

CALIFORNIA DEPARTMENT OF JUSTICE

UPDATED INFORMATIVE DIGEST

In response to the passage of Assembly Bill (AB) 528 (Chapter 677, Statutes of 2019) and the inclusion of Schedule V in the CURES reporting requirements effective January 1, 2021, the Department has added the definition of “Applicable Controlled Substance” to distinguish between references to specific controlled substances versus the more generalized definition of “Controlled Substances.” References to controlled substances throughout the regulations were amended accordingly.

The Department has amended the definitions of “Bona Fide Research,” “Bona Fide Researcher,” and “Team Member” to sufficiently limit who may have access to sensitive health information and adequately protect patient privacy.

The Department has amended the definition of “Law Enforcement Agency” to reference “a public entity as defined in Government Code section 811.2” and more accurately describe which entities qualify as a Law Enforcement Agency in relation to CURES.

The Department has removed the definition of “Research Requestor” and references to this definition in all sections of the proposed regulations, to remove ambiguity as to which requirements apply to public or private entities, Bona Fide Researchers, Team Members, or Interested Parties.

The Department has removed the definition of “Secure Lab” as this term is no longer utilized in the text of the proposed regulations.

In response to the passage of AB 528, the Department has replaced the phrase “Under His or Her Care” with “Under the Practitioner’s Care” and “Under the Pharmacist’s Care” to conform to the revised statutory language.

The Department has revised the definition of “Under the Care of” to include an additional authorizing scenario for Prescriber-Users or Interstate Prescribers when “the patient presents to an emergency department for treatment and the Prescriber-User or Interstate Prescriber is involved in or oversees the intake or professional medical consultation of that patient within the emergency department.”

The Department has revised the Search Period during which a Prescriber-User, Pharmacist-User, Interstate Prescriber, or Interstate Pharmacist may access patient information from “12 months” to “24 months” from the date of the search.

The Department has revised the timeframe during which a Prescriber-User or Interstate Prescriber may access a patient’s information in CURES, when a patient is Under the Care of a Prescriber-User but the patient does not have an ongoing provider-patient relationship with the Prescriber-User, from “24 hours, or the previous business day” to “7 days” before an appointment.

The Department has amended the language specifying that a Prescriber-User's Delegate or Pharmacist-User's Delegate must only access the Web-Based Application, changing "must only" to "may."

The Department has added the new section 824, subdivision (a)(2), and section 825, subdivision (a)(2) to address the termination of a Regulatory Agency Official's or Law Enforcement Official's access to CURES when no longer employed by a Regulatory Agency or Law Enforcement Agency, or no longer authorized by the Regulatory Agency or Law Enforcement Agency to access CURES.

The Department has amended the supporting documentation required to be submitted with a Regulatory Agency Official Registration Application, to replace "board-issued identification card" with "Regulatory Agency-issued identification card" and to clarify that the required letter must be signed by the applicant's supervisor, or if required by the applicant's Regulatory Agency, the head of the applicant's Regulatory Agency.

The Department has added new subdivisions (d)(1)(F) and (d)(1)(G), and revised subdivision (d)(3), of section 824 to further clarify the authorized purposes for which a Regulatory Agency Official may access CURES, and has added "unless otherwise required by law" to the limitation on use, disclosure, or transfer of data to the original authorized purpose.

The Department has amended the requirement that a Law Enforcement Official Registration Application be accompanied by a letter from the applicant's supervisor, to clarify that this letter must be signed by the applicant's supervisor.

The Department has amended the prohibition on a Law Enforcement Official who is a coroner, medical examiner, or directly assisting a coroner or medical examiner, obtaining a Prescriber History Report or a Pharmacy History Report from CURES. The Department changed "a Law Enforcement Official who is a coroner, medical examiner, or officer or employee of a Law Enforcement Agency" to "a Law Enforcement Official acting in the capacity of a coroner or medical examiner, or a Law Enforcement Official directly assisting an individual acting in the capacity of a coroner or medical examiner." The Department has applied the same change in a circumstance where the subject of the search is deceased, and the Law Enforcement Official is not required to provide a violation code or a crime code.

The Department has deleted the section 825 language that stated that by accepting benefits provided under the Medi-Cal program, the individual has agreed to the practices described in the notice of privacy practices, and has added a requirement that any Law Enforcement Official requesting a Patient Activity Report must provide an affidavit to the effect that such official is complying with certain terms of the federal Medicaid regulations.

The Department has added, "[u]nless otherwise required by law" as an exemption to the restriction prohibiting a Law Enforcement-User from using, disclosing, or transferring data for a purpose other than the authorized purpose for which the information was originally requested.

The Department has amended the section 825, subdivision (f)(4)(A)(i)c requirement that, a Law Enforcement-User must provide a search authorization that includes a search warrant, court order, or an approved exception specified in subdivision (d)(5), to request a Patient Activity Report. The Department has amended this subdivision from “search warrant, court order, or an approved exception” to “search warrant, court order, or documentation of an approved exception.”

The Department has amended the information required from a Law Enforcement-User to request a Patient Activity Report, from “[p]atient first name or patient last name” to “[p]atient first name and patient last name.”

The Department has amended section 826 of the proposed regulations to specify that references to “the Department” mean “the Department’s Research Center.” The Department has added an exemption for a Bona Fide Researcher who only obtains Aggregated Data from the requirement that a Bona Fide Researcher must provide a complete draft of any report, evaluation, or other document, sufficiently in advance of any publication or dissemination, and the final publication.

The Department has further amended section 826 to add “documents” from CURES to the types of information that an Interested Party must not release, disclose, or disseminate, and has added “[n]ame,” “[d]ate of birth,” and enumerated “HIPPA identifiers” to the list of what is considered identifying information that has a reasonable possibility of indirectly identifying an individual. With regard to when releasing rates, frequencies, other tabulations, or combined factors may be considered to have a reasonable possibility of indirectly identifying an individual, the Department has replaced, “which result in fewer than 20 individuals in the data set” with “which result in the reporting of data for fewer than 20 individuals.”

The Department has added subdivision (d)(12) to section 826 to provide that a Team Member is limited to accessing or analyzing data obtained by a Bona Fide Researcher.

The Department has amended subdivision (f)(3)(K)(vi) of section 826 to specify that the exception to the requirement to provide a copy of the institutional review board approval and all documentation submitted as part of that review and approval process, is only applicable when a public health officer requests De-Identified Individual-Level Data from CURES.

The Department has amended subdivisions (f)(3)(K)(vii)-(f)(3)(K)(vii)b.2. of section 826 to limit disclosures of Identified Individual-Level Data from CURES, specifically to restrict disclosures only to disclosures that are consistent with the requirements of Civil Code section 1798.24, subdivision (b).

The Department has amended subdivision (f)(6) of section 826 to clarify the requirement for the Department to notify a Bona Fide Researcher ahead of the expiration date of an approved Data Request Application.

The Department has deleted the section 828 requirement that a HIT System must submit a View Notification to the Information Exchange Web Service.

There have been no other changes in the applicable laws or to the effect of the proposed regulations from the laws and effects described in the Notice of Proposed Regulatory Action.