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| 1.01 | Proposed Article 2.7. § 827.4 Restrictions on Accessing CURES or Data from CURES.<br><br>EFF and ACLU California Action support the view largely reflected in the proposed regulations that law enforcement agencies may obtain Patient Activity Reports only with a warrant or court order. We believe this is the right policy in light of the involuntary nature of patients' disclosure to the government that they have been prescribed controlled substances and "the particularly private nature of the medical information at issue" in state PDMP databases.<br><br>A court order or warrant is also appropriate because the necessity of medical services means that even patients' sharing of prescription drug information with their medical providers or pharmacists is involuntary. As the Supreme Court has made clear, the warrant requirement applies even when the government seeks to compel a third party to produce records in which an individual has a reasonable expectation of privacy. *Carpenter v. United States*, 138 S. Ct. 2206, 2221–22 (2018). In that circumstance, the use of an administrative subpoena is unreasonable under the Fourth Amendment, and a warrant is required instead.<br><br>Although the regulations require a warrant or court order in most cases, there are gaps in the existing regulations' protections against law enforcement access that are not addressed in the proposed regulations. Subsection § 827.4(m) of the proposed regulations still allows for access in absence of a warrant if the Law Enforcement Official provides a federal | Commenters express concern with section 827.4, subdivision (m)(3), which permits the Drug Enforcement Administration (DEA) to obtain CURES records without a court order or a search warrant by issuing an administrative subpoena under title 21, United States Code section 876 of the Controlled Substances Act. No change has been made in response to this comment. The Ninth Circuit U.S. Court of Appeals has held that under title 21, United States Code section 876, the DEA has the authority to obtain patient records without a court order by issuing an administrative subpoena. See *Oregon Prescription Monitoring Program v. U.S. Drug Enf't Admin.*, 860 F.3d 1228 (9th Cir. 2017); see also *United States v. California*, Case No. 3:18-cv-02868 (S.D. Cal. May 9, 2019).<br><br>The Department's requirement for a search warrant or court order to obtain Patient Activity Reports is the result of a policy decision. The enforcement of that policy takes into account the critical needs of agencies combating the problem of the Diversion and Resultant Abuse of Controlled Substances in this state. The protocols outlined in section 827.4, subdivision (m)(6), among other protections contained in sections 827.4 and 827.5, safeguard patients' prescription data while |

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| | grand jury subpoena, a subpoena from a federal, state or local prosecutor under certain circumstances, an administrative subpoena issued under 21 U.S.C. § 876 of the Controlled Substances Act, or a patient's death certificate in certain circumstances. Likewise, § 827.4(m) allows for access if the Official has written approval from the Attorney General or is a member of a department investigative team. All of these avenues circumvent judicial process.<br><br>The policy of not requiring any process beyond an administrative subpoena is highly suspect under the Fourth Amendment, and we stand firmly against the proposed rule.<br><br>The other exceptions to the warrant requirement are not even based on federal statutory authority. Allowing law enforcement to obtain highly sensitive records without the approval of a neutral judge misses a key tenet of our criminal legal system. If a Law Enforcement Official may bypass judicial process to access prescription records, they have done so in violation of the Fourth Amendment. | ensuring that critical law enforcement programs are not disabled. The written authorization from the Attorney General required by section 827.4, subdivision (m)(6), sufficiently ensures that CURES data can be accessed by individuals within the Department only for authorized purposes related to official functions of the Department. |

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| 1.02 | Proposed Article 2.7. § 827.4 Restrictions on Accessing CURES or Data from CURES.<br><br>"Additionally, the regulations fail to require that a Law Enforcement Officer obtain a warrant for other searches that include patients' personal information and prescription records, such as prescriber history reports and pharmacy history reports. Whether a CURES query is of a patient's prescription information or the provider or pharmacist's CURES history, personally identifiable patient prescription information is reported. For example, a provider search of a doctor who specializes in transition-related care would reveal the names and prescriptions of the patients of that doctor, outing those individuals and their sensitive medical diagnoses just as much as if a patient search had been done for those individuals. A warrant should be required for all prescription information that identifies, or is capable of identifying, the patient.<br><br>Technology currently exists to link a patient's CURES records across different addresses and variations in name spellings. Anonymizing or redacting patient names and information from CURES records for warrantless government searches of prescriber or pharmacy histories might therefore allow for identification of over-prescribing doctors while also preventing unchecked access to patients' identities, personal information, and prescription history without any probable cause of wrongdoing. If the redacted or anonymized patient information pointed to a possible violation of law, a warrant could be obtained to unmask the patient whose records raised the red flag." | No change has been made in response to this comment. There are meaningful distinctions between Patient Activity Reports and Prescriber History Reports or Pharmacy History Reports that account for a divergence in the application of the search warrant or court order policy requirement. Prescriber History Reports or Pharmacy History Reports are centered on the prescribing or dispensing activity of the Health Care Practitioner or pharmacy that is the subject of the report. From a patient privacy standpoint, a Prescriber History Report or Pharmacy History Report generally does not encapsulate a comprehensive dispensation history of a patient. The patient data for any individual patient is very limited in most instances. Even though the data fields between the reports are similar, many Prescriber History Reports or Pharmacy History Reports would need to be generated, consolidated, and sorted to obtain almost the same information produced by a single Patient Activity Report.<br><br>Regarding anonymizing or redacting patient names, no change has been made in response to this comment. If patient information were redacted, Users would not be able to assess the data on a patient-level basis, because a grouping of the dispensations by patient would not be possible. The alternative is to substitute patient |

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| | | information with a unique identifier. However, because there is no unique data element reported about patients, such as a social security number, patient entity linking is challenging. There are algorithms that attempt to do this, but the output of such will inevitably result in a certain level of false positives and false negatives—meaning the dispensations for a given patient could be over-inclusive or under-inclusive. And because the data is de-identified, the User cannot evaluate these linkages to ensure accuracy. |
| 1.03 | Proposed Article 2.7. § 827.4 Restrictions on Accessing CURES or Data from CURES.<br><br>"Another exception to the warrant requirement is § 827.4(m)(4), which states that a Law Enforcement Official is not required to provide a warrant or a court order if the Law Enforcement Official is an officer or employee of the Department's Bureau of Medi-Cal Fraud and Elder Abuse or the Department of Health Care Services, and provides CURES or CURES PDMP with a Medi-Cal beneficiary status report indicating that the individual to be searched was a Medi-Cal beneficiary or applicant during the Search Period included in the Patient Activity Report.<br><br>As a practical matter, this provision discriminates against individuals enrolled in California's public health program by affording recipients lesser privacy rights than their non-enrolled counterparts, making the receipt of a public benefit contingent on surrendering a privacy right. The | No change has been made in response to this comment. In this rulemaking package, section 827.4, subdivision (m)(4) was only revised in non-substantive ways to change the name of the Department's division responsible for investigating Medi-Cal fraud, and to change the format of the referenced federal regulations. Furthermore, no change was made because the federal Medicaid statutes and the regulations promulgated thereunder permit such a disclosure. The federal Medicaid statutes and regulations require that a state Medicaid (Medi-Cal in California) plan must provide safeguards that restrict the use or disclosure of information concerning applicants and beneficiaries to purposes directly connected with the administration of the plan. (42 USC § 1902(a)(7); 42 CFR § 431.300(a).) Under the federal |

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| | proposed regulations fail to remedy this problem with the existing regulations.<br><br>Because officers of the Bureau of Medi-Cal Fraud and Elder Abuse investigate fraudulent performance of health care services by health care professionals and fraudulent use of a Medi-Cal enrollee's benefits by a non-enrollee, their investigations must comport with the Fourth Amendment. Instituting a requirement for a warrant or court order benefits both healthcare providers and patients. Healthcare providers are assured due process when a search of their patients' records is overseen by a judge, and patients are afforded a greater level of security in their prescription information.<br><br>. . .<br><br>The regulations should be amended to require that Law Enforcement Officials must obtain a warrant or court order to access any individual's prescription records, regardless of whether they receive healthcare from the state." | regulations, purposes directly related to plan administration include, among other things, conducting or assisting an investigation, prosecution, or civil or criminal proceeding related to the administration of the plan. (42 CFR § 431.302.)<br><br>Pursuant to section 827.4, subdivision (m)(4)(B)1., the Department still requires that the investigating Law Enforcement Official provide an affidavit to the effect that such official is conducting or assisting an investigation, prosecution, or civil or criminal proceeding, related to one or both of (i) the administration of the Medi-Cal plan within the meaning of title 42, Code of Federal Regulations, section 431.302, subdivision (d), or (ii) activities consistent with the duties and responsibilities of the Medicaid Fraud Control Unit as set forth in title 42, Code of Federal Regulations section 1007.11. This provides not only a federal statutory basis for requiring the information being sought, but also a basis for disclosure of the information permitted under California Civil Code section 1798.24, subdivision (e). |
| 1.04 | Proposed Article 2.7. § 827.4 Restrictions on Accessing CURES or Data from CURES. | No change has been made in response to this comment. The investigation and evaluation of compliance with federal law is not beyond the purview of certain Regulatory Agencies. For example, the Board of |

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| | The regulations, both existing and proposed, do not require government agencies other than law enforcement agencies to obtain a warrant for any CURES information, notwithstanding that government searches by non-law enforcement agencies are equally subject to the warrant requirements of the Fourth Amendment. By permitting wide access to CURES information without a warrant to protect sensitive patient records, the regulations fail to meet constitutional requirements.<br><br>Some might argue that the health care industry or the pharmaceutical industry are "closely regulated" for purpose of the warrantless administrative search doctrine, but the Supreme Court has recognized only four "closely regulated" businesses over the past forty-five years. *City of Los Angeles v. Patel*, 135 S. Ct. 2443, 2454–55 (2015) (selling liquor, dealing firearms, mining, and operating an automobile junkyard). Even assuming that health care falls within the exception to the Fourth Amendment requirements for a "closely regulated industry," warrantless administrative inspections are permissible only when there is "a substantial government interest" in the regulatory scheme; "the warrantless inspections [are] necessary to further [the] regulatory scheme;" and the state operates an inspection scheme with sufficient "certainty and regularity" to provide "a constitutionally adequate substitute for a warrant." *Killgore v. City of S. El Monte*, 3 F.4th 1186, 1192 (9th Cir. 2021). Warrantless inspections of personal prescription information fail to satisfy these requirements for at least two reasons. First, even if non-law enforcement entities have a substantial interest in accessing information about prescribers, it is not clear why accessing the prescription information | Pharmacy has authority to investigate compliance with federal law. California pharmacy law has several provisions that reference and overlap with federal law, including the drug inventory requirements, the patient health information privacy requirements, and the drug distribution, wholesaling, and authorized drug purchasing requirements. In addition, and more directly, California pharmacy law grants the Board of Pharmacy authority to bring disciplinary action on the basis of any federal law regulating controlled substances and dangerous drugs. See Business & Professions Code section 4301, subdivision (j), providing that "[t]he board shall take action against any holder of a license who is guilty of. . . [a] violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs"; see also, Business & Professions Code section 4301, subdivision (o), providing that "[t]he board shall take action against any holder of a license who is guilty of. . . [v]iolating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established |

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| | of identifiable, individual patients is "necessary" to advance those interests. Second, unlike industries where random inspections are necessary to identify violations, there is no such risk of disappearance or alteration of evidence here, as the records sought are held securely in a state database out of reach of any meddling hands. Warrantless access is simply not necessary to further any government's agencies investigative interests. | by the board or by any other state or federal regulatory agency."<br><br>The CURES database contains sensitive and private patient information. Access by Law Enforcement Officials to a Patient Activity Report, which encapsulates significant information about individual patients, necessitates sufficient procedural safeguards, including adequate justification. Furthermore, while investigators for the Department of Consumer Affairs may properly qualify as Regulatory Board Officials under these regulations when conducting non-criminal investigations, it is appropriate to classify such investigators as Law Enforcement Officials and subject them to the corresponding requirements when such investigators are investigating criminal offenses or enforcing criminal law.<br><br>The law has traditionally distinguished between searches for criminal purposes and those for administrative/regulatory purposes, requiring warrant protection for the former, while allowing more relaxed standards, including statutory schemes, for the latter. The Department continues this distinction with these regulations. |

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| 1.05 | Proposed Article 2.1. § 821.1 Eligibility for Access to CURES, Proposed Article 2.2. § 822.1 Eligibility for Access to CURES, Proposed Article 2.3. § 823.1 Eligibility for Access to CURES, Proposed Article 2.4. § 824.1 Eligibility for Access to CURES, Proposed Article 2.6. § 826.1 Eligibility to Access CURES or Obtain Data from CURES, Proposed Article 2.7. § 827.1 Eligibility to Access CURES or Obtain Data from CURES.<br><br>"The proposed regulations are insufficient to ensure that anyone with a CURES registration who is no longer eligible for access does not access CURES. For some types of CURES users, the proposed regulations rightly require notification to CURES that the individual is no longer eligible to access CURES. In most instances, however, the proposed regulations simply ask that someone no longer eligible to access CURES refrain from using CURES. At the very least, all CURES users should be required to self-report to CURES that they no longer are eligible to access the system. Ideally, the regulations should require a process similar to that which applies to the delegate-users, whereby someone with authority over the user must immediately terminate the user's authority to use CURES upon that user no longer being eligible for access to CURES. Additionally, each time a user of CURES logs in, they should be required to check a box under penalty of perjury stating that they remain eligible to access CURES data." | The Department accepts this comment in part and has revised section 821.1, subdivision (e), to add "in writing" for Out-of-State Prescribers, and section 823.1, subdivision (d), to add "in writing" for Out-of-State Pharmacists.<br><br>The Department has not accepted the other comments and suggestions since it already has safeguards in place to ensure only those who are eligible, access CURES. For instance, for California licensed Prescribers and Pharmacists, the Department conducts automated license status verifications in conjunction with the California Department of Consumer Affairs to verify whether an individual's California State License Number is in good standing with the applicable Licensing Board. This automated California State License Number check is performed at the time of registration, and weekly thereafter to ensure the California State License Number is still active. The Department conducts daily DEA Registration Certificate status verifications with a master DEA file from the DEA. If a DEA Registration Certificate is indicated on that DEA file, the Prescriber-User or prescribing Pharmacist's account will stay active. However, if the DEA Registration Certificate is no longer found on the master DEA file, the Prescriber- |

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| | | User will be transferred into a Non-DEA Practitioner-User role, so long as the California State License Number is active, and the prescribing Pharmacist's account will transfer into a standard Pharmacist account, so long as the California State License Number is active.<br><br>Additionally, there is no automated process in place for the Department to verify whether Regulatory Agency-Users and Law Enforcement-Users are still eligible to access CURES, since Regulatory Agency-Users and Law Enforcement-Users account statuses are not dependent of an associated State License Number. As such the Department accepts this comment in part, and has revised section 826.1, subdivision (c), and section 827.1, subdivision (c), to specify that the Regulatory Agency or Law Enforcement Agency must notify the CURES PDMP in writing that the Regulatory Agency Official or Law Enforcement Official is no longer eligible to access CURES. Upon receipt of that written notification by the applicable Regulatory Agency or Law Enforcement Agency, CURES PDMP must terminate that user's access to CURES. |

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| | | Additionally, the Department has already specified the requirement in Article 2.4, section 824.1, subdivision (b) that an Authorizing User must immediately terminate that Authorizing User's delegation of authority to a Delegate under this article, including cancellation of the Delegate association with that Delegate under section 824.8, subdivision (c), when the specified instances occur. Furthermore, section 824.1, subdivision (c), specifies that if a Delegate is terminated under section 824.1, subdivision (b)(4), and is licensed by a Licensing Board or Out-of-State Licensing Board, the Authorizing User must also immediately notify the Delegate's Licensing Board or Out-of-State Licensing Board in writing of the termination and the basis of the termination.<br><br>Regarding the suggestion that each time a User logs into CURES, the User must check a box under penalty of perjury, no change has been made in response to this comment. The Department requires a User to agree to the Terms and Conditions of CURES prior to such User registering for access to CURES, prior to accessing patient information, and when the User is completing an annual renewal of that User's CURES account. The Terms and Conditions of CURES includes the requirement that only eligible Users are |

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| | | accessing the system and data. The Department included the Terms and Conditions of CURES as a verification step, and believes that the Terms and Conditions of CURES already address the concern raised by this comment about requiring the User to check a box to verify that the User is still eligible to access CURES. The verification step prior to accessing patient information helps not only prevent ineligible Users from logging into CURES, but also serves as a reminder when the User accesses a patient's information in CURES. Requiring a User to agree to the Terms and Conditions of CURES prior to accessing patient information helps protect the data contained therein. |
| 1.06 | Proposed Article 3. § 828.6 Procedures for Requesting Identified Individual-Level Data and De-Identified Individual-Level Data from CURES.<br><br>"The proposed regulations also fail to ensure that patients are notified when their sensitive medical information is accessed by law enforcement officials or regulatory agency officials, and in some cases, researchers. Indeed, by allowing researchers to obtain individual-level information using the process in subdivision (t) of Civil Code § 1798.24, the proposed regulations create an exception to the current regulation's requirement that researchers obtain consent from any patient whose information they will obtain. Prescription information reveals sensitive information about | No change has been made in response to this comment. Requiring Law Enforcement Officials or Regulatory Agency Officials to notify individuals when accessing their information in CURES may hinder those officials in their investigations or interfere with the investigations. Indeed, California law has treated investigatory records differently to not disrupt active investigations. (See e.g., Gov. Code, § 6254, subd. (f).) Additionally, because the operation of CURES must comply with all applicable federal and state privacy and security laws and regulations, the regulations incorporate the process in Civil Code § |

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| | individuals, and they should be made aware of who is accessing this information and why." | 1798.24, subdivision (t). Researchers may use either Civil Code § 1798.24, subdivision (b) or Civil Code § 1798.24, subdivision (t) to request information. Allowing researchers two methods to request information, will provide the researchers with access to the information to aid in important public policy research, while still protecting the privacy rights of individuals whose information is sought. |
| 1.07 | Proposed Article 2.1. § 821.2 Procedures to Register for Access to CURES, Proposed Article 2.2. § 822.2 Procedures to Register for Access to CURES, Proposed Article 2.3. § 823.2 Procedures to Register for Access to CURES, Proposed Article 2.4. § 824.3 Procedures to Register for Access to CURES, Proposed Article 2.6. § 826.2 Procedures to Register for Access to CURES, and Proposed Article 2.7. § 827.2 Procedures to Register for Access to CURES.<br><br>"The proposed regulations require people with CURES access to provide their mother's maiden name as part of setting up an account with CURES. This policy is both privacy invasive and outdated. A mother's maiden name is often used as a security question for financial and other sensitive matters and providing this information to the government seems unnecessary given the other personally identifying information required to create an account, particularly absent any way for the government to verify whether a CURES user provided an accurate answer to this question. Additionally, given the cultural shifts in recent years, the utility of this information is questionable at best. Many women are opting not to change | No change has been made in response to this comment. The Department acknowledges the concern but is limited by technological and fiscal constraints to address the concern during this current rulemaking proceeding. The Department intends to revisit the regulation in a future package to determine the feasibility of alternative options. |

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| | their surname, making the answer to this question potentially public knowledge, and family structures include families with no female parent, making this question inapplicable to some potential CURES users. Given these concerns, we suggest removing the requirement that applicants provide their mother's maiden name." | |
| 2.01 | Proposed Article 2.4. § 824.9 Procedures for Use of CURES by Delegate-Users.<br><br>"We understand that the Department has prioritized data security in these regulations and while we agree that security is necessary to protecting patient and user information, we are concerned that some provisions in the proposed regulations elevate data security at the expense of ensuring efficient clinical workflow. CMA has urged that electronic systems be interoperable and integrated into clinical practice workflows. Obtaining essential information, including PDMP data, often requires multiple "clicks," opening multiple windows, and the use of separate logins even before the physician locates what he or she is looking for - and that situation must be repeated for each patient and every prescription for a controlled substance. Effective PDMP and electronic health record integration means that the clinical workflow must achieve "functional interoperability," or the ability for systems to exchange, incorporate and display data in a meaningful and contextual manner. In addition, access to | No change has been made in response to this comment. In April 2022, the Department will release an optimized CURES. CURES will be updated to provide an improved User interface and new system features, including functionality mandated through recent legislation. Many of the new features will be seamless and easy to use by requiring fewer clicks when navigating the system. Based on preliminary user feedback, the optimized CURES will provide a better User experience.<br><br>Regarding Delegate access to the Information Exchange Web Service (IEWS), no change has been made in response to that comment for the reason stated in response to a similar comment, see response to comment 2.07. |

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| | the CURES PDMP for delegates should be the same whether the delegate uses the Web-based system or the Information Exchange Web Service." | |
| 2.02 | Proposed Article 2.1. § 821.2 Procedures to Register for Access to CURES and Proposed Article 2.2. § 822.2 Procedures to Register for Access to CURES.<br><br>"(c)(2)(H) Category of Licensure. The proposed regulations require that if an applicant is licensed by the Medical Board of California or the Dental Board of California, the applicant must provide the applicant's specialty and indicate whether the applicant is board-certified. While this language already exists in the current regulations, we note that this section should be amended for accuracy to include licensees of the Osteopathic Medical Board of California because these physicians are also prescribers and equivalent to allopathic physicians regulated by the Medical Board of California. There are other professions, including nurse practitioners, physician assistants, podiatrists, and pharmacists who may be required to use CURES, have a specialty and are certified by a board, who should also be required to report this information as part of their application.<br><br>It is also unclear why physicians are required to provide their specialty and board certification, as California's physician and surgeon certificates are plenary licenses that confer the same rights and privileges to the licensee regardless of medical specialty. While physicians may report board | The Department accepts this comment in part. In order to recognize the various professionals who may have certifications and specialties, the Department decided to remove Board Certification and Specialty as required fields, and the Department has made those fields optional for all applicable user types. |

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| | certification to the licensing board, it is not a requirement for medical licensure and prescribing authority is the same for all licensed physicians with a DEA registration and is not limited by board certification of specialty. The proposed regulations specifically identify physicians and dentists as professions that must report their specialty and if they hold a board certification. We request additional clarification how board certification and specialty data is used with the CURES PDMP." | |
| 2.03, 4.02 | Proposed Article 2.1. § 821.2 Procedures to Register for Access to CURES and Proposed Article 2.2. § 822.2 Procedures to Register for Access to CURES.<br><br>"(c)(2) (K) & (L) Email address and Phone Number – The proposed regulations require the applicant to indicate whether the applicant's email address and phone number may be shared in CURES if the applicant is approved for access to CURES. We recommend clarifying that the default selection will be for the email address and phone number not to be shared and that applicants must "opt-in" to making this information available to other users." | No change has been made in response to this comment. This field is already defaulted to not share the applicant's email and phone number in CURES. |
| 2.04 | Proposed Article 2.4. § 824.2 Delegate Agreement between Authorizing User and Delegate.<br><br>"New subdivision (a) was added to set forth the requirement that an Authorizing User must enter into a Delegate Agreement with each Delegate to whom that Authorizing User delegates authority under this article. New subdivision (a)(2) was added to establish that a Delegate | The Department accepts this comment and has revised Article 2.4, subdivision 824.2, in response to this comment. An Authorizing User may now enter into a Delegate Agreement with one or more Delegates. |

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| | Agreement must only be between one Delegate and one Authorizing User. The proposed regulations state that authorizing Users may have multiple Delegates, and Delegates may be associated with multiple Authorizing Users, so long as each Delegate and Authorizing User have entered into a Delegate Agreement.<br><br>While we recognize the need to maintain appropriate security and controls to prevent unauthorized access to the CURES PDMP, the requirements set forth in the proposed regulations could create significant administrative burdens for prescribers, delegates, medical practices, hospitals and clinics related to keeping agreements current and entering information into the CURES PDMP. In many settings, prescribers do not exclusively work with one or two delegates. Medical assistants, nurses, nurse practitioners, physician assistants and other allied health professionals are working with multiple physicians and may be working with different physicians at any given time. The proposed regulations would potentially require each potential prescriber or delegate in some health care settings to enter into and maintain multiple delegate agreements. For example, in a practice with 15 physicians and 10 potential delegates, this would require the practice to manage 150 separate agreements. In larger settings, such as a hospital, where there may be movement between departments depending on staffing needs, there could potentially be the need to maintain even more agreements to minimize disruptions in care and workflow."<br><br>"We recommend that the regulations be amended to allow Authorizing Users to enter into delegate agreements with multiple delegates . . . ." | |

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| 2.05 | Proposed Article 2.4. § 824.2 Delegate Agreement between Authorizing User and Delegate.<br><br>"The proposed regulations also require each Authorizing User to individually authorize and terminate each delegate relationship within the CURES PDMP. The proposed regulations do not allow Authorizing Users to designate a delegate who is authorized to electronically update delegate agreements in the CURES PDMP."<br><br>"We recommend that . . . the CURES PDMP allow the Authorizing User to designate a delegate with administrator privileges who can assist with managing these agreements and ensuring that the information is entered into the CURES PDMP in a timely manner." | No change has been made in response to this comment. An Authorizing User is responsible for all access and use of CURES by a Delegate-User to whom that Authorizing User has delegated authority under these regulations, including the Delegate-User's compliance with the requirements of these regulations. As such, the Department believes it is appropriate for Authorizing Users to maintain this level of oversight of their Delegates who will now have direct access to the entire CURES database, rather than delegating the responsibility to a Delegate.<br><br>However, the Department intends to revisit the regulation in a future package to evaluate the feasibility of establishing a third role to assist an Authorizing User in the administration of such functions. |
| 2.06 | Proposed Article 2.1. § 821.1 Eligibility for Access to CURES, Proposed Article 2.2. § 822.1 Eligibility for Access to CURES, Proposed Article 2.3. § 823.1 Eligibility for Access to CURES, Proposed Article 2.4. § 824.1 Eligibility for Access to CURES, Proposed Article 2.6. § 826.1 Eligibility to Access CURES or Obtain Data from CURES, Proposed Article 2.7. § 827.1 Eligibility to Access CURES or Obtain Data from CURES.<br><br>"We recognize the need to ensure appropriate access to the CURES PDMP for authorized users to protect patient and user privacy. The proposed | The Department has amended these regulations in response to a similar comment, see response to comment 1.05. |

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| | regulations describe the procedures for terminating CURES access for various defined users: Prescribers, Out-of-State Prescribers, Non-DEA Practitioners, Pharmacists, Out-of-State Pharmacists, and Delegates. We recommend the use of a standard process for terminating access for ineligible individuals that includes:<br><br>• Requiring that the individual must not access CURES;<br>• Requiring the individual or the Authorizing User to notify the CURES PDMP about ineligibility within a defined time period; and<br>• Requiring the CURES PDMP to notify the individual and the Authorizing User when CURES access is terminated.<br><br>The proposed regulations require some types of users to simply stop accessing the CURES PDMP and others to "immediately notify" the CURES PDMP when they are ineligible. Additional clarification is needed regarding the type of notification that is required (ex. formal written notice, accessing the CURES PDMP to update permissions, etc.)." | |
| 2.07 | Proposed Article 2.4. § 824.9 Procedures for Use of CURES by Delegate-Users.<br><br>"CMA has urged that electronic systems be interoperable and integrated into clinical practice workflows. Obtaining essential information, including PDMP data, often requires multiple "clicks," opening multiple windows, and the use of separate logins even before the physician locates what he or she is looking for - and that situation must be repeated for each patient and every prescription for a controlled substance. Effective PDMP and | No change has been made in response to this comment.. The Department acknowledges the concern, but there are technology constraints precluding the Department from incorporating Delegate access through the IEWS. With respect to Delegate use of CURES, the CURES Program must be able to identify the Delegate submitting a request, and the Authorizing User on whose behalf such Delegate is acting. Delegates can have multiple Authorizing |

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| | electronic health record integration means that the clinical workflow must achieve "functional interoperability," or the ability for systems to exchange, incorporate and display data in a meaningful and contextual manner.<br><br>The CURES regulations that became effective July 1, 2020, were amended to state that delegates may—not must—access the CURES PDMP through the Web-Based Application with the intent that delegates could access the CURES PDMP through other channels, including interfaces integrated into electronic health record systems. Furthermore, the proposed regulations retain the provision stating "A Delegate User may access the Web-Based application." Article 5 of the proposed regulations pertaining to the Information Exchange Web Service, however, identifies the categories of authorized users who are the intended recipients of the CURES data accessed through the Information Exchange Web Service and do not identify Delegate-Users as being eligible to access information through the Information Exchange Web Service.<br><br>As currently drafted, the regulations appear to inhibit clinical workflow and run contrary to statute and the will of the Legislature when they passed A.B. 40. (Health & Safety Code §11165.1(a); A.B. 40, Stats. 2017, ch. 607.) Per the law, approved health care practitioners and pharmacists will be permitted to use a health information technology system, including an electronic health record system, to access CURES data so long as the entity certifies that it meets certain criteria. Therefore, an entity could feasibly meet the criteria as specified in statute, submit a complete application | Users, and Authorizing Users can have multiple Delegates, so identification of one is not sufficient to reveal the other. The Department leverages National Council for Prescription Drug Programs (NCPDP) technology standards for transmission of data via IEWS. The NCPDP standard presently lacks the ability to transmit both the Delegate and the Authorizing User identities associated with a request. To incorporate Delegate access via IEWS, the Department has requested a revision to the NCPDP technology standards. According to the NCPDP, the Department's request would need to be incorporated into the Medicare Modernization Act (MMA) and subsequently approved through rules issued by the Centers for Medicare and Medicaid Services. The Department was recently informed that the NCPDP voted to request DOJ's requested changes be made under the MMA.<br><br>If approved, the revision would meet the Department's auditing requirements and permit Delegate access in IEWS in the future. Should the request be approved, the Department intends to revisit the regulations in the future to determine the feasibility of allowing Delegate access through IEWS. |

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| | package with an executed Memorandum of Understanding, onboarding questionnaire and payment for applicable fees, but yet still not be able to have all approved users, such as delegates, access the Information Exchange Web Service.<br><br>. . .<br><br>To ensure that Delegate-Users will continue to be able to access the CURES PDMP through other interfaces besides the Web-Based Application, Article 5 should be amended to specifically state that Delegate-Users are authorized to access the CURES PDMP on behalf of Authorized Users through an Information Exchange Web Service. Specifically, § 830.3. Requirements for HIT System Use of the Information Exchange Web Service should be amended, where appropriate, to reference 'an authorized Prescriber-User, Non-DEA Practitioner User, or Pharmacist-User or their authorized Delegate-Users'." | |
| 2.08, 4.06 | Proposed Article 5. § 830.3 Requirements for HIT System Use of the Information Exchange Web Service.<br><br>"In addition, under the recently completed California HIE Onboarding Program ("CalHOP"), administered by the Department of Health Care Services, all participating health information organizations (HIOs) were required to build an interface to the CURES PDMP. This requirement was included because HIOS can facilitate easier, more streamlined access to CURES data for prescribers and their delegates. These regulations should acknowledge that work that has already been done." | No change has been made in response to this comment. With respect to acknowledging the work done for CalHOP and HIOs, the comment is not specific enough for the Department to respond to or make a change in the regulations. In general, when implementing the CURES statutes through these regulations, the Department seeks to balance the need for efficient access to confidential medical information with the need to protect the accuracy, security and privacy of the information. |

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| 3.01 | Proposed Article 2.1. § 821.2 Procedures to Register for Access to CURES and Proposed Article 2.2. § 822.2 Procedures to Register for Access to CURES.<br><br>"Section 821.2(c)(2)(K) & (L) and Section 822.2(c)(2)(J) and (K) require the applicant to indicate whether the applicant's email address and phone number may be shared in CURES if the applicant is approved for access to CURES. CAFP recommends clarifying that the default selection will be for the email address and phone number not to be shared and that applicants must "opt-in" to making this information available to other users." | No change has been made in response to this comment for the reason stated in response to a similar comment, see response to comment 2.03. |
| 3.02 | Proposed Article 2.4. § 824.2 Delegate Agreement between Authorizing User and Delegate.<br><br>"New subdivision (a) was added to set forth the requirement that an Authorizing User must enter into a Delegate Agreement with each Delegate to whom that Authorizing User delegates authority. Moreover, subdivision (a)(2) provides that the Delegate Agreement must only be between one Delegate and one Authorizing User. The Authorizing User may have multiple Delegates, or a Delegate may have multiple Authorizing Users provided that each Delegate and Authorizing User have entered into a Delegate Agreement.<br><br>While we recognize the need to maintain appropriate security and controls to prevent unauthorized access to the CURES Prescription Drug Monitoring Program (PDMP), the requirements set forth in the proposed regulations could create significant administrative burdens for prescribers, | The Department has amended these regulations in response to a similar comment, see response to comment 2.04. |

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| | delegates, physician practices, and clinics. In many settings, prescribers do not exclusively work with one or two delegates. Physicians can work with multiple medical assistants, nurses, nurse practitioners, physician assistants, and other allied health professionals, and vice versa. The proposed regulations would potentially require each potential prescriber and delegate to enter into and maintain multiple Delegate Agreements. For example, in a practice with 15 physicians and 10 potential delegates, the practice would be required to manage 150 separate agreements. These are a substantial number of agreements to manage, particularly when they have to be renewed every 12 months, as required by the proposed regulations. Accordingly, CAFP recommends that the regulations be amended to allow Authorizing Users to enter into a Delegate Agreement with multiple Delegates rather than entering into a Delegate Agreement with each Delegate." | |
| 3.03 | Proposed Article 2.4. § 824.8 Delegate Agreement between Authorizing User and Delegate.<br><br>"Section 824.8 requires each Authorizing User to individually establish, approve, and cancel each Delegate association within the CURES PDMP. The proposed regulations do not allow Authorizing Users to designate a Delegate to administer these procedures. In order to alleviate the administrative burden, CAFP recommends that the regulations be amended to allow the Authorizing User to designate a Delegate with administrator privileges to assist with managing these agreements and to ensure that the information is entered into the CURES PDMP in a timely manner." | No change has been made in response to this comment for the reason stated in response to a similar comment, see response to comment 2.05. |

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| 3.04 | Proposed Article 2.4. § 824.9 Procedures for Use of CURES by Delegate-Users and Article 5. § 830.3 Requirements for HIT System Use of the Information Exchange Web Service.<br><br>"CAFP's comments in 2019 raised that Health & Safety Code §11165.1(a)(1)(D) allowed an approved health care practitioner, pharmacist, *and any person acting on behalf of a health care practitioner or pharmacist* to use a health information technology system, including an electronic health record system, to access information in the CURES database so long as the entity certifies that it meets certain criteria. Accordingly, the CURES regulations that became effective July 1, 2020, were amended to state that Delegates may—not must—access the CURES PDMP through the Web-Based Application indicating that Delegates could access the CURES PDMP through other channels, including interfaces integrated into electronic health record systems. However, the proposed regulations do not explicitly provide for the ability of Delegates to access information in the CURES database through a health information technology system, including an electronic health record system. Section 824.9 continues to provide that, "[a] Delegate User may access the Web-Based application," but does not explicitly specify that they may also use a health information technology system, including an electronic health record system, to access information in the CURES database. Moreover, Section 830.3 identifies the categories of authorized users who are the intended recipients of the CURES data accessed through the Information Exchange Web Service but does not identify Delegate Users as one of those authorized users eligible to access information through the | No change has been made in response to this comment for the reason stated in response to a similar comment, see response to comment 2.07. |

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| | Information Exchange Web Service. In order to ensure Delegate Users are allowed to access information in the CURES database through a health information technology system, as provided for in Health & Safety Code §11165.1(a)(1)(D), CAFP urges that the proposed regulations be amended to specifically state so and Section 830.3 be amended to include, where appropriate, Delegate Users when referencing authorized Prescriber-Users, Non-DEA Practitioner Users, or Pharmacist-Users." | |
| 3.05 | Proposed Article 2.7. § 827.4 Restrictions on Accessing CURES or Data from CURES.<br><br>"Section 827.4(k) requires a search warrant or court order to be provided in order to obtain a Patient Activity Report. CAFP supports such a requirement to protect the privacy and security of patient information and to ensure that Law Enforcement Officials cannot access it outside of their statutorily mandated duties related to CURES. However, this requirement is not similarly applied when obtaining a Prescriber History Report, Pharmacy History Report, or Serialized Prescription History Report under sections 827.4(b) – (d). A search warrant or court order is not required for these reports despite major commonality in the data contained in each. As such, CAFP urges that the proposed regulations be amended to apply the same criteria for obtaining a Patient Activity Report, Prescriber History Report, Pharmacy History Report, or Serialized Prescription History Report." | No change has been made in response to this comment for the reason stated in response to a similar comment, see response to comment 1.02. |

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| 4.01 | Proposed Article 2.1. § 821.2 Procedures to Register for Access to CURES and Proposed Article 2.2. § 822.2 Procedures to Register for Access to CURES.<br><br>"(c)(2)(H) Category of Licensure – The proposed regulations require that if an applicant is licensed by the Medical Board of California or the Dental Board of California, the applicant must provide the applicant's specialty and indicate whether the applicant is board-certified. While this language already exists in the current regulations, we note that this section should be amended for accuracy to include licensees of all boards that license persons that can be prescribers. This includes references to the boards for osteopathic medicine (Osteopathic Medical Board of California); nurse-midwifes and nurse practitioners (California Board of Registered Nursing) pharmacists (California State Board of Pharmacy); and physician assistants (State of California Physician Assistant Board). Additionally, it is also unclear why physicians are required to provide their specialty and board certification, as California's physician and surgeon certificates are plenary licenses that confer the same rights and privileges to the licensee regardless of medical specialty. Furthermore, while physicians may report board certification to the licensing board, it is not a requirement for medical licensure and prescribing authority is the same for all licensed physicians with a DEA registration and is not limited by board certification of specialty. We request additional clarification how board certification and specialty data is used with the CURES PDMP." | The Department has amended these regulations in response to a similar comment, see response to comment 2.02. |

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| 4.03 | Proposed Article 2.4. § 824.2 Delegate Agreement between Authorizing User and Delegate.<br><br>"The proposed regulations state that authorizing Users may have multiple delegates, and delegates may be associated with multiple authorizing users, so long as each delegate and authorizing user have entered into a delegate agreement. While we recognize the need to maintain appropriate security and controls to prevent unauthorized access to the CURES PDMP, the requirements set forth in the proposed regulations could create significant administrative burdens for community health center prescribers and delegates. In health centers, prescribers do not exclusively work with one or two delegates. Health centers rely on a care-team model whereby medical assistants, nurses, and other allied health professionals are working with multiple clinicians (nurse practitioners, physicians, and physician assistants). At any time, and any day of the week, the team may shift depending on work schedules and clinical needs. The proposed regulations would potentially require each potential prescriber or delegate in a health center to enter into and maintain multiple delegate agreements. For example, in a health center with 15 clinicians and 10 potential delegates, this would require the practice to manage 150 separate agreements. In multi-site health centers, where there may be movement between sites depending on staffing needs, there could potentially be the need to maintain even more agreements to minimize disruptions in care and workflow. . . . " | The Department has amended these regulations in response to a similar comment, see response to comment 2.04. |

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| | "We recommend that the regulations be amended to allow authorizing users to enter into delegate agreements with multiple delegates . . . ." | |
| 4.04 | Proposed Article 2.4. § 824.2 Delegate Agreement between Authorizing User and Delegate.<br><br>"The proposed regulations also require each Authorizing User to individually authorize and terminate each delegate relationship within the CURES PDMP. The proposed regulations do not allow Authorizing Users to designate a delegate who is authorized to electronically update delegate agreements in the CURES PDMP.<br><br>We recommend that . . . the CURES PDMP allow the Authorizing User to designate a delegate with administrator privileges who can assist with managing these agreements and ensuring that the information is entered into the CURES PDMP in a timely manner." | No change has been made in response to this comment for the reason stated in response to a similar comment, see response to comment 2.05. |
| 4.05 | Proposed Article 2.1. § 821.1 Eligibility for Access to CURES, Proposed Article 2.2. § 822.1 Eligibility for Access to CURES, Proposed Article 2.3. § 823.1 Eligibility for Access to CURES, Proposed Article 2.4. § 824.1. | The Department has amended these regulations in response to a similar comment, see response to comment 1.05. |

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| | Eligibility for Access to CURES, Proposed Article 2.6. § 826.1 Eligibility to Access CURES or Obtain Data from CURES, Proposed Article 2.7. § 827.1 Eligibility to Access CURES or Obtain Data from CURES.<br><br>"We recognize the need to ensure appropriate access to the CURES PDMP for authorized users to protect patient and user privacy. The proposed regulations describe the procedures for terminating CURES access for various defined users: Prescribers, Out-of-State Prescribers, Non-DEA Practitioners, Pharmacists, Out-of-State Pharmacists, and Delegates. We recommend the use of a standard process for terminating access for ineligible individuals that includes:<br><br>• Requiring that the individual must not access CURES;<br>• Requiring the individual or the authorizing user to notify the CURES PDMP about ineligibility within a defined time period (ex. upon termination of employment); and<br>• Requiring the CURES PDMP to notify the individual and the authorizing user when CURES access is terminated.<br><br>The proposed regulations require some types of users to simply stop accessing the CURES PDMP and others to "immediately notify" the CURES PDMP when they are ineligible. Additional clarification is needed regarding the type of notification that is required (ex. electronic Administrator action, formal written notice, accessing the CURES PDMP to update permissions, etc.)." | |

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| 4.07 | Proposed Article 5. § 830.3 Requirements for HIT System Use of the Information Exchange Web Service.<br><br>"CPCA has urged that electronic systems be interoperable and integrated into clinical practice workflows. Obtaining essential information, including PDMP data, often requires multiple "clicks," opening multiple windows, and the use of separate logins even before the user locates what he or she is looking for - and that situation must be repeated for each patient and every prescription for a controlled substance. Effective PDMP and electronic health record integration means that the clinical workflow must achieve "functional interoperability," or the ability for systems to exchange, incorporate and display data in a meaningful and contextual manner.<br><br>The CURES regulations that became effective July 1, 2020, were amended to state that delegates may—not must—access the CURES PDMP through the Web-Based Application with the intent that delegates could access the CURES PDMP through other channels, including interfaces integrated into electronic health record systems. Furthermore, the proposed regulations retain the provision stating, "A Delegate User may access the Web-Based application." Article 5 of the proposed regulations pertaining to the Information Exchange Web Service, however, identifies the categories of authorized users who are the intended recipients of the CURES data accessed through the Information Exchange Web Service and do not identify Delegate-Users as being eligible to access information through the Information Exchange Web Service." | No change has been made in response to this comment for the reasons stated in response to similar comments, see responses to comments 2.01 and 2.07. |

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| 5.01 | Proposed Article 2.1. § 821.2 Procedures to Register for Access to CURES and Proposed Article 2.2. § 822.2 Procedures to Register for Access to CURES.<br><br>"(c)(2) (H) Category of Licensure. The previous version of the proposed regulations required that if an applicant is licensed by the Medical Board of California or the Dental Board of California, the applicant must provide the applicant's specialty and indicate whether the applicant is board-certified. In our previous comments, CMA noted that there are other professions, including nurse practitioners, physician assistants, podiatrists, and pharmacists who may be required to use CURES, have a specialty and are certified by a board, who should also be required to report this information as part of their application if this remains a requirement. CMA also requested additional clarification about how board certification and specialty data is used with the CURES PDMP.<br><br>CMA supports the current version of the proposed regulations that deletes references to the Medical Board of California and the requirement to report specialty and board certification status." | The Department appreciates this comment of support. No change was made in response to this comment because it agreed with the proposed regulations. |
| 5.02 | Proposed Article 2.4. § 824.2 Delegate Agreement between Authorizing User and Delegate.<br><br>"In the previous version, new subdivision (a) was added to set forth the requirement that an Authorizing User must enter into a Delegate Agreement with each Delegate to whom that Authorizing User delegates authority under this article. New subdivision (a)(2) was added to establish | The Department appreciates this comment of support. No change was made in response to this comment because it agreed with the proposed regulations. |

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| | that a Delegate Agreement must only be between one Delegate and one Authorizing User. The proposed regulations stated that authorizing Users may have multiple Delegates, and Delegates may be associated with multiple Authorizing Users, so long as each Delegate and Authorizing User have entered into a Delegate Agreement.<br><br>In our comments, CMA recommended that the regulations be amended to allow Authorizing Users to enter into delegate agreements with multiple delegates and that the CURES PDMP allow the Authorizing User to designate a delegate with administrator privileges who can assist with managing these agreements and ensuring that the information is entered into the CURES PDMP in a timely manner.<br><br>CMA supports the amendments to define "Delegate Agreement" as an agreement between an Authorizing User and one or more Delegates and specifically stating that Delegates may have more than one Authorizing User." | |
| 5.03 | Proposed Article 2.1. § 821.1 Eligibility for Access to CURES, Proposed Article 2.2. § 822.1 Eligibility for Access to CURES, Proposed Article 2.3. § 823.1 Eligibility for Access to CURES, Proposed Article 2.4. § 824.1 Eligibility for Access to CURES, Proposed Article 2.6. § 826.1 Eligibility to Access CURES or Obtain Data from CURES, Proposed Article 2.7. § 827.1 Eligibility to Access CURES or Obtain Data from CURES. | The Department appreciates this comment of support. No change was made in response to this comment because it agreed with the proposed regulations. |

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| | "We recognize the need to ensure appropriate access to the CURES PDMP for authorized users to protect patient and user privacy. The proposed regulations describe the procedures for terminating CURES access for various defined users: Prescribers, Out-of-State Prescribers, Non-DEA Practitioners, Pharmacists, Out-of-State Pharmacists, and Delegates. We recommend the use of a standard process for terminating access for ineligible individuals that includes:<br><br>• Requiring that the individual must not access CURES;<br>• Requiring the individual or the Authorizing User to notify the CURES PDMP about ineligibility within a defined time period; and<br>• Requiring the CURES PDMP to notify the individual and the Authorizing User when CURES access is terminated.<br><br>In the previous version of the regulations, some types of users were required to simply stop accessing the CURES PDMP and others to "immediately notify" the CURES PDMP when they are ineligible. CMA requested additional clarification regarding the type of notification that is required (ex. formal written notice, accessing the CURES PDMP to update permissions, etc.).<br><br>CMA supports the amendments specifying that requests to DOJ to terminate access to the CURES PDMP for various users should be made in writing." | |

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| 5.04 | Proposed Article 2.4. § 824.9 Procedures for Use of CURES by Delegate-Users.<br><br>"CMA has urged that electronic systems be interoperable and integrated into clinical practice workflows. Obtaining essential information, including PDMP data, often requires multiple "clicks," opening multiple windows, and the use of separate logins even before the physician locates what he or she is looking for - and that situation must be repeated for each patient and every prescription for a controlled substance. Effective PDMP and electronic health record integration means that the clinical workflow must achieve "functional interoperability," or the ability for systems to exchange, incorporate and display data in a meaningful and contextual manner.<br><br>The CURES regulations that became effective July 1, 2020, state that delegates may—not must—access the CURES PDMP through the Web-Based Application with the intent that delegates could access the CURES PDMP through other channels, including interfaces integrated into electronic health record systems or connections to health information organizations (HIOs). CMA recommends additional clarification to explicitly state that delegates may also access the CURES PDMP through the Information Exchange Web Service, which would allow delegates to access the CURES PDMP through electronic health record (EHR) systems that have integrated CURES functionality or HIOs. | No change has been made in response to this comment for the reasons stated in response to similar comments, see responses to comments 2.01 and 2.07. |

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| | The proposed regulations do not explicitly prohibit delegates from accessing the CURES PDMP through the Information Exchange Web Service. Article 5 of the proposed regulations pertaining to the Information Exchange Web Service, however, identifies the categories of authorized users who are the intended recipients of the CURES data accessed through the Information Exchange Web Service and do not identify Delegate-Users as being eligible to access information through the Information Exchange Web Service. As currently drafted, the proposed regulations appear to inhibit clinical workflow and run contrary to statute and the will of the Legislature when they passed A.B. 40. (Health & Safety Code §11165.1(a); A.B. 40, Stats. 2017, ch. 607.) Per the law, approved health care practitioners and pharmacists will be permitted to use a health information technology system, including an electronic health record system, to access CURES data so long as the entity certifies that it meets certain criteria. Therefore, an entity could feasibly meet the criteria as specified in statute, submit a complete application package with an executed Memorandum of Understanding, onboarding questionnaire and payment for applicable fees, but yet still not be able to have all approved users, such as delegates, access the Information Exchange Web Service."<br><br>. . .<br><br>"To ensure that Delegate-Users will continue to be able to access the CURES PDMP through other interfaces besides the Web-Based Application, Article 5 should be amended to specifically state that | |

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| | Delegate-Users are authorized to access the CURES PDMP on behalf of Authorized Users through an Information Exchange Web Service. Specifically, § 830.3. Requirements for HIT System Use of the Information Exchange Web Service should be amended, where appropriate, to reference "an authorized Prescriber-User, Non-DEA Practitioner User, or Pharmacist-User or their authorized Delegate-Users"." | |
| 5.05 | Proposed Article 5. § 830.3 Requirements for HIT System Use of the Information Exchange Web Service.<br><br>"In addition, under the recently completed California HIE Onboarding Program ("CalHOP"), administered by the Department of Health Care Services, all participating health information organizations (HIOs) were required to build an interface to the CURES PDMP. Seven HIOs, representing thousands of prescribers, took advantage of this opportunity. This requirement was included because HIOS can facilitate easier, more streamlined access to CURES data for prescribers and their delegates. These regulations should acknowledge that work that has already been done." | No change has been made in response to this comment for the reason stated in response to a similar comment, see response to comment 2.08. |

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| 6.01 | Proposed Article 2.4. § 824.9 Procedures for Use of CURES by Delegate-Users.<br><br>Email Communication from Yvonne Choong:<br><br>"As we develop our comments on the 15-Day Modification, we had a question about whether the Department intends to limit Delegate-User access to CURES to the Web-Based Application only. The proposed regulations do not explicitly prohibit Delegate-Users from accessing CURES through an Information Exchange Web Service (meaning accessing CURES through a system in which CURES is integrated into an EHR), but Delegate-Users are also not mentioned as a recognized user in the section on the Information Exchange Web Service. The proposed regulations also state that the definition of the Web-Based Application does not include use of access through the Information Exchange Web Service.<br><br>Additional clarification would be helpful in determining how best to direct our formal comments on this issue." | No change has been made in response to this comment. The Department responded to this email using the same response to a similar comment, see response to comment 2.07. |
| 7.01 | Proposed Article 2.1. § 821.1 Eligibility for Access to CURES, Proposed Article 2.2. § 822.1 Eligibility for Access to CURES, Proposed Article 2.3 § 823.1 Eligibility for Access to CURES, Proposed Article 2.4. § 824.1 Eligibility for Access to CURES, Proposed Article 2.6. § 826.1 Eligibility to Access CURES or Obtain Data from CURES, Proposed Article 2.7. § 827.1 Eligibility to Access CURES or Obtain Data from CURES. | No change has been made in response to this comment for the 15-day public comment period, for the reason stated in response to a similar comment, see response to comment 1.05. |

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| | "While the modifications are an improvement over the originally proposed regulations, they continue to be insufficient to ensure that anyone with a CURES registration who is no longer eligible for access does not access CURES. We very much appreciate the modification that upon written notification that a regulatory agency officer or law enforcement agency officer should no longer have access to CURES, CURES must terminate that person's access. This is an important protection that should be extended to anyone who is no longer authorized to access CURES.<br><br>Additionally, the modifications propose that for some types of CURES users, the individual must now submit in writing that they are no longer eligible to access CURES. This is a helpful clarification; however, in most instances, the proposed and modified regulations continue only to ask that someone no longer eligible to access CURES refrain from using CURES. At the very least, all CURES users should be required to self-report to CURES that they no longer are eligible to access the system.<br><br>Ideally, the regulations should require a process similar to that which applies to the delegate-users, whereby someone with authority over the user must immediately terminate the user's authority to use CURES upon that user no longer being eligible for access to CURES. Additionally, each time a user of CURES logs in, they should be required to check a box under penalty of perjury stating that they remain eligible to access CURES data." | |

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| 7.02 | Proposed Article 2.7. § 827.4 Restrictions on Accessing CURES or Data from CURES.<br><br>"While the modified proposed regulations for CURES contain some limited improvements to the loss of eligibility for access concerns we raised in our previous comments, they continue to fail to address CURES' most serious privacy and due process risks as outlined in our previous comments:<br><br>• allowing administrative subpoenas to substitute for court-issued warrants in some cases;" | No change has been made in response to this comment for the reason stated in response to a similar comment, see response to comment 1.01. |
| 7.03 | Proposed Article 2.7. § 827.4 Restrictions on Accessing CURES or Data from CURES.<br><br>"While the modified proposed regulations for CURES contain some limited improvements to the loss of eligibility for access concerns we raised in our previous comments, they continue to fail to address CURES' most serious privacy and due process risks as outlined in our previous comments:<br><br>• depriving individuals enrolled in public health programs of equal privacy rights;" | No change has been made in response to this comment for the reason stated in response to a similar comment, see response to comment 1.03. |

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| 7.04 | Proposed Article 2.7. § 827.4 Restrictions on Accessing CURES or Data from CURES.<br><br>"While the modified proposed regulations for CURES contain some limited improvements to the loss of eligibility for access concerns we raised in our previous comments, they continue to fail to address CURES' most serious privacy and due process risks as outlined in our previous comments:<br><br>• failing to require a warrant before a regulatory agency may obtain patient information;" | No change has been made in response to this comment for the reason stated in response to a similar comment, see response to comment 1.04. |
| 7.05 | Proposed Article 2.1. § 821.1 Eligibility for Access to CURES, Proposed Article 2.2. § 822.1 Eligibility for Access to CURES, Proposed Article 2.3. § 823.1 Eligibility for Access to CURES, Proposed Article 2.4. § 824.1 Eligibility for Access to CURES, Proposed Article 2.6. § 826.1 Eligibility to Access CURES or Obtain Data from CURES, Proposed Article 2.7. § 827.1 Eligibility to Access CURES or Obtain Data from CURES.<br><br>"While the modified proposed regulations for CURES contain some limited improvements to the loss of eligibility for access concerns we raised in our previous comments, they continue to fail to address CURES' most serious privacy and due process risks as outlined in our previous comments: | No change has been made in response to this comment for the 15-day public comment period, for the reason stated in response to a similar comment, see response to comment 1.05. |

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| | • providing inadequate safeguards to ensure that users who should no longer have access to CURES cannot access the database; | |
| 7.06 | Proposed Article 3. § 828.6 Procedures for Requesting Identified Individual-Level Data and De-Identified Individual-Level Data from CURES.<br><br>"While the modified proposed regulations for CURES contain some limited improvements to the loss of eligibility for access concerns we raised in our previous comments, they continue to fail to address CURES' most serious privacy and due process risks as outlined in our previous comments:<br><br>• failing to require patients be notified that their records have been accessed by regulatory or law enforcement officers and some researchers; and" | No change has been made in response to this comment for the reason stated in response to a similar comment, see response to comment 1.06. |
| 7.07 | Proposed Article 2.1. § 821.2 Procedures to Register for Access to CURES, Proposed Article 2.2. § 822.2 Procedures to Register for Access to CURES, Proposed Article 2.3. § 823.2 Procedures to Register for Access to CURES, Proposed Article 2.4. § 824.3 Procedures to Register for Access to CURES, Proposed Article 2.6. § 826.2 Procedures to Register for Access to CURES, and Proposed Article 2.7. § 827.2 Procedures to Register for Access to CURES.<br><br>"While the modified proposed regulations for CURES contain some limited improvements to the loss of eligibility for access concerns we | No change has been made in response to this comment for the reason stated in response to a similar comment, see response to comment 1.07. |

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| | raised in our previous comments, they continue to fail to address CURES' most serious privacy and due process risks as outlined in our previous comments:<br><br>• requiring people accessing CURES to provide their mother's maiden name." | |
| 8.01 | Proposed Article 3. § 828.6 Procedures for Requesting Identified Individual-Level Data and De-Identified Individual-Level Data from CURES.<br><br>"The DOJ proposed text at 828.6(c)(11)(H) provides that Identified Individual-Level Data may be accessed via Civil Code section 1798.24, subdivision (b) or Civil Code section 1798.24, subdivision (t). Under the discussion on access to the data via Civil Code section 1798.24, subdivision (b), DOJ requires the use of the above referenced DOJ Consent form. While UC believes that DOJ may have developed the consent form as a resource to its constituents, we are concerned about privacy risks it presents, in addition to barriers it creates when the form is used for research purposes. UC asks that DOJ specify within the regulatory text that the DOJ Consent form would not be used for accessing Identified Individual-Level Data for research purposes."<br><br>"UC strongly recommends the DOJ make clear that researchers accessing Identified Individual-Level Data pursuant to 1798.24 subdivision (t) do | No substantive change has been made to the regulations in response to this comment. The Department believes that the regulations are clear as currently drafted. Civil Code section 1798.24, subdivisions (b) and (t) represent two distinct pathways to Identified Individual-Level Data. The former is reflected exclusively in the regulations section 828.6, subdivision (c)(11)(H)1.; the latter is reflected exclusively in the regulations section 828.6, subdivision (c)(11)(H)2. Additionally, the prefatory clause in 828.6, subdivision (c)(11)(H) identifies these as distinct pathways by virtue of the "or" disjunctive. Furthermore, the only reference to the Department of Justice Consent for Use of Personal Information from CURES form (Consent Form) is in section 828.6, subdivision (c)(11)(H)1., which solely describes requirements for compliance with subdivision (b) of Civil Code section 1798.24. |

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| | not need to use the DOJ Consent form. See underlined suggested language below:<br>"2. To comply with Civil Code section 1798.24, subdivision (t), for purposes of this article, the Bona Fide Researcher must obtain formal approval for the use of Identified Individual-Level Data, in accordance with the requirements of Civil Code section 1798.24, subdivision (t), by the Committee for the Protection of Human Subjects for the California Health and Human Services Agency or the Bona Fide Researcher's institutional review board, if that institutional review board has a written agreement with the Committee for the Protection of Human Subjects for that institutional review board to provide the data security approvals required by Civil Code section 1798.24, subdivision (t). <u>The Bona Fide Researcher requesting Identified Individual-Level Data are not required to use the Consent for Use of Personal Information from CURES Form (Orig. 07/2021) to comply with Civil Code section 1798.24, subdivision (t).</u> The Bona Fide Researcher may first submit its application to the Department's Research Center. The Department's Research Center may provide written documentation to the Bona Fide Researcher to allow the Committee for the Protection of Human Subjects to review the Bona Fide Researcher's application. The Bona Fide Researcher must provide written verification to the Department's Research Center of formal approvals by the Committee for the Protection of Human Subjects or the Bona Fide Researcher's institutional review board, if operating under a written agreement under Civil Code section 1798.24, subdivision (t), for the request of Identified Individual-Level Data from CURES. The written verification must include the review and determination by the Committee | Additionally, the Consent Form was not developed as a resource for the researchers, but was developed for the Department to know when an individual has consented and the information could be released pursuant to Civil Code section 1798.24, subdivision (b), and these regulations.<br><br>To avoid confusion, the Department non-substantively revised the Consent Form to clarify the existing citation in the introductory language of the form, such that it now states, "A Bona Fide Researcher is required to submit the completed form with any Data Request Application for Identified Individual-Level Data under California Code Regulations, title 11, section 828.6, subdivision (c)(11)(H)1." |

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| | for the Protection of Human Subjects or the Bona Fide Researcher's institutional review board, if operating under a written agreement under Civil Code section 1798.24, subdivision (t), that the data security approvals required by Civil Code section 1798.24, subdivision (t), have been satisfied"<br><br>"The DOJ proposed text provides that Identified Individual-Level Data may be accessed via Civil Code section 1798.24, subdivision (b) or Civil Code section 1798.24, subdivision (t). Under the discussion on access to the data via subdivision (b) (see proposed text at 828.6(c)(11)(H)(1)), there is a requirement to use a specified DOJ Consent form. Most researchers accessing data would likely utilize access to Identified Individual-Level Data following 1798.24 subdivision (t) and seek review by the Committee for the Protection of Human Subjects or another applicable institutional review board." | |
| 8.02 | Proposed Article 3. § 828.6 Procedures for Requesting Identified Individual-Level Data and De-Identified Individual-Level Data from CURES.<br><br>"UC fully supports the fundamental need to ensure the privacy and security of identifiable data, particularly with respect to sensitive medical information, such as controlled substance use. We agree that it is important that state agencies adopt policies and practices to prevent unauthorized or unnecessary use or release of this information. However, we believe that the use of the DOJ Consent form does not necessarily achieve this goal. The form requires collecting personal information, such | No changes have been made in response to the comment. The Consent Form was not created for the researchers to use in lieu of other consent forms that they may be required to use or to satisfy their obligations under 45 CFR 46 or other informed consent. Rather, the Consent Form was created so that the Department could confirm and verify that an individual had provided consent under Civil Code section 1798.24, subdivision (b), and these regulations. The Department had to create a process that was uniform for it to confirm and verify that an individual had provided |

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| | as all variations of an individual's name and address, as well as either a) copy of an identification card or b) notarized identity confirmation. The collection of this information is considerably more than what is required for typical patient or research consent, even for research on highly sensitive topics such as illicit drug use or other illegal activities. This not only places a burden on those who would consent to the use of their data, but also requires the collection of more information than is necessary to accomplish the intended purpose of a particular request for use of the data. As such, we believe that using the DOJ Consent form creates unnecessary privacy risks."<br><br>"Informed consent is an ethical and legal requirement for research involving human participants and is the cornerstone of the underlying federal regulations for the protection of human subjects (45 CFR 46). However, the proposed DOJ Consent form runs counter to the spirit and letter of 45 CFR 46 in several ways.<br><br>First, the DOJ Consent form is not consistent with commonly accepted best practices (encouraged by 45 CFR 46) that consent documents should be concise, focused, and easy to understand. The DOJ Consent form does not allow adequate space for description of the overall study, of which Individual level CURES data may be only one component. Thus, any researcher using the DOJ Consent form would have to use an additional consent form to adequately explain the study, increasing participant burden with no corresponding benefit. Moreover, the DOJ Consent form is filled with jargon and legalese that most participants would not | consent under Civil Code section 1798.24, subdivision (b), and these regulations, rather than relying on various researchers' and institutions' consent forms. Additionally, given the sensitive confidential and medical information contained in CURES, the Department determined that on balance, the requirements in the Consent Form were necessary to confirm and verify the individual had consented to the use of their information being released to avoid improper release.<br><br>Further, because the individual is consenting to the use of their information, the Department had to balance requiring the individuals to report their names and addresses used, rather than the suggested proposal to search based on birthdate, etc. (though birthdate is a relevant identifier used in the form). Because there is no unique data element reported about patients, such as a social security number, dispensations reflecting the same name and same birthdate could be attributable to different individuals. Indeed, this is inevitable given the volume of data contained in CURES. The fewer patient identifiers provided, the more difficult it becomes for the Department to necessarily know if patient records match the same individual who has consented. When describing the standard practices on |

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| | understand. As just one example, the DOJ Consent form frequently uses the term "bona fide researcher" which has no meaning in everyday language and so would confuse most research participants.<br><br>Second, the DOJ Consent form places unnecessary burdens on participants and, paradoxically, increases risks for loss of patient privacy and data confidentiality by requiring notarized identity authorization or a copy of participants' photo identification. The requirement to notarize individual consent forms is far outside standard research practice. How would researchers even obtain notarization if, for example, they were recruiting patients in clinic, hospital, or other research settings? The proposed DOJ requirement of including a photocopied identification form (which in practice would likely be patient driver's licenses) increases risk to patient privacy by collecting additional sensitive information (e.g. driver's license number) that is not necessary for research studies with no corresponding benefit. Requiring a copy of a participant's driver's license reduces patient privacy and is analogous to, say, police officers requiring motorists to give their medical record number when motorists are stopped for a traffic violation.<br><br>Third, requiring a list of all permutations for patient information (first and last name, full address, date of birth) is counterproductive because pharmacies manually maintain this information making it subject to human error and variations in the way the information is recorded, particularly for addresses and hyphenated names (e.g., CURES records often reverse patient last and middle names). The process for matching | how Health Care Practitioners and Pharmacists query CURES, commenters have omitted the "picklist" step through which such Health Care Practitioners and Pharmacists exercise their discretion in determining which name, date of birth, and address variations match the patient who is under the care of that Health Care Practitioner or Pharmacist.<br><br>Again, to balance protecting the privacy of individuals' information in CURES, the Department chose one way to capture most, if not all, of the individual's records, without potentially releasing others who may have the same birthdate. |

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| | Identified Individual-Level Data from CURES should allow for broader searches that mirror how CURES is actually used clinically. For example, clinicians typically search for CURES identities using date of birth, last name, and either first name or first initial. In practice, clinicians never restrict searches by address because requiring an exact match on address would miss a large number of valid prescription records. For example, a search restricted to the street address "123 Main Street" would not match if pharmacies reported the address to CURES as 123 Main St." | |
| 9.01 | Proposed Article 3. § 828.6 Procedures for Requesting Identified Individual-Level Data and De-Identified Individual-Level Data from CURES.<br><br>Suggestion: Make the following addition to §8268.6(c)(11)(H)2.:<br><br>"2. To comply with Civil Code section 1798.24, subdivision (t), for purposes of this article, the Bona Fide Researcher must obtain formal approval for the use of Identified Individual-Level Data, in accordance with the requirements of Civil Code section 1798.24, subdivision (t), by the Committee for the Protection of Human Subjects for the California Health and Human Services Agency or the Bona Fide Researcher's institutional review board, if that institutional review board has a written agreement with the Committee for the Protection of Human Subjects for that institutional review board to provide the data security approvals required by Civil Code section 1798.24, subdivision (t). Bona Fide Researchers requesting Identified Individual-Level Data are not required to use the Consent for Use of Personal Information from CURES Form | No substantive change has been made in response to this comment for the reason stated in response to a similar comment, see response to comment 8.01. The Department has non-substantively amended the Consent Form in response to a similar comment, see response to comment 8.01. |

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| | (Orig. 07/2021) to comply with Civil Code section 1798.24, subdivision (t). The Bona Fide Researcher may first submit its application to the Department's Research Center. The Department's Research Center may provide written documentation to the Bona Fide Researcher to allow the Committee for the Protection of Human Subjects to review the Bona Fide Researcher's application. The Bona Fide Researcher must provide written verification to the Department's Research Center of formal approvals by the Committee for the Protection of Human Subjects or the Bona Fide Researcher's institutional review board, if operating under a written agreement under Civil Code section 1798.24, subdivision (t), for the request of Identified Individual-Level Data from CURES. The written verification must include the review and determination by the Committee for the Protection of Human Subjects or the Bona Fide Researcher's institutional review board, if operating under a written agreement under Civil Code section 1798.24, subdivision (t), that the data security approvals required by Civil Code section 1798.24, subdivision (t), have been satisfied.<br><br>Rationale: The proposed addition clarifies that the Consent for Use of Personal Information from CURES Form (originally published by DOJ on 07/2021 and incorporated into the modified proposed regulations by reference in §8268.6(c)(11)(H)(1)) applies only to requests for Identified Individual-Level Data made under Civil Code section 1798.24, subdivision (b) and not to requests for Identified Individual-Level Data made under Civil Code section 1798.24, subdivision (t). We believe this addition better aligns the proposed regulation with the letter and intent of | |

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| | California law without adding any additional risks to privacy or safety for Californians.<br><br>As researchers, we understand and strongly support the need to ensure the privacy and security of identifiable data. We also believe that state agencies should adopt policies and practices to prevent unauthorized or unnecessary use or release of this information. Neither the proposed regulations in §8268.6(c)(11)(H)(1) nor the text of Civil Code section 1798.24, subdivision (b) mention approval by the Committee for the Protection of Human Subjects (CHPS) or another institutional review board. Thus, it may be helpful for DOJ to provide a specific consent form for researchers requesting Identified Individual-Level data under Civil Code section 1798.24, subdivision (b).<br><br>However, requests made under Civil Code section 1798.24, subdivision (t) must be approved by CPHS or another institutional review board. Study protocols, security measures, and (when relevant) the wording of any consent document must comply with best practices for human subjects research as set out in 45 CFR 46 in order to be approved by CPHS and so should not be dictated by DOJ regulations."<br><br>. . .<br><br>"Benefits. As described above, our suggested addition to the regulations provides clarity to researchers and will promote use of safer, clearer | |

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| | consent forms for requests made under Civil Code section 1798.24, subdivision (t).<br><br>Statutory concerns. As modified by AB-527 (Wood) in 2021, Section 11165(c)(2)(A) of the Health and Safety Code states that "The University of California shall be provided access to identifiable data for research purposes if the requirements of subdivision (t) of Section 1798.24 of the Civil Code are satisfied." Our proposed addition to the regulations is thus clearly aligned with California law. Based on our reading of the statutory language, the Civil Code does not appear to allow DOJ the discretion to add to or alter the requirements contained in Civil Code Section 1798.24, subdivision (t) by, for example, mandating that researchers use a specific consent form when requesting Identified Individual-Level Data under Civil Code Section 1798.24, subdivision (t)." | |
| 9.02 | Proposed Article 3. § 828.6 Procedures for Requesting Identified Individual-Level Data and De-Identified Individual-Level Data from CURES.<br><br>"CPHS and other institutional review boards follow 45 CFR 46 when evaluating research proposals. Informed consent is central to ethical research. However, the Consent for Use of Personal Information from CURES Form (hereafter, "the DOJ Consent Form") runs counter to the spirit and letter of 45 CFR 46 in several ways:<br><br>1) The DOJ Consent Form is not consistent with accepted best practices that consent documents should be concise and easy to understand. The | No changes have been made in response to this comment for the reasons stated in response to a similar comment, comment 8.02 |

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| | DOJ Consent Form does not allow adequate space for researchers to describe their overall study. Thus, any researcher using the DOJ Consent Form would have to use an additional consent form to adequately explain the study, increasing participant burden with no corresponding benefit. Moreover, the DOJ Consent Form is filled with jargon that most participants would not understand. As just one example, the DOJ Consent Form frequently uses the term "bona fide researcher" which has no meaning in everyday language and so would confuse most research participants.<br><br>2) The DOJ Consent Form places unnecessary burdens on participants and, paradoxically, increases risks for loss of patient privacy and data confidentiality by requiring notarized identity authorization or a copy of participants' photo identification. The requirement to notarize individual consent forms is far outside standard research or and clinical practice. We have conducted research on highly sensitive topics (e.g., cancer treatments, arrest records) and have never required or been asked to require notarized proof of identity from research participants. The alternative of including a photocopied identification form increases risk to patient privacy by collecting additional sensitive information (e.g., driver's license number or social security number) that is not necessary for the study and provides no corresponding benefit. Requiring a copy of a participants' driver's license reduces patient safety and is analogous to, say, police officers requiring motorists to give their hospital medical record and bank account number when motorists are stopped for a traffic violation. | |

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| | 3) Requiring a list of all permutations for patient information (first and last name, full address, date of birth) is counterproductive because how pharmacies store and report information is subject to random mistakes and variations, particularly for addresses and hyphenated names. The process for accessing Identified Individual-Level Data should allow for broader searchers that mirror how CURES is actually used clinically. For example, prescribers typically search for CURES identities using date of birth, last name, and either first name or first initial. In practice, clinicians almost never restrict searches by address because requiring an exact match on address would miss a large number of valid prescription records. For example, a search restricted to the street address "123 Front Street" would not match if pharmacies reported the address to CURES as 123 Front St."<br><br>. . .<br><br>"Potential Counter Arguments. Some might argue that all requests for Identified Individual-level Data should use the same form. However, for the reasons mentioned above, the proposed DOJ Consent Form does not follow accepted practices required for compliance with Civil Code 1798.24, subdivision (t)." | |
| 10.01 | Proposed Article 3. § 828.6 Procedures for Requesting Identified Individual-Level Data and De-Identified Individual-Level Data from CURES.<br><br>Email Communication from Dr. Henry: | No substantive change has been made in response to this comment for the reason stated in response to a similar comment, see response to comment 8.01. The Department has non-substantively amended the Consent |

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| | "I was preparing a new research grant proposal using CURES data and came across a new DOJ consent form on the CURES website (see attached).<br><br>Does the DOJ intend to require this consent form for all research studies requesting identified individual-level CURES data?<br><br>If so, can I schedule phone meeting with DOJ to discuss this form? I have concerns that using this form would be both ineffective and entails unnecessary /unjustifiable risks to patient privacy (compared to standard consent forms)" | Form in response to a similar comment, see response to comment 8.01. |
| 11.01 | Proposed Article 2.1. § 821.2 Procedures to Register for Access to CURES and Proposed Article 2.2. § 822.2 Procedures to Register for Access to CURES.<br><br>"(c)(2) (H) Category of Licensure. The previous version of the proposed regulations required that if an applicant is licensed by the Medical Board of California or the Dental Board of California, the applicant must provide the applicant's specialty and indicate whether the applicant is board-certified. In our previous comments, CPCA noted that there are other professions, including nurse practitioners, physician assistants, podiatrists, and pharmacists who may be required to use CURES, have a specialty and are certified by a board, who should also be required to report this information as part of their application if this remains a requirement. | The Department appreciates this comment of support. No change was made in response to this comment because it agreed with the proposed regulations. |

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| | CPCA also requested additional clarification about how board certification and specialty data is used with the CURES PDMP.<br><br>CPCA supports the current version of the proposed regulations that deletes references to the Medical Board of California and the requirement to report specialty and board certification status." | |
| 11.02 | Proposed Article 2.4. § 824.2 Delegate Agreement between Authorizing User and Delegate.<br><br>"In the previous version, new subdivision (a) was added to set forth the requirement that an Authorizing User must enter into a Delegate Agreement with each Delegate to whom that Authorizing User delegates authority under this article. New subdivision (a)(2) was added to establish that a Delegate Agreement must only be between one Delegate and one Authorizing User. The proposed regulations stated that authorizing Users may have multiple Delegates, and Delegates may be associated with multiple Authorizing Users, so long as each Delegate and Authorizing User have entered into a Delegate Agreement.<br><br>In our comments, CPCA recommended that the regulations be amended to allow Authorizing Users to enter into delegate agreements with multiple delegates and that the CURES PDMP allow the Authorizing User to designate a delegate with administrator privileges who can assist with managing these agreements and ensuring that the information is entered into the CURES PDMP in a timely manner. | The Department appreciates this comment of support. No change was made in response to this comment because it agreed with the proposed regulations. |

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| | CPCA supports the amendments to define "Delegate Agreement" as an agreement between an Authorizing User and one or more Delegates and specifically stating that Delegates may have more than one Authorizing User. This amendment acknowledges the unique health center model that relies on a care-team model whereby medical assistants, nurses, and other allied health professionals are working with multiple clinicians (nurse practitioners, physicians, and physician assistants) to provide timely, quality access to care." | |
| 11.03 | Proposed Article 2.1. § 821.1 Eligibility for Access to CURES, Proposed Article 2.2. § 822.1 Eligibility for Access to CURES, Proposed Article 2.3. § 823.1 Eligibility for Access to CURES, Proposed Article 2.4. § 824.1 Eligibility for Access to CURES, Proposed Article 2.6. § 826.1 Eligibility to Access CURES or Obtain Data from CURES, Proposed Article 2.7. § 827.1 Eligibility to Access CURES or Obtain Data from CURES.<br><br>"We recognize the need to ensure appropriate access to the CURES PDMP for authorized users to protect patient and user privacy. The proposed regulations describe the procedures for terminating CURES access for various defined users: Prescribers, Out-of-State Prescribers, Non-DEA Practitioners, Pharmacists, Out-of- State Pharmacists, and Delegates. We recommended the use of a standard process for terminating access for ineligible individuals that includes:<br><br>• Requiring that the individual must not access CURES; | The Department appreciates this comment of support. No change was made in response to this comment because it agreed with the proposed regulations. |

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| | • Requiring the individual or the authorizing user to notify the CURES PDMP about ineligibility within a defined time period (ex. upon termination of employment); and<br>• Requiring the CURES PDMP to notify the individual and the authorizing user when CURES access is terminated.<br><br>In the previous version of the regulations, some types of users were required to simply stop accessing the CURES PDMP and others to "immediately notify" the CURES PDMP when they are ineligible. CPCA requested additional clarification regarding the type of notification that is required (ex. formal written notice, accessing the CURES PDMP to update permissions, etc.).<br><br>CPCA supports the amendments specifying that requests to DOJ to terminate access to the CURES PDMP for various users should be made in writing." | |
| 11.04 | Proposed Article 2.4. § 824.9 Procedures for Use of CURES by Delegate-Users.<br><br>"CPCA has urged that electronic systems be interoperable and integrated into clinical practice workflows. Obtaining essential information, including PDMP data, often requires multiple "clicks," opening multiple windows, and the use of separate logins even before the physician locates what he or she is looking for - and that situation must be repeated for each patient and every prescription for a controlled substance. Effective PDMP | No change has been made in response to this comment for the reason stated in response to a similar comment, see response to comment 2.07. |

**PUBLIC COMMENTS AND DEPARTMENT OF JUSTICE RESPONSES**

| FIRST 15-DAY PUBLIC COMMENT PERIOD | | |
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| **Comment Number (s)** | **Summarized Comment** | **Department of Justice Response** |
| | and electronic health record integration means that the clinical workflow must achieve "functional interoperability," or the ability for systems to exchange, incorporate and display data in a meaningful and contextual manner.<br><br>The CURES regulations that became effective July 1, 2020, state that delegates may—not must—access the CURES PDMP through the Web-Based Application with the intent that delegates could access the CURES PDMP through other channels, including interfaces integrated into electronic health record systems or connections to health information organizations (HIOs). CPCA recommends additional clarification to explicitly state that delegates may also access the CURES PDMP through the Information Exchange Web Service, which would allow delegates to access the CURES PDMP through electronic health record (EHR) systems that have integrated CURES functionality or HIOs.<br><br>The proposed regulations do not explicitly prohibit delegates from accessing the CURES PDMP through the Information Exchange Web Service. Article 5 of the proposed regulations pertaining to the Information Exchange Web Service, however, identifies the categories of authorized users who are the intended recipients of the CURES data accessed through the Information Exchange Web Service and do not identify Delegate-Users as being eligible to access information through the Information Exchange Web Service. As currently drafted, the proposed regulations appear to inhibit clinical workflow and run contrary to statute and the will of the Legislature when they passed A.B. 40. | |

**PUBLIC COMMENTS AND DEPARTMENT OF JUSTICE RESPONSES**

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| **Comment Number (s)** | **Summarized Comment** | **Department of Justice Response** |
| | (Health & Safety Code §11165.1(a); A.B. 40, Stats. 2017, ch. 607.) Per the law, approved health care practitioners and pharmacists will be permitted to use a health information technology system, including an electronic health record system, to access CURES data so long as the entity certifies that it meets certain criteria. Therefore, an entity could feasibly meet the criteria as specified in statute, submit a complete application package with an executed Memorandum of Understanding, onboarding questionnaire and payment for applicable fees, but yet still not be able to have all approved users, such as delegates, access the Information Exchange Web Service."<br><br>. . .<br><br>"To ensure that Delegate-Users will continue to be able to access the CURES PDMP through other interfaces besides the Web-Based Application, Article 5 must be amended to specifically state that Delegate-Users are authorized to access the CURES PDMP on behalf of Authorized Users through an Information Exchange Web Service. Specifically, § 830.3. Requirements for HIT System Use of the Information Exchange Web Service should be amended, where appropriate, to reference "an authorized Prescriber-User, Non-DEA Practitioner User, or Pharmacist-User or their authorized Delegate-Users"." | |
| 11.05 | Proposed Article 5. § 830.3 Requirements for HIT System Use of the Information Exchange Web Service. | No change has been made in response to this comment for the reason stated in response to a similar comment, see response to comment 2.08. |

## PUBLIC COMMENTS AND DEPARTMENT OF JUSTICE RESPONSES

| FIRST 15-DAY PUBLIC COMMENT PERIOD | | |
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| | In addition, under the recently completed California HIE Onboarding Program ("CalHOP"), administered by the Department of Health Care Services, all participating health information organizations (HIOs) were required to build an interface to the CURES PDMP. Seven HIOs, representing thousands of prescribers, took advantage of this opportunity. This requirement was included because HIOS can facilitate easier, more streamlined access to CURES data for prescribers and their delegates. California's HIOs are prepared and ready to fully participate in CURES PDMP.<br><br>Lastly, this policy must also be appreciated in the context of the Centers for Medicare & Medicaid Services' (CMS) December 29, 2021 approval of the California Department of Health Care Services' (DHCS') request for a five-year extension of its Medicaid section 1115 demonstration and a five-year extension of its Medicaid managed care section 1915(b) waiver. Both were scheduled to expire on December 31, 2021. The demonstration and managed care 1915(b) combination re-named "California Advancing and Innovating Medi-Cal" (CalAIM) includes important provisions to advance health equity, fund key services, like home and community-based services (HCBS) for underserved communities and improve access to care. As part of CalAIM, California commits to a Health HIT Plan that requires access to the PDMP through the health information exchange. The DOJ must make every effort, including through this rule making, to guarantee alignment with CalAIM. | With respect to CalAIM, this comment is not specific enough for the Department to respond to or make a change in the regulations. |

## PUBLIC COMMENTS AND DEPARTMENT OF JUSTICE RESPONSES

| SECOND 15-DAY PUBLIC COMMENT PERIOD | | |
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| **Comment Number (s)** | **Summarized Comment** | **Department of Justice Response** |
| 12.01 | Proposed Article 5. Information Exchange Web Service<br><br>"I wanted to check with the team to see if any of the proposed changes may impact our Clearinghouse project or IEWS customers." | No change has been made in response to this comment. Comment asked for clarification of the application of the regulations and did not relate to any modification to the text for the 15-day comment period. |