

DEPARTMENT OF HEALTH CARE ACCESS AND INFORMATION

NOTICE OF EMERGENCY REGULATIONS

CHAPTER 8.5. HEALTH CARE PAYMENTS DATA PROGRAM [127671 - 127674.1]

NOTICE OF PROPOSED EMERGENCY ACTION

Government Code Section 11346.1(a)(2) requires that, at least five working days prior to submission of a proposed emergency action to the Office of Administrative Law (OAL), the adopting agency provide a notice of the proposed emergency action to every person who has filed a request for notice of regulatory action with the agency. After submission of the proposed emergency to OAL, OAL shall allow interested persons five calendar days to submit comments on the proposed emergency regulations as set forth in Government Code Section 11349.6.

FINDING OF EMERGENCY

The Department of Health Care Access and Information (HCAI) is statutorily required to establish and administer the Health Care Payments Data Program (HPD) to collect health care data from health care plans, health insurers, government agencies and others (Health and Safety Code Section 127671.1.). HCAI is required to adopt emergency regulations to implement HPD by December 31, 2021 and the initial adoption of these regulations is statutorily deemed to be an emergency for purposes of administrative rulemaking (Health and Safety Code Section 127673, subdivisions (e) and (f).). This is HCAI's initial adoption of regulations to implement the HPD.

NECESSITY OF PROPOSED REGULATIONS

Health and Safety Code Section 127673, subdivision (e), specifically requires HCAI to adopt emergency regulations about the following areas to start the HPD: who is required to submit data, what data must be submitted, frequency and deadlines for data submissions, format and content of data submissions, and methods of data collection. The proposed emergency regulations address these areas and are needed to implement the HPD.

DOCUMENTS RELIED UPON

None.

AUTHORITY AND REFERENCE

The authority under which these regulations are proposed is Health and Safety Code, Section 127673, subdivisions (e) and (f).

The particular code sections that are being implemented, interpreted, or made specific are Health and Safety Code, Sections 127671, 127673, 127673.1, 127673.2, and 127673.4.

INFORMATIVE DIGEST

Existing law requires HCAI to establish the HPD Program to collect health care data from health plans, insurers, government agencies, and others. Eventually, the HPD is

expected to produce public reports from this data and to make this data available for research. The statutory goal of HPD is, while protecting individual privacy, to provide greater transparency to Californians regarding health care costs, quality, and equity, which can then be used to inform policy decisions to improve health care in the state.

Existing law also requires HCAI to adopt emergency regulations by December 31, 2021 to start the HPD and requires regulations stating who must submit data, what data must be submitted, the format and content of data submissions, timelines and frequency of data submissions, and methods of data collection. These proposed emergency regulations are to comply with this statutory mandate and to start the HPD.

For the format and content of data submissions, HCAI proposes to incorporate by reference the *Common Data Layout for All-Payer Claims Databases, Version 2.1*, released July 1, 2021 (“APCD-CDL™”). The APCD-CDL™ is a national standard developed by the University of New Hampshire and the National Association of Health Data Organizations to harmonize data collection across states and reduce the burden of data submission. The APCD-CDL™ is available from the APCD Council through its website at <https://www.apcdcouncil.org/common-data-layout>.

HCAI also proposes to incorporate by reference *the Health Care Payments Data Program: Data Submission Guide*, dated September 1, 2021, which was developed by HCAI. This document has additional requirements for submitter registration and offers additional detail for data submissions not covered in the APCD-CDL™. The Data Submission Guide document will be available on, and may be downloaded from, the HCAI website.

There is no comparable federal statute or regulation. The proposed regulation is not inconsistent or incompatible with existing state regulations.

OTHER SPECIFIC STATUTORY REQUIREMENTS

There are no other specific statutory requirements for these regulations.

LOCAL MANDATE DETERMINATION

HCAI determined that these emergency 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 also applicable to public and private entities and is not unique to local government.

COST AND SAVINGS ESTIMATES

HCAI estimates that the proposed changes for commercial submitters are \$500,000 for the initial implementation, and then \$100,000 per year for ongoing costs.

HCAI estimates the following other cost and savings impacts:

- Cost or savings any state agency: None
- Reimbursable cost to any local government agencies: None
- Nondiscretionary cost or savings imposed on local agencies: None
- Cost or savings in federal funding to the state: None

PROPOSED TEXT OF EMERGENCY REGULATIONS

Title 22, Division 7 - Health Care Payments Data Program.

Article 1. Chapter Definitions

§ 97300. Definitions.

The following definitions shall apply to the regulations contained in this chapter:

- (a) “Director” means the Director of the Department of Health Care Access and Information.
- (b) “Department” means the Department of Health Care Access and Information.
- (c) “Program” means the Health Care Payments Data Program established pursuant to Health and Safety Code Section 127671.1.
- (d) “System” means the Health Care Payments Data System.
- (e) “Health plan” means a health care service plan as defined in the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code) or a specialized health care service plan offering pharmacy, behavioral health (psychological), or dental services. “Health plan” does not include a health care service plan that holds a restricted or limited license only; pursuant to Health and Safety Code Section 127673(e)(3) such plans are defined as administrators of plan benefits on behalf of the full-service health plans with which they contract. Student health plans and supplemental plans (including Medicare supplemental coverage) are not considered health plans.
- (f) “Health insurer” means an insurer licensed to provide health insurance, as defined in Section 106 of the Insurance Code, and an insurer offering specialized health insurance offering pharmacy, behavioral health (psychological), or dental services. Insurers providing only other specialized health insurance, or stop-loss insurance, student health insurance, supplemental insurance (including Medicare supplemental insurance), or discount-only insurance, are not considered health insurers.
- (g) “Public self-insured plan” means
 - (1) A self-insured plan subject to Health and Safety Code Section 1349.2, or
 - (2) A state entity, city, county, or other political subdivision of the state, or a public joint labor management trust, that offers self-insured or multiemployer-insured plans that pay for or reimburse any part of the cost of health care services.

- (h) “Dental Plan” means a specialized health care service plan covering dental services only, a dental-only insurance plan, or a public self-insured plan covering dental services only.
- (i) “Voluntarily participating entity” means an entity that chooses to voluntarily submit data to the Program consistent with the criteria established by the Department and has been approved by the Department to submit data, and that is one of the following:
 - (1) A self-insured employer that is not subject to Health and Safety Code Section 1349.2.
 - (2) A multiemployer self-insured plan that is responsible for paying for health care services provided to beneficiaries.
 - (3) The trust administrator for a multiemployer self-insured plan.
 - (4) A provider, as defined in paragraph (2) of subdivision (b) of Health and Safety Code Section 1367.50, that is a hospital or clinic.
 - (5) A supplier, as defined in paragraph (3) of subdivision (b) of Health and Safety Code Section 1367.50, that has an independent scope of practice and submits claims electronically.
 - (6) A health plan or health insurer exempt from the requirements of this Chapter.
- (j) “Plan” means a non-exempt health plan, health insurer, or public self-insured plan; and any voluntarily participating entity.
- (k) “Qualified Health Plan” means a Qualified Health Plan offered by the California Health Benefit Exchange, also known as Covered California.
- (l) “Qualified Dental Plan” means a plan providing limited scope dental benefits as defined in 26 USC Section 9832(c)(2)(A), including the pediatric dental benefits meeting the requirements of 42 USC Section 18022(b)(1)(J).
- (m) “Member” means a person who is enrolled in or covered by a plan.
- (n) “Registered submitter” means a plan that has registered to submit data to the system. An entity that is a delegated submitter under Section 97318, “Coordination of data submissions” that has registered to submit data will be considered a registered submitter.
- (o) “Delegated submitter” means an entity identified pursuant to Section 97318, “Coordination of data submissions” as responsible for submitting data to the system on behalf of a plan.

- (p) “Designated submitter representative” means an individual or individuals designated by a registered submitter to submit data on behalf of the registered submitter and receive all communications from the System and the Department regarding data submissions.
- (q) “Data portal” means the secure data submission mechanism through which plans register to submit data and through which data files are submitted to the System. The data portal is available via the Department's internet web site.
- (r) “Data Submission Guide” means the Health Care Payments Data Program: Data Submission Guide, dated September 1, 2021 and hereby incorporated by reference. The Data Submission Guide document is available on, and may be downloaded from, the Department’s website.
- (s) “APCD-CDL™” means the Common Data Layout for All-Payer Claims Databases, Version 2.1, released July 1, 2021, as developed by the University of New Hampshire and the National Association of Health Data Organizations (NAHDO), and hereby incorporated by reference. The APCD-CDL™ is available for download from the APCD Council website.

Note: Authority Cited: Sections 127671.1 and 127673, Health and Safety Code.
Reference: Sections 127671, 127673, 127673.1, and 127673.2, Health and Safety Code.

Article 2. Voluntary Participation in the Program

§ 97305. Voluntary Participation in the Program.

- (a) To request to become a voluntarily participating entity, an entity, or authorized agent of the entity, shall submit to the Department an application to participate in the program.
- (b) The application shall be submitted through the data portal.
- (c) Each application will include the type of business entity (see Article 1. Definitions - “Voluntarily participating entity”), the number of covered lives, the types of coverage offered, and contact person information.
- (d) The Department shall notify applicants if they are approved to participate in the program.

Note: Authority Cited: Sections 127671.1 and 127673, Health and Safety Code.
Reference: Sections 127673, and 127673.2, Health and Safety Code.

Article 3. General Provisions

§ 97310. Plan Size Thresholds.

(a) A health plan, health insurer, or public self-insured plan that has fewer than 40,000 California members through both Medicare Advantage plans and private plans or insurance is exempt from the requirements of this Chapter, unless the plan is a Qualified Health Plan. For the purposes of this section, number of California members shall be counted as of December 31 of each calendar year.

(b) Application of threshold requirements

(1) A non-exempt health plan, health insurer, or public self-insured plan with enrollment that drops below 40,000 as of December 31, shall be responsible for submitting data files for time periods through December. The health plan, health insurer, or public self-insured plan shall notify the Program of its change in status. Such a plan or insurer may elect to become a voluntarily participating entity.

(2) An exempt health plan, health insurer, or public self-insured plan that gains members to become no longer exempt shall be responsible for submitting data for time periods beginning on January 1 of the next calendar year.

(3) A newly created health plan, health insurer, or public self-insured plan that on December 31 of the year in which it is created is not exempt because of size shall be responsible for submitting data for time periods beginning on January 1 of the next calendar year.

Note: Authority Cited: Sections 127671.1 and 127673, Health and Safety Code.
Reference: Section 127673, Health and Safety Code.

§ 97312. Dental Plans.

Dental plans are exempt from the requirements of this Chapter until the system capacity has been enhanced as necessary and additional regulatory structure adopted.

Note: Authority Cited: Sections 127671.1 and 127673, Health and Safety Code.
Reference: Sections 127671, 127673 and 127673.1, Health and Safety Code.

§ 97314. Qualified Health and Dental Plans.

A Qualified Health Plan or Qualified Dental Plan that has been granted an exemption from reporting information to the program by Covered California is not required to register with or submit data files to the data portal.

Note: Authority Cited: Sections 127671.1 and 127673, Health and Safety Code.
Reference: Section 127673, Health and Safety Code.

§ 97316. Restricted or Limited Plan Data.

A health plan that has contracted with a restricted or limited licensee to perform health

plan functions shall be responsible for reporting all required data associated with the functions delegated to the restricted or limited licensee as if the health plan had performed the functions.

Note: Authority Cited: Sections 127671.1 and 127673, Health and Safety Code.
Reference: Sections 127673 and 127673.1, Health and Safety Code.

§ 97318. Coordination of Data Submissions.

- (a) If a plan contracts with other entities to administer plan benefits, the plan shall be responsible for the submission of all data for the plan's members. Entities that are contracted to administer plan benefits may include but are not limited to, pharmacy benefit managers and behavioral health organizations and, for a health plan, restricted or limited health plan licensees with which they contract. The plan shall either:
 - (1) Obtain necessary data from the contracted entity and submit the data to the system, or
 - (2) Ensure that the contracted entity submits the data directly to the system.
 - (A) The plan shall identify each such contracted entity through the registration process.
 - (B) Each contracted entity shall register pursuant to Article 4 and identify the plan or plans for which it will submit data; the entity will be referred to as a delegated submitter.

Note: Authority Cited: Sections 127671.1 and 127673, Health and Safety Code.
Reference: Sections 127673 and 127673.1, Health and Safety Code.

Article 4. Data Portal Registration

§ 97330. Registration Requirement.

- (a) A health plan, health insurer, or public self-insured plan shall register to submit data to the data portal.
 - (1) Initial registration for the new program must be completed by April 29, 2022.
 - (2) When any health plan, health insurer, or public self-insured plan becomes subject to this Chapter, it shall register at least 15 calendar days before its first data files are due.
- (b) A voluntarily participating entity, directly or through an authorized agent of the entity,

shall register to submit data to the data portal.

- (1) Prior to registering, the entity must have been approved, pursuant to Section 97305, to submit data.

Note: Authority Cited: Sections 127671.1 and 127673, Health and Safety Code.

Reference: Sections 127673, 127673.1 and 127673.2 Health and Safety Code.

§ 97332. Registration Process.

- (a) A plan, and any delegated submitters, must register through the data portal and provide all required information as specified in the Data Submission Guide.
- (b) Each plan or delegated submitter shall identify two or more designated submitter representatives and provide business title, email, and phone contact information for each person.
- (c) Each registering plan will identify all delegated submitters, and which files each delegated submitter will be submitting on behalf of the plan.
- (d) Each delegated submitter must identify the plan or plans for which they will be submitting data, and which data file types they will submit for each.
- (e) A plan and any delegated submitter(s) will be notified when registration is approved.

Note: Authority Cited: Sections 127671.1, and 127673, Health and Safety Code.

Reference: Sections 127673 and 127673.1, Health and Safety Code.

§ 97334. Registration Information Update.

- (a) Each plan or other entity that has registered to submit data must update registration information within 15 calendar days of any change in the required contact information.
- (b) Each plan or other registered entity must review and update or confirm all registration information annually by the last calendar day of February.

Note: Authority Cited: Sections 127671.1 and 127673, Health and Safety Code.

Reference: Sections 127673 and 127673.1, Health and Safety Code.

Article 5. Monthly Data File Submission

§ 97340. Monthly Data Submission.

- (a) Plans shall submit data files monthly through the data portal.

- (b) Each monthly file shall be submitted by the first business day of the second month after the report month.

Note: Authority Cited: Sections 127671.1 and 127673, Health and Safety Code.
Reference: Sections 127673 and 127673.1, Health and Safety Code.

§ 97342. Data File Contents.

- (a) The following files, as specified in the Data Submission Guide in conjunction with the APCD-CDL™, shall be submitted.
- (1) Member Eligibility File (ME) – contains demographic information for each individual member residing in California, regardless of whether the member utilized services during the reporting period.
 - (2) Medical Claims File (MC) – contains service-level medical claims and encounter data processed during the reporting period, that were not fully denied, except as prohibited by federal or state law.
 - (3) Pharmacy Claims File (PC) – contains detailed pharmacy claims and encounter data processed during the reporting period, that were not fully denied, except as prohibited by federal or state law.
 - (4) Provider File (PV) – contains demographic-type data on every provider included on the ME, MC or PC files during the reporting period.
- (b) Files shall exclude data for any members who are exclusively enrolled in Medi-Cal or one of the following types of coverage:
- (1) Dental-only
 - (2) Supplemental (including Medicare supplemental)
 - (3) Student health
 - (4) Chiropractic-only
 - (5) Acupuncture-only
 - (6) Vision-only

Note: Authority Cited: Sections 127671.1 and 127673, Health and Safety Code.
Reference: Sections 127673 and 127673.1, Health and Safety Code.

§ 97344. Data File Technical Requirements.

Data files shall comply with file format, technical specifications, and other standards specified in the Data Submission Guide and the APCD-CDL™.

Note: Authority Cited: Sections 127671.1 and 127673, Health and Safety Code.
Reference: Sections 127673 and 1227673.1, Health and Safety Code.

§ 97346. Submission Completion.

If a registered plan has identified one or more delegated submitters to submit information directly to the data portal on behalf of the plan, the plan's data submission shall not be considered complete until all required files have been received.

Note: Authority Cited: Sections 127671.1 and 127673, Health and Safety Code.
Reference: Sections 127673 and 127673.1 Health and Safety Code.

§ 97348. Test File Submission.

Registered submitters shall use the data portal to submit test files to confirm and test their ability to create data files meeting the data submission standards. Test files will be identified as specified in the Data Submission Guide. Test files will not be considered to have been submitted to the program.

Note: Authority Cited: Sections 127671.1 and 127673, Health and Safety Code.
Reference: Sections 127673.4. Health and Safety Code.

Article 5.5. Special rules for program opening and historical data submission:

§ 97350. Preparation for Historical Data Submission.

Each registered submitter shall use the test function to prepare for data file submission; plans shall successfully complete the testing process by July 29, 2022.

Note: Authority Cited: Sections 127671.1 and 127673, Health and Safety Code.
Reference: Section 127673, Health and Safety Code.

§ 97351. Historical Data Files.

(a) Plans shall submit historical data files including, to the extent the plans have such data available, all data that would have been included in monthly files as described in Sections 97342 and 97344 for the calendar years 2019, 2020, and 2021.

(b) Historical data shall be filed by October 28, 2022.

Note: Authority Cited: Sections 127671.1 and 127673, Health and Safety Code.
Reference: Sections 127673, Health and Safety Code.

§ 97352. Initiation of Monthly File Reporting.

Plans shall begin regular monthly reporting with monthly files for November 2022, or earlier at their election. By February 1, 2023, plans shall file all data that would have been included in monthly files for the months of 2022 prior to their first regular monthly submission.

Note: Authority Cited: Sections 127671.1 and 127673, Health and Safety Code.
Reference: Section 127673, Health and Safety Code.

Article 6. Data Acceptance and Correction

§ 97360. Data Acceptance.

- (a) Data files that are submitted to the data portal but do not meet the intake specifications detailed in the Data Submission Guide will not be accepted.
- (a) A plan and the delegated submitter will be notified within 3 business days of whether a data file submission has been accepted or rejected.

Note: Authority Cited: Sections 127671.1, 127673, and 127673.4, Health and Safety Code. Reference: Sections 127673.1 and 127673.4, Health and Safety Code.

§ 97362. Data Review and Correction.

If the Department determines that accepted files contain initially unidentified errors or anomalous data inconsistent with data standards, historical trends, or benchmarks, such files may be flagged, and the submitter requested to address the issues by either confirming that the data are correct or correcting and resubmitting the file within 45 days or as specified by the Department.

Note: Authority Cited: Sections 127671.1, 127673, and 127673.4, Health and Safety Code. Reference: Sections 127673.1 and 127673.4, Health and Safety Code.

Article 7. Variances

§ 97370. Requesting a Variance.

- (b) A plan that is unable to submit accepted data files may request a temporary variance to data standards.
- (c) Variance requests shall be submitted through the data portal, and shall clearly identify the current issues, the plan for correction, and the anticipated date of correction.

Note: Authority Cited: Sections 127671.1, 127673, and 127673.4, Health and Safety Code. Reference: Sections 127673.1 and 127673.4, Health and Safety Code.

§ 97372. Response to Variance Request.

The Department may grant variances to allow a plan time to review and correct data file submissions.

Note: Authority Cited: Sections 127671.1, 127673, and 127673.4, Health and Safety Code. Reference: Sections 127673.1. and 127673.4, Health and Safety Code.
