DEPARTMENT OF HEALTH CARE ACCESS AND INFORMATION

FINDING OF EMERGENCY AND NOTICE OF PROPOSED EMERGENCY REGULATIONS

HEALTH CARE PAYMENTS DATA PROGRAM
[Health and Safety Code sections 127671 - 127674.1]

SUBJECT MATTER OF PROPOSED REGULATIONS
Implementation and start of the Health Care Payments Data Program (HPD) pursuant to Health and Safety Code (HSC) sections 127671 to 127674.1.

REQUIRED 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.

This document provides the required notice that the Department of Health Care Access and Information (HCAI), formerly the Office of Statewide Health Planning and Development, will submit a proposed emergency action to the OAL to initially implement the HPD, pursuant to HSC sections 127673(e) and (f).

As required by subdivisions (a)(2) and (b)(2) of Government Code section 11346.1, this notice includes and incorporates the following: (1) the specific language of the proposed regulations and (2) the Finding of Emergency, including specific facts demonstrating the need for immediate action, the authority and reference citations, the informative digest and policy statement overview, and required determinations.

SPECIFIC FACTS DEMONSTRATING THE NEED FOR IMMEDIATE ACTION
HCAI is statutorily required to establish and administer the HPD to collect health care data from health care plans, health insurers, government agencies and others (HSC section 127671.1). Currently, 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 (HSC section 127673(e) and (f)). This is HCAI's initial adoption of regulations to implement the HPD.

AUTHORITY AND REFERENCE
The authority under which these regulations are proposed is HSC section 127673, subdivisions (e) and (f).

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

INFORMATIVE DIGEST

Existing Law

Existing law requires HCAI to establish the HPD Program to collect health care data from health plans, insurers, government agencies, and others, and states that HCAI is to "substantially complete" the development of the HPD system no later than July 1, 2023.

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.

General Policy Statement

Eventually, once it has collected and processed sufficient data, 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.

These proposed emergency regulations have been developed to initiate HPD's first stage, which is to start collecting core health care data by identifying submitters, specifying data to be collected, creating a process for data submission, and stating the timeline of data collection. After this stage, HCAI plans to expand HPD and its regulations to collect other types of data and, while protecting privacy, to release/analyze data to meet its purpose of bringing transparency and ultimately improving health care in California.

Documents Incorporated by Reference in the Proposed Emergency Regulations

As discussed in more detail below, 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.

Also as discussed in more detail below, HCAI also proposes to incorporate by reference *The Health Care Payments Data Program: Data Submission Guide*, dated November 23, 2021 (hereinafter "DSG"). This document has additional requirements for submitter registration and offers additional detail for data submissions not covered in the APCD-CDL™. The DSG will be available on, and may be downloaded from, the HCAI website.

Necessity of Each Proposed Regulation to Effectuate Statute

HSC section 127673(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 are to be added to address these areas and are needed to implement the HPD.

The following states the specific purpose of each proposed regulatory provision and information explaining why each regulatory provision is needed to effectuate HPD statute. Many of these provisions are based on the information and recommendations in *The Health Care Payments Data Program: Report to the Legislature*, dated March 9, 2020 (hereinafter "HPD Legislative Report"). HCAI[1] was required to prepare this report for the California Legislature based on input of a committee and others about how HPD should be implemented. (*See* Assembly Bill No. 1810, section 23 (2017-2018); and HSC section 127672(d) (2019) [requiring HCAI to create the legislative report for HPD].)

1. California Code of Regulations (CCR), title 22, section 97300, "Definitions"

HCAI proposes this regulation for the purpose of providing definitions for several terms used in later proposed regulations. The definitions are needed to ensure that the regulations that follow meet the clarity requirement and to provide the specificity necessary for compliance with the regulations. Specific explanations for each definition are below:

Terms in Section 97300, subdivisions (a) "APCD-CDL™", and (c) "Data Submission Guide": HCAI proposes to incorporate two documents by reference into these HPD regulations. As these documents are mentioned in multiple regulations, these provisions are to incorporate by reference these documents, respectively, in one place and identify these documents using simpler terms instead of having to repeatedly describe the documents in multiple areas.

The reasons why these two documents have been incorporated by reference will be discussed in the sections that require their usage.

Terms in Section 97300, subdivisions (b) "Data Portal", (d) "Delegated Submitter", and (h) "Designated Submitter Representative": Multiple regulations use the terms "delegated submitter," "designated submitter representative," and "data portal." HCAI introduces and defines these terms here, so they do not have to be repeatedly defined in regulation.

Term in Section 97300(e) "Dental Data" and (f) "Dental Plan": Subsequent proposed regulations have different timelines for mandatory submitters that only provide dental services and for data exclusively related to dental services. These terms, "Dental Data" and "Dental Plan," define the data and entities that are subject to these different

[1] This was when HCAI was named the "Office of Statewide Health Planning and Development."

timelines for clarity because these terms are used in several proposed regulations.

Generally, HCAI has discretion to adopt emergency regulations regarding the "timelines for data submission." (HSC section 127673(e)(4).) Under this authority, HCAI is requiring later registration and data submission deadlines for dental plans and dental data compared to other entities and other required data. The reason for this is that the HPD system will not be ready to collect dental data until those later dates. Compared to medical coverage, "[d]ental coverage is not normally integrated with medical coverage and features a distinct set of market players and characteristics." (HPD Legislative Report, page 57.) Because of these significant differences and the complexity in collecting core medical data alone, HCAI is implementing the HPD system in stages and anticipates the system will be ready for dental data at a later date. (*See* HPD Legislative Report, pages 21-22; Exhibit 11 [noting HCAI's plan to include dental data in "Tier 2" of HPD implementation].) The later deadlines for dental plans and dental data reflect this.

There is a separate definition for "dental data" because non-dental plans may also provide dental services along with other health care services. For the reasons noted above, the HPD system will not be ready to accept this type of data.

The specific deadlines related to dental plans and dental data are discussed below in the relevant proposed regulations.

Terms in Section 97300, subdivisions (g) "Department", (i), "Director", (n) "Program", and (r) "System": These terms, "Director," "Department," "Program," and "System," and the definitions of these terms are taken directly from statute, HSC section 127671(f).

Term in Section 97300(j) "Health Insurer": Under HPD statute, "an insurer licensed to provide health insurance, as defined in Section 106 of the Insurance Code" is a mandatory submitter of data to HPD. (Health and Safety Code section 127673(c)(2).) The regulatory term "health insurer" is a simpler term for this type of entity and the definition of "health insurer" reiterates the statutory description for these entities.

Pursuant to HSC section 127673(e), HCAI is required, through regulation, to identify "required and exempted lines of business" for HPD data reporting. HCAI does this by including and excluding certain types of health insurance entities in its definition of "health insurer" (see HPD Legislative Report, pages 60-61, regarding meaning of "lines of business").

HCAI only includes the following types of specialized health insurance providers in its definition of "health insurer": pharmacy, behavioral health (psychological), and dental services; and excludes insurers which only offer other types of specialized health insurance, supplemental insurance, discount-only, and student health insurance. This was done to be consistent with HCAI's definition of "health plan" as discussed and explained below.

HCAI also excludes stop-loss insurance from this definition because these are not health insurance as noted in the HPD Legislative Report, page 60, and this is stated to

make clear that those insurers just offering this type of insurance are not subject to HPD.

Term in Section 97300(k), "Health Plan": The term "health plan" is a simpler form of the terms "health care service plan" and "specialized health care service plan" which are used, but not defined, in HPD statute. Per statute, these plans are "mandatory submitters" of data to HPD. (HSC section 127673(c)(1).)

This definition is needed because statute does not define the statutory terms, "health care service plan" and "specialized health care service plan." This section makes clear that these terms are defined pursuant to the Knox-Keene Health Care Service Plan Act of 1975 because HSC section 127674.1 clearly means this by referring to "health care service plans" licensed by the Department of Managed Health Care (DMHC), the department that implements the Knox-Keene Act.

Pursuant to HSC section 127673(e), HCAI is required, through regulation, to identify the "required and exempted lines of business" for HPD data reporting. HCAI does this for health care service plans through this proposed regulation by including plans that provide certain services and excluding plans that exclusively provide certain services in its definition of "health plan." (*See* HPD Legislative Report, pages 60-61, regarding "lines of business").

DMHC has the following categories of specialized health care service plans: chiropractic, dental, dental/vision, discount, pharmacy, psychological, and vision.[2] The HPD Legislative Report recommended not to collect data from plans that just offer chiropractic, discount, and vision services because such plans, unlike dental, pharmacy and psychological, are "only tangentially related to… or are substantially different from standard medical benefits such that [their data] are not comparable" to the majority of data HPD would collect. Collection of this data would be a "relatively high burden and relatively low value." The HPD Legislative Report also noted the same problems for supplemental plans and student health plans and recommended to exclude these plans as well. (HPD Legislative Report, pages 61 and 71.)

HCAI followed these recommendations and defined "health plan" to only include specialized health care service plans offering pharmacy, psychological, or dental services, excluding plans that just offer chiropractic, discount, and vision services. HCAI also specifically excludes plans that just offer supplemental or student health plans in this definition. This is to prevent collection of less useful data and save costs to both HCAI and plans.

Furthermore, as discussed in the HPD Legislative Report, pages 59-60, DMHC gives restricted or limited licenses to health care providers who may share financial risk with the health care service plans with which they contract. These entities are not really health plans as they only subcontract with fully licensed health care service plans and do not directly sell to employers or consumers. The contracting fully licensed health

[2] This information is from the Department of Managed Health Care website at https://wpso.dmhc.ca.gov/dashboard/SearchHealthPlan.aspx, last accessed on November 5, 2021.

plan receives data from these restricted/limited licensees. For these reasons, HCAI excludes these restricted/limited plans from the definition of "health plan" to make clear that they are not mandatory submitters.

Terms in Section 97300(l) "Member": Several subsequent regulations use the term "member" (sections 97310, 97318, and 97342). HCAI introduces and defines this term here, so it does not have to be repeatedly defined in regulations.

Term in Section 97300(m) "Plan": The term "plan" is for the purpose of having a simple term to identify all types of entities submitting data to HPD for subsequent regulations.

Term in Section 97300(o) "Public Self-Insured Plan": Under HPD statute the following types of entities are mandatory submitters of data to HPD:

> "a self-insured plan subject to [HSC section] 1349.2, or 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." (HSC section 127673(c)(3).)

HSC section 1349.2 is in regard to health care service plans "operated" by a governmental entity or a public joint labor management trust.

This term, "public self-insured plan," is a simpler term for this type of entity for use in subsequent regulations and the definition of "public self-insured plan" reiterates the statutory description for this type of entity.

Terms in Section 97300(p) "Qualified Health Plan": HPD statute has special provisions for "qualified health plans offered by the California Health Benefit Exchange." (HSC section 127673(e)(1) and (g)(1).) This term, "qualified health plan," is to have a clear and simple term for these entities for clarity purposes because there are multiple regulatory provisions for them.

Terms in Section 97300(q) "Registered Submitter": Several subsequent regulations use the term "registered submitter." HCAI introduces and defines this term here, so it does not have to be repeatedly defined in regulation.

HCAI also clarifies that "delegated submitters" are also "registered submitters" here to avoid confusion.

Term in Section 97300(s) "Voluntarily Participating Entity": HPD statute authorizes the collection of data from "voluntary submitters." (HSC section 127673(b).) HPD statute provides a nonexclusive list of entities that can be "voluntary submitters" and gives HCAI discretion to accept voluntary data. (HSC section 127673(d).)

The purpose of this term, "voluntarily participating entity," is to have a term for those entities who have been approved by HCAI to voluntarily submit data to HPD for clarity purposes and also to identify what types of entities are eligible to voluntarily submit data

because statute provides a nonexclusive list. This is to notify potential voluntary submitters of their eligibility and to prevent other types of entities from trying to submit to HPD.

For this term, HCAI incorporates the list of entities and language from HSC section 127673(d) and also adds one more type of entity: "a health plan or health insurer exempt from the requirements of" HPD. HCAI adds this additional category because such an entity may be exempt from HPD because of threshold limits—that is, the number of members it has (*see* proposed section 97310 below). A reason for threshold limits is so HPD does not create undue hardships for small entities who are not capable of meeting HPD reporting requirements. However, if a small entity is capable of meeting HPD reporting requirements, this gives them the option to submit data to the HPD.

2. CCR, title 22, section 97305, "Voluntary Participation in the Program"

HCAI proposes adopting this regulation to provide the process for which an entity may be approved to voluntarily submit data to HPD. This regulation specifies how to request approval, states what information must be provided to HCAI, and notes that HCAI will notify those approved to be voluntary submitters.

Regarding why this regulation is needed, the overall purpose of HPD is to create a centralized system to collect health care information to increase transparency and improve health care in California. (HSC section 127671.) Approximately 4.6 million Californians are under employer self-insured health plans covered by the federal Employee Retirement Income Security Act of 1974 (ERISA)—about 12% of Californians that have health care coverage. (HPD Legislative Report, page 49, Exhibit 18.) Because of a United States Supreme Court decision, *Gobeille v. Liberty Mutual Ins. Co.*, 577 U.S. 312 (2016), the State of California cannot compel these self-insured ERISA entities to provide health care data to HPD. (*See* HPD Legislative Report, pages 66-67.) However, as these ERISA entities data covers a substantial amount of Californians, this data is important to analyze health care in California. For this reason, the HPD Legislative Report recommended that HCAI "develop an appropriate process to encourage voluntary data submission." (HPD Legislative Report, page 71, Recommendation 9(b).)

HPD statute reflects this recommendation and states that HCAI will, at its discretion, accept voluntarily submitted data from "self-insured employers," and other entities, which are under ERISA. HPD statute also states that "providers," "suppliers," and others can be voluntary data submitters. (HSC section 127673(d).)

This regulation is to effectuate this recommendation and this legislative directive by giving notice to potential voluntary submitters of the process to become HPD voluntary data submitters and providing a simple and convenient process to encourage entities to become voluntary submitters. This regulation requires a written request to allow HCAI

to keep track of requests and to evaluate requests better. For convenience, this regulation allows an authorized agent of an eligible entity to make a request because many eligible entities contract with third-party administrators, who administer their health care programs.

HCAI requests the following information on requests to become a voluntarily participating entity: (1) type of business entity, (2) number of covered lives, (3) the types of coverage offered, and (4) contact information. "Type of business entity" is needed so HCAI can determine whether the applicant is an entity that is eligible per statute and regulation. The "number of covered lives" and "the types of coverage offered" are needed for HCAI to determine whether the entity is a good source of data versus the cost of collecting and processing the data. If the available data is too limited or too dissimilar to HPD data, HCAI may determine the entity is not a good candidate to be a voluntary data submitter. Lastly, contact information is needed to be able to communicate with the applicant if more information is needed to process the request and to inform the entity if it is approved to be a voluntary submitter.

3. CCR, title 22, section 97310, "Plan Size Thresholds"

For HPD, HCAI is required to adopt emergency regulations about:

> "plan size thresholds for submitters, with consideration given to implementation costs for both the submitter and the department. Thresholds shall not apply to qualified health plans offered by the California Health Benefit Exchange or submitters covering more than a total of 50,000 Californians through both Medicare Advantage plans and the private plans and insurance described in subdivision (b)." (HSC section 127673(e)(1).)

The above requires HCAI to set a minimum plan size threshold for entities to be mandatory submitters (i.e., "health plans," "health insurers," and "public self-funded plans" as defined in section 97300), and this proposed regulation is to effectuate this. This HPD statute also states that HCAI can exempt small entities from HPD requirements because of cost impacts and sets a minimum threshold of 50,000 members. This proposed regulation also details when and how this threshold will be applied.

Subdivision (a) of this proposed regulation exempts entities with "fewer than 40,000 California members" from the HPD (with "member" defined in section 97300). Per the considerations in HSC section 127673(e)(1), HCAI chose this threshold as the proper balance between completeness of data versus the costs to HCAI to collect and process smaller datasets and the costs to smaller entities to submit data.

HCAI determined, per the HPD Legislative Report, that a threshold of 40,000 members would include the vast majority of Californians with commercial health care coverage—

98.25% of such Californians—and would include about 18 mandatory submitters. HCAI considered going to a threshold of 30,000 members but determined that some entities captured by this threshold were so small that they would have difficulty submitting data and would be harmed by such a requirement. Also, going from 40,000 to 30,000 would only have increased the amount of data by less than 1% of Californians, which HCAI determined was not the worth the costs of data collection. (*See* HPD Legislative Report, pages 63-64 [health care coverage thresholds].)

Also, per the HPD Legislative Report, a threshold of 40,000 members would include the vast majority of Californians with commercial dental coverage—about 98.10% of such Californians—and would include about 32 mandatory submitters. A threshold of 30,000 members may not include any additional dental submitters per the HPD Legislative Report. As stated above, HCAI determined that going lower than 40,000 members was not worth the costs of collection based on the amount of data that would be collected. (*See* HPD Legislative Report, pages 65 and 176 [dental thresholds].)

This regulation notes that this plan size threshold does not apply to "Qualified Health Plan" (as defined in section 97300) as mandated by HSC 127673(e)(1).

Subdivision (a)(1) of this proposed regulation states how the number of California members will be counted for each entity. This states that the number is calculated by adding together all the California members in an entity's "Medicare Advantage plans, private health plan products, and private health insurance products." This standard is from HSC section 127673(e)(1), which mandates that thresholds do not apply to "submitters covering more than a total of 50,000 Californians through Medicare Advantage plans and the private plans and insurance described in subdivision (b)" of HSC 127673. HCAI uses this statutory standard as it is for the same purpose and clarified it in this proposed regulation by stating that the number of members had to be added from each of these three types of health care products mentioned in statute.

Subdivision (a)(1) of this proposed regulation also defines "private" to avoid confusion with the proposed term, "public self-insured plans" or other references to public employers. The HPD Legislative Report, pages 30 and 37, discusses "commercial" health care coverages and states this term includes health care products obtained by private employers, public employers or purchasers, individuals/families, and Medicare Advantage. From this, it seems the term "private" in HSC 127673(e)(1) means "commercial" health care products except Medicare Advantage. For this reason, "private" is defined to exclude only the general public health care programs, Medi-Cal and Medicare, and not public employers.

This proposed regulation also specifies how the threshold limit will be applied to potential mandatory submitters and to give notice to affected entities and to establish clear rules for HCAI to follow. HCAI decided to have the number of Californian members counted once a year on December 31—that is, an entity that has 40,000 or

more members on December 31 has to report data for the next full calendar year. By having this calculated once a year at the end of the year, and requiring reporting for the entire calendar year, HCAI will be able to obtain consistent and comparable data from reporting entities to make data analysis better and better meet HPD's purposes. Also having only one calculation per year will reduce administrative costs to HCAI and uncertainty for data submitters.

For those already mandatorily submitting data to HPD, if they drop below the 40,000 threshold as of December 31, this regulation requires such entities to notify HCAI of this change because the entity would be in the best position to have this knowledge. Also, this regulation provides notice that such an entity may become a voluntary submitter as a way to encourage continued data submission to have more consistent and complete data.

This regulation also discusses the scenario when a potential mandatory submitter is newly created and that the threshold for such an entity will be determined on December 31 of the year the entity is created. For these entities, if they meet the 40,000 threshold, the regulation clearly states they are required to report data the next calendar year on January 1. This again is to have consistency in data reporting requirements and the collected data.

4. CCR, title 22, section 97314, "Qualified Health Plans"

HSC section 127673(g)(1) requires a "qualified health plan" to submit data directly to HPD or through the California Health Benefit Exchange, "as determined by the exchange." This proposed regulation notes that if the Exchange has exempted a qualified health plan from directly reporting to HPD, that entity is not required to register or submit data to the HPD data portal. The purpose of this proposed regulation is to clearly notify Exchange-exempted qualified health plans that they have no HPD obligations, including registration.

5. CCR, title 22, section 97318, "Coordination of Data Submissions"

For HPD, HCAI is required to adopt emergency regulations about:

> "Coordination of submission in cases where submitters contract with other entities to administer health care benefits." (HSC section 127673(e)(3).)

This proposed regulation is to meet this mandate which is to set how data submissions will be coordinated between mandatory/voluntary data submitters and their contractors. This regulation makes data submitters responsible for submitting health care data that their contractors have regarding the data submitters' members. This regulation also provides a non-exclusive list of examples of contractors that are covered by this requirement.

This regulation is necessary because many data submitters contract with other entities to administer, either in whole or in part, their health benefit programs (discussed in the HPD Legislative Report, pages 58-60). As HPD requires this data to effectively carry out its overall purpose of transparency and improving health care in California, this regulation puts the responsibility on the contracting data submitters because they are in the best position to know their contractors and to make sure that contractor data is submitted to HPD.

This proposed regulation also provides options to the mandatory submitter to meet this responsibility—either (1) the mandatory submitter directly obtains and submits the data from its contractors, or (2) the mandatory submitter ensures that the contractors directly submit data. This is to give flexibility to mandatory submitters in meeting this requirement.

The proposed regulation, if (2) is chosen, requires the mandatory submitter to identify each contractor through the registration process, and for such contractors, referenced as "delegated submitters," to register themselves in HPD and also identify the mandatory submitters for which the contractors will submit data. These requirements are needed so that there is clear record identifying contractors, and clearly linking contractors to their contracting data submitters as this information is needed to have complete and accurate data.

6. CCR, title 22, section 97330, "Registration Requirement"

Subdivisions (a) and (b) of this proposed regulation establishes the requirement that mandatory submitters and approved voluntary submitters register with HCAI before submitting data to HPD. Submitters are required to register instead of HCAI contacting potential submitters because submitters are in the best position to determine whether they are subject to HPD and can easily provide information to HCAI.

In general, registration is needed because HPD needs a record of HPD data submitters to keep track of those who are submitting data to HPD. Furthermore, registration is needed for data submitters because, per HSC section 127673.3(a), HCAI is mandated to create a "master payer index," which is a record "that keeps track of a [payer's] various identifiers." (HPD Legislative Report, pages 40.) Data submitters will for the most part be "payers" and information received through registration will be used to create this master payer index in HPD. An index like this is needed because, as statute indicates, this will "enable the matching" of various records to a single payer/submitter, which allows HPD to have accurate and useful data for analysis.

Subdivision (a) of this proposed regulation, for the beginning of HPD, requires mandatory data submitters to HPD to register by certain deadlines. Subdivision (a) provides a later registration deadline for dental plans compared to other mandatory submitters—for the reasons for this, see above regarding the definitions of "dental data" and "dental plan" (proposed section 97300(e) and (f)).

Subdivision (a)(1) requires mandatory submitters, except dental plans (as defined in section 97300), to register by May 27, 2022. As these regulations are expected to go

into effect around January 1, 2022, HCAI believes this deadline gives entities a reasonable amount of time, five months, to determine if they are non-dental mandatory submitters and to register with HCAI. HCAI has been meeting with potential mandatory submitters and stakeholders about HPD for more than a year and thus, the start of HPD registration at this time will not be a surprise to affected entities. HCAI also meets with potential mandatory submitters on a regular basis.

Subdivision (a)(2) requires dental plans who are mandatory submitters, to register by March 29, 2024. By this time, the HPD system should be ready to accept dental data, and this provides dental plans sufficient time to determine whether they are mandatory submitters and to register.

Subdivision (a)(3) of this proposed regulation requires mandatory submitters that newly become subject to HPD to register "at least 15 calendar days before its first data files are due." The purpose of this is to give HCAI sufficient time before receiving data to process information about the new mandatory submitter before receiving data.

Subdivision (b) of this proposed regulation also allows an approved voluntary data submitter to register through an authorized agent, such as a third-party administrator. As discussed above for section 97305, voluntary data is important to analyze health care in California, and thus, this is to encourage entities to become voluntary submitters by making the process more convenient.

Subdivision (b)(1) reminds potential voluntary submitters that they must go through the voluntary submitter application process and be approved by HCAI before registering. This is to avoid confusion and to prevent entities from registering before going through the request process.

7. CCR, title 22, section 97332, "Registration Process"

This proposed regulation requires data submitters to register through the HPD data portal. This is required because electronic registration is the most efficient and convenient method for HCAI to receive registration information and for data submitters to submit such information.

This proposed regulation also requires data submitters to provide the required information specified in *The Health Care Payments Data Program: Data Submission Guide*, dated November 23, 2021 (hereinafter "DSG"), which was developed by HCAI. The reason why this information is in the DSG is to make it more convenient for data submitters to look up this information and to have it in a more readable text format so data submitters will be more likely to read and understand these requirements. The DSG's registration requirements will be discussed later when the DSG is discussed.

8. CCR, title 22, section 97334, "Registration Information Update"

Subdivision (a) of this proposed regulation requires registered submitters to update their registration information within 15 calendar days of any change in the required contact information. The purpose of this is to make sure that HCAI has the most up-to-date

contact information, so HCAI knows who to contact if there is an urgent problem or concern, and also gives submitters a reasonable amount of time to report the change. Without this information being updated timely, it may take an inordinate amount of time for HCAI to locate the right person to communicate with about urgent problems or concerns.

Subdivision (b) of this proposed regulation requires registered submitters to review and update/confirm all registration information annually by the last calendar day of February. The purpose of this subdivision is to make sure that submitters have the most accurate information in HPD every year. This will help make sure that data submitted is accurate and complete and for HPD to make necessary changes or additions to the master payer index (as discussed above). This requirement is set at the same time every year to make compliance easier.

9. CCR, title 22, section 97340, "Monthly Data File Submission"

For HPD, HCAI is required to adopt emergency regulations about "timelines for data submission, and the methods of data collection…" and "[f]requency of submission by… mandatory submitters of all core data…." (HSC section 127673(e)(4) and (5).) This proposed regulation sets the frequency of data submissions and methods of data collection as required by statute.

Subdivision (a) of this proposed regulation requires submitters to submit monthly data files through the data portal. HCAI chose monthly submissions because since California is so large, any larger time period, such as quarterly submissions, would result in huge file sizes that could create challenges in sending and receiving the files. (HPD Legislative Report, page 66.) Any smaller time period would be burdensome for submitters and HCAI to submit, process, and review submissions so frequently. Monthly submissions have a better balance in obtaining relevant data while accounting for potential technical issues and work submitters and HCAI have to do.

Data submissions are required electronically through the data portal because that is the most secure and convenient method currently available for submitters and HCAI. Any form of hardcopy transmission is not practical with the amount of data and may be insecure as documents have to be delivered. The data portal will be controlled by HCAI and will be secure to prevent the loss of confidential health care information.

Subdivision (b) of this proposed regulation sets the deadline to file as "the first business day of the second month after the report month." For instance, for data from August 2022, a submitter would be required to submit this data on October 3, 2022. This essentially gives a submitter one month to put together its data for the previous month and submit it to HPD. HCAI believes this is a reasonable amount of time for submitters to be able to put together data files and submit. This requirement is also consistent with industry data submission practices.

10. CCR, title 22, section 97342, "Data File Contents"

HPD statute requires submitters to submit the following data to HPD: (1) utilization data from medical payments or encounter data, (2) pricing information for health care items and services, including contracted fees and other cost information, (3) personally identifiable information about members, and (4) personal health information. (HSC section 127673(b).) In addition to this, HCAI is required to adopt emergency regulations about the "content… for data submission" and that in developing these regulations, HCAI had to consider "national, regional, and other all-payer claims databases' standards." (HSC section 127673(e)(4).) This proposed regulation describes the specific content that data submitters must submit to HPD to effectuate these statutes.

For data submission content, HCAI complied with statute and considered and now seeks to adopt in this proposed regulation the only national standard available for state health care databases: *The Common Data Layout for All-Payer Claims Databases, Version 2.1,* released July 1, 2021 ("APCD-CDL™"), which has hundreds of data elements to collect from health care entities. (*See* HPD Legislative Report, pages 30-31.) The APCD-CDL™ is a national standard developed by the University of New Hampshire and the National Association of Health Data Organizations to harmonize health care data collection across states and reduce the burden of data submission. The APCD-CDL™ was developed specifically for efforts like the HPD and was based on standards used by health care entities for financial transactions. HPD statute also indirectly references the APCD-CDL™ and requires that HCAI collect data consistent with it. (*See* HSC section 127673(b)(1) [utilization and encounter data submissions to be consistent with the standard "proposed by… the University of New Hampshire, and the National Association of Health Data Organizations"].)

HCAI seeks to incorporate the APCD-CDL™ by reference into these regulations as it would be burdensome and impractical to state the hundreds of data elements in the APCD-CDL™ with their corresponding descriptions, codes, and sources in regulation text.

HCAI wishes to adopt the APCD-CDL™ also because the HPD Legislative Report recommended it. The Report recommended the APCD-CDL™ because:

> "Discussions with the likely submitters to the HPD Program indicate a preference for the emerging APCD-CDL™ standard. Payers that operate in multiple states especially appreciate the prospect of a standard format that can be used to support multiple APCD systems. [The Department of Health Care Services] has also indicated a preference for providing data in this format." (HPD Legislative Report, page 31.)

Not only does the APCD-CDL™ provide data elements that are required under HPD statute, but seemingly will also reduce the burden of data reporting for data submitters increasing efficiency and consistency in data reporting.

The APCD-CDL™ requires HCAI to clarify and specify some of its data elements. To do this, HCAI prepared the DSG, which is also required by this proposed regulation. HCAI did this through a document incorporated by reference, the DSG, because it would be impractical and burdensome to list the hundreds of specifications HCAI made

to the data elements of the APCD-CDL™. Regarding the DSG's specific requirements, see the later discussion of the DSG in this document.

Subdivision (a) of this proposed regulation notes that five types of files be submitted as specified by the DSG and the APCD-CDL™: (1) member eligibility file, (2) medical claims file, (3) pharmacy claims file, (4) dental claims file, and (5) provider file. These five types of files are categories of data elements from the APCD-CDL™ and the descriptions of these files in this proposed regulation are a summary of the descriptions from the APCD-CDL™, pages 5 to 7. This is needed to specify what parts of the APCD-CDL™ HCAI proposes to adopt into HPD. These types of files also are of the type of information HSC section 127673(b) requires HPD to collect.

Furthermore, HSC section 127673.3(a) mandates that HCAI create a "master person index" and "master index of providers and suppliers." Indexes like these are needed because, as statute indicates, this will "enable the matching" of various records about these persons/entities, which allows HPD to have accurate and useful data for analysis. The member eligibility file and provider files provide information to create these indexes.

Subdivision (b) of this proposed regulation discusses what data should not be submitted to HPD. This subdivision excludes data for a submitter's members exclusively enrolled in Medi-Cal because HPD will separately obtain data about Medi-Cal recipients through the Department of Health Care Services (*see* HSC section 127673(g)(2) [requiring the Department of Health Care Services to submit Medi-Cal data to HPD]) and thus, this data would be duplicative and unnecessary.

This subdivision (b) also excludes several types of coverage that a submitter may offer from the submitter's data submission: supplemental, student health, chiropractic, acupuncture and vision. As discussed above, the definitions of "health plan" and "health insurer" exclude certain entities from HPD that exclusively provide types of coverages that are not relevant for the purpose of HPD or are of little value versus the cost of collection. This section does the same by excluding the same types of coverages in data submissions to HPD. For the reasons why these types of coverages are excluded, see the explanations above for the definitions of "health plans" and "health insurers" (respectively, in section 97300(j) and (k)).

11. CCR, title 22, section 97344, "Data File Technical Requirements"

For HPD, HCAI is required to adopt emergency regulations about the "file formats… for data submission" and that in developing these regulations, HCAI had to consider "national, regional, and other all-payer claims databases' standards." (HSC section 127673(e)(4).) HPD needs a consistent way or format for submitters to submit data so HPD can efficiently process the submissions and check files for completeness and errors.

This proposed regulation sets the format for data submissions and requires submitters to conform their data files to the "file format, technical specifications, and other standards" specified in the DSG and the APCD-CDL™. The DSG and APCD-CDL™ are used for the same reasons stated above for section 97342.

12. CCR, title 22, section 97346, “Submission Completion”

This proposed regulation states that a submitter’s data submission is incomplete until all of its delegated submitters submit their data on behalf of the submitter. As previously discussed, section 97318 states that primary data submitters are responsible for their delegated submitters, and this proposed regulation specifies what this responsibility entails.

The purpose of this regulation is to make it clear to submitters who have delegated submitters when it becomes an issue if delegated submitters fail to submit data. Clear requirements for this are needed because HCAI is required to notify the relevant licensing authorities if a submitter fails to comply with HPD requirements and those licensing authorities are to take appropriate action to bring the submitters into compliance per HSC section 127674.1.

13. CCR, title 22, section 97348, “Test File Submission”

The HPD data portal will have a function that allows registered submitters to “submit” test data files to determine their ability to create and send data files per HPD requirements. This proposed regulation requires submitters to perform this test function. This is needed to make sure the data file submission process goes smoothly when submitters begin to submit data files, and to make sure that a submitter resolves any problems well before any data submission deadlines.

This proposed regulation requires that test files be identified as test files per the DSG so that it is clear to HCAI that the submitters is sending test files. This proposed regulation also makes clear that test files sent to HPD are not officially submitted to HPD.

14. CCR, title 22, section 97350, “Preparation for Historical Data Submission”

As discussed later, HSC section 127673(h)(1) requires HCAI to seek data from data submitters for years before the start of HPD and proposed section 97351 requires this historical data. Subdivision (a) of this proposed regulation requires data submitters use the HPD data portal’s test function to prepare for historical file submission. This is to make sure that submissions of historical data files will go smoothly and by the deadline required.

Subdivisions (b) and (c) of this proposed regulation treats dental plans differently from other mandatory submitters and provides a later deadline for testing registration deadline for dental plans. For the reasons why, see above regarding the definitions of “dental data” and “dental plan” (proposed section 97300(e) and (f)).

Subdivision (b) of this proposed regulation requires non-dental plans to use the test function by July 29, 2022 and proposed regulation requires HPD registration for non-dental plans by May 27, 2022. Subdivision (c) of this proposed regulation requires dental plans to use the test function by July 31, 2024 and proposed regulation requires HPD registration for dental plans by March 29, 2024. HCAI believes that, respectively,

two months and four months from the registration deadline to the test deadline gives these data submitters more than enough time to perform the test function in preparation of actual data submission.

15. CCR, title 22, section 97351, "Historical Data Files"

HSC section 127673(h)(1) requires HCAI, for the "initial implementation" of HPD, to "seek data for the three years prior to the effective date of this chapter," which was June 29, 2020[3]. Thus, HPD statute states that HCAI must try to obtain data from June 29, 2017 through June 29, 2020 for HPD. HPD statute also requires HCAI to be able to "provide data for no less than three years" and authorizes HCAI to "seek data for longer time periods to support the intent" of HPD. (HSC section 127673(h)(2).)

The HPD Legislative Report, pages 24 and 37, also recommended that HCAI collect three years of historical data "at the onset" of HPD. Such historical data is needed for HPD because:

> "Starting at least three years of data will allow for calculation of the initial measures over multiple years and support some analysis of trends. Generation of the initial measures; careful examination of results by year, payer type, and individual submitter; and stakeholder and partner engagement with the results are essential steps prior to public release of the first HPD Program results." (HPD Legislative Report, page 20.)

Having this historical data will allow HPD to release information sooner than later to achieve the HPD's purpose to increase transparency in health care and to inform health care policy decisions in California. This proposed regulation is to acquire this historical data for HPD.

Pursuant to statute, this proposed regulation requires HPD data submitters to submit historical data to HPD for the time period from June 29, 2017 through December 2021. This covers the statutorily mandated time period under HSC section 127673(h)(1). This also covers the time period from July 2020 through December 2021, which is between the end of the statutorily mandated time period for historical data and the start of HPD (anticipated to be January 1, 2022). HCAI is authorized to collect data for this additional period under HSC section 127673(h)(2) in order to be able to provide at least three years of data and to support the intent of HPD. Also, data from July 2020 to December 2021 must be collected because if it was not collected, there would be a hole in HPD's records that would impair later data analyses and would not be consistent with HPD's records.

For HPD, HCAI is required to adopt emergency regulations about "timelines for data submission." (HSC section 127673(e)(3).) This proposed regulation also sets the timelines for historical data submission. Subdivisions (a) and (b) of this proposed regulation sets different timelines for historical dental data submission compared to

[3] The effective date is from the approval date of Assembly Bill No. 80 (2019-2020 Reg. Sess.). Per section 75 of the legislation, this bill was a budget bill that immediately took effect upon approval.

other historical data. For the reasons why, see above regarding the definitions of "dental data" and "dental plan" (proposed section 97300(e) and (f)).

Subdivision (a) of this proposed regulation requires non-dental historical data to be filed by October 28, 2022. HCAI believes this is a sufficient amount of time for initial data submitters to be able to submit this data to HPD. The deadline of October 28, 2022 would be ten months after the anticipated start of HPD and five months after the deadline to register to HPD.

Subdivision (b) of this proposed regulation requires historical dental data to be filed by October 31, 2024. HCAI believes this is a sufficient amount of time for dental data submitters to be able to submit this data to HPD. This deadline would be seven months after the deadline for dental plans to register to HPD.

16. CCR, title 22, section 97352, "Initiation of Monthly File Reporting"

For HPD, HCAI is required to adopt emergency regulations about "timelines for data submission. (HSC section 127673(e)(3).) This proposed regulation does this for regular HPD data reporting and states when the reporting will begin for mandatory submitters at the start of HPD. This proposed regulation also requires the submission of data for the period between the start of HPD (anticipated around January 1, 2022) and the submitter's first monthly submission.

Subdivisions (a) and (b) of this proposed regulation sets different timelines for the submission of dental data compared to other required data. For the reasons why, see above regarding the definitions of "dental data" and "dental plan" (proposed section 97300(e) and (f)).

Subdivision (a) is for non-dental plans and states that monthly reporting of non-dental data for these entities will begin for the month of November 2022 (which, per proposed section 97340, will be due on January 2, 2023). Subdivision (a) also sets a deadline of February 1, 2023 for these entities to submit non-dental data for the rest of 2022 (January through October). A delayed time period from the start of HPD to monthly reporting is needed to give HPD's initial data submitters enough time to prepare for data submission and to allow them time to report historical data as discussed above. After discussions with potential data submitters and stakeholders, HCAI believes this is sufficient time for initial data submitters to be able to start reporting monthly data and to report data for 2022.

Subdivision (a)(1) also gives non-dental plans the option of providing monthly data before November 2022. This is to give these plans flexibility and the ability to submit data earlier in order to make it less burdensome for these entities to comply with HPD as the HPD system will be ready to accept this data earlier.

Subdivision (b) is for the submission of dental data. This subdivision states that all plans must start monthly reporting of dental data for the month of November 2024 (which, per proposed section 97340, will be due on January 2, 2025). Subdivision (b)

also sets a deadline of February 1, 2025 for all plans to submit dental data for the time period from the start of HPD and their first dental data monthly submission. By the time of these deadlines, the HPD system will be able to accept dental data and these deadlines will give plans, especially dental plans who are required to register by March 29, 2024, sufficient time to prepare for and start submitting dental data.

17. CCR, title 22, section 97360, "Data Acceptance"

Subdivision (a) of this proposed regulation states that data files submitted to HPD that do not meet the file intake requirements of the DSG (as required by proposed section 97344) will not be accepted (*see* later section regarding the DSG for explanations of the DSG file intake specifications). The purpose of this is to notify data submitters of what occurs if they do not comply with the file intake specifications of the DSG and to ensure that submissions meet these specifications. As discussed earlier for proposed section 97344, HCAI needs submissions to meet these requirements in order to efficiently process and review files for problems. Problems with data submissions also need to be dealt with at intake to avoid "problems associated with processing incorrect data that require greater levels of time and effort to correct down the road." (HPD Legislative Report, page 112.)

Subdivision (b) of this proposed regulation states that HCAI will notify data submitters within three business days of whether a data file has been accepted and rejected. The purpose of this is to inform data submitters of problems quickly while giving HCAI enough time to review data files for problems. This also requires HCAI to notify data submitters that their files were accepted so data submitters know filing requirements were met. This is needed to set expectations for submitters and HCAI staff on the process of acceptance.

18. CCR, title 22, section 97362, "Data Review and Correction"

HSC section 127673.4 requires HCAI to "develop regulations on data quality and improvement processes" and for data quality processes to "be applied to each major phase of the [HPD] system life cycle… including "source data intake" and "data conversion and processing." This proposed regulation accomplishes this and states that HCAI will examine data files after acceptance for "initially unidentified errors." This is needed because errors may not have been identified due to the short turnaround time between submission and acceptance/rejection per section 97360. HCAI will more thoroughly review submissions shortly after acceptance because correction of data at later stages is very costly and time-consuming. (*See* HPD Legislative Report, page 113.)

This proposed regulation notes that if HCAI detects errors, the data file "shall be flagged, and the submitter requested to address such issues" by confirming the data or correcting and resubmitting data within 45 days of HCAI's error notification. The purpose of this is to establish a clear process for potential errors to be resolved with the submitter so errors do not remain in HPD that could affect later data analyses.

19. CCR, title 22, section 97370, "Requesting a Variance"

Subdivision (a) of this proposed regulation states that a submitter unable to submit data files meeting the DSG's file intake specifications may request and obtain a "temporary variance to those requirements." HCAI recognizes that, in some circumstances, a submitter may not reasonably be able to meet the DSG's file intake requirements. This regulation is necessary to give HCAI flexibility in dealing with such submitters and to allow changes from HPD requirements as needed for specific circumstances to give submitters time to adjust or correct issues. Since consistency of data is needed for later analysis, this proposed regulation only allows temporary variances and there is an expectation that all submitters will eventually meet DSG requirements.

Subdivision (b) of this proposed regulation states the process in which a submitter may request a variance and requires that the submitter "clearly identify the current issues, the plan for correction, and the anticipated date of correction. This gives submitters a convenient process to request a variance and the requested information is needed for HCAI to analyze the situation and decide whether it should grant a variance. The specific requirements are general as circumstances necessitating a variance may be varied and specific to the submitter. HCAI needs this information to assess whether to approve the request or not.

Subdivision (c) of this proposed regulation states that HCAI will approve or disapprove variance requests within 30 days of the request submission. Each variance request will be reviewed on a case-by-case basis based on the specific circumstances of the request and requests may be denied based on that review. The purpose of this is to notify data submitters that variance requests will not be automatically approved. HCAI believes a 30-day response period is reasonable to assess a request.

20. The Data Submission Guide (DSG)

Prior proposed sections, including sections 97332, 97342, 97344, 97348 and 97360, incorporate by reference requirements in the document, *The Health Care Payments Data Program: Data Submission Guide*, dated November 23, 2021, which was developed by HCAI. The reason why these requirements were incorporated in the DSG was to make it more convenient for data submitters to look up information and to have it in a more readable text format so data submitters will be more likely to read and understand these requirements. It was also impractical to have the hundreds of data elements discussed in the DSG to be in regulation text. This section will go through the various requirements of the DSG.

Part 1 of DSG, "Introduction": This part of the DSG describes the DSG in general and that it is for the HPD and maintained and updated by HCAI. This part also notes that the DSG offers additional detail to the APCD-CDL™ which is the core file format for HPD data submissions. This part is needed to give background to the DSG and to note that it is to be used with the APCD-CDL™ for clarity purposes and to prevent confusion.

Part 2 of DSG, "Registration": This part notes that there are two types of registration for HPD so entities are aware that they may need to register for two things.

Proposed regulation, section 97332, notes that a "plan" as defined and delegated submitters must register and "provide all required information as specified in the" DSG. Part 2 of the DSG provides these requirements.

Part 2.1 of DSG, "Plan Registration": This part goes through one type of registration necessary for HPD—this one is for the legal entity that is responsible for the data being submitted (i.e., the mandatory and approved voluntary submitters).

This part clarifies that "licensed entities" such as health plans or insurers, registration must be "at the license level." The purpose of this is to ensure that all mandatory submitters are in compliance and that appropriate linkage can be establish between data submitted and market segment.

As required by proposed section 97332, part 2.1 of the DSG then states the information needed for registration from mandatory and voluntary submitters. As discussed above for proposed section 97330 above, generally, this information is needed to keep track of those who are submitting data to HPD and to create a "master payer index" per HSC section 127673.3(a). The DSG requires the following information for this type of registration:

- "Legal entity name and address": The legal entity name is needed so HCAI knows the actual legal entity responsible for data submission to take legal or administrative action for noncompliance or other violations of HPD law. The address is needed in case HCAI needs to mail any notice or document to the entity and to verify the entity with records from the entity's respective licensing authorities.

- "Type of entity: mandatory or voluntary, and whether: plan/insurer, public self-insured, private self-insured": HCAI needs to know whether a submitter is mandatory or voluntary as mandatory submitters may be subject to administrative or licensing actions and thus, entities will be treated differently based on whether they are mandatory or not. HCAI also needs to know what type of entity the submitter is so that data submissions can be analyzed by type of entity to ensure all market segments of data are represented.

- "National Association of Insurance Commissioners (NAIC) Code": This is a national identifier that will help HCAI identify the entity in market segment analyses.

- "Product type(s)": These data elements will be used by HCAI to analyze data submission by market segment.

- "License Type and License Number": This information is necessary to identify any discrepancies between information received by HCAI and information that the relevant licensing authorities have about the entity, and to ensure that all mandatory submitters are in compliance.

- "Lines of Business": This information will be used by HCAI to analyze data submission by market segment.

- "A regulatory contact (first and last name, phone, email and address)": This is required for compliance issues identified by HCAI during the operation of the HPD program.

- "A business contact for submission issues (name, phone, email and address)": This is required in case ongoing communication is needed with general business-related questions that HCAI may have in the operation of the HPD program.

- "If the plan will be submitting its own data, list the types of data files that will be submitted": This information is needed for HPD to accurately identify and link the data being submitted and to keep track of whether an entity is submitting all required data. This will allow HCAI to determine who to contact if data is missing.

- "If the plan is delegating submission, the plan shall provide a list of submitters, and the following information for each submitter": This requires plans to identify all their delegated submitters and to identify what data each delegated submitter will file on behalf of the plan. This information is needed for HPD to accurately identify and link the data being submitted and the plan is in the best position to provide this information instead of HCAI trying to figure this out on its own. This information is also needed to make sure delegated submitters are submitting all data as required because this information lets HCAI efficiently check this.

    - "Legal entity name": The legal name of the delegated submitter is needed in case HCAI needs to identify this submitter to the contracting data submitter or to take administrative action.

    - "Contact information (name, title, phone, email and address)": This is the contact information for the delegated submitter.

    - "The type of data files to be submitted": See above regarding "A list of delegated submitters, and the following information for each delegated submitter."

Finally, part 2.1 states that an entity that registers under this part will be notified and receive a "unique Payer Code." As noted in part 2.1, this is used "in data submission to identify data [the entity is] responsible for. Submitted files that contain an invalid Payer Code will not be accepted." The unique payer code is needed for the APCD-CDL™ and because:

> "data from each line of business [of a submitter] might come from different places within the submitting [entity] due to mergers, legacy claims systems, and other reasons. Some submitters will submit one large feed for all lines of business;

others will submit one data feed per line of business." (HPD Legislative Report, page 44.)

Having a unique HPD payer code will assist HCAI in organizing data and linking it to the right entities if data comes in from various places. This is needed to efficiently create the HPD and analyses. It is noted that a submission with an incorrect payer code will not be accepted to ensure that the submitter inputs this correctly.

Part 2.2 of DSG, "Submitter Registration": This part goes through the registration of all data submitters to HPD. A submitter could be the plan who is responsible for the data or a delegated submitter. Different information from "Plan Registration" is required for the actual data submitters as discussed below.

As required by proposed section 97332, part 2.2 of the DSG then states the information needed for registration of submitters. The DSG requires the following information for this type of registration:

- "Legal entity name and address": The legal entity name is needed so HCAI knows the actual legal entity responsible for data submission to take legal or administrative action for noncompliance or other violations of HPD law. The address is needed in case HCAI needs to mail any notice or document to the entity.

- "At least two designated submitter representatives (first and last name, title, phone, email and address)": This requires submitters to identify at least two individuals working for the submitter who would be the technical point of contact should any issues arise with data submission. The purpose of this is so that HCAI knows who to contact if there are issues with a submitter's data submission. Without this information, it may take HCAI a long time to find someone to communicate with about problems or concerns with submissions. Two contacts are required in case one contact is unavailable and there is an urgent situation.

- "A list of all plans who they will submit data on behalf of. For each plan entity, the following information is required": This requires submitters to identify the plans for which they are submitting data, if any, and what data file types they are submitting. This information is needed for HPD to accurately identify and link the data being submitted and the submitter is in the best position to provide this information instead of HCAI trying to figure this out on its own. This information is also needed to make sure submitters are submitting all data as required because this information lets HCAI efficiently check this.

    - "Payer Code and Name": The payer code is issued to an entity once they register per part 2.1 above. This code is needed to properly link data to the correct plan in the HPD to ensure accurate and complete data.

    - "A complete list of all data file types (Eligibility, Medial Claims, Pharmacy Claims, Dental Claims, and Provider) they will submit for each Payer

Code": See above regarding "A list of all plans who they will submit data on behalf of. For each plan entity, the following information is required."

Part 2.2 states that upon approval of this registration, the delegated submitter will be notified and receive a "unique Submitter Code" to be used in data submission "to identify data [the submitters are] responsible for." The unique submitter code is needed because having a unique HPD submitter code will assist HCAI in organizing data and linking it to the right entities if data comes in from various places. A submitter code is needed as well as a payer code as a plan could also be a delegated submitter for other entities.

Lastly, part 2.2 notes that files with "an invalid Submitter Code or invalid Payer Code/Submitter Code combination will not be accepted." This is to make sure that the submitter inputs the correct submitter and payer code.

Part 3 of DSG, "Test File Submission": Proposed section 97348 notes that test files will be "identified as specified in" the DSG. Part 3 is about this.

Part 3 notes that test files are required to be submitted through the HPD data portal, which reiterates section 97348.

Part 3 also notes that test files will be identified with a "T" in an identified data element on the APCD-CDL™ (currently data element "CDLHD008", which is the data element for "test file flag"). This is to make sure that HCAI recognizes a submission as just a test file instead of a real (production) submission.

Part 4 of DSG, "File Intake Specifications": Proposed sections 97342 and 97344 require submission of data content and in formats as required by the APCD-CDL™ and the DSG. Proposed section 97360 notes that files will not be accepted unless it meets the requirements of the DSG. Part 4 provides these requirements.

First, part 4 notes that the HPD assigned payer code and data submitter code are required data elements within submitted data files, which reiterates requirements in part 2 to ensure compliance with these important requirements.

The APCD-CDL™ requires a "header record" and also a "trailer record" for every data file submission. Part 4 incorporates this requirement.

The APCD-CDL™ has data definitions for each data element in its tables of data elements. Part 4 makes clear that these definitions in APCD-CDL™ must be followed.

Part 4 describes the tables that are in parts 4.1 to 4.7 of the DSG. It notes that the tables that follow in the DSG are data elements from the APCD-CDL™ and each data element included is designated "required" or "situational." The DSG notes that "required" must be populated at all times while "situational" means must be submitted only in the specific circumstances described in the data element. There is a minimum set of data elements that must be received by the HPD to ensure that the data is viable for analytical purposes. HCAI worked with stakeholders and submitters to determine

the minimum data necessary and HCAI designated data elements from the APCD-CDL™ accordingly.

Part 4 notes that for all other data elements in the APCD-CDL™ not mentioned in the DSG are required to "be populated with available data." The purpose of this is to enable the maximum amount of data to be collected. While the minimum data necessary is explicitly specified, the rest of the data on the APCD-CDL™ are valuable for analysis and HCAI would like these data to be submitted if the submitter has the data available.

Part 4 then states, reiterating proposed section 97360, that submitted data files will be accepted or rejected and goes through the reasons for rejection. This is to clearly notify submitters of common problems or issues to look out for before submitting a data file, including improper file formats, and data types, inconsistent dates based on reporting period, and invalid entries for required/situational data elements.

Part 4 notes that a variance has to be requested and approved for a data file to have missing required/situational data elements, and that a data file will be rejected for missing values for any such element without an approved variance. This is to make clear that these elements are absolutely needed, and the variance process must be followed to get an exception to this.

Parts 4.1 to 4.6 of the DSG are the tables of data elements from the APCD-CDL™ that must be submitted and includes the data element number, name and whether the data element is "required" or "situational," and any notes specific to a data element for clarification. These are needed to clarify the information that needs to be provided for each data element and to make sure the proper values are inputted for the data elements.

Comparable Federal Regulation or Statute

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

Inconsistency or Incompatibility with Existing State Regulations

HCAI is not aware of any existing state regulations with which the proposed emergency regulations are inconsistent or incompatible.

OTHER MATTERS AS PRESCRIBED BY STATUTE APPLICABLE TO HCAI OR HPD

As noted above, HCAI is required to adopt the initial regulations to implement HPD as emergency regulations pursuant to Health and Safety Code section 127673, subdivisions (e) and (f).

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.

ECONOMIC IMPACE AND FISCAL IMPACTS

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 no cost or savings impacts to any state agency, local agencies or in federal funding to the state.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDY, REPORTS, OR DOCUMENTS RELIED UPON

HCAI relies on *The Health Care Payments Data Program: Report to the Legislature*, dated March 9, 2020, by the Office of Statewide Health Planning and Development (HCAI's former name).