State of California
Office of Administrative Law

In re: **Department of Health Care Access and Information** **Regulatory Action:** **Title 22, California Code of Regulations** **Adopt sections: 97380, 97382, 97384, 97386, 97388, 97390, 97392, 97393, 97394, 97396, 97398, 97400, 97402, 97404, 97406, 97408, 97410, 97412, 97414, and 97416**	**DECISION OF DISAPPROVAL OF REGULATORY ACTION** **Government Code Section 11349.3** **OAL Matter Number: 2024-0528-01** **OAL Matter Type: Regular (S)**

SUMMARY OF REGULATORY ACTION

In this regulatory action, the Department of Health Care Access and Information (the "Department" or "HCAI") proposes to adopt regulations to allow the public and other state agencies to access and use Health Care Payments Data Program (the "Program" or "HPD") data.

On May 28, 2024, the Department submitted the above-referenced regulatory action to the Office of Administrative Law ("OAL") for review. On July 10, 2024, OAL notified the Department of OAL's decision to disapprove the proposed regulations.

DECISION

OAL disapproved the above-referenced action because the proposed regulations failed to comply with the clarity and necessity standards of the Administrative Procedure Act (the "APA"), as well certain APA procedural requirements. All of these issues must be resolved prior to OAL's approval of the regulations. This Decision of Disapproval of Regulatory Action explains the reasons for OAL's action.

DISCUSSION

The Department's regulatory action must satisfy requirements established by the part of the APA that governs rulemaking by a state agency. Any regulation adopted, amended, or repealed by a state agency to implement, interpret, or make specific the law enforced or administered by it, or to govern its procedure, is subject to the APA unless a statute expressly exempts the regulation from APA coverage. (Gov. Code, sec. 11346.) No exemption applies to this regulatory action.

Before any regulation subject to the APA may become effective, the regulation is reviewed by OAL for compliance with the procedural requirements of the APA and the standards for administrative regulations in Government Code section 11349.1. Generally, to satisfy the APA standards, a regulation must be legally valid, supported by an adequate record, and easy to understand. In this review, OAL is limited to the rulemaking record and may not substitute its judgment for that of the rulemaking agency regarding the substantive content of the regulation. This review is an independent check on the exercise of rulemaking powers by executive branch agencies intended to improve the quality of regulations that implement, interpret, and make specific statutory law, and to ensure that the public is provided with a meaningful opportunity to comment on the regulations before they become effective.

1. Clarity Standard

In adopting the APA, the Legislature found that the language of many regulations was unclear and confusing to persons who must comply with the regulations. (Gov. Code, sec. 11340, subd. (b).) Government Code section 11349.1, subdivision (a)(3), requires that OAL review all regulations for compliance with the clarity standard. Government Code section 11349, subdivision (c), defines "clarity" to mean "written or displayed so that the meaning of regulations will be easily understood by those persons directly affected by them."

The "clarity" standard is further defined in section 16 of title 1 of the California Code of Regulations ("CCR"), which provides:

> In examining a regulation for compliance with the "clarity" requirement of Government Code section 11349.1, OAL shall apply the following standards and presumptions:
> (a) A regulation shall be presumed not to comply with the "clarity" standard if any of the following conditions exists:
> (1) the regulation can, on its face, be reasonably and logically interpreted to have more than one meaning; or

> (2) the language of the regulation conflicts with the agency's description of the effect of the regulation; or
> (3) the regulation uses terms which do not have meanings generally familiar to those "directly affected" by the regulation, and those terms are defined neither in the regulation nor in the governing statute; or
> (4) the regulation uses language incorrectly. This includes, but is not limited to, incorrect spelling, grammar or punctuation; or
> . . . .
> (b) Persons shall be presumed to be "directly affected" if they:
> (1) are legally required to comply with the regulation; or
> (2) are legally required to enforce the regulation; or
> (3) derive from the enforcement of the regulation a benefit that is not common to the public in general; or
> (4) incur from the enforcement of the regulation a detriment that is not common to the public in general.

The following provisions in the Department's proposed regulatory action do not satisfy the clarity standard.

1.1. Required Access Level

Subsection (a)(19)(C) of proposed Section 97392, subsection (a)(20)(C) of proposed Section 97393, subsection (a)(23)(C) of proposed Section 97394, and subsection (a)(17)(C) of proposed Section 97400 require an applicant to identify the "required access level" for each individual who will access data through the enclave. However, nothing in the underlying statutes, existing regulations, or the proposed regulations outlines different access levels. For this reason, these proposed regulations are unclear because the regulations use a term which does not have meaning generally familiar to those "directly affected" by the regulations, and that term is defined neither in the regulations nor in the governing statutes. (Cal. Code Regs., tit. 1, sec. 16, sub. (a)(3).)

1.2. Good Cause

Subsection (a)(2) of proposed Section 97412 states, "For non-confidential program data, the Department **may**, for **good cause**, require an approved applicant or the persons who will observe, use, or control program data to execute data use agreements." (Emphasis added.) The initial statement of reasons (the "ISR") provides the following:

> However, HPD data may include other sensitive information, such as personal information about individual medical providers, and proprietary contracting/pricing information. This subsection gives HCAI the discretion to impose a data use agreement in

circumstances in which HCAI determines that HPD data is sensitive and needs more protection. This will be done on a case-by-case basis depending on the data and data use.

The Department articulates specific standards in the ISR as to what constitutes "good cause". Those standards need to be in the proposed regulations—not just the rulemaking file—so that those persons directly affected by the proposed regulations can easily understand the kinds of situations and circumstances the Department will find constitute "good cause" in this context. (Gov. Code, sec. 11349, subd. (c).) Additionally, use of the word "may" makes it unclear under what circumstances the Department will choose to impose this requirement despite the existence of "good cause". (*Ibid.*)

1.3. "Specific Restrictions or Requirements"

Subsection (a) of proposed Section 97388 states the following:

> This section applies to all applications for program data submitted to the Department under this Article. There may be **specific restrictions or requirements** depending on the type of data request. [(Emphasis added.)]

The reference to "specific restrictions or requirements" is too vague as the Department does not identify what those restrictions or requirements "may be". This issue was also raised by a commenter, who stated that the proposed regulation "is overly broad and ambiguous, suggesting the Department can create additional restrictions and requirements for applications on a case-by-case basis." As such, subsection (a) of proposed Section 97388 is unclear because the "specific restrictions or requirements" cannot be easily identified by those persons directly affected by the proposed regulation. (Gov. Code, sec. 11349, subd. (c).) Furthermore, if there are specific restrictions or requirements that are going to be imposed for a specific type of data request, the Department needs to include those regulations in this regulatory text.

1.4. Cost, Fee, and Price

It is unclear whether the Department is using the terms "cost", "fee", and "price" interchangeably to refer to the same thing, or whether each of these three terms carries a distinct and separate meaning. The Department uses "cost" in subsection (b) of proposed Section 97384, "fee" throughout proposed Section 97384, and "price" in subsection (b)(2)(A) of proposed Section 97410 and throughout proposed Section 97414. Health and Safety Code section 127674, subdivision (f)(1), permits the Department to "impose a data user fee for an eligible user", as specified. Subdivisions (f)(2) and (f)(3) of that statute further authorize the Department to adopt regulations establishing fee waivers.

Regarding "prices", subdivisions (a) and (b) of Health and Safety Code section 127673.8 permit the Department to establish "pricing mechanisms" for data products and custom reports, respectively. Health and Safety Code section 127673.82, subdivision (f), requires that the Department "establish a pricing mechanism for the use of nonpublic data."

It is within the statutory context outlined above that references to "cost", "fee", and "price" in the proposed regulations are unclear. Proposed section 97384 prescribes an application "fee". Proposed subsection (b) of that section states, in pertinent part, "The paid fee shall be applied to the total **cost** for the data if the application is approved." (Emphasis added.) From this use, it appears as though "cost" refers to something other than the $100 fee. It may be that "cost" is a reference to the "price" in proposed Section 97410, subsection (b)(2)(A), and proposed Section 97414, but nothing in the proposed regulations connects the two terms. Furthermore, it is unclear which, if any, of the statutory provisions discussed above relate to each "cost", "fee", or "price" reference. For these reasons, the proposed regulations are unclear because the Department's uses of "cost", "fee", and "price" can, on their face, be reasonably and logically interpreted to have more than one meaning. (Cal. Code Regs., tit. 1, sec. 16, sub. (a)(1).)

1.5. "May Deny a Data Application"

Subsection (c) of proposed Section 97388 states, in pertinent part, "The Department **may** deny a data application, in whole or in part, if the Department determines there is good cause to deny the application, including, but not limited to, the following . . . ." (Emphasis added.) The Department's use of "may" is ambiguous. Unless there are circumstances under which the Department determines there is good cause to deny the application but decides not to do so, the word "may" needs to be changed to "shall". Regardless, subsection (c) of proposed Section 97388 is unclear because if and when this discretion will be exercised cannot be easily understood by those persons directly affected by the proposed regulation. (Gov. Code, sec. 11349, subd. (c).)

1.6. Data Use Agreements

In proposed Section 97412, the Department refers to "data use agreements" in a way that makes it unclear whether there is only one data use agreement or two different data use agreements—one for confidential data and one for non-confidential data. The Department proposes the following:

> (a) Required Data Use Agreements.
> (1) Prior to receiving confidential data pursuant to an approved data application:
> (A) Each approved applicant shall execute a data use agreement.

(B) Each person who will observe, use, or control confidential data under an approved application shall execute a data use agreement.
(2) For non-confidential program data, the Department may, for good cause, require an approved applicant or the persons who will observe, use, or control program data to execute data use agreements .
(b) Contents for Confidential Data Use Agreements. A data use agreement between the Department and the applicant or persons approved for confidential data under this Article shall have, at least, the following:
(1) The applicant or person shall only observe, use, control, or store confidential data in the United States of America.
(2) The data use agreement shall be governed, and construed in accordance with, the laws of the State of California and all litigation that may arise as a result of the agreement shall be litigated in the Superior Court of California, County of Sacramento.

In subsection (b) of proposed Section 97412, the Department introduces the term "confidential data use agreements" but then reverts back to only referring to a "data use agreement" throughout the remainder of the subsection. As such, proposed Section 97412 is unclear because the regulations can, on their face, be reasonably and logically interpreted to have more than one meaning. (Cal. Code Regs., tit. 1, sec. 16, sub. (a)(1).)

1.7. Certification of "Truthful and Accurate Information"

Subsection (a)(10) of proposed Section 97390, subsection (a)(20) of proposed Section 97392, subsection (a)(21) of proposed Section 97393, subsection (a)(24) of proposed Section 97394, subsection (a)(21) of proposed Section 97396, subsection (a)(25) of proposed Section 97398, and subsection (a)(18) of proposed Section 97400 require the applicant to certify the information contained in the application. However, in the ISR, the Department further clarifies that this certification is to ensure the Department's receipt of "truthful and accurate information". Since this further clarification regarding the certification is missing from the proposed regulations, the language of the regulations conflicts with the Department's description of the effect of the regulations. (Cal. Code Regs., tit. 1, sec. 16, sub. (a)(2).)

1.8. Request Numbers

In several instances in the proposed regulations, the Department refers to a "request number" without specifying what a "request number" is and when it is issued by the Department. (See, e.g., proposed Sections 97392, sub. (a)(1) and

(5), and 97393, sub. (a)(1) and (5).) As such, these proposed regulations are unclear because the regulations use a term which does not have meaning generally familiar to those "directly affected" by the regulations, and that term is defined neither in the regulations nor in the governing statutes. (Cal. Code Regs., tit. 1, sec. 16, sub. (a)(3).)

1.9. Syntax Issue

A grammatical correction is required due to a post-notice modification to subsection (a)(1)(B) of proposed Section 97410, as it currently reads as an unfinished sentence:

> (1) The Department shall notify applicants in writing of its decision on the data application within 120 days of the complete submission of the data application unless one or more of the following occur:
> (A) A longer period is agreed to by the appliant; or
> (B) For data applications in which a Data Release Committee recommendation is required or if the Department requests input from the Committee; or
> (C) The data request includes data subject to review by the Department of Health Care Services under Section 97408; or
> . . . .

Due to this syntax issue, the proposed regulation uses language incorrectly. (Cal. Code Regs., tit. 1, sec. 16, sub. (a)(4).)

2. Necessity Standard

OAL must review regulations for compliance with the necessity standard of Government Code section 11349.1, subdivision (a)(1). Government Code section 11349, subdivision (a), defines "necessity" as follows:

> "Necessity" means the record of the rulemaking proceeding ***demonstrates by substantial evidence the need for a regulation*** to effectuate the purpose of the statute, court decision, or other provision of law that the regulation implements, interprets, or makes specific, taking into account the totality of the record. For purposes of this standard, evidence includes, but is not limited to, facts, studies, and expert opinion. [(Emphasis added.)]

To further explain the meaning of "substantial evidence" in the context of the necessity standard, subsection (b) of section 10 of title 1 of the CCR provides:

> (b) In order to meet the "necessity" standard of Government Code section 11349.1, the record of the rulemaking proceeding shall include:
> (1) A statement of the specific purpose of each adoption, amendment, or repeal; and
> (2) information explaining why each provision of the adopted regulation is required to carry out the described purpose of the provision. Such information shall include, but is not limited to, facts, studies, or expert opinion. When the explanation is based upon policies, conclusions, speculation, or conjecture, the rulemaking record must include, in addition, supporting facts, studies, expert opinion, or other information. An "expert" within the meaning of this section is a person who possesses special skill or knowledge by reason of study or experience which is relevant to the regulation in question.

In the first modified regulation text made available pursuant to Government Code section 11346.8, subdivision (c), and section 44 of title 1 of the CCR, the Department adopted a $100 application fee in subsection (b) of proposed Section 97384. In the final statement of reasons (the "FSR"), the Department provides the following necessity for this $100 fee:

> HCAI added a specific amount for the application fee here because HCAI decided to have one clear application fee for all requests and not to have a separate fee schedule listing different application fees based on the request type. Also, HCAI decided on $100 because HCAI believes this is a high enough amount that will deter uncommitted or sham applicants who would otherwise waste HCAI's resources, but would still be reasonable for serious applicants, ensuring that only those committed to utilizing the data will proceed with their requests and that HCAI's resources are used well.

While the Department explains in the FSR why ***a*** fee is necessary, it fails to adequately justify the actual proposed $100 amount. The Department must explain why the newly proposed fee amount is necessary to accomplish the Department's implementation of statute. Specifically, the Department "must show '(1) the estimated costs of the service or regulatory activity, and (2) the basis for determining the manner in which the costs are apportioned, so that charges allocated to a payor bear a fair or reasonable relationship to the payor's burdens on or benefits from the regulatory activity.' " (*California Farm Bureau Federation v. State Water Resources Control Bd.* (2011) 51 Cal.4th 421, 436-437 [quoting *Sinclair Paint Co. v. State Bd. of Equalization* (1997) 15 Cal.4th 866, 878].) Additionally, if the Department is relying upon a new technical, theoretical, or empirical study, report, or similar document in proposing this fee, it

must make the document available for at least 15 days pursuant to Government Code section 11347.1.

For the reason discussed above, the proposed regulatory changes failed to comply with the necessity standard of the APA.

3. Incorrect Procedure

3.1. Failure to Clearly Illustrate Post-Notice Modifications

Subdivision (c) of Government Code section 11346.8 requires that, when an agency makes a change sufficiently related to the original text (hereafter, "Modified Regulation Text"), the resulting change must be clearly indicated. (See also Cal. Code Regs., tit. 1, secs. 44 and 46.) Here, the Department made two sets of Modified Regulation Text available to the public for comment and neither set showed the full text of the originally proposed regulations with proposed changes clearly indicated. These inconsistencies must be resolved in any future Modified Regulation Text made available pursuant to Government Code section 11346.8, subdivision (c), and section 44 of title 1 of the CCR.

3.2. Updated Informative Digest

The rulemaking file is missing "an updated informative digest containing a clear and concise summary of the immediately preceding laws and regulations, if any, relating directly to the adopted, amended, or repealed regulation and the effect of the adopted, amended, or repealed regulation." (Gov. Code, sec. 11346.9, subd. (b); see also Gov. Code sec. 11347.3, subd. (b)(2).) The Department must include an updated informative digest in any future resubmittal of this regulatory action.

CONCLUSION

For the foregoing reasons, OAL disapproved the above-referenced regulatory action. Pursuant to Government Code section 11349.4, subdivision (a), the Department may resubmit revised regulations within 120 days of its receipt of this Decision of Disapproval of Regulatory Action. A copy of this Decision will be emailed to the Department on the date indicated below.

The Department must make any substantive regulatory text changes, which are sufficiently related to the originally noticed text, available for public comment for at least 15 days pursuant to subdivision (c) of Government Code section 11346.8 and section 44 of title 1 of the CCR. Additionally, any document the Department may create or propose to add to the rulemaking record to address the necessity standard deficiency discussed above must be made available for public comment for at least 15 days pursuant to Government

Code section 11347.1. Any comments received in response to the proposed modifications must be summarized and responded to in the FSR. The Department must resolve all other issues raised in this Decision of Disapproval of Regulatory Action prior to the resubmittal of this regulatory action.

Date: July 17, 2024

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