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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

This notice of proposed rulemaking commences the Department of Health Care Access and Information's (Department or HCAI) rulemaking to make permanent the December 2021 emergency regulations for the Health Care Payments Data Program (HPD) after considering all comments, objections, and recommendations regarding the proposed action. The Department also proposes some updates and changes to the 2021 emergency regulations.

#### 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 his or her 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 his or her 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 October 3, 2023. 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.

Sherry Mung, Health Program Specialist II  
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Department of Health Care Access and Information  
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Mailing address: 2020 West El Camino Avenue, Suite 1100  
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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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Department of Health Care Access and Information  
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### III. AUTHORITY AND REFERENCE

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, 127673.2, and 127673.4.

### IV. INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

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

Existing law requires the Department to establish the HPD to collect health care data from health plans, insurers, government agencies, and others. Furthermore, existing law requires the Department to “substantially complete” the development of the HPD System no later than July 1, 2023. The Department substantially completed the development of the HPD System through the release of the HPD Program’s first public report, the HPD Snapshot visualization, on June 27, 2023. The HPD Snapshot can be viewed at <https://hcai.ca.gov/visualizations/healthcare-payments-data-hpd-snapshot/>.

The primary purpose of this rulemaking proposal is to make permanent the emergency regulations the Department adopted on December 20, 2021, which started data collection for the HPD. The emergency rulemaking added Chapter 11 of Division 7 of Title 22 of the California Code of Regulations (sections 97300 to 97370). With this rulemaking, the Department will be able to continue collecting data for the HPD and this rulemaking permanently establishes the following to implement the HPD:

- Definitions for HPD (section 97300);
- A process for entities to become voluntary data submitters (section 97305);
- Who mandatory HPD data submitters are, including exemptions such as plan size thresholds (sections 97300(j), 97300(k), 97310, and 97314);
- Obligations for mandatory data submitters to coordinate data submissions with their contractors (sections 97318 and 97346);
- Registration processes for mandatory submitters and any entity transmitting data for mandatory submitters (sections 97330 to 97334);

- Frequency and timelines for data submissions (section 97340);
- Content, specification, and format requirements for data submissions (section 97342 to 97344);
- A process for test data submissions (section 97348);
- Special rules for the start of the HPD, including initial registrations, the start of data collection, and collection of historical data (sections 97349 to 97352);
- The process for HCAI to review and accept/reject data submissions (sections 97360 to 97362); and
- The process for data submitters to request a variance if they are unable to submit data as required (section 97370).

The Department also proposes to update and modify parts of the emergency regulations because of updates to documents incorporated by reference, and to clarify data collection requirements for the HPD data collection. These changes include:

- Incorporating new versions of the Common Data Layout for All-Payer Claims Databases (APCD-CDL™) from Version 2.1 to 3.0.1 and accordingly, a new version of the HPD Data Submission Guide from Version 1.0 to 2.0 (section 97300(a) and (c));
- Clarification of registration requirements and requiring re-registrations each year (sections 97330 to 97334);
- For the transition to the new APCD-CDL™, establishing a special timeline for January 2024 data submissions (section 97340(c));
- Making test file submission discretionary instead of mandatory (section 97348); and
- Moving the requirement for initial dental plan registration from section 97330 to new section 97349.

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. Data collection for the HPD Program is now occurring for health plans, health insurers, and government plans and this rulemaking will allow this to continue.

Regarding benefits of this rulemaking, this rulemaking will allow HPD to continue collecting health care data to help inform the state's approach to improving health care in California. 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.

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 proposed regulations and determined that these proposed regulations are not inconsistent with or incompatible with existing state regulations.

e. Documents Incorporated by Reference

The following are documents HCAI intends to incorporate by reference through these proposed regulations:

- *The Common Data Layout for All-Payer Claims Databases, Version 2.1*, released July 1, 2021;
- *The Common Data Layout for All-Payer Claims Databases, Version 3.0.1*, released April 1, 2023;

- *The Health Care Payments Data Program: Data Submission Guide, Version 1.0*, dated November 23, 2021; and
- *The Health Care Payments Data Program: Data Submission Guide, Version 2.0*, dated July 17, 2023.

## **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 has determined that the permanent adoption of the HPD emergency regulations would not have a significant adverse economic impact on any businesses in California who are mandated by statute, not these regulations, to submit data for the HPD program. The emergency regulations implemented the statutory reporting requirement for the HPD Program and HCAI was successful in collecting data from mandatory and voluntary plans from the adoption of the emergency regulations to present.

Regardless, to understand what impacts there may be to mandatory plans, HCAI administered a survey to all currently registered plans and submitters. The survey assessed the one time and ongoing costs for complying with HPD emergency regulations, whether jobs were created or eliminated, and the types of jobs used to support HPD data collection. A total of six health plans and insurers responded to the survey representing 16 data submitters. The size of these health plan and insurer

respondents ranged from providing medical coverage to 89,000 to 8.2 million covered lives. The results of the survey concluded that there was an economic impact to registered plans and submitters (see part IX below), however, the impact did not eliminate jobs. One respondent concluded that the requirements of HPD data collection created an estimated one to three jobs. This supports HCAI's position that this regulatory action does not have a significant adverse economic impact on businesses required to report for the HPD program.

## **IX. COST IMPACTS ON REPRESENTATIVE PRIVATE PERSON OR BUSINESS**

As stated above, HCAI administered a survey to all currently registered plans and submitters to assess the one time and ongoing costs for complying with HPD emergency regulations, whether jobs were created or eliminated, and the types of jobs used to support HPD data collection. A total of six health plans and insurers responded to the survey representing 16 data submitters. The total covered lives served by these health plan and insurer respondents ranged from 89,000 to 8.2 million. Plans at the lower range of total covered lives membership (with annual revenues at least in the tens of millions of dollars<sup>1</sup>) indicated that the estimated one-time cost were \$50,000 or less and ongoing annual costs were \$25,000 or less. This is compared to plans at the higher range of total covered lives membership (with annual revenues in the billions of dollars<sup>2</sup>) who indicated the estimated one-time cost were \$1 million and estimated annual ongoing costs were \$650,000. Based on the results of the survey, HCAI estimates the total one-time cost for all submitters implementing the requirements of HPD data collection regulations to be approximately \$11,659,084; the total ongoing costs to be approximately \$5,052,290; and the total statewide costs to comply with this regulatory action for initial start-up costs and the first year of annual costs to be \$16,711,974. Based on this information, HCAI has determined that there is a cost impact to registered plans and submitters, however the impact does not impede health plans and submitters from complying with the requirements of HPD data collection.

## **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:

- a. Will likely not create jobs within the state;
- b. Will likely not eliminate jobs within the state;
- c. Will not create new businesses;
- d. Will not eliminate existing businesses; and

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<sup>1</sup> Information from the California Department of Managed Health Care, "Health Plan Financial Summary Report," available at <https://wpsso.dmhc.ca.gov/flash/> (last visited on June 20, 2023).

<sup>2</sup> See above footnote.

- e. Will not affect the expansion of businesses currently doing business in the state.

As stated previously in the Informative Digest, this regulatory action is to implement statutory requirements which are intended to improve the health and welfare of California residents by having HCAI collect, aggregate and process fragmented health care data 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. 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. 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 health care data to HPD is a statutory mandate and does not originate from this regulatory action.

The proposed regulations require HPD mandatory data submitters and their delegated submitters to register and to re-register each year. To the extent these are considered "reports," HCAI 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**

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 persons.

#### **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/>.