the state's approach to improving health care in California by adding the collection of NCP data. As stated in HSC section 127671, by collecting, aggregating, and processing this health care data, the HPD will provide greater transparency about California's health care system to the State and the public, which will inform health care policy decisions. By studying HPD data, California will learn more about its health care system and hopefully will 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. It is also hoped that the

public and government agencies will also use HPD data to develop innovative approaches, services, and programs that may have the potential to improve health care for Californians.

To be as comprehensive as possible and to maximize the utility and value for California policymakers and others interested in improving California's healthcare system, the HPD must expand its data collection efforts to include NCP data. As described in HSC section 127673, health plans and submitters are required to submit NCP data to the HPD System. This will include monthly capitation files and annual non-claims payment and pharmacy rebate and cost files. The collection of NCP data is especially important given the presence of managed care in California's market. This information will be necessary to calculate the total cost of care, which is an essential part of understanding what is driving increases in health care costs.

c. Existing Comparable Federal Regulation or Statute

The Department is not aware of any comparable federal statute or regulation to the proposed regulations.

d. Evaluation of Inconsistency/Incompatibility with Existing State Regulations

The Department evaluated the language contained in the proposed regulations and determined that these proposed regulations are not inconsistent with or incompatible with existing state regulations. These regulations are necessary to enhance the clarity and efficacy of a statutorily mandated program.

e. Documents Incorporated by Reference

The Department intends to incorporate by reference the following documents for the proposed regulations:

- The Health Care Payments Data Program: Data Submission Guide, Version 3.0, dated June 14, 2024.
- NCP Data Layout™: A Data Layout for Non-Claims Payments, Version 1.0, released April 2024.

V. MANDATE ON LOCAL AGENCY OR SCHOOL DISTRICT

HCAI determined that these regulations do not impose a mandate on local agencies or school districts because it does not mandate a new program or a higher level of service of an existing program pursuant to Part 7 (commencing with Section 17500) of Division 4 of the Government Code. These regulations are applicable to public and private entities and are not unique to local government.

VI. FISCAL IMPACT ESTIMATES

The Department has made the following fiscal impact estimates:

- a. Cost or savings to any state agency: None.
- b. Cost to any local agency or school district which must be reimbursed in accordance with Government Code sections 17500 through 17630: None.
- c. Other nondiscretionary cost or savings imposed on local agencies: None.
- d. Cost or savings in federal funding to the state: None

VII. HOUSING COSTS

The Department determined that the proposed regulations will not impact housing costs.

VIII. SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING ABILITY TO COMPETE

HCAI believes this regulation is a minor reporting requirement for health plans, health insurers, and other mandatory data submitters to the HPD based on a survey provided to mandatory data submitters. To understand what potential economic impacts there may be to HPD data submitters, HCAI released a survey to all currently registered plans, submitters, and anticipated mandatory dental plans. The survey assessed the one-time cost, ongoing system costs, and types of jobs created or eliminated to comply with NCP data collection for the HPD. Six registered health plans and one registered delegated submitter provided feedback on the survey. Although no dental plans responded to the survey, HCAI anticipates that dental plans will not have NCP data to report because their services are typically submitted on a fee-for-service basis.

The total covered lives served by these health plans and insurers range from 13,000 to 8.2 million. The results of the survey concluded that there is an economic impact to registered plans and submitters. However, the impact will not eliminate jobs. One respondent concluded that the requirements of NCP data collection 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 report NCP data to the HPD.

IX. COST IMPACTS ON REPRESENTATIVE PRIVATE PERSON OR BUSINESS

As stated above, HCAI released a survey to all currently registered plans, submitters, and anticipated mandatory dental plans. The survey assessed the one-time cost, ongoing system costs, and types of jobs created or eliminated to comply with NCP data collection for the HPD. A total of six registered health plans and one registered

delegated submitter responded to the survey, with the registered delegated submitter representing two public self-insured entities and one registered health plan. The total covered lives served by these health plans and insurers range from 13,000 to 8.2 million. Plans at the lower range of total covered lives membership (with annual revenues of at least in the hundreds of millions of dollars) indicated that the estimated one-time cost would be \$50,000 or less, and estimated ongoing annual costs would be \$25,000 or less. This is compared to plans at the higher range of total covered lives membership (with annual revenues in the tens of billions of dollars), who indicated that the estimated one-time cost was between \$300,001 and \$500,000, while estimated ongoing annual costs would be between \$25,001 and \$50,000.

Based on the results of the survey, HCAI estimates the total one-time cost for all submitters implementing the requirements of NCP data collection regulations to be approximately \$2,300,007. HCAI also estimates the total ongoing annual costs for all submitters implementing the requirements of NCP data collection regulations to be approximately \$375,003. 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 \$2,675,010.

Based on this information, HCAI has determined that there is an economic impact to registered plans and submitters. However, the impact does not impede health plans and submitters from complying with the requirements of NCP data collection for the HPD.

X. STATEMENT OF THE RESULTS OF THE ECONOMIC IMPACT ANALYSIS (EIA)

The Department surveyed those health plans, insurers, and public self-insured entities which are currently registered and submitting data to the HPD. From this, the Department concludes that this regulatory action will:

- a. Likely not create jobs within the state;
- b. Likely not eliminate jobs within the state;
- c. Not create new businesses within the state;
- d. Not eliminate existing businesses within the state;
- e. Not affect the expansion of businesses currently doing business in the state; and
- f. Not have any anticipated benefits to worker safety or the state's environment.
- g. This regulatory action would benefit the health and welfare of California residents.

This regulatory action is to adopt HPD regulations to collect NCP information including capitation, other alternative payment arrangements, and pharmacy rebates as required in HSC section 127673(b)(2) in an effort to expand the types of data being collected in the HPD. In this way, the HPD will provide greater transparency about California's health care system to the state and the public, which will inform health care policy

decisions. In turn, this 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 care system and companies. 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 to improve health care for Californians. Furthermore, there are no anticipated benefits of these regulations to worker safety or the state’s environment.

XI. BUSINESS REPORT

The proposed regulatory requirements for businesses to submit NCP data to HPD is a statutory mandate as specified in HSC section 127673.

The proposed regulations require HPD mandatory data submitters and their delegated submitters to register and re-register each year. To the extent these are considered “reports,” the Department finds that this is necessary for the health, safety, and welfare of the public that this applies to businesses.

XII. EFFECT ON SMALL BUSINESS

The Department has determined that the regulations will have no effect on small businesses. The health plans and insurers who are mandated to report data to the HPD program are not part of the small business community. The smallest health plan who is mandated to report for the HPD program is estimated to have between 50-200 employees and has a total annual revenue of over \$35 million. All other health plans and insurers have greater than 200 employees and annual revenues greater than \$35 million.

XIII. REASONABLE ALTERNATIVE INFORMATION

In accordance with Government Code Section 11346.5, subsection (a)(13), the Department must determine that no reasonable alternative considered by the Department or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

The Department invites interested persons to present statements or arguments with respect to alternatives to the proposed rulemaking action during the written comment period.

XIV. AVAILABILITY OF EXPRESS TERMS, INITIAL STATEMENT OF REASONS, AND INFORMATION UPON WHICH PROPOSED RULEMAKING IS BASED

The Department will have the entire rulemaking file available for inspection and copying throughout the rulemaking process at its office at the address given for the contact persons. As of the date this notice is published, the rulemaking file consists of this notice, the text of the proposed regulations, all documents incorporated by reference as identified in this notice, the initial statement of reasons, an economic impact analysis, and all information upon which this proposed rulemaking is based. Copies may be obtained by contacting the listed contact persons using the contact information above and parts of the rulemaking file are available at <https://hcai.ca.gov/about/laws-regulations/>.

XV. AVAILABILITY OF SUBSTANTIAL CHANGES TO ORIGINAL PROPOSAL

After considering all timely and relevant comments received, the Department may adopt the proposed regulations substantially as described in this notice. If the Department makes modifications which are sufficiently related to the originally proposed text, it will make the modified text, with the changes clearly indicated, available to the public for at least 15 days before the Department adopts the regulations as revised.

Please send requests for copies of the modified text to the listed contact person. The modified text will also be available on the website at <https://hcai.ca.gov/about/laws-regulations/>. The Department will accept written comments on the modified regulations for 15 days after the date on which they are made available.

XVI. AVAILABILITY OF FINAL STATEMENT OF REASONS

The Final Statement of Reasons, including all of the comments and responses, will be available, after its completion, through the Department's website at <https://hcai.ca.gov/about/laws-regulations/>. The Final Statement of Reasons will also be available from the above contact person(s).

XVII. AVAILABILITY OF DOCUMENTS ON THE INTERNET

Copies of this notice, the initial statement of reasons, the text of the proposed regulations, and other documents can be accessed through the Department's website at <https://hcai.ca.gov/about/laws-regulations/>.