## **NOTICE OF PROPOSED RULEMAKING**

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

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

#### 06/02/2023

NOTICE IS HEREBY GIVEN that the Department of Health Care Access and Information (HCAI) proposes, for the Health Care Payments Data Program, to add Article 8, "Data Use, Access and Release," (sections 97380, 97382, 97384, 97386, 97388, 97390, 97392, 97394, 97396, 97398, 97400, 97402, 97404, 97406, 97408, 97410, 97412, 97414, and 97416), to Title 22, Division 7, Chapter 11 of the California Code of Regulations.

The Department proposes to adopt the regulations described herein after considering all comments, objections, and recommendations regarding the proposed action.

#### I. PUBLIC HEARING

HCAI has not scheduled a public hearing. Any interested person, or his or her duly authorized representative, may submit a written request for a public hearing, pursuant to Section 11346.8(a) of the Government Code. The written request for a hearing must be received by HCAI's contact person, designated below, no later than 15 days prior to the close of the written comment period.

#### II. WRITTEN 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 HCAI by 5:00 PM on July 18, 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 faxed, hand delivered, or mailed.

Sandra Bannerman, Research Data Manager Office of Information Services Department of Health Care Access and Information Tel: (916) 326-3733 Fax: (916) 445-7534 Email: <u>hpddatarelease@hcai.ca.gov</u> Mailing address: 2020 West El Camino Avenue, Suite 1100 Sacramento, CA 95833-1880

Inquiries and comments may also be directed to the backup contact person:

Caily Langston, Assistant Branch Chief Information Services Division Department of Health Care Access and Information Tel: (916) 326-3812 Fax: (916) 445-7534 Email: <u>hpddatarelease@hcai.ca.gov</u> Mailing address: 2020 West El Camino Avenue, Suite 1100 Sacramento, CA 95833-1880

Each comment may include the author's name, U.S. Postal Service address, and e-mail address, if applicable, so that they may be included in future communications if the text of the currently proposed regulations changes.

#### I. AUTHORITY AND REFERENCE

Health and Safety Code section 127673, subdivision (f), authorizes HCAI to adopt these proposed regulations. These proposed regulations implement, interpret, and make specific sections 127673.5, 127673.6, 127673.8, 127673.81, 127673.82, 127673.83, 127673.84, and 127674 of the Health and Safety Code; section 1798.24 of the Civil Code; section 14100.2 of the Welfare and Institutions Code; and section 1396a of title 42 of the United States Code.

#### II. INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

#### 1. <u>Summary of Existing Laws and Effect of the Proposed Regulations</u>

The Department of Health Care Access and Information (HCAI) is required to establish the Health Care Payments Data Program (HPD) by California Health and Safety Code

(HSC) sections 127671 to 127674.1. 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 and to improve health care in California. A statutory purpose of the HPD is also to release HPD data to members of the public and other state agencies so they can use the data to improve health care in California.

HCAI promulgated emergency regulations for the collection of HPD data on December 20, 2021 (Cal. Code of Regs., title 22, sections 97300 to 97370). HCAI started collecting routine HPD data in November 2022. This data includes a substantial amount of private personal data about Californians such as Social Security Numbers, dates of birth, medical diagnoses, prescribed drugs, and other medical information. For this reason, HPD statute makes clear that although HPD data should be released to data users, HCAI must preserve consumer privacy and must ensure that the privacy, security, and confidentiality of consumers' individually identifiable health information is protected.

These proposed regulations are to create the HPD's Data Use, Access, and Release Program to allow the public and other state agencies to access and use HPD data for the benefit of Californians while protecting the privacy of Californians.

#### 2. <u>Policy Statement Overview/Specific Benefits of Proposed Regulations</u>

The intent for these proposed regulations that establish the program is to allow outside entities to receive and use HPD data to supplement and add to the work being done by HCAI to analyze HPD data and thus, maximize the usefulness of HPD data and bring more benefits to California.

Through the analysis and research of HPD data, healthcare entities will be able to innovate their services and programs to provide more cost effective and responsive health care to Californians. In addition, the disclosure of HPD data to analysts and researchers will reveal and publicize gaps in health care and will help address inequities in health care access throughout the state. Data disclosure will also increase openness and transparency in businesses and governmental agencies involved in health care. As such, the public will become more aware of healthcare costs and utilization.

These regulations, while potentially providing access to a vast sum of highly sensitive data and private medical information as required by statute, will also diligently protect sensitive and private HPD data so that it will not be improperly used or disclosed to damage individual Californians. HCAI attempts to balance data access and data

protection in these regulations, although HCAI will generally favor protection over access to prevent harm to individual Californians. In these regulations, HCAI defines what HPD data is protected and how members of the public and other state agencies can receive HPD data, including confidential HPD data. These proposed regulations will provide access but protect privacy primarily by screening data applicants through a comprehensive data application process and restrictions on how HPD data can be used and publicized.

#### 3. Determination of Inconsistency/Incompatibility with Existing State Regulations

HCAI evaluated the language contained in the proposed regulations. HCAI has determined that these proposed regulations are not inconsistent with or incompatible with existing state regulations. These regulations are necessary to establish a statutorily mandated program.

#### 4. Documents to be Incorporated by Reference in the Proposed Regulations

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

- The Federal Information Processing Standards Publication 200, "Minimum Security Requirements for Federal Information and Information Systems," dated March 2006.
- The National Institute of Standards and Technology (NIST) Special Publication 800-53, Revision 5, "Security and Privacy Controls for Information Systems and Organizations," dated September 2020.
- The NIST Special Publication 800-53B, "Control Baselines for Information Systems and Organizations," dated October 2020.
- The NIST Special Publication 800-88, Revision 1, "Guidelines for Media Sanitization," dated December 2014.
- The California Health and Human Services Agency's "Data De-Identification Guidelines (DDG)," version 1.0 dated September 23, 2016.

#### III. DISCLOSURES REGARDING THE PROPOSED ACTION

There is no economic impact of these regulations; no requirements are imposed and requesting and obtaining HPD data are voluntary actions. HCAI has made the following initial fiscal impact determinations:

- a. Mandate on local agencies and school districts: 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 to any state agency: None. State agencies will be eligible to request program data and are exempt from application fees set by the Department. The California Health and Human Services Agency's institutional review board, the Committee for the Protection of Human Subjects is required to review/approve projects requesting confidential data; DHCS is required to review/approve projects requesting Medi-Cal data. No administrative fiscal impact is expected.
- e. Cost or savings in federal funding to the state: None.

# VI. STATEMENT OF THE RESULTS OF THE ECONOMIC IMPACT ANALYSIS (EIA)

The proposed regulations will only impact entities who choose to request and obtain HPD data. Therefore, economically, HCAI concludes that:

- The agency is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action;
- (2) this regulatory action will not create jobs within the state;
- (3) this regulatory action will not eliminate jobs within the state;
- (4) this regulatory action will not create new businesses;
- (5) this regulatory action will not eliminate existing businesses;
- (6) this regulatory action will not affect the expansion of businesses currently doing business in the state;

- (7) Significant statewide adverse economic impact directly affecting business, including ability to compete. None. The agency has made an initial determination that proposal will not have such an impact.
- (8) this regulatory action will not impact small business because the proposed regulations create a voluntary program, as such, small business are not legally required to comply with the regulations, nor to enforce the regulations, and subsequently, do not derive a benefit from the enforcement of the regulation; nor incur a detriment from the enforcement of the regulation. It is optional to request HPD data, but small businesses may be affected by the proposed regulations if they choose to request program data; and
- (9) this regulatory action will not directly impact housing costs;

Regarding the benefits of the HPD Data Use, Access, and Release regulations to the health and welfare of California residents, worker safety, and the state's environment, a statutory purpose of the HPD is to release HPD data to members of the public and other state agencies so they can use the data to improve health care in California while properly protecting individual privacy. There are no anticipated benefits to worker safety or the state's environment The Legislature hoped that by having HPD data released, members of the public would use the data to develop innovative approaches, services, and programs that may have the potential to deliver health care that is both cost effective and responsive to the needs of Californians and also would increase the transparency of health care costs and utilization. The benefit of having more comparable and useful cost transparency data is difficult to quantify as it can affect many aspects of healthcare and the economy.

#### IV. REASONABLE ALTERNATIVES STATEMENT

In accordance with Government Code Section 11346.5, subsection (a)(13), HCAI must determine that no reasonable alternative it considered or that has otherwise been identified and brought to the attention of the agency would be more effective in carrying out the purpose for which the action is proposed or 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.

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

At this time, HCAI has not identified any reasonable alternatives other than the proposed regulatory action.

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

HCAI 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 in the Notice Register, the rulemaking file consists of this notice, the text of the proposed regulations, the initial statement of reasons, economic impact assessment, and information upon which this proposed rulemaking is based, and all documents incorporated by reference. Copies may be obtained by contacting the listed contact person using the contact information above.

#### VI. AVAILABILITY OF SUBSTANTIAL CHANGES TO ORIGINAL PROPOSAL

After considering all timely and relevant comments received, HCAI may adopt the proposed regulations substantially as described in this notice. If HCAI makes modifications which are sufficiently related to the originally proposed text, it will make the modified text (with changes clearly indicated) available to the public for at least 15 days prior to the date HCAI 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 HCAI's website at: https://HCAI.ca.gov/about/laws-regulations/

HCAI will accept written comments on the modified regulations for 15 days after the date on which they are made available.

#### VII. AVAILABILITY OF FINAL STATEMENT OF REASONS AND RULEMAKING FILE

The Final Statement of Reasons and Rulemaking File including a summary of all comments and responses will be available, after its completion, through HCAI's website at: <u>https://HCAI.ca.gov/about/laws-regulations/</u>.

The Final Statement of Reasons will also be available for review from the designated contact person.

#### VIII. AVAILABILITY OF DOCUMENTS ON THE INTERNET

Copies of the Notice of Proposed Action, the Initial Statement of Reasons, text of the proposed regulations, the economic impact assessment, and information upon which this proposed rulemaking is based, and all documents incorporated by reference can be accessed through our website at: <u>https://hcai.ca.gov/about/laws-regulations/</u>.