PUBLIC COMMENTS AND DEPARTMENT OF JUSTICE RESPONSES

#	Summarized Comment	Department of Justice Response
1.01	Objection No. 1.01 [Proposed Article 1. § 820(i) "Connectivity Fee'" Defined] "Article 1. §820. (i) Indicates that the 'Connectivity Fee' has been set at a $1500. It appears from the proposed regulations that this fee will be the same for a rural solo family physician as it would be for the entire Kaiser Permanente organization. This amount is cost prohibitive, particularly for family physicians and other primary care physicians whose payment rates are significantly lower than all other physicians and for small and solo physicians with partial or complete ownership who bear responsibility for infrastructure investments in their practice…. CAFP urges the Department to adopt a sliding scale or allow for hardship exemptions to the cost of the Connectivity Fee."	No change has been made in response to this comment. This is a one-time fee, which does not create an ongoing fiscal impact, and a sliding scale would significantly complicate administration of this fee. Furthermore, integration is voluntary.
1.02	Objection No. 1.02 [Proposed Article 1. § 820(q) "Delegate" Defined] "In Article 1. §820. (q), 'Delegate' is defined as 'an individual to whom a Prescriber-User or Pharmacist-User has delegated authority to order Patient Activity Reports from CURES under Business and Professions Code section 209, subdivision (b).' The quality of patient care improves when clinical team members under physician supervision have flexibility to accomplish tasks that are well within their abilities and scope of practice. By limiting the Delegate to ordering reports, the proposed regulations sacrifice the ability to streamline care without gaining any patient data confidentiality. HIPAA and other patient privacy laws already govern what can and cannot by shared by health care providers…. CAFP urges DOJ to establish the greatest amount of flexibility possible within the scope of existing clinical guidelines for Delegates to undertake requirements associated with CURES, including allowing Delegates to satisfy the View Notification requirement as part of a HIT system."	No change has been made in response to this comment. Existing law limits delegate functionality. Assembly Bill (AB) 528 (Chapter 677, Statutes of 2019), the relevant aspect of which will become effective on July 1, 2021, will amend Business and Professions Code section 209 and Health and Safety Code section 11165.1 to allow delegates to access information from CURES on behalf of a Health Care Practitioner or Pharmacist. The Department will address this aspect of delegate access in a subsequent regulations package in response to the amendments of AB 528 (Chapter 677, Statutes of 2019). With respect to the View Notification, the Department has removed this requirement in its entirety from section 828 of the proposed

		regulations. Therefore, the Department will make no change in response to this comment.
1.03	Objection No. 1.03 [Proposed Article 2. § 821(c)(2) Data Accessible to a Prescriber-User in CURES] "Article 2. §821. (c) (2) intends to limit Prescriber-User access to patient information to no more than 12 months. At the heart of the specialty of family medicine is an ongoing, continuous relationship with a patient that can last decades and often incorporates several generations of one family. This type of longitudinal relationship between patient and physician has proven to be a key factor in maintaining an individual's health. Limiting information to merely 12 months hurts a physician's ability to track care over an extended amount of time and creates obstacles to diagnosis and health trend identification. The proposed limitation is also concerning given that the draft regulations allow Regulatory Agency Officials to obtain data from CURES for as long as the data is retained in CURES. CAFP sees no justification for why prescription data history should be limited, particularly when it is often necessary for a clinician to make appropriate prescribing decisions based on that data…. CAFP urges the Department to extend a physician's access to all the data that exists within CURES for a patient in their care. In addition, a licensee must be able to query their own data and activity for as long as the data exists, with the ability to verify and correct errors, if necessary."	Similar comment, see response 4.06.
1.04	Objection No. 1.04 [Proposed Article 2. § 821(f)(2) Procedures for Use of CURES by Prescriber-Users] "Article 2. §821. (f)(2) Requires a patient's care team to create a new CURES password every 90 days, a frequency many of our members consider to be too high. This task is often accompanied by numerous other steps, including email verification, and leads to poor password storing practices and weakened security. It encourages the use of weaker passwords and wastes considerable time. These password-changing requirements can actually increase risk and are considered obsolete."	No change has been made in response to this comment. The password policy is a requirement of the minimum standard of security set forth by Criminal Justice Information Services Division systems to ensure continuity of information protection. Furthermore, the essential premise of this security standard is to provide the appropriate controls to protect Department information, including CURES information, from unintended or unauthorized dissemination, whether at rest or in transit.

1.05	Objection No. 1.05 [Proposed Article 2. § 821(g)(3)(A) Delegate Use of CURES] "Article 2. §821. (g)(3)(A) limits a patient's care team to accessing CURES information through a web-based application, and not an Information Exchange Web Service or HIT system. This runs contrary to AB 40 (2017), which allowed interoperability of CURES with HIT systems. Additionally, AB 528 (2019) expanded Delegate access beyond ordering patient activity reports for the prescriber. This limitation undercuts the ability of a patient's care team to improve clinical and provider workflow…. CAFP Urges the Department to follow existing law which permits approved health care practitioners and pharmacists to use a health information technology system, including an EHR system, to access CURES data so long as the entity certifies that it meets designated criteria."	Similar comment, see response 4.08.
1.06	Objection No. 1.06 [Proposed Article 2. § 825(d)(2) / (d)(3) / (d)(5) Restrictions on Use or Disclosure of Data Obtained from CURES by Law Enforcement] "Article 2. §825. (d)(3) indicates that a search warrant or court order is required as a condition for accessing a Patient Activity Report. CAFP could not agree more with that provision. A higher evidentiary threshold to access CURES data is necessary as it contains patient information and it ensures that Law Enforcement Officials cannot access it outside of their statutorily mandated duties related to CURES. However, in Article 2. §825. (d)(5), this same evidentiary threshold is not similarly applied – access to a Prescriber History Report or a Pharmacy History Report does not require a search warrant or court order, but only an investigation (e.g., case number and violation code or crime code), despite major commonality in the data contained in each. In addition, the proposed regulations list a number of exceptions to the search warrant or court order requirement, including that law enforcement officials may access a Patient Activity Report under an administrative subpoena…. CAFP urges the Department to delete the provisions in 825(d)(5) which create significant exceptions to the warrant or court order requirement in (d)(3)(C). In addition, CAFP urges the Department to add the requirement for a search warrant or court order to 825(d)(2)."	Similar comment, see response 4.11.
1.07	Objection No. 1.07 [Proposed Article 2. § 826(f) Procedures for Requesting Identified Individual-Level Data and De-Identified Individual-Level Data from CURES]	In response to comments from the directly affected public, the Department revised section

	"Article 2. §826. (f) allows for a Researcher to have access to Identified Individual-Level Data. CAFP sees no reason as to why that information should be made available to Researchers. Ensuring patient confidentiality should be the top priority if this data is not being used in a clinical setting."	826, subdivision (f), to limit disclosures of Identified Individual-Level Data from CURES. These revisions restrict disclosures only to disclosures that are consistent with the requirements of Civil Code section 1798.24, subdivision (b). The Department believes that protecting patient privacy is of the utmost importance. In light of this, the Department has made considerable revisions to section 826, subdivision (f), to help ensure patient privacy.
1.08	Objection No. 1.08 [Proposed Article 1. and 2.] "We have seven recommendations based on what we've seen so far. And I'll go through each one…. The first recommendation is on Article 1, 820(i), and this has to do with a Connectivity Fee of $1,500 – $1,500 Connectivity Fee. The – the issue with this is – this is to connect, you know, our to CURES database which is mandatory. For a big organization, it is just fine, so, you know, organization like Kaiser or any other big insurance company, but for the solo practitioner or a small group, particularly, role, (phonetic), this may be quite a hardship. And we're asking to consider a sliding scale for hardship for – for people who are out on their own or in small groups…. And number 2 is on Article 1, 820(q). This is a definition of what is a delegate, and it defines a delegate as somebody who has the authority to order a Patient Activity Report. That's the only definition for a delegate. And we may be using our delegates for other reasons not just to request the report. We're required to do – to satisfy review notification requirements. That doesn't necessarily mean we need to request the report. It's just to view and make sure that's no chew (phonetic) going on. Also, for example, I have a colleague who, whenever he has a back patient – back pain patient come in, creates the database first to make sure there's no issues even before he sees the patient. So it's an issue of where the delegate may be looking at the – the CURES	 Regarding the comments relating to section 820, subdivision (i), "Connectivity Fee," see response 1.01. Regarding the comments relating to section 820, subdivision (q), "Delegate," see response 1.02.

	database but not actually requesting a report. It's kind of perusing and making sure there's nothing – nothing – nothing in the past. So we want to generalize what the definition of a delegate is, especially since we have to satisfy review notification requirement which doesn't necessarily request a report….	
	Comment number 3 is in Article 2, 821(c). This is – this section limits the – the time that the – the time that we can see what's going on in the database, and it says only 12 months. And for a physician, we need – we need to know what's been going on for the last few years for a patient. So we really want that to be extended longer than 12 months. And, interestingly, other regulatory agencies can look at it as far as they want to but the doctors can't. So we need the same freedom. A corollary to this, and this is issue number 4, and this doesn't really come up anywhere else, is that we should be able to look at the data on ourselves. Just like doing a credit report and see if there's some issue going on our credit reports, we as physicians would like to know, is someone actually using our name or is some – something else going on. So we would like to query ourselves to see what – what is in that. And that's not addressed anywhere in here….	Regarding the comments relating to section 821, subdivision (c)(2), and the 12 month Search Period, see response 4.06.
	Next issue is Article 2, 821(f). And this has to do with changing the password every 90 days, which is just a pain in the butt for everybody just having to do it, let alone . . . trying to remember what your password is so often. In the handout I'm giving you, there will be a reference, a link that – an article that says, 'Microsoft says mandatory password change is ancient and obsolete.' So we would like to have our passwords for longer period of times and easier to remember, and actually it's – actually safer if you have your passwords to keep it somewhere….	Regarding the comments relating to section 821, subdivision (f)(2), and the password policy, see response 1.04.
	Next issue is Article 2, 821(g). And this defines a team is to access CURES through a web-based application. And now most of us are having connectivity with our EMR, Electronic Medical Record, which really we aren't then going to a web-based application. We are actually doing it through our EMR not actually going through a web-based application. And since we're required to do that, we need to – it's page 17 – page 17 of the – yeah, the big one…. So changing that wording from web-based	Regarding the comments relating to section 821, subdivision (g)(3)(A), and Delegate access, see response 4.08.

	application because we really use an exchange [web] or our EMR to get to CURES now for a lot of people…. The next one is Article 825(d) – Article 2, 825(d). This has to do with who has access to CURES besides physicians. And so the first part of this is – talks about needing a search warrant and a court order, and we certainly agree with that. That's actually really well-written. But later on – so (d)(5) – so (d)(3) is the one we wholeheartedly agree with. (d)(5) talks about other entities that can look into the record, and even if it includes just investigating fraud or something like that, that doesn't require a search warrant or a court order, and we think anyone other than physicians who are looking at the CURES database should have a search warrant or court order. And that's page 34 and 35. So (d)(3) we wholeheartedly agree with, but (d)(5) is not restrictive enough of who gets to look at the database. Section (d)(3) we wholeheartedly agree, and Section (d)(5) needs to be more restrictive as to who is able to look into the database…. And the last issue is Article 2, 826(f), page 43, and this has to do with researchers being able to get into the database at the Identified Individual-Level. So there's not confi- – confidentiality to the patient who has not really given their permission for researchers to use their data. So we really need to kind of prevent that unless person says it's okay to use their data for research."	Regarding the comments relating to section 825, subdivisions (d)(3) and (d)(5), and search warrants and court orders, see response 4.11. Regarding the comments relating to section 826, subdivision (f)(3), and Identified Individual-Level Data, see response 1.07.
2.01	Objection No. 2.01 [Proposed Article 1. § 820(h) "Compliant Password" Defined] "While we appreciate the Department's need to maintain the security of the CURES database, we are concerned with the stringent password requirements. Our members log-in to view patient information from CURES in the context of a fast-paced emergency department (ED) where time is of the essence. Our members do not have office practices and the requirement to change your password every 90 days, coupled with the fact that no previous password may be reused, creates delays for them accessing this information and is unnecessarily burdensome. While this may seem trivial, it is the most common complaint we hear from our members and we are concerned about the unintended consequences it has for care delivery in the ED. We	Similar comment, see response 1.04.

	request that the time interval between required password changes be extended to at least 120 days and that previously used passwords be allowed for reuse after some set period of time."	
2.02	Objection No. 2.02 [Proposed Article 1. § 820(nnn) / (ooo) "Under His or Her Care" / "Under the Care of" Defined] "The proposed regulations seek to define the establishment of the provider-patient relationship in the context of accessing information in CURES. According to the Initial Statement of Reasons, the Department states that this definition is necessary because it provides specificity to the vague language used in statute as a condition of CURES access. The Department asserts that clearly defining the circumstances under which a physician may consider a patient to be 'Under His or Her Care' provides the medical community, regulatory entities, and affected members of the public with a defined standard under which use of CURES is justifiable. We disagree with the Department's justification to define 'Under His or Her Care.' Establishment of the physician-patient relationship is a complex legal question that has major implications. In fact, California courts have yet to decide when a physician–patient relationship has been established in many circumstances. Whether a physician–patient relationship exists depends on the specific facts and circumstances of each situation. It is not within the purview of the Department to define the context of the physician-patient relationship, a matter that has not yet been decided within California, and which is beyond the scope of the rulemaking authority conferred to the Department. We urge the Department to withdraw its proposed definitions for 'Under His or Her Care' and 'Under the Care Of' and leave the meaning as defined in the statute, Health & Safety Code §11165.1(a)(1)(A)(i). We are also concerned that this proposed definition may adversely affect the use of innovative health information technology tools currently integrated with CURES that provide unique benefit in combatting the opioid epidemic in the ED.	Similar comment, see response 4.05.

	Our members appreciate the important information available in the CURES database. Given the fast-paced nature of the ED, we sponsored AB 40, which was enacted in 2017, to allow CURES access via intermediating health information technology systems. For example, Collective Medical's EDie system is currently interfaced with the CURES Information Exchange Web Service (IEWS), as allowed by AB 40. The system is able to provide alerts and notifications in real-time to providers in the ED when a patient that meets a facility's predetermined risk threshold – such as an individual with five or more ED visits in the past year – registers at any ED that subscribes to Collective EDie. For the purposes of its CURES integration, Collective queries its own database when a patient registers at a subscriber ED, as well as that of CURES, using the credential of the ED medical director because the provider that will provide direct treatment typically has not yet been assigned. The ED is sent an alert and notification – a concise summary of the patient's conditions and utilization of hospital services – when a patient exceeds an ED-specified risk threshold. This can include CURES data if the patient, based on a Collective query to CURES, exceeds certain criteria established by Collective's community of ED physicians, such as four or more schedule II – IV prescriptions or three or more prescribers in the past 12 months. The benefit of such tools for ED physicians include the ability to have these alerts and notifications pushed into their workflow through integration with their electronic health record systems. Having the concise, targeted information in these notifications aids them in making better treatment decisions because they have a much fuller picture of a patient's condition and history at the beginning of the ED encounter. The approach also alleviates the need for those physicians to query multiple systems in a way that is simply impractical given the fast-paced nature of the ED. Our concern with the proposed regulations is they might be interpreted in a way that would limit the use case and approach of tools like Collective EDie. One might read the regulations as requiring that only providers providing direct treatment of a patient can query and access CURES records, and that 'view notifications' be provided back	

	to DOJ that affirm that the person asking for the data was the person who viewed it. Our view is that an approach in which, for instance, an ED medical director's credentials are used conforms to the letter and intent of the underlying statute to the degree that all patients who register at an ED can be validly construed as being 'under the care of' that medical director. This principle is embodied in the memorandum of understanding the ED medical directors execute with Collective to establish the CURES integration. (To be clear, use of the ED Medical Director's credential does not necessarily mean that individual will see the data unless the patient is assigned to them – it is used as a proxy to trigger the push notification necessary for the Collective CURES use case). We would urge that the language of the proposed regulations be modified to clarify this understanding. In addition, we support ensuring the proposed regulations are clarified to reflect this understanding with respect to view notifications – and these notifications ultimately reflecting both the ED medical director, on whose behalf the data was requested, and the treating provider ultimately assigned, who was the intended recipient of the information pushed into the EMR."	
2.03	Objection No. 2.03 [Proposed Article 2. § 821(g) Delegate Use of CURES] "While not specifically stated, these proposed regulations appear to require that a Prescriber-User submit an application for each Delegate. This is unnecessarily burdensome as our members supervise many Delegates. We request that the regulations be amended to clearly allow for a Provider-User, or group of Provider-Users, to submit a single application to designate multiple Delegates."	No change has been made in response to this comment. Prescribers and Pharmacists are responsible for individually adding and deleting delegates who access the CURES database on their behalf. The Delegate Registration Application simply requires that a Prescriber or Pharmacist enter the delegate's first name, last name, and email address, which the Department does not view as overly burdensome.
3.01	Objection No. 3.01 [Proposed Article 2. § 821(c)(2) Data Accessible to a Prescriber-User in CURES] "The Department has proposed that a Prescriber-User may access patient information in CURES for a search period not to exceed 12 months from the date of the search. According to the Initial Statement of Reasons, this subdivision is 'necessary to limit	Similar comment, see response 4.06.

	the temporal scope of information that a Prescriber-User may access, to only that information which the Department has determined is authorized and is necessary to assist a Prescriber-User in appropriately prescribing to a patient Under His or Her Care.' The Department claims that limiting the search period to 12 months is necessary to ensure that a Prescriber-User is only permitted to access data for patients currently under his or her care, pursuant to Health & Safety Code § 11165.1. There is no adequate justification provided as to why the Department should limit how much prescription data history is necessary for a clinician to make appropriate prescribing decisions. The Department did not clearly establish why prescribers should be able to view such a limited prescription drug history in order to make an informed prescribing history. If a patient has previously received treatment for any substance abuse disorder (SUD) or engaged in drug shopping in a prior year and does not volunteer this information during their health care visit, it would be impossible for the prescriber to make an informed and appropriate treatment plan despite the Department storing this information within CURES. This can commonly happen in dentistry, such as during an oral surgery visit when there is a likelihood of prescribing a controlled substance. Additionally, as best practices are evolving for dentists in response to the national opioid epidemic, including the assessment of patients for SUD, it is critical for dentists to have as much prescriber history available to them when considering prescribing controlled substances to their patients even when a patient is not actively sharing their SUD diagnosis or substance use history with their health care practitioner. CURES is a useful decision support tool that can inform a dentist of a patient's prescription history, which should include information beyond the immediate past 12 months. CDA urges the Department to consult with prescribers to determine the most appropriate timeframe for patient prescription data history that supports and optimizes health care delivery at the point of care."	
3.02	Objection No. 3.02 [Proposed Article 2. § 821(g)(3)(A) Delegate Use of CURES] "The Department has proposed that while delegates may access the Web-Based Application of CURES, they may not have access to the Information Exchange Web	Similar comment, see response 4.08.

	Service. It is important that electronic systems be interoperable and integrated into all health care practice workflows, including EHR systems in dental offices. Obtaining important information, including CURES data, often requires multiple 'clicks,' opening multiple windows and the use of separate logins even before the prescriber 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 CURES and electronic health record integration means that the workflow must achieve 'functional interoperability,' or the ability for systems to exchange, incorporate and display data in a meaningful and contextual manner. The Department's proposed restriction on delegate access to the Information Exchange Web Service inhibits clinical workflow and runs contrary to the legislative intent of California Health & Safety Code § 11165.1 (a) as codified through AB 40. This bill intended to enable healthcare providers to query CURES within their existing EHR systems, which would significantly improve querying time and allow them to more smoothly incorporate use of the system into their daily practice. Per the law, approved prescribers and dispensers can use an EHR 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 (MOU), onboarding questionnaire and payment for applicable fees and yet not be able to have all approved users, including delegates, access CURES unless they separately login through a web browser. The Department provides no reasoning or justification for why delegates are denied access to the Information Exchange Web Service. This limitation has the potential to severely disrupt clinical workflow. CDA strongly urges the Department to amend the regulation by permitting the ability for delegates to access CURES when accessing the database through an EHR integration."	
4.01	Objection No. 4.01 [Proposed Article 1. § 820(e) "Bona Fide Research" Defined] "CMA generally supports research and epidemiological studies which have the potential to estimate the magnitude of health problems, determine the distribution of	The Department accepts this comment and has revised section 820, subdivision (e), to replace "any" qualities with "all" qualities. The Department further revised the qualities to

	illness in a population, depict the natural history of a disease, generate hypotheses, stimulate research, evaluate control measures, monitor changes, and facilitate planning and policy development. Modern computing and technological advances provides researchers with numerous new techniques for exploring and identifying correlations in large data warehouses, such as CURES. Common to such efforts is the need for access to large quantities of potentially sensitive patient health information, or protected health information. While providing access to sufficiently detailed information for adequate research is laudable, it must be appropriately balanced with patient privacy and confidentiality protections. The risk of inadvertent disclosure rises with the number of authorized users regardless of the perceived level of security at each access point. CMA is concerned that the Department's definitions for what encompasses 'Bona Fide Research' and 'Bona Fide Researcher' do not sufficiently limit who may have access to sensitive health information and adequately protect patient privacy. Instead, CMA suggests the following amended language for Subdivision (e)…: (e) 'Bona Fide Research' means research that is characterized by ~~any~~ all of the following qualities…[']"	remove "basic" and to replace "will be accepted for publication in a peer-reviewed journal" with "may support publication in a peer-reviewed, journal, program evaluation and quality improvement, public health surveillance, or policy development."
4.02	Objection No. 4.02 [Proposed Article 1. § 820(f) "Bona Fide Researcher" Defined] "CMA is concerned that the Department's definitions for what encompasses 'Bona Fide Research' and 'Bona Fide Researcher' do not sufficiently limit who may have access to sensitive health information and adequately protect patient privacy. CMA suggests the following amended language for… Subdivision (f): 'Bona Fide Researcher' means a ~~principle~~ principal investigator~~, team lead, or other individual,~~ who conducts Bona Fide Research. A ~~principle~~ principal investigator~~, team lead, or other individual~~, is considered a Bona Fide Researcher if that ~~principle~~ principal investigator, ~~team lead, or other individual~~ meets ~~any~~ all of the following qualities…"	The Department accepts this comment and has revised section 820, subdivision (f), to remove the clauses, "team lead, or other individual," and "[a] principle investigator, team lead, or other individual, is considered a Bona Fide Researcher if that principle investigator, team lead, or other individual." The Department further revised section 820, subdivision (f), to replace "principle" with "principal" and "any of the following requirements" with "all of the following requirements."

4.03	Objection No. 4.03 [Proposed Article 1. § 820(b) / (p) "Aggregated Data" / "De-Identified Individual-Level Data" Defined] "Current regulations on the use of protected health information for research purposes under the Health Insurance Portability and Accountability Act (HIPAA) divide medical record sets into three categories: identified data, deidentified data, and limited data. Deidentified data is data with all such identity information removed (i.e., HIPAA provides a specific list of 18 data elements that must minimally be removed). There is an assumption that deidentified data is generally safe for public consumption. However, the open accessibility of large demographic databases across a variety of platforms and topics may disprove this assumption. For example, students at the Massachusetts Institute of Technology were able to re-identify 35 percent of the records in a 30-year span of the Chicago homicide victims' database by correlating data elements with records in the Social Security Death Index, even though both sets were public and were considered to be deidentified. The Department defines 'Aggregated Data' to mean data that does not include PII or Personal Identifying Information as set forth in Penal Code section 530.55, subdivision (b), and is presented in summary counts. Additionally, the Department defines 'De-Identified Individual-Level Data' to mean individually disaggregated data that does not include any PII, or Personal Identifying Information as set forth in Penal Code section 530.55, subdivision (b). Given that the Department is citing PII, which covers identifying information that differs from the data elements contained in HIPAA, and given the risk for re-identification even when de-identified, CMA requests that the Department provide specificity regarding the methodology it intends to employ for data exclusion (e.g., data fields, summary counts, etc.)."	No change has been made in response to this comment. The definitions of De-Identified Individual-Level Data and Aggregated Data have appropriate safeguards in place to protect the privacy of patients. Moreover, the Department does not make De-Identified Individual-Level Data or Identified Individual-Level Data publically available; its provision is restricted to qualifying Bona Fide Researchers who satisfy all the requirements of these regulations. Furthermore, the Department has broadly defined Personal Identifying Information (PII) in order to be intentionally over-inclusive of identifying information. Thus, the list of information included in the Department's definition of PII encompasses the identifiers listed in HIPAA. However, in response to comments from the directly affected public, the Department revised section 826, subdivision (d)(6), to further specify the conditions of release, disclosure, or dissemination of data or documents from CURES that may have a reasonable possibility of directly or indirectly identifying any individual. These revisions include the addition of section 826, subdivision (d)(6)(A)(xi), which directly lists HIPAA identifiers. Access to De-Identified Individual-Level Data and Aggregated Data is necessary for research endeavors. However, the Department believes that protecting patient privacy is of the utmost

		importance. In light of this, the Department has made considerable revisions to section 826 to help ensure patient privacy.
4.04	Objection No. 4.04 [Proposed Article 1. § 820(eee) "Research Requestor" Defined] "Particularly as more third-party data companies assemble and track statistical health information, CMA suggests the Department be mindful that even aggregated information can be used in ways that many patients did not ever consent to nor consider. CMA urges the Department to sufficiently limit who may qualify as a Research Requestor by putting parameters around what encompasses a public or private entity."	No change has been made in response to this comment. The Department believes there are appropriate safeguards in place to protect the privacy of patients. The terminology of "public or private entities" is introduced by our governing statutes. Health and Safety Code section 11165, subdivision (c)(2)(A), provides that "[d]ata may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, if patient information, including any information that may identify the patient, is not compromised." The Department believes that the safeguards it has established to provide data to public or private entities for educational, peer review, statistical, or research purposes are appropriate to protect patient privacy and prevent identification. Such safeguards include the restriction that public or private entities that do not qualify as a Bona Fide Researcher are limited to accessing or obtaining Aggregated Data from CURES. Due to the strict limitations on access to data from CURES applicable to public or private entities that do not qualify as a Bona Fide Researcher, it is unnecessary to further define the qualifying parameters of a public or private entity.

		With no relation to this comment, the Department, in an effort to clarify the text of the proposed regulations, has removed section 820, subdivision (eee), "Research Requestor," and made revisions to section 826 to better specify which subdivisions are applicable to public or private entities, Bona Fide Researchers, or Team Members.
4.05	Objection No. 4.05 [Proposed Article 1. § 820(nnn) / (ooo) "Under His or Her Care" / "Under the Care of" Defined] "The Department has taken liberties to define the establishment of the provider-patient relationship (inclusive of, and hereinafter referred to as the 'physician-patient relationship'), in the context of accessing information in CURES. Current law states the following: 'A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule II, or Schedule IV controlled substances pursuant to Section 11150 shall, before July 1, 2016, or upon the receipt of a federal Drug Enforcement Administration (DEA) registration, whichever occurs later, submit an application developed by the department to obtain approval to electronically access information regarding the controlled substance history of a patient that is maintained by the department. Upon approval, the department shall release to the practitioner the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in the CURES Prescription Drug Monitoring Program (PDMP).' (Health & Safety Code §11165.1(a)(1)(A)(i).) [Emphasis added] The Department has defined Subdivision (nnn) 'Under His or Her Care' or referred to as Subdivision (ooo) 'Under the Care of' to encompass any of the following situations: ▪ The patient has had a professional medical consultation with the 'Prescriber-User,' or physician, and has an ongoing physician-patient relationship;	No change has been made in response to this comment. Contrary to the suggestion of the commenter, these regulations do not define the establishment of the provider-patient relationship. These regulations seek to clarify and make specific the primary statutory limitation on the circumstances under which a Prescriber or Pharmacist may access a patient's records—namely, that the patient must be under "the practitioner's care" or "the pharmacist's care." CURES users have minimal guidance, if any, in understanding or applying this statutory constraint as applied to the access of patient information in CURES. Regulations are an appropriate vehicle to provide this clarity. These regulations provide specific, authorizing scenarios when a patient is under the care of a Prescriber or Pharmacist. While a provider-patient relationship is one of the necessary conditions for access to patient information in two of the four authorizing scenarios, the Department makes no attempt to define the

	▪ The patient has an appointment for a professional medical consultation with the physician; or, ▪ The patient has not had a professional medical consultation with the physician, but the physician is part of the patient's 'organized health care arrangement' and the patient has a physician-patient relationship with the physician. According to the Initial Statement of Reasons, the Department states that this definition is necessary because it provides specificity to the vague language used in statute as a condition of CURES access. The Department asserts that clearly defining the circumstances under which a physician may consider a patient to be 'Under His or Her Care' provides the medical community, regulatory entities and affected public with a defined standard under which use of CURES is justifiable. CMA, as part of the medical community, wholeheartedly disagrees with the Department's justification to define 'Under His or Her Care.' Establishment of the physician-patient relationship is a complex legal question that has major implications for determining when a physician has a duty to treat, when a physician may be sued for malpractice, when a physician has 'abandoned' a patient and other serious matters. In fact, California courts have yet to decide when a physician–patient relationship has been established in many particular circumstances. Whether a physician–patient relationship exists depends on the specific facts and circumstances of each situation. (1 Cal. Med. Malprac. L. & Prac. §1:2 (2014 ed.).) The basic question is whether a patient reasonably believes that the physician will provide necessary medical care to that patient. (Id.) (citing Kramer v. Policy Holders' Life Insurance Assn. (1935) 5 Cal.App.2d 380, 382).) As a general rule, a physician-patient relationship is established when a physician conducts the initial history and physical examination. However, depending on the circumstances, such a relationship may exist even earlier. In other instances, a limited relationship may exist but which does not establish the physician-patient relationship because the intent is to inform a third party.	provider-patient relationship in this context, or any other. Because the existence of this relationship is a factually and legally complex question, these regulations recognize that the licensed clinicians and their institutions, not the CURES Program, must determine if and when that relationship exists. Furthermore, clarifying the circumstances under which a Prescriber or Pharmacist may access patient information, the Department helps to inform patients regarding the point at which they should expect that providers will have access to their patient information.

	In instances where a physician provides an evaluation of a patient for the benefit of a third party, such as for an employer, insurance company, court (e.g., independent medical evaluation) or as a professional courtesy for a colleague, a physician-patient relationship is typically not established. A sufficient physician–patient relationship has probably not been established to give rise to such liability, because the patient has no reason to believe that the physician is acting primarily for their benefit. (California Tort Guide §9.69 (3d ed. Cal. CEB).) Even principles of medical ethics acknowledge that the specific facts and circumstances of the situation will dictate establishment of the physician-patient relationship. The American Medical Association's Council on Ethical and Judicial Affairs has issued the following opinion on physician-patient relationships: E-1.1.1 Patient–Physician Relationships The practice of medicine, and its embodiment in the clinical encounter between a patient and a physician, is fundamentally a moral activity that arises from the imperative to care for patients and to alleviate suffering. The relationship between a patient and a physician is based on trust, which gives rise to physicians' ethical responsibility to place patients' welfare above the physician's own self-interest or obligations to others, to use sound medical judgment on patients' behalf, and to advocate for their patients' welfare. A patient–physician relationship exists when a physician serves a patient's medical needs. Generally, the relationship is entered into by mutual consent between physician and patient (or surrogate). However, in certain circumstances a limited patient–physician relationship may be created without the patient's (or surrogate's) explicit agreement. Such circumstances include: (a) When a physician provides emergency care or provides care at the request of the patient's treating physician. In these circumstances, the patient's (or surrogate's) agreement to the relationship is implicit.	

	(b) When a physician provides medically appropriate care for a prisoner under court order, in keeping with ethics guidance on court-initiated treatment. (c) When a physician examines a patient in the context of an independent medical examination, in keeping with ethics guidance. In such situations, a limited patient–physician relationship exists. AMA Principles of Medical Ethics: I, II, IV, VIII. (Last modified 2017.) It is not within the purview of the Department to define the context of the physician-patient relationship, on a matter that has not yet been decided within California, and which is beyond the scope of the Department's rulemaking authority conferred to the Department. CMA urges the Department to withdraw its proposed definitions for 'Under His or Her Care' and 'Under the Care Of' and leave the meaning as defined in the statute, Health & Safety Code §11165.1(a)(1)(A)(i)."	
4.06	Objection No. 4.06 [Proposed Article 2. § 821(c)(2) Data Accessible to a Prescriber-User in CURES] "Per §821(c)(2), the Department has proposed that a Prescriber-User may access patient information in CURES for a search period not to exceed 12 months from the date of the search. According to the Initial Statement of Reasons, this subdivision is 'necessary to limit the temporal scope of information that a Prescriber-User may access, to only that information which the Department has determined is authorized and is necessary to assist a Prescriber-User in appropriately prescribing to a patient Under His or Her Care.' The Department claims that limiting the search period to 12 months is necessary to ensure that a Prescriber-User is only permitted to access to data for patients currently Under His or Her Care, pursuant to Health & Safety Code §11165.1 There is no adequate justification provided as to why the Department should limit how much prescription data history is necessary for a clinician to make appropriate prescribing decisions. PDMPs can be a useful tool to support safer prescribing and dispensing practices for scheduled medications. An American Medical Association survey found that 87 percent of responding physicians supported PDMPs because they	The Department accepts this comment in part and has revised section 821, subdivision (c)(2), to replace"12 months" with "24 months." Until now, there has been minimal interest expressed in extending this access period. In response to these public comments, the Department has doubled the original access period to allow practitioners access to additional information that may better inform their ability to make appropriate prescribing decisions. However, in appearing to reject any temporal constraints, this comment fails to consider patient privacy as a countervailing interest when establishing the access period for practitioners to search CURES. Protecting patient privacy is of the utmost importance to the Department. As such, the Department believes it is appropriate to impose reasonable limitations on the search period for practitioners accessing patient information.

	help prescribers become more informed about a patient's prescription history. PDMPs may also be a helpful tool to identify patients who merit an assessment for a substance use disorder. The course of a patient's treatment may see them on multiple medications and visiting several doctors over the treatment time line, whether it's an acute condition or chronic disease; PDMPs are a useful decision support tool for prescribers when considering whether to prescribe a controlled substance or a medication that could have harmful drug-drug interactions with a controlled substance prescribed or dispensed by another party. The Department has limited the search term to access patient data to 12 months for Prescriber-Users and Pharmacist-Users; however, both authorized Regulatory Agencies and Law Enforcement Entities are permitted to access patient data for the full scope of the patient history, with no temporal limitations at all. In many ways, the Department is inappropriately setting forth a standard of care – is the expectation that a Prescriber-User would only need to review 12 months of prescription data history to ensure they are making 'appropriate prescribing' decisions? As mentioned earlier, CURES is also a clinical-decision making tool and should be prioritized as such. CMA urges the Department to consult with clinicians to determine the most appropriate time frame for patient prescription data history that supports and optimizes health care delivery at the point of care. At a minimum, CMA requests the Department to explain its methodology in determining why 12 months is the appropriate search term for physicians to access patient prescription history in making 'appropriate prescribing' decisions – particularly when it appears that the technological capability is there for others to search the full patient history, such as with Regulatory Agencies and Law Enforcement Entities."	Furthermore, the Department's revised access period aligns more closely with the access periods of other state prescription drug monitoring programs.

4.07	Objection No. 4.07 [Proposed Article 2. § 821(d)(1)(A) Restrictions on Accessing Patient Information in CURES] "Some of the complications stated earlier in defining 'Under the Care of' similarly arise in this Subdivision. The Department has proposed that a Prescriber-User must only access patient information to 'Treat a patient Under the Care of the Prescriber-User.' Again, this brings up legal issues related to establishment of the physician-patient relationship that have not yet been settled in California. Even the term 'treat' raises concerns as it supposes that there is a duty to treat and diagnose a patient in that context. Equally concerning, the Department is proposing a time limit upon when the CURES database must be consulted prior to providing medical treatment. They state the following at Subdivision (d)(1)(A)(i): 'If a patient is Under the Care of the Prescriber-User within the meaning of section 820, subdivision (ooo)(1)(B), but the patient does not have an ongoing provider-patient relationship with the Prescriber-User, the Prescriber-User must not access the patient's information in CURES earlier than 24 hours, or the previous business day, before the appointment for a professional medical consultation with the Prescriber-User.' In attempting to put parameters on accessing patient information in CURES when an 'appointment for a professional medical consultation' has been established, the Department has overstepped its authority. Not even the duty to consult mandate in statute considers such - for purposes of compliance, the requirement states that a physician must consult CURES no earlier than 24 hours or the previous business day, prior to the prescribing, ordering, administering, or furnishing of a controlled substance to the patient. (Health & Safety Code §11165.4(a)(2); S.B. 482, Stats. 2016, ch. 708.). However, this is prior to the act of prescribing, ordering, administering, or furnishing of a controlled substance to the patient, and it certainly doesn't preclude a physician from checking CURES outside of the 24 hour window. Moreover, there are many instances when a physician may consider taking on a complex patient within their panel, but may need to access the patient prescription	The Department accepts this comment in part and has revised section 821, subdivision (c)(2), to replace "24 hours, or the previous business day" with "7 days." Appointments are sometimes scheduled months in advance. Some of those appointments will be canceled before the scheduled visit. The Department believes that access to a patient's information should have a reasonable proximity to the consultation wherein that patient will be treated when there is no preexisting provider-patient relationship. Furthermore, this restriction is intended to provide patients with guidelines that provide them a reasonable expectation as to when a Health Care Practitioner may access their data. The Department considered disallowing access to a patient's records until the patient had appeared at the consultation and signed relevant disclosure forms. However, the Department believed that this would be too restrictive in many scenarios, and took this modified approach. In response to this comment the Department has further extended this period to 7 days, which the Department believes is an appropriate amount of time for a Health Care Practitioner to consult CURES in this circumstance, while still balancing patient privacy. This would allow a Health Care Practitioner to consult CURES a week prior to an appointment, though the Department would

	history to properly inform the medical examination. Obtaining a full medical history will be the basis for a risk assessment between the clinician and patient, and this process is typically done prior to the actual physical examination. The Department is proposing that access to CURES information on any prospective patients may occur no earlier than 24 hours prior to the appointment, but it neglects to consider clinician workflow and how medical practices structure their patient assessments. Similar to our request for Subdivision (nnn) 'Under His or Her Care' and Subdivision (ooo) 'Under the Care of,' CMA strongly suggests that the Department withdraw Subdivision (d)(1)(A) and Subdivision (d)(1)(A)(i)."	note that in order for a Health Care Practitioner to satisfy the duty to consult CURES as set forth in Health and Safety Code section 11165.4, the Health Care Practitioner would be required to consult CURES no earlier than 24 hours, or the previous business day, before the Health Care Practitioner prescribes, orders, administers, or furnishes a Controlled Substance to the patient. Regarding the comment that inclusion of the term "treat" is problematic, the Department notes that this term is introduced by our governing statutes. Health and Safety Code section 11165.1, subdivision (a)(1)(B), provides that "a subscriber may be suspended, for reasons which include, but are not limited to, the following . . . [a]ccessing information for a reason other than to diagnose or treat a patient, or to document compliance with the law." Regarding the comment relating to the "under the care of" terminology, see comment 4.05 for more information.
4.08	Objection No. 4.08 [Proposed Article 2. § 821(g)(3)(A) Delegate Use of CURES] "Per Subdivision (g)(3)(A), the Department has stipulated that while delegates may access the Web-Based Application, they may not have access to the Information Exchange Web Service. 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	The Department accepts this comment in part and has revised section 821, subdivision (g)(3)(A), to replace "must only" with "may" in response to comments from the directly affected public. This subdivision does not restrict delegate access. This subdivision is located in a Delegate's "Procedures for Use of CURES" section and is therefore intended to be descriptive rather than proscriptive.

	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. It is CMA's assertion that the Department's proposed restriction on delegate access to the Information Exchange Web Service not only inhibits clinical workflow, but it runs 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. In the Initial Statement of Reasons, the Department provides no reasoning or justification for why delegates are denied access to the Information Exchange Web Service. This limitation has the potential to severely disrupt the achievements made per A.B. 40 and clinical workflow, and CMA would strongly urge the Department to amend the regulation by deleting the requirement that Delegates must only access the Web-Based Application."	
4.09	Objection No. 4.09 [Proposed Article 2. § 823(a) Eligibility for Access to Data from CURES by Interstate Prescribers and Interstate Pharmacists] "Currently, the CURES database contains information related to controlled substances prescriptions dispensed within California. Consequently, when a physician consults a patient activity report in CURES prior to writing a prescription, the patient's prescription history does not reflect prescriptions written in other states. Many states	No change has been made in response to this comment. The access and handling restrictions that will be included in such interstate data sharing agreements will conform to California law, as required by Health and Safety Code section 11165, subdivision (h)(3), and section 823, subdivision (a)(1), of these proposed regulations. However, probable variances in the

	already participate in one of several interstate data sharing hubs that allow for the exchange of prescription information across state lines. CMA is supportive of a comprehensive CURES database, but we have concerns that there is a lack of adequate privacy protections for the protected health information contained in CURES, and thus, sharing of such data across state lines could weaken the state's ability to meet a patient's reasonable expectation of privacy. Historically, the Department's patient privacy and data security policies for CURES have not been sufficiently subject to public input or adequately memorialized to hold up as a standard for other states accessing data in CURES. As it stands, the proposed regulations provide little specificity regarding the terms and conditions contained within the memoranda of understanding that is to be entered into between the Interstate Prescriber or Interstate Pharmacist's PDMP and the Department, and the memoranda of understanding between the authorized interstate data sharing hub and the Department, as specified in Subdivision (a)(1)(A) and Subdivision (a)(1)(C). CMA strongly encourages the Department to mandate the memoranda of understanding terms via regulation that address breach liability, jurisdiction over a contract breach and enforcement of these terms." Furthermore, in the Initial Statement of Reasons, the Department refers to Health & Safety Code §11165(h) as authorizing interstate data sharing. Health & Safety Code §11165(h)(3) specifies that any agreement entered into for interstate data sharing must ensure that access to CURES data is handled consistent with California law, including regulations, and meet the same patient privacy, audit and data security standards employed and required for direct access to CURES. In §823(a)(1)(C), the proposed regulation is specific about what laws an Interstate Prescriber or Interstate Pharmacist must comply with, including but not limited to the Confidentiality of Medical Information Act, HIPAA and Health & Safety Code §11165(a). However, in §823(a)(1)(D), the section on Interstate Prescriber or Interstate Pharmacist's PDMP and its applicable privacy, confidentiality and security standards, the Department has omitted specific references to California and federal law. Doing such creates ambiguity and it is not clear why there is dissimilar language for both the Interstate Prescriber or Interstate Pharmacist and Interstate Prescriber or	applicability of federal laws to other state PDMPs do not permit enumeration. For example, HIPAA will be applicable to all Interstate Prescribers and Interstate Pharmacists, but it may govern only a few, if any, state PDMPs. A list of all laws applicable to interstate PDMPs is likely to be over-inclusive for some state PDMPs, and under-inclusive for other state PDMPs.

	Interstate Pharmacist's PDMP. Having less prescriptive language for PDMPs is concerning as they are large databases with volumes of sensitive patient health information, and the scale of risk and impact involved if there was a breach is quite high. CMA urges the Department to specifically list the same federal and State privacy, confidentiality and security laws and regulations for Interstate Prescriber or Pharmacist's PDMPs as it does for Interstate Prescribers or Interstate Pharmacists."	
4.10	Objection No. 4.10 [Proposed Article 2. § 824(d)(1) Restrictions on Use or Disclosure of Data Obtained from CURES by Regulatory Agency Officials] "In §824(d)(1), the proposed regulation lists all of the purposes for which a Regulatory Agency can access CURES data. As noted in the Initial Statement of Reasons, this Subdivision is necessary to ensure that information contained in CURES is used solely for the purposes in which it was intended and are based upon a Regulatory Agency's efforts to control the Diversion and Resultant Abuse of Schedule II, Schedule III and Schedule IV Controlled Substances. While CMA agrees that it is within the purview of a Regulatory Agency to investigate licensees as specified, §824(d)(1)(A) - §824(d)(1)(E) includes language that is overly-broad and outside the scope of the statute that permits enforcement action by Regulatory Agencies, or licensing boards. (Business & Professions Code §2240.) While the term 'to investigate' is within the authority of Regulatory Agencies, it is not clear to us that to 'evaluate compliance by a licensee with any State or federal law or regulation…' is within the purview of these entities as well. Furthermore, the Regulatory Agencies' authority is limited to enforcing state laws, but §824(d)(1)(A) provides that they can access CURES data to investigate or evaluate compliance with 'any state or federal law…' CMA requests that the language must be limited to investigations of violations that are within the power of the Regulatory Agency to enforce. As such, CMA suggests the Department amend §824(d)(1)(A) - §824(d)(1)(E) to remove the words 'evaluate' and remove reference to 'federal' in §824(d)(1)(A)."	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 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 by the board or by any other state or federal regulatory agency." Moreover, the Department disagrees with the commenter's suggestion that the term "evaluate," in contrast to the term "investigate," exceeds the statutory authority granted to Regulatory Agencies.
4.11	Objection No. 4.11 [Proposed Article 2. § 825(d)(3) / (d)(5) Restrictions on Use or Disclosure of Data Obtained from CURES by Law Enforcement] "CMA applauds the Department for memorializing a search warrant or court order requirement as a condition for accessing a Patient Activity Report, per §825(d)(3). As indicated in the accompanying Initial Statement of Reasons, including a higher evidentiary threshold to access CURES data is necessary as it contains patient information and it ensures that Law Enforcement Officials cannot access it outside of their statutorily-mandated duties related to CURES. Unlike a search warrant issued by a neutral magistrate upon a finding of probable cause, permitting access to prescription history at a much lower standard is concerning as it can be issued by the government when an agent merely believes that the records will be 'relevant or material' to an investigation. Further, recent data as compiled by the Department indicates that hundreds of law enforcement officials have faced accusations of misusing computer databases - the last 10 years have resulted in over 1,000 cases of computer database misuse being confirmed. This is concerning as prescription drug records can reveal highly sensitive information that will often disclose a patient's underlying medical condition.	No change has been made in response to this comment. Regarding the first concern raised by the commenter, there are meaningful distinctions between Patient Activity Reports and Prescriber or Pharmacy History Reports that account for a divergence in the application of the search warrant or court order policy requirement. Prescriber 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 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

	Consequently, CMA has two specific concerns regarding law enforcement access of CURES: 1. This same evidentiary threshold for a search warrant or court order for a Patient Activity Report is not similarly applied in §825(d)(2), as access to a Prescriber History Report or a Pharmacy History Report does not require a search warrant or court order, but only an investigation (e.g., case number and violation code or crime code). As defined earlier in the proposed regulations, Prescriber History Reports are reports generated by CURES of the controlled substances prescribing history of a prescriber. A comparison between the data fields for the Patient Activity Report and Prescriber History Report indicate many commonalities (similar data fields that appear in both reports are bolded). In fact, many of the same sensitive patient information and data fields may be accessed via Prescriber History Reports, which is problematic if the goal is to ensure patient privacy and that Law Enforcement Officials cannot access this information outside of statutorily-mandated duties related to CURES…. 2. As found at §825(d)(5), the proposed regulation provides a number of exceptions to the search warrant or court order requirement for law enforcement as it concerns Patient Activity Reports. For example, §825(d)(5)(C) states that law enforcement officials may access a Patient Activity Report if they provide the CURES PDMP with an administrative subpoena issued under 21 U.S.C. §876 of the Controlled Substances Act. While the Initial Statement of Reasons provides justification as to why search warrants or court orders are necessary in §825(d)(3), the same justification regarding why these exceptions to the search warrant or court order requirement is not considered. Instead, the reasoning for why exceptions are provided pursuant to §825(d)(5) is merely that they are based 'upon circumstances that the Department has encountered' and 'are necessary because they delineate the mechanisms other than a search warrant of court order that call for the release of CURES data.'	the reports are similar, many Prescriber or Pharmacy History Reports would need to be generated, consolidated, and sorted to obtain the same information produced by a single Patient Activity Report. Regarding the commenter's second concern, each of the exceptions to the search warrant or court order requirement is based either on the preemptive effect of federal law or specific circumstances in which a patient's privacy interests benefit from other procedural protections or have been diminished (for example, when the patient is deceased). The commenter specifically questioned the basis for section 825, subdivision (d)(5)(C), which states that law enforcement officials may access a Patient Activity Report if they provide the CURES PDMP with an administrative subpoena issued under 21 United States Code section 876 of the Controlled Substances Act. This exception is consistent with federal law. The Ninth Circuit U.S. Court of Appeals has held that under Title 21, United States Code section 876, the Drug Enforcement Administration 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).

	CMA has repeatedly underscored the importance of confidentiality of medical information as an indispensable component of quality medical care that patients have a privacy interest in their medical information maintained in CURES, particularly in the digital age where technology has facilitated the government's ability to store and mine large amounts of data In Lewis v. Superior Court (Medical Board of California) (2017) 3 Cal.5th 561 the California Supreme Court concluded that the Medical Board did not violate California's constitutional right to privacy when it obtained CURES data as a routine part of its investigations, and that the government interest in protecting the public outweighed any potential privacy interest. However, writing both for the majority and in a concurring opinion, Justice Liu clearly articulated that patients have a reasonable exception of privacy in their prescription records. Moreover, the majority indicated that its analysis might have been different if the plaintiff had asserted the protection from unreasonable search and seizure. (Lewis, 3 Cal.5th at 578). The existence of a reasonable expectation of privacy in their prescription records requires a showing of probable cause by Law Enforcement Official prior to searching those records. Accordingly, CMA urges the Department to delete the provisions in §825(d)(5), which would create significant, unjustified and potentially unlawful exceptions to the warrant or court order requirement in (d)(3)(C). Similarly, we urge the Department to add to §825(d)(2) the requirement for a search warrant or court order in (d)(3)(C) in order to adequately protect patient prescription records that may be derived from a Prescriber History Report."	As to both concerns, a premise advanced is that "recent data as compiled by the Department indicates that hundreds of law enforcement officials have faced accusations of misusing computer databases - the last 10 years have resulted in over 1,000 cases of computer database misuse being confirmed." This information is incorrect. Outside agencies have obtained individual CLETS "Misuse Reports" submitted by individual law enforcement agencies and have independently compiled and interpreted data from those reports that pertain to both sworn and nonsworn personnel. None of these accusations concerns access to the CURES PDMP or CURES PDMP data.
4.12	Objection No. 4.12 [Proposed Article 1. and 2.] "In my comment, I'd like to highlight a few of the provisions that we have some concerns about. We've submitted a full comment letter which provides additional detail. I want to first start with the definition of 'Under the care of.' We feel like in this instance DOJ has defined the establishment of the physician-patient relationship and the timing as to the provision of medical care when accessing CURES. According to	Regarding the comments relating to section 820, subdivision (ooo), "Under the Care of," see response 4.05.

	the Initial Statement of Reasons, the Department has asserted that clearly defining the circumstances under which a physician may consider a patient to be under his or her care provides the medical community, regulatory entities and affected public with a defined standard under which use of CURES is justifiable. CMA would disagree. We think that establishment of the physician-patient relationship is a complex legal question and has major implications concerning when a physician has a duty to treat, when a physician has abandoned a patient and other serious matters. In fact, the California courts have yet to decide when a patient-physician relationship has been established. For example, an instance in which a physician may be asked to provide evaluation of a patient by a third party, whether it's an employer, insurance company or independent medical evaluation. Many times that physician-patient relationship has not been established. We think the regulations as stated do not consider or contemplate this. We would even state that principles of medical ethics and that the specific facts and circumstances of the situation will dictate establishment of the physician-patient relationship. CMA, in particular to this definition and inclusive of the time limitation around the 24-hour access requirement when there's not an ongoing provider-patient relationship, we would assert it's not within the purview of the Department to define the context of that physician-patient relationship, especially on a matter that has not yet been decided within the state of California and which we consider to be beyond the scope of the Department's rulemaking authority conferred upon the Department. We would strongly urge the Department to withdraw its definition of 'Under the care of' and leave the statute as is.	Regarding the comments relating to section 821, subdivision (d)(1)(A), and the 24-hour access restriction, see response 4.07.
	Another area that our members have discussed with us as being potentially problematic is the restriction on prescription access to only 12 months of patient data. DOJ in its reasoning says that it's necessary to restrict to 12 months because it will assist a physician and prescriber in appropriately prescribing to a patient. Yet, we find the restriction or limits is not imposed upon regulatory agencies or law enforcement entities and they may have access to a patient's full prescription data here with no limitations. CMA would argue over the course of the patient's treatment they may be on multiple medication, multiple doctors, whether it's an acute condition or chronic disease. We know PDMPs are a useful tool for prescribers when considering whether to prescribe a controlled substance or a medication that could have potentially harmful	Regarding the comments relating to section 821, subdivision (c)(2), and the 12 month Search Period, see response 4.06.

	drug-to-drug interactions or whether or not a prescription prescribed by another party may fit with the totality of the patient's drug regimen. We also know they would be helpful in an assessment for a substance use order. CMA would request DOJ to explain its methodology in determining why 12 months is the appropriate search term for physicians to access patient prescription history in making appropriate prescribing decisions, particularly when it appears that the technological capability is there for others to search the full patient history, such as with law enforcement entities and regulatory oversight boards." Another area that we also have some concern around is the delegate access or delegate use of CURES. While delegates may access CURES on behalf of prescribers, the DOJ stipulated that delegates may access the web-based application of CURES and not the Information Exchange Web Service or Joint Health Records System. CMA has urged that electronic systems be interoperable knowing that it takes time to click, and often requiring multiple clicks and you have to repeat that process for each patient. So that situation can increase the administrative burden on a practice and reduces the time a physician and their staff have with that patient. DOJ has proposed a restriction on delegate access. We, in our opinion, believe that not only inhibits clinical workflow, but it runs contrary to the statute and the will of the legislature when they passed AB 40, which was CMA supported legislation, that essentially allowed access to CURES data as long as authorized entities certified it meets their criteria. In the Initial Statement of Reasons, the Department provides, in our opinion, no reason or justification for why delegates are denied access to the Information Exchange Web Service, so we would really strongly urge DOJ to explain the reasoning as to why delegates are denied access to this platform, and we would suggest amending the regulation by deleting that requirement. I'm also going to just touch upon some of the patient privacy, confidentiality provisions in accessing CURES as it concerns law enforcement entities. We want to first recognize and thank the Department for memorializing a search warrant or court order requirement as a condition for accessing patient's protected health information, patient activity reports. As the Department indicated in its reasoning, including a higher evidentiary threshold to access CURES is necessary because it does contain a	Regarding the comments relating to section 821, subdivision (g)(3)(A), and Delegate access, see response 4.08. Regarding the comments relating to section 825, subdivisions (d)(3) and (d)(5), and search warrants and court orders, see response 4.11.

	significant amount of patient information and it ensures that law enforcement officials cannot access it outside the statutorily-mandated duties related to CURES. Unlike a search warrant that is issued by a judge upon a finding of probable cause, permitting access to prescription history at a much lower standard can be concerning as it is issued by the government when an agent merely believes that the records will be relevant or material to an investigation. We think this can be problematic because prescription drug records hold sensitive medical information which can provide a patient's underlying medical diagnosis" CMA has repeatedly over the years underscored for confidentiality of medical information, quality medical care in that patients have a privacy interest in their medical information contained in CURES, particularly in a digital age where technology has facilitated the government's ability to access large databases. CMA acknowledges the progress made accessing patient information, but the proposed regulation also provides a number of exceptions to the search warrant requirement for law enforcement as it concerns patient activity reports. And, you know, while the Initial Statement of Reasons provides justification as to why search warrants or court orders are necessary for accessing patient data, we find that the same justification is not provided as to why these exceptions are necessary other than the fact that the Department asserts it is based upon circumstances that DOJ has encountered. Additionally, we also find that that same evidentiary threshold for a search warrant or court order is not similarly provided for a pharmacy history report, which does not require search warrants. It requires an active or only investigation with a case number and violation code. When we did a comparison between the data fields for a patient activity report and prescriber history report, we found there were many commonalities. In fact, many of the same patient sensitive information and data fields may be accessed by prescriber history report, which is problematic if the goal as stated by DOJ is to protect privacy. So CMA would argue that the existence of a reasonable expectation of privacy in patient prescription records requires a showing of probable cause by a law enforcement official. CMA urges the Department to delete the provisions in Section 825(d)(5), which creates significant, unjustified and potentially unlawful exceptions to the search warrant requirements. We would also urge the Department to add the requirement for a search warrant or court order in order to adequately protect patient prescription records which may be derived from a prescriber history report."	

5.01	Objection No. 5.01 [Proposed Article 2. § 821 / 822] "Process of granting access, and 're-upping' access to the database (through the Web or an Exchange)…. Consideration: Inclusion of processes for the termination of access, voluntarily or involuntarily (e.g., User/Delegate leaves the employ or changes job duties within an organization)."	No change has been made in response to this comment. Authorized users and Delegates may contact the Department in order to terminate their account. Typically, a Health Care Practitioner CURES account would only need to be terminated if the Health Care Practitioner no longer possesses an active state professional license or an active DEA Registration Certificate. Changes in employment merely necessitate the updating of profile information. Furthermore, in response to other comments from the directly affect public, the Department has formalized a termination process for Regulatory Agency Officials and Law Enforcement Officials who are no longer employed by a Regulatory Agency or Law Enforcement Agency.
5.02	Objection No. 5.02 [Proposed Article 2. § 821 / 822 Prescribers and Pharmacists] "Procedures to use the system, and "rules of access"…. Consideration: Inclusion of consequences if DOJ learns a User/Delegate is not following the rules (aside from possible prosecution)."	No change has been made in response to this comment. The Department will be addressing the topic of enforcement in a subsequent regulations package.
5.03	Objection No. 5.03 [Proposed Article 2. § 821 / 822 Prescribers and Pharmacists] "Terms and conditions require the User/Delegate to keep information obtained from CURES private/secure in accordance with federal and state laws…. Consideration: Include reference to Breach reporting. Most, if not all Prescribers and Pharmacists are likely Covered Entities or Business Associates under HIPAA." Additional consideration: Inclusion of breach reporting requirement for those entities not covered by HIPAA, but by California state law."	No change has been made in response to this comment. It is a Prescriber's or Pharmacist's responsibility to comply with all applicable state and federal laws and regulations regarding breach reporting.

5.04	Objection No. 5.04 [Proposed Article 2. § 827 Individual Requestors] "Process for granting Individuals access to their own information contained in the CURES database." "Consideration: Inclusion of a timeline for DOJ granting that access, or providing copies."	No change has been made in response to this comment. California Civil Code section 1798.34 already defines the process and timeframe under which the Department must respond to an individual's request for that individual's information contained in the CURES database.
5.05	Objection No. 5.05 [Proposed Article 2. § 826 Research] "Process and Procedures for Research access, and destruction of the CURES database information at the end of the research program…. Consideration: Inclusion of a maximum time limit for notifying DOJ following the conclusion of the project and the destruction of the information."	No change has been made in response to this comment. Section 826, subdivision (f)(6), specifies that the conclusion of the research project is the event which determines when this requirement must be fulfilled.
6.01	Objection No. 6.01 [Proposed Article 2. § 821(c)(2) Data Accessible to a Prescriber-User in CURES] "CPCA urges the Department to remove the 12-month restriction on provider access to CURES; or as an alternative, work with providers to redefine the most reasonable patient prescription history. Per §821(c)(2), the Department has proposed that a Prescriber-User may access patient information in CURES for a search period not to exceed 12 months from the date of the search. According to the Initial Statement of Reasons, this subdivision is 'necessary to limit the temporal scope of information that a Prescriber-User may access, to only that information which the Department has determined is authorized and is necessary to assist a Prescriber-User in appropriately prescribing to a patient Under His or Her Care.' The Department claims that limiting the search period to 12 months is necessary to ensure that a Prescriber-User is only permitted to access to data for patients currently Under His or Her Care.	Similar comment, see response 4.06.

	There is no adequate justification provided as to why the Department should limit how much prescription data history is necessary for a clinician to make appropriate prescribing decisions. Prescription Drug Monitoring Programs (PDMPs) can be a useful tool to support safer prescribing and dispensing practices for scheduled medications. An American Medical Association survey found that 87 percent of responding physicians supported PDMPs because they help prescribers become more informed about a patient's prescription history. PDMPs may also be a helpful tool to identify patients who merit an assessment for a substance use disorder. Over a course of treatment, providers may see the patients on multiple occasions and write multiple prescription for their patients. The amount and intensity of medical care depend on the nature of the chronic condition. PDMPs are a useful decision support tool for prescribers when considering whether to prescribe a controlled substance or a medication that could have harmful drug-drug interactions with a controlled substance prescribed or dispensed by another party. Limiting provider access to patient data to 12 months, instead of the full patient history, inhibits a provider's ability to ensure they are making 'appropriate prescribing' decisions."	
6.02	Objection No. 6.02 [Proposed Article 2. § 821(d)(1)(A)(i) Restrictions on Accessing Patient Information in CURES by Prescriber-Users] "CPCA urges the Department to withdraw the requirement that limits provider access to CURES to 24-hour time window prior to a medical appointment…. The Department seems to overstep its authority when putting 24-hour time limit on accessing patient information in CURES. There is no precedent or existing medical practices or guidelines that limit provider access to a patient record. Moreover, there are many instances when a physician may consider taking on a complex patient within their panel, but may need to access the patient prescription history to properly inform the medical examination. Obtaining a full medical history will be the basis for a risk assessment between the clinician and patient, and this process is typically done prior to the actual physical examination. CPCA urges the Department to withdraw this	Similar comment, see response 4.07.

	requirement and consider clinician workflow and how medical practices structure their patient assessments which is far advanced of 24 hours before a visit."	
6.03	Objection No. 6.03 [Proposed Article 2. § 821(g)(3)(A) Delegate Use of CURES] "CPCA urges the Department to remove restrictions on delegate access to CURES database. The proposed regulation provides that while delegates may access the Web-Based Application, they may not have access to the Information Exchange Web Service. 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. For that reason, electronic systems should be interoperable and integrated into clinical practice workflows. 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. The Department's proposed restriction on delegate access to the Information Exchange Web Service not only inhibits clinical workflow, but also runs contrary to the legislative intent."	Similar comment, see response 4.08.
7.01	Objection No. 7.01 [Proposed Article 2. § 828(c)(5) Requirements for HIT System Use of the Information Exchange Web Service] "The definition of and requirements regarding a 'View Notification' under subdivision 828(c)(5) would be modified to accommodate use cases in which an HIT System utilizes the CURES credentials of a pre-defined Prescriber-User (e.g., those of the ED Medical Director or other supervising physician) to initiate a CURES request, provided that the patient in question is Under the Care of such Prescriber-User, as defined under the revised subdivision 820(ooo)(1)(C)."	The Department has made a programmatic change and the View Notification requirement has been removed in its entirety. Therefore, the Department considers this comment resolved.
7.02	Objection No. 7.02 [Proposed Article 1. § 820(ooo)(1)(C) "Under the Care of" Defined / Article 2. § 821(d) Restrictions on Accessing Patient Information in CURES by Prescriber-Users]	The Department accepts this comment in part and has revised section 820, subdivision (ooo)(1), "Under the Care of," to add

	"The definition of 'Under the Care of' in subdivision 820(ooo)(1)(C) would be modified to accommodate the fact that a patient may be deemed to be Under the Care of certain supervising physicians other than the patient's own attending physician where both the supervising physician as well as the attending physician are part of that patient's 'organized health care arrangement.' Subdivision 821(d) would be read in light of the updated definition under subdivision 820(ooo)(1)(C)."	subdivision (ooo)(1)(D). This revision encompasses scenarios where patients presenting to an emergency department for treatment may be considered under the care of a Prescriber-User or Interstate Prescriber if that Prescriber-User or Interstate Prescriber is involved in or oversees the intake or medical consultation of that patient within the emergency department. The Department believes this is a practicable and appropriate solution, which recognizes the unique workflows and proactive delivery of critical care insights required in emergency department settings, while still balancing patient privacy.
8.01	Objection No. 8.01 [Proposed Article 2. § 825(d)(5)(C) / (d)(5)(G) Restrictions on Use or Disclosure of Data Obtained from CURES by Law Enforcement] "EFF and the ACLU of CA support the DOJ's proposed regulation that law enforcement agencies may only obtain Patient Activity Reports with a warrant or court order. We believe this is the right policy in light of the sensitive nature of prescription drug information and the involuntariness of patients' disclosure to the state that they have been prescribed controlled substances. The proposed regulations state that Law Enforcement Officials may acquire direct electronic access to Patient Activity Reports in CURES, but only if they provide a case number, violation/crime code, and a search warrant or court order. EFF and the ACLU of CA support this policy due to 'the particularly private nature of the medical information at issue,' Oregon Prescription Drug Monitoring Program v. United States Drug Enforcement Administration, 860 F. 3d 1228, 1235 (9th Cir. 2017), in state PDMP databases. See Tucson Woman's Clinic v. Eden, 379 F.3d 531, 550 (9th Cir. 2004) (requiring warrant for search of medical records in abortion clinic because 'all provision of medical services in private physicians' offices carries with it a high	Commenters express concern with section 825, subdivision (d)(5)(C), which permits the Drug Enforcement Administration 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. Commenters stated that the Controlled Substances Act preempts the Department's proposed general rule of requiring a warrant or court order. As Commenters acknowledged, section 825, subdivision (d)(5)(C), is consistent with federal law. The Ninth Circuit U.S. Court of Appeals has held that under Title 21, United States Code section 876, the Drug Enforcement Administration has the authority to obtain patient records without a court order by issuing

	expectation of privacy for both physician and patient'); Doe v. Broderick, 225 F.3d 440, 450 (4th Cir. 2000) ('[A] patient's expectation of privacy . . . in his treatment records and files maintained by a substance abuse treatment center is one that society is willing to recognize as objectively reasonable.'); State v. Skinner, 10 So. 3d 1212, 1218 (La. 2009) ('[W]e find that the right to privacy in one's medical and prescription records is an expectation of privacy that society is prepared to recognize as reasonable.'). Another reason why the requirement for a court order or warrant is appropriate is that patients' prescription drug information is shared with medical providers involuntarily. As the Supreme Court recently 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. Id. The Court explained that the cases on which the third-party doctrine is based—United States v. Miller, 425 U.S. 435 (1976), and Smith v. Maryland, 442 U.S. 735 (1979)—require a dual inquiry into 'the nature of the particular documents sought' and whether they were 'voluntar[ily] expos[ed].' 138 S. Ct. at 2219–20. Courts have considered information sharing to be involuntary when an individual has no choice but to forgo a constitutional right due to the necessity of the service. '[T]he rule in Miller pertains to objects or information voluntarily turned over to third parties. A decision to use a bank may be voluntary. A decision to use a hospital for emergency care is not.' Thurman v. State, 861 S.W.2d 96, 98 (Tex. App. 1993) (citation omitted). Despite the requirement for a warrant or court order in most cases, there are gaps in the proposed regulations' protections against law enforcement access. Subsection § 825(d)(5)(C) of the proposed regulations still allows for access in absence of a warrant if the Law Enforcement Official provides an administrative subpoena issued under 21 U.S.C. § 876 of the Controlled Substances Act, while § 825(d)(5)(G) allows for access if the Official has written approval from the Attorney General. Both of these avenues circumvent judicial process. EFF and the ACLU of CA recognize that the Controlled Substances Act preempts the California DOJ's proposed general rule of	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). Commenters expressed concern that section 825, subdivision (d)(5)(G), permits the Department to obtain CURES records without judicial process, but with written approval from the Attorney General. No change has been made in response to this comment. Judicial process is not necessary because section 825, subdivision (d)(5)(G), requires written authorization from the Attorney General, which sufficiently ensures that CURES data can be accessed by individuals within the Department only for authorized purposes related to official functions of the Department of Justice.

	requiring a warrant or court order, but we find the policy of not requiring any process beyond an administrative subpoena to be highly suspect under the Fourth Amendment, and stand firmly against the rule. The exception outlined in § 825(d)(5)(G), on the other hand, is not based on federal preemption, and should be amended. The Initial Statement of Reasons reads, 'Subdivision (d)(5)(G) provides an exemption to the search warrant or court order rule for a Law Enforcement Official who is an officer or employee of the Department and who has written approval from the Attorney General to access CURES, or request data from CURES, on behalf of the Department.' Allowing law enforcement to obtain highly sensitive records without the approval of a neutral judge misses the point of a key tenet of our country's criminal legal system. If a Law Enforcement Official may bypass judicial process to access prescription records, she has done so outside the ambit of the Fourth Amendment. The Initial Statement of Reasons states that the exceptions to the warrant/court order requirement 'are based on circumstances that the Department has encountered,' but this explanation is insufficient to justify the departure from routine judicial process that § 825(d)(5)(G) permits. What are these circumstances? This vague, blanket reason does not pass muster. Moreover, this explanation treats each exception as if they all present the same level of concern and/or urgency, when in fact some circumstances seem so routine that adherence to the warrant or court order requirement would be appropriate, while others present more exigent circumstances that justify deviating from the requirement."	
8.02	Objection No. 8.02 [Proposed Article 2. § 825(d)(5)(E) Restrictions on Use or Disclosure of Data Obtained from CURES by Law Enforcement] "Another proposed exception to the warrant requirement is § 825(d)(5)(E), 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 during the Search Period included in the Patient Activity Report.'"	The Department accepts this comment in part and has (a) deleted the sentence that states that by accepting benefits under the Medi-Cal program the individual agreed to the practices described in the notice of privacy, and (b) added a requirement that any Law Enforcement Official requesting a Patient Activity Report must provide an affidavit to the effect that such official is complying with certain terms of the federal Medicaid regulations. The Department

	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 proposed regulations try to justify this disparate treatment, saying: 'By accepting benefits provided under the Medi-Cal program, the individual has agreed to the practices described in the notice of privacy practices provided to that individual by the California Department of Health Care Services in connection with that individual's enrollment in Medi-Cal.' The California Department of Health Care Notice of Privacy Practices states, 'We can share health information about you in response to a court or administrative order, or in response to a subpoena.' EFF and the ACLU of CA believe this justification is inadequate. 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 nonenrollee, their investigations must comport with the Fourth Amendment. Instituting a requirement for a warrant or court order benefits both health care providers and patients. Health care 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. Legal scholar Khiara Bridges writes about the forced surrender of privacy rights in exchange for public benefits. She argues in her article 'Privacy Rights and Public Families' that 'indigent families are made public upon their receipt of state assistance,' and that 'the poor barter their privacy rights in exchange for government assistance.' EFF and the ACLU of CA believe that privacy rights should not be reserved for the wealthy or propertied. Indeed, Article 1, § 1 of the California Constitution states, 'All people are by nature free and independent and have inalienable rights. Among these are enjoying and defending life and liberty, acquiring, possessing, and protecting property, and pursuing and obtaining safety, happiness, and privacy.' Cal. Const. art. I, § 1 (amended 1972)."	deleted the privacy notice sentence not because it does not believe that by accepting benefits the Medi-Cal beneficiary has waived the Medi-Cal beneficiary's expectations of privacy, but because the Department believes the Law Enforcement Official affidavit requirement will improve enforcement of the Medi-Cal antifraud provisions. The federal Medicaid statutes and the regulations promulgated thereunder 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 U.S.C. § 1902(a)(7); 42 C.F.R. § 431.300(a).) Under the federal 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 C.F.R. § 431.302.) The recent amendments to this section deleted the sentence that stated that by accepting benefits provided under the Medi-Cal program, the individual has agreed to the practices described in the notice of privacy practices. As an alternative, and to improve the Department's ability to enforce state and federal anti-fraud provisions against Medi-Cal beneficiaries, the Department added to section 825, subdivision

	Law Enforcement Officials must obtain a warrant or court order to access any individual's prescription records, regardless of whether they receive health care from the state."	(d)(5)(E), a requirement that the investigating Law Enforcement Official must 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).
8.03	Objection No. 8.03 [Proposed Article 2. § 826(f)(5) Procedures for Requesting Identified Individual-Level Data and De-Identified Individual-Level Data from CURES] "We recognize the concern for patient safety, but we also believe that linking someone's criminal history, the content of which may have no relation to harm to persons via access to IILD, requires several logical leaps."	In response to comments from the directly affected public, the Department revised section 826, subdivision (f), to limit disclosures of Identified Individual-Level Data from CURES. These revisions restrict disclosures only to disclosures that are consistent with the requirements of Civil Code section 1798.24, subdivision (b). The Department believes that protecting patient privacy is of the utmost importance. In light of this, the Department has made considerable revisions to section 826, subdivision (f) to maintain patient privacy. Regarding the requirement relating to a background check, the Department has removed

		this requirement. Therefore, the Department considers this comment resolved.
9.01	Objection No. 9.01 [Proposed Article 2. § 821(g) / 822(g) Delegate Use of CURES] "The proposed regulations do not specify a maximum number of delegates to whom a prescriber or pharmacist may delegate CURES access and use. DOJ should specify a maximum number of delegates in the proposed regulations. A prescriber or pharmacist and DOJ should also be required to take affirmative steps to remove delegate access once a delegate no longer works for the prescriber or pharmacist, and should annually reaffirm that a delegate requires access to CURES. Proposed Change: Add subdivision 821(g)(1)(C) as follows: (1) Restrictions on Delegate Use of CURES. (A) A Prescriber-User is responsible for the access and use of CURES of each of that Prescriber-User's Delegates. (B) If a Delegate initiates a request to CURES on behalf of a Prescriber-User the request must conform to that Prescriber-User's restrictions on accessing patient information under subdivision (d). (C) In the event a Delegate is no longer employed by a Prescriber-User or no longer works in the capacity of a Delegate to a Prescriber-User, the Prescriber-User must notify the Department. Upon receiving the Prescriber-User's notification, the Department shall terminate the Delegate's access to CURES. Proposed Change: Add subdivision 821 (g)(3)(C)(iv) as follows: (C) Procedure to Complete an Annual Renewal. (i) A Delegate must complete the Annual Renewal every 365 days. (ii) A Delegate must update the Delegate's email address on the Annual Renewal, if applicable. (iii) To submit the Annual Renewal, a Delegate must agree to the Terms and Conditions of CURES.	No change has been made in response to this comment. A Prescriber-User or Pharmacist-User already has the functionality to terminate Prescriber-User's or Pharmacist-User's Delegates' access to CURES. This is a simple process which can be performed by a Prescriber-User or Pharmacist-User through the Web-Based Application. While there is technically a maximum number of Delegates a Prescriber-User or Pharmacist-User may have, it has never been reached, and the Department believes there is little benefit to defining it through the proposed regulations. With respect to annually reaffirming Delegate access, AB 528, the relevant aspect of which will become effective on July 1, 2021, will expand Delegate access to CURES. In response to this, the Department anticipates promulgating further regulations which will address the eligibility and restrictions of Delegate access.

	(iv) A Prescriber-User must annually reaffirm that a Delegate should maintain access to CURES. Proposed Change: Add subdivision 822(g)(1)(C) as follows: (1) Restrictions on Delegate Use of CURES. (A) A Pharmacist-User is responsible for the access and use of CURES of each of that Pharmacist-User's Delegates. (B) If a Delegate initiates a request to CURES on behalf of a Pharmacist-User, the request must conform to that Pharmacist-User's restrictions on accessing patient information under subdivision (d). (C) In the event a Delegate is no longer employed by a Pharmacist-User or no longer works in the capacity of a Delegate to a Pharmacist-User, the Pharmacist-User must notify the Department. Upon receiving the Pharmacist-User's notification, the Department shall terminate the Delegate's access to CURES. Proposed Change: Add subdivision 822(g)(3)(C)(iv) as follows: (C) Procedure to Complete an Annual Renewal. (i) A Delegate must complete the Annual Renewal every 365 days. (ii) A Delegate must update the Delegate's email address on the Annual Renewal, if applicable. (iii) To submit the Annual Renewal, a Delegate must agree to the Terms and Conditions of CURES. (iv) A Pharmacist-User must annually reaffirm that a Delegate should maintain access to CURES."	
9.02	Objection No. 9.02 [Proposed Article 2. § 824(a) Eligibility to Access CURES or Obtain Data from CURES by Regulatory Agency Officials] "A Regulatory Agency should immediately notify DOJ when a Regulatory Agency Official ceases to be employed by the Agency or is no longer authorized to access CURES. Upon receiving the Agency's notification, DOJ should remove CURES access for such persons.	The Department accepts this comment and has added section 824, subdivision (a)(2). To conform to the style and format of the proposed regulations, section 824, subdivision (a)(2), differs slightly from the draft provision proposed by this comment.

	Proposed Change: Add subdivision 824(a)(2) as follows: (a) Eligibility to Access CURES or Obtain Data from CURES. (1) A Regulatory Agency Official is eligible to access CURES or obtain data from CURES. (2) In the event a Regulatory Agency Official is no longer employed by a Regulatory Agency or is no longer authorized by the Regulatory Agency to access CURES, the Regulatory Agency must notify the Department. Upon receiving the Regulatory Agency's notification, The Department shall terminate the Regulatory Agency Official's access to CURES."	
9.03	Objection No. 9.03 [Proposed Article 2. § 824(b)(3)(c) Procedures to Register for Access to CURES by Regulatory Agency Officials] "The proposed regulation would allow users at a Regulatory Agency to access CURES based on a supervisor's approval. The Board believes that such access should only be granted by the head of the Regulatory Agency. Proposed Change: Modify subdivision 824(b)(3)(C)(ii) as follows: (C) Submit supporting documentation. which must include a photocopy of all of the following: (i) The applicant's ~~board issued~~ Regulatory Agency-issued identification card. (ii) A letter from the head of the applicant's Regulatory Agency ~~supervisor~~, on the Regulatory Agency's official letterhead, explaining the applicant's need for access to CURES and confirming the applicant's employment by that Regulatory Agency.	The Department accepts this comment and has revised section 824, subdivisions (b)(3)(c)(i) and (b)(3)(c)(ii). To conform to the style and format of the proposed regulations, these proposed revisions differ from the revisions proposed by this comment.
9.04	Objection No. 9.04 [Proposed Article 2. § 824(d)(2) / (d)(3) Restrictions on Accessing CURES or Data from CURES by Regulatory Agency Officials] "The restrictions on accessing CURES data by Regulatory Agency Officials investigating violations of criminal law is unnecessarily burdensome on the Board, and on the Board's investigations conducted by the Department of Consumer Affairs (DCA).	The Department accepts this comment in part and has added section 824, subdivisions (d)(1)(F) and (d)(1)(G), which substantially conform to the additions proposed by the commenter. The Department disagrees with the commenter's characterization of the access requirements on

	The DCA's Division of Investigation routinely investigates licensee violations of civil and criminal laws when conducting investigations. The Health Quality Investigation Unit under DCA's Division of Investigation investigates licensees on behalf of the Board. An investigation may begin strictly as an investigation into violations of administrative civil law, but as evidence is developed, it may extend into an investigation about violations of criminal law. Additionally, the Board accesses CURES to investigate licensee compliance with the terms of probation related to licensee practice restrictions and to obtain data to be used as evidence in prosecutions. The proposed regulations prohibit DCA investigators from investigating criminal law violations, unless they comply with the unnecessarily burdensome requirements associated with Law Enforcement Officials. As a Regulatory Agency Official investigating a civil law violation under proposed section 824 a DCA investigator could obtain a patient activity report without a search warrant or court order. But as a Law Enforcement Official investigating a crime, or conducting a combined criminal/civil law investigation, a DCA investigator could not obtain a patient activity report without a search warrant or court order, and for purposes of its civil investigation, a DCA investigator could not directly access the patient activity report, and would instead need to request permission from DOJ in writing. (Proposed Regulation § 825, subd. (d)(3)(C) & (d)(4).) These proposed regulations will create significant hurdles and delays in the Board's cases investigated by DCA investigators. Proposed Change: Modify subdivision 824(d) as follows: (d) Restrictions on Accessing CURES or Data from CURES. (1) A Regulatory Agency Official must only access CURES, or obtain data from CURES, on behalf of a Regulatory Agency, to assist the efforts of that Regulatory Agency to control the Diversion and Resultant Abuse of Schedule II, Schedule Ill, or Schedule IV Controlled Substances, <u>or</u> for any of the following authorized purposes: <u>(F) To investigate or evaluate a licensee's compliance with the terms of probation relating to practice restrictions imposed by a Licensing Board.</u> <u>(G) To use as evidence in a prosecution of a licensee.</u>	Law Enforcement Officials investigating criminal offenses or enforcing criminal law as unnecessarily burdensome. The CURES database contains sensitive and private patient information. Access by Law Enforcement Officials to a Patient Activity Reports, which encapsulate 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. 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.

	~~(2) A Regulatory Agency Official must not access CURES, or obtain data from CURES, for the purpose of enforcing or investigating a suspected violation of any criminal law, except as specified in subdivision (d)(3).~~ ~~(3) A Regulatory Agency Official who requests access to CURES, or requests data from CURES, for the purpose of enforcing or investigating a suspected violation of any criminal law, must request access to CURES, or request data from CURES, as a Law Enforcement Official and comply with all requirements of section 825 of this chapter.~~"	
9.05	Objection No. 9.05 [Proposed Article 2. § 824(e) Restrictions on Use or Disclosure of Data Obtained from CURES by Regulatory Agency Officials] "There are occasions where the Board may be required by law to share CURES data, such as compliance with a court order. To address such circumstances, the Board suggests the following change to the proposed regulation. Proposed Change: Modify subdivision 824(e) as follows: (e) Restrictions on Use or Disclosure of Data Obtained from CURES. (1) Unless otherwise required by law, a~~A~~ Regulatory Agency-User must not use, disclose, or transfer data obtained from CURES unless the use, disclosure, or transfer is consistent with both of the following: (A) The use, disclosure, or transfer is for the same authorized purpose for which the information was originally requested. (B) The use, disclosure, or transfer complies with all applicable federal and State privacy, confidentiality, and security laws and regulations, including, but not limited to, the California Uniform Controlled Substances Act, including Health and Safety Code section 11165."	The Department accepts this comment in part and has revised section 824, subdivision (e)(1)(A), to add, "Unless otherwise required by law." The Department believes this revision will help to ensure that a Regulatory Agency is not prevented from complying with applicable state and federal laws and regulations, while still balancing patient privacy.
9.06	Objection No. 9.06 [Proposed Article 2. § 825(d)(5) Restrictions on Accessing CURES or Data from CURES by Law Enforcement Officials] "As discussed in the prior comment related to proposed regulation section 824, subdivision (d), the proposed regulations would unnecessarily burden and delay the DCA's investigations on behalf of the Board. As a possible alternative to the	No change has been made in response to this comment. First, see response to comment 9.04. Second, the commenter suggests that "as a possible alternative to the suggested change proposed in the prior comment, the Board proposes DCA be exempt from the requirement

	suggested change proposed in the prior comment, the Board proposes DCA be exempt from the requirement that it obtain a search warrant or court order, similar to the Department of Justice's exemption from the requirement. Proposed Change: Add subdivision 825(d)(5)(I) as follows: (5) Notwithstanding subdivision (d)(3)(C), a Law Enforcement Official is not required to provide a search warrant or a court order to obtain a Patient Activity Report under any of the following circumstances:…. (I) The Law Enforcement Official is employed by the California Department of Consumer Affairs or the Dental Board of California."	that it obtain a search warrant or court order similar to the Department's exemption from the requirement." No change has been made in response to this portion of the comment, specifically because the DCA is not in the same position as the Department for purposes of serving a search warrant to obtain CURES data. That is, the reason there is an exception for Law Enforcement Officials who are employees of the Department, is because CURES is an agency within the Department. Without an exception, the Department would be in the strange situation of having to serve itself. DCA is not in a similar position, and thus does not require this exception.
9.07	Objection No. 9.07 [Proposed Article 2. § 824(e) Restrictions on Use or Disclosure of Data Obtained from CURES by Law Enforcement Officials] "There are occasions where a Law Enforcement User may be required by law to share CURES data, such as compliance with a court order. To address such circumstances, the Board suggests the following change to the proposed regulation. Proposed Change: Modify subdivision 825(e) as follows: (e) Restrictions on Use or Disclosure of Data Obtained from CURES. (1) Unless otherwise required by law, a~~A~~ Law Enforcement-User must not use, disclose, or transfer data obtained from CURES unless the use, disclosure, or transfer is consistent with both of the following: (A) The use, disclosure, or transfer is for the same authorized purpose for which the information was originally requested. (B) The use, disclosure, or transfer complies with all applicable federal and State privacy, confidentiality, and security laws and regulations,	The Department accepts this comment in part and has revised section 825, subdivision (e)(1)(A), to add "Unless otherwise required by law." The Department believes this revision will help to ensure that a Law Enforcement Agency is not prevented from complying with applicable state and federal laws and regulations, while still balancing patient privacy.

	including, but not limited to, the California Uniform Controlled Substances Act, including Health and Safety Code section 11165."	
9.08	Objection No. 9.08 [Proposed Article 2. § 826(b) Data from CURES that is Accessible to a Research Requestor] "The Board has concerns regarding the sharing of identifiable patient data to research requestors. The Board believes access to identifiable patient data should be removed entirely to ensure patient privacy."	In response to comments from the directly affected public, the Department revised section 826, subdivision (f), to limit disclosures of Identified Individual-Level Data from CURES. These revisions restrict disclosures only to disclosures that are consistent with the requirements of Civil Code section 1798.24(b). The Department believes that protecting patient privacy is of the utmost importance. In light of this, the Department has made considerable revisions to section 826, subdivision (f), to help ensure patient privacy.
10.01	Objection No. 10.01 [Proposed Article 2. § 821(g)(3)(A) Delegate Use of CURES] "Under Article 2, section 821, covering prescribers and out-of-state prescribers, it states that delegates must only access CURES through the web-based application. By preventing delegate access to the HIT system, it does not go far enough to ease the technical burden imposed by the gateway solution. Requiring delegates to exit their workflow and log into a web portal, it strains resources and increases the risk of errors." The use of the PDMP correlates with ease of access, making integration critical for the full potential of the PDMP to be realized. Essentially, without integration, the PDMP is not used routinely, creating the risk of fatal treatment errors. Forcing providers or their delegates to leave their workflow, increase their number of clicks, and have to enter credentials or separate logins, provider satisfaction and efficiency is significantly decreased. When the PDMP is integrated into the electronic health record (EHR), it becomes established into the workflow and becomes a natural part of patient record review increasing patient safety and improving care coordination.	Similar comment, see response 4.08.

	It has been established that patients receive better care when provider workflows are streamlined and integrated. This applies to all members of the care team, not solely physicians, as fully informed, efficient staff provide more successful, coordinated care. To ensure all members of the care team are on the same page, they must all access the same information in the most efficient manner available. In this case, this is the HIT system. This difference in workflows is not seen elsewhere, as nurses and other support staff enter clinical notes into the same system. The required use of an alternative system or method for checking patient information results in providers and delegates viewing what may be different information. The risk of varied patient comprehension between staff members could result in misunderstandings or disagreements between care team members. These misunderstandings and disagreements increase the likelihood of errors in patient care which could be devastating. To avoid these risks, allow delegates to access CURES through the same point as providers, through the web system."	
10.02	Objection No. 10.02 [Proposed Article 2. § 821(d)(1)(A)(i) Restrictions on Accessing Patient Information in CURES by Prescriber-Users] "The DOJ is inflicting restrictions on the provider-patient relationship which reduce the reach and efficiency of telehealth delivery and overstepping its authority. These restrictions are the 24 hour window for viewing of a patient's CURES information, and the requirement the patient be 'Under the Care of the Prescriber-User' which is scarcely defined. The DOJ claims the 24 hour restriction is in line with current Health and Safety Codes, but this restriction only applies where a provider is prescribing, ordering, administering, or furnishing controlled substances, and is designed to prevent the provider from checking the information prior to 24 hours and possibly overlooking a more recent prescription which may overlap with the provider's secondary administration of a controlled substance. OCHIN requests the removal of this arbitrary restriction which serves no reasonable purpose.	Similar comment, see response 4.07. With respect to appointments for professional medical consultations, these regulations do not define the qualities of a professional medical consultation.

	OCHIN would also like to request clarification of 'Under the Care of.' Although it is defined as a patient who has had or has an appointment for a professional medical consultation, it is unclear what this means, or whether it can be done virtually. It is OCHIN's concern that where this definition requires a face-to-face initial interaction that patients living in geographically isolated areas will be at a disadvantage to receiving care. Although we agree where it is feasible, this is a reasonable request by a provider to physically examine a patient when they are initially seeking to create a patient-provider relationship, in some cases it may not be a viable option, but this should not prevent the patient from being able to receive care."	
10.03	Objection No. 10.03 "OCHIN recommends moving the CURES program to the California Department of Health Care Services (DHCS). Currently, CURES is housed under the Department of Justice, and is currently viewed as an enforcement tool. Moving the program to DHCS would increase confidence in the program that the focus is on improving health care delivery and patient safety over policing. Just the basic placement of the program has serious implications as to its true purpose and the perception to the public."	No change has been made in response to this comment. This comment is irrelevant to the proposed regulations.
10.04	Objection No. 10.04 [Proposed Article 2. § 821(c)(2) Data Accessible to a Prescriber-User in CURES] "Under the current draft, CURES data is only accessible to providers for a 12 month period, whereas full patient data without a time limitation is available to law enforcement. This arbitrarily gives preference to law enforcement over the clinical care processes of providers with no justification. CURES should primarily be a clinical care tool, as expressed by the statement that the 'CURES PDMP is necessary to ensure health professionals have the necessary data to make informed treatment decisions…' "OCHIN strongly urges the removal of this restriction on providers, as previous prescription use by the patient is arguably more important to clinicians and providers than law enforcement. Where a patient has a history of use or a use disorder, it is	Similar comment, see response 4.06.

	imperative the provider have this information to ensure similar events are avoided when treating a serious condition or ailment."	
10.05	Objection No. 10.05 [Proposed Article 2. § 821(f)(3)(C)(iv)b. Procedures for Use of CURES by Prescriber-Users] "Many small, rural providers continue to operate solely with a P.O. Box due to their geographic isolation. By requiring the use of a physical address to register for CURES, this carves out these small providers. Similar issues occur in e-prescribing where a user must be validated with an authorized address rather than a P.O. Box. Instead, a valid postal address must be permissible for credentialing to better accommodate rural providers. Where governmental agencies such as the Internal Revenue Service (IRS) will accept a P.O. Box where the U.S. Postal Service will not offer mail delivery to a street address, it seems only reasonable that the Department of Justice and CMS should as well. We urge the DOJ to reconsider this arbitrary restriction and make exceptions where a rural provider cannot supply a physical address for credentialing purposes."	No change has been made in response to this comment. The Department is seeking the physical work address of the Prescriber-User, not a mail deliverable address. Furthermore, P.O. Boxes present a unique technical challenge for the CURES registration process, the accommodation of which would require system modifications.
11.01	Objection No. 11.01 [Proposed Article 1. § 820(e) "Bona Fide Research" Defined] Make modifications to §820(e) and add the following definitions to §820: "Program Evaluation and Quality Improvement," "Public Health Surveillance," "Bona Fide Public Health Official," "Program Evaluation and Quality Improvement Purposes," "Public Health Purposes."	The Department accepts this comment in part and has revised former section 820, subdivision (e)(4), to add "program evaluation and quality improvement, public health surveillance, or policy development."
11.02	Objection No. 11.02 [Proposed Article 2. § 826(c)(1) Restrictions on Accessing Data from CURES] "Make the following changes to §826(c)(1) and to other places in the proposed regulations where 'Research' or 'Research Purposes' should be amended to include program evaluation and quality improvement or public health surveillance to ensure consistency with changes proposed in Suggestion 1.	No change has been made in response to this comment. These purposes are now encompassed by the definitions of "Bona Fide Research" and "Research Purposes." Furthermore, the Department intends for this restriction to emphasize the language of Health and Safety Code section 11165(c)(2)(A), which provides that "Data may be provided to public or

	§826(c)(1) A Research Requestor must only obtain data from CURES for educational purposes, Peer Review purposes, statistical purposes, ~~or~~ Research Purposes, Program evaluation and quality improvement purposes, or Public health purposes."	private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes . . ." Therefore, the Department believes that the modifications to section 800, subdivision (f), are a practicable solution to this comment.
11.03	Objection No. 11.03 [Proposed Article 2. § 826(d)(7) Restrictions on Use or Disclosure of Data Obtained from CURES by Researchers] Make the following changes to §826(d)(7), add language "[h]owever, the Department must then give the research requestor the opportunity to revise the presentation of research analysis results so that their publication, dissemination, disclosure, or release of data from CURES would not compromise the identify of any individual."	No change has been made in response to this comment. The proposed regulations do not prohibit opportunities to make revisions and seek further approval from the Department's Research Center.
11.04	Objection No. 11.04 [Proposed Article 2. § 826(e)(4) Procedures for Requesting Aggregated Data from CURES] "Add the following after to §826(e)(4). §826(e)(5). These regulations do not apply to aggregated data from CURES that the Department of Justice makes publicly available either when required by statute or when the Department determines that publication of aggregated data will benefit the health, welfare and safety of California residents. Such data can be downloaded and used by Researchers or other individuals without prior approval or notification of the Department."	No change has been made in response to this comment. Data made publically available by the Department are not restricted by section 826.
11.05	Objection No. 11.05 [Proposed Article 2. § 826(f)(3)(I)(iv) Procedures for Requesting Identified Individual-Level Data and De-Identified Individual-Level Data from CURES] "Delete §826(f)3(I)(iv)…. This section asks the Research Requestor to identify team members who are part of the 'IT team.' This term is ambiguous, not defined in	No change has been made in response to this comment. It is necessary for the Department to understand in what context a Team Member is accessing information from CURES, including a Team Member who is accessing information to provide technical assistance to other Team Members.

	proposed regulations, and not relevant to Department review of research applications."	
11.06	Objection No. 11.06 [Proposed Article 2. § 826(f)(3)(K)(i)f.6. Procedures for Requesting Identified Individual-Level Data and De-Identified Individual-Level Data from CURES] "Delete §826(f)(3)(K)(i)(f)(6)…. This section asks whether data from CURES will be stored on a computer with internet access. Presumably, this requirement has the intended purpose of improving data security. However, in the 21st century internet access is a requirement for doing research, so Department should presume that all data released to researchers is stored on computers that have internet access. Asking about internet access will not help Department to further the goal of protecting the security of the patient information contained within CURES."	No change has been made in response to this comment. It is necessary for the Department to understand all aspects the security measures employed by the Bona Fide Researcher to prevent the unauthorized access of any hard copy or electronic file containing Identified Individual-Level Data or De-Identified Individual-Level Data from CURES. Furthermore, there is no undue burden imposed upon a Bona Fide Researcher by this requirement; inclusion of this information requires negligible effort.
11.07	Objection No. 11.07 [Proposed Article 2. § 826(f)(3)(K)(vii)b. Procedures for Requesting Identified Individual-Level Data and De-Identified Individual-Level Data from CURES] "Make the following changes to §826(f)(3)(K)(vii)(b)…. The Research Requestor must obtain an individual's written consent ~~not more than 30 days before obtaining that individual's Identified Individual-Level Data from CURES, or in an~~ and may only obtain that individual's identified individual-level data from CURES during the access period agreed to by that individual in that individual's written consent. A Research Requestor must not obtain an individual's Identified Individual-Level Data from CURES outside of ~~that 30 days or~~ the access period agreed to in that individual's written consent, absent the receipt of renewed written consent."	In response to comments from the directly affected public, the Department revised section 826, subdivision (f), to limit disclosures of Identified Individual-Level Data from CURES. These revisions restrict disclosures only to disclosures that are consistent with the requirements of Civil Code section 1798.24(b). The Department believes that protecting patient privacy is of the utmost importance. In light of this, the Department has made considerable revisions to section 826, subdivision (f), to help ensure patient privacy. Regarding this time limit, the Department has revised former section 826, subdivision (f)(3)(K)(vii)b., to more accurately specify that "Bona Fide Researcher must obtain an individual's written consent not more than 30

		days before obtaining that individual's Identified Individual-Level Data from CURES, or within the time limit agreed to by the individual in the individual's written consent." Civil Code section 1798.24(b) permits agency disclosure of identifying information "With the prior written voluntary consent of the individual to whom the information pertains, but only if that consent has been obtained not more than 30 days before the disclosure, or in the time limit agreed to by the individual in the written consent." The Department believes that incorporation of this temporal restriction is appropriate in order to safeguard patient privacy.
11.08	Objection No. 11.08 [Proposed Article 2. § 826(f)(4) Procedures for Requesting Identified Individual-Level Data and De-Identified Individual-Level Data from CURES] Make the following changes to §826(f)(4), remove language ~~the Research Requestor, including all members of the research team, must complete and submit a notarized identification verification. After the notarized identification verification is received~~.	No change has been made in response to this comment. A notarized identification verification is necessary to ensure the identity of the Bona Fide Researcher and all Team Members. The Department believes that verifying the identity of the Bona Fide Researcher and all Team Members is critical to the approval of a research project and ensures that any information disclosed as part of a research project is disclosed to properly identified individuals. Therefore, the Department believes this is an appropriate restriction in order to safeguard patient privacy.
11.09	Objection No. 11.09 [Proposed Article 2. § 826(f)(6) Procedures for Requesting Identified Individual-Level Data and De-Identified Individual-Level Data from CURES] "Make the following additions to §826(f)(6)	The Department accepts this comment in part and has revised former section 826, subdivision (f)(6), to specify that "The Department's Research Center will notify the Bona Fide Researcher to submit a project renewal before

	(6) A Research Requestor must complete the Department's Research Center renewal process during the 90 days before the expiration date of the approved Data Request Application. The Department will notify the research requester of the expiration data and need to submit a renewal requirement 90 days before the expiration date of the approved Data Request application. A project renewal must be submitted in writing, on the Research Requestor's official letterhead, to the Department's Research Center, and include all of the following information…"	the expiration date of the approved Data Request Application." The Department believes that this revision sufficiently address the concern raised by this comment.
11.10	Objection No. 11.10 [Proposed Article 2. § 826(f)(5) Procedures for Requesting Identified Individual-Level Data and De-Identified Individual-Level Data from CURES] "Make the following changes to §826(f)(5) (5) If the Data Request Application is approved, and is for Identified Individual-Level Data, access by the Bona Fide Researcher may be restricted to the Department's Secure Lab. To access the Department's Secure Lab, an approved Bona Fide Researcher and Team Members who will access or analyze Identified Individual-Level data must successfully pass a fingerprint criminal history background check through the Department. If the approved Bona Fide Researcher successfully passes the fingerprint criminal history background check, the Department's Research Center will send a written approval letter to the approved Bona Fide Researcher and contact the approved Bona Fide Researcher to schedule on-site access by the approved Bona Fide Researcher and Team Members who will access or analyze Identified Individual-Level data. (A) The Department Research Center will work with the Research Requester to implement procedures to ensure that the approved research can be conducted in an efficient, timely, and secure manner when research team members are working on projects that involve access to the Secure Lab. These procedures and protocols will be tailored to the needs of each individual project that involves access to the Secure Lab. Procedures and protocols may include but are not limited to…'"	In response to comments from the directly affected public, the Department revised section 826, subdivision (f), to limit disclosures of Identified Individual-Level Data from CURES. These revisions restrict disclosures only to disclosures that are consistent with the requirements of Civil Code section 1798.24(b). The Department believes that protecting patient privacy is of the utmost importance. In light of this, the Department has made considerable revisions to section 826, subdivision (f), to help ensure patient privacy. With respect to former section 826, subdivision (f)(5), the Department has removed this section in its entirety because it became unnecessary following the substantial revisions to section 826, subdivision (f), referenced above.

11.11	Objection No. 11.11 [Proposed Article 2. § 826 Research] Add provision for a procedure to obtain data from CURES for Program Evaluation and Quality Improvement focused on the CURES Program.	No change has been made in response to this comment. These purposes are already encompassed by the definitions of "Bona Fide Research" and the request processes enumerated in section 826.
11.12	Objection No. 11.12 [Proposed Article 2. § 826 Research] Add provision regarding the process by which data from CURES may be used for Public Health Surveillance or other public health purposes.	No change has been made in response to this comment. These purposes are already encompassed by the definition of "Bona Fide Research" and the request processes enumerated in section 826.

PUBLIC COMMENTS AND DEPARTMENT OF JUSTICE RESPONSES

15-DAY COMMENT PERIOD

#	Summarized Comment	DOJ Response
12.01	Objection No. 12.01 [Proposed modifications to Article 2. § 826 Research] "In reviewing the regulations, it appears the proposed regulations released to the public for comment in October of 2019 provided two appropriate avenues for Bona Fide Researchers to access II-Level Data for the purposes of Bona Fide Research (as defined in §826(f). These provisions were included in the initial regulations and were considered during the public comment and public hearing period. It is further my understanding that following the public comment/hearing phase, the proposed regulations were revised and subsequently released on January 16, 2020, with a 15-day comment period ending January 31, 2020. Absent from these revised regulations were the sections allowing for research access to II-Level Data without the prior written consent of the patient. (§826(f)(3)K(3)(vii)(a) and §826(f)(5). Despite requests to DOJ, my office has been unable to identify the rationale and reasoning for elimination of these provisions. Clearly, if they were inconsistent with any existing state or federal laws, they would not have been included in the original proposals. Since the stringent process for obtaining II-Level Data outlined in the original proposal has already in place and has been used for many years to grant research access and thus could not be in violation of the Health Insurance Portability and Accountability Act or other existing Federal or States laws/regulation, it can only be assumed that the removal of this access was at the request of interested stakeholders. While all stakeholder input should be considered and valued, it should also be considered against any potential downside. If removal of these provisions are in conflict with State or Federal statutes or regulations, I would appreciate receiving information delineating the conflicts. Should the eliminated sections actually be in conflict with existing laws or regulations, I would urge DOJ to continue to explore other options that would allow for the II-Level Data to	No changes are being made in response to this comment. The Department received diametrically opposed comments on this topic. The Department has decided to err on the side of privacy and thus has decided not to make this change. As currently drafted, the regulations authorize, among other things, release of (i) Identified Individual-Level Data to a Bona Fide Researcher with the prior written voluntary consent of the individual for whom such data is being requested, and (ii) De-Identified Individual-Level Data without such consent. Bona Fide Researchers may continue to benefit from such access. The Department is committed to ensuring beneficial access to CURES information for educational, peer review, statistical, and research purposes. But the Department is also committed to ensuring patient privacy. As such, the Department intends to continue to monitor researcher needs for information in the CURES database and possibly to propose additional, future regulations. The Department encourages the commenters to submit this and other comments in future rulemaking proceedings.

	be available for Bona Fide Research without having to obtain individual written permission. In the absence of such conflict, I would urge the Department to reinstate §826(f)(3)K(3)(vii)(a) and §826 (f)(5) as originally proposed, back into the regulations. The elimination of these sections from the final regulations would preclude Bona Fide Researchers and state agencies from accessing statewide II-Level CURES data for research and public health purposes. Requiring researchers and public agencies to obtain individual patient consent is both impracticable and impossible. As an example, it would be impossible for a researcher to cross reference Department of Public Health death certificate data with CURES data to ascertain whether an individual who died from an opioid overdose was cut off from legitimate prescriber issued prescriptions and instead turned to the illicit market in order to obtain other opioid-based drugs such as heroin and fentanyl. Without II-Level Data for this type of research it would be impossible to identify whether in this instance, trends in prescriber behavior is driving patients underground for their medication. Without understand the underlying cause and what is driving patient behavior, how could we take appropriate steps to curb both prescriber and patient behavior? Imagine trying to conduct a research project in even a small county like Mendocino. In 2018 there were 87,550 opioid prescriptions issued in Mendocino, a county with a population just under 90,000. If we assume just 10% of the population received an opioid prescription and the sampling for the study was even just 10% of that, it would represent nearly 900 hundred individuals researchers would need to contact in order to obtain permission. Clearly, this is an insurmountable obstacle for research purposes. Further, I would like to add that in my opinion, the procedures, protocols and requirements for researchers to access II-Level Data are quite stringent. The fact that II-Level-Data never leaves the secure DOJ environment as individually identified data, that data transmission requirements for privacy and patient protection are so rigid, that background checks and fingerprinting requirements for are employed for key researchers and ultimately that DOJ has final review of proposed publications, establishes a	

	reasonable basis for patient and prescriber protection under the Controlled substance Utilization Review and Evaluation System (CURES)."	
13.01	Objection No. 13.01 [Proposed modifications to Article 1. § 820(i) "Connectivity Fee" Defined] "Article 1. §820. (i) indicates that the 'Connectivity Fee' has been set at a $1500. It appears from the proposed regulations that this fee will be the same for a rural solo family physician as it would be for the entire Kaiser Permanente organization. This amount is cost prohibitive, particularly for family physicians and other primary care physicians whose payment rates are significantly lower than all other physicians and for small and solo physicians with partial or complete ownership who bear responsibility for infrastructure investments in their practice…. CAFP urges the Department to adopt a sliding scale or allow for hardship exemptions to the cost of the Connectivity Fee."	No change has been made in response to this comment. This is a one-time fee, which does not create an ongoing fiscal impact, and a sliding scale would significantly complicate administration of this fee. Furthermore, integration is voluntary.
13.02	Objection No. 13.02 [Proposed modifications to Article 1. § 820(q) "Delegate" Defined] "In Article 1. §820. (q), 'Delegate' is defined as 'an individual to whom a Prescriber-User or Pharmacist-User has delegated authority to order Patient Activity Reports from CURES under Business and Professions Code section 209, subdivision (b).' The quality of patient care improves when clinical team members under physician supervision have flexibility to accomplish tasks that are well within their abilities and scope of practice. By limiting the Delegate to ordering reports, the proposed regulations sacrifice the ability to streamline care without gaining any patient data confidentiality. HIPAA and other patient privacy laws already govern what can and cannot by shared by health care providers…. CAFP urges DOJ to establish the greatest amount of flexibility possible within the scope of existing clinical guidelines for Delegates to undertake requirements associated with CURES, including allowing Delegates to satisfy the View Notification requirement as part of a HIT system."	No change has been made in response to this comment. Existing law limits delegate functionality. AB 528, the relevant aspect of which will become effective on July 1, 2021, will amend Business and Professions Code section 209 and Health and Safety Code section 11165.1 to allow delegates to access information from CURES on behalf of a Health Care Practitioner or Pharmacist. The Department will address this aspect of delegate access in a subsequent regulations package in response to the amendments of AB 528. With respect to the View Notification, the Department has removed this requirement in its entirety from section 828 of the proposed regulations. Therefore, the Department will make no changes in response to this comment.

13.03	Objection No. 13.03 [Proposed modifications to Article 2. § 821(c)(2) Data Accessible to a Prescriber-User in CURES] "Article 2. §821. (c)(2) intends to limit Prescriber-User access to patient information to no more than 12 months. At the heart of the specialty of family medicine is an ongoing, continuous relationship with a patient that can last decades and often incorporates several generations of one family. This type of longitudinal relationship between patient and physician has proven to be a key factor in maintaining an individual's health. Limiting information to merely 12 months hurts a physician's ability to track care over an extended amount of time and creates obstacles to diagnosis and health trend identification. The proposed limitation is also concerning given that the draft regulations allow Regulatory Agency Officials to obtain data from CURES for as long as the data is retained in CURES. CAFP sees no justification for why prescription data history should be limited, particularly when it is often necessary for a clinician to make appropriate prescribing decisions based on that data.... CAFP urges the Department to extend a physician's access to all the data that exists within CURES for a patient in their care. In addition, a licensee must be able to query their own data and activity for as long as the data exists, with the ability to verify and correct errors, if necessary."	Similar comment, see response 16.06.
13.04	Objection No. 13.04 [Proposed modifications to Article 2. § 821(f)(2) Procedures for Use of CURES by Prescriber-Users] "Article 2. §821. (f)(2) requires a patient's care team to create a new CURES password every 90 days, a frequency many of our members consider to be too high. This task is often accompanied by numerous other steps, including email verification, and leads to poor password storing practices and weakened security. It encourages the use of weaker passwords and wastes considerable time. These password-changing requirements can actually increase risk and are considered obsolete…. CAFP urges the Department to require users to create a strong password that they will be able to use for long periods of time, and develop a method to identify and alert users to unauthorized logins."	No change has been made in response to this comment. The password policy is a requirement of the minimum standard of security set forth by Criminal Justice Information Services Division systems to ensure continuity of information protection. Furthermore, the essential premise of this security standard is to provide the appropriate controls to protect Department information, including CURES information, from unintended or unauthorized dissemination, whether at rest or in transit.
13.05	Objection No. 13.05 [Proposed modifications to Article 2. § 825(d)(2) / (d)(3) / (d)(5) Restrictions on Use or Disclosure of Data Obtained from CURES by Law Enforcement]	Similar comment, see response 16.11.

	"Article 2. §825. (d)(3) indicates that a search warrant or court order is required as a condition for accessing a Patient Activity Report. CAFP could not agree more with that provision. A higher evidentiary threshold to access CURES data is necessary as it contains patient information and it ensures that Law Enforcement Officials cannot access it outside of their statutorily mandated duties related to CURES. However, in Article 2. §825. (d)(5), this same evidentiary threshold is not similarly applied – access to a Prescriber History Report or a Pharmacy History Report does not require a search warrant or court order, but only an investigation (e.g., case number and violation code or crime code), despite major commonality in the data contained in each. In addition, the proposed regulations list a number of exceptions to the search warrant or court order requirement, including that law enforcement officials may access a Patient Activity Report under an administrative subpoena…. CAFP urges the Department to delete the provisions in 825(d)(5) which create significant exceptions to the warrant or court order requirement in (d)(3)(C). In addition, CAFP urges the Department to add the requirement for a search warrant or court order to 825(d)(2)."	
13.06	Objection No. 13.06 [Proposed modifications to Article 2. § 826(f) Procedures for Requesting Identified Individual-Level Data and De-Identified Individual-Level Data from CURES] "Article 2. §826. (f) allows for a Researcher to have access to Identified Individual-Level Data. CAFP remains concerned about the access and use of this data. In the 15-Day Modification, the Department continues to define "Aggregated Data" to mean data that does not include Personal Identifying Information as set forth in Penal Code section 530.55, subdivision (b). Additionally, the Department defines 'De-Identified Individual-Level Data' to mean individually disaggregated data that does not include any Personal Identifying Information. Given that the Department cites Personal Identifying Information, which covers identifying information that differs from the data elements contained in HIPAA, and given the risk for re-identification even when deidentified, CAFP urges much more detail in the proposed regulations. CAFP is further concerned that the definition of 'research requestors' has been amended to now reference 'public or private' entities. The continued use of vague language and	In response to comments from the directly affected public, the Department revised section 826, subdivision (f), to limit disclosures of Identified Individual-Level Data from CURES. These revisions restrict disclosures only to disclosures that are consistent with the requirements of Civil Code section 1798.24(b). The Department believes that protecting patient privacy is of the utmost importance. In light of this, the Department has made considerable revisions to section 826, subdivision (f), to help ensure patient privacy.

	limited parameters in the regulations highlight the insufficient checks in place to prevent or limit a violation of patient and provider privacy.... If the Department remains unwilling to severely limit access to the sensitive data in CURES, CAFP urges that the Department provide specificity regarding the methodology it intends to employ for data exclusion (e.g., data fields, summary counts, etc.) and access by outside entities."	
14.01	Objection No. 14.01 [Proposed modifications to Article 2. § 826(f) Procedures for Requesting Identified Individual-Level Data and De-Identified Individual-Level Data from CURES] "I am writing on behalf of the California Department of Public Health (CDPH) to urge that the final regulations governing CURES data access should continue to make CURES as available as possible for research and public health purposes, as has been the case in the past. Specifically, access to statewide-identified individual-level CURES data for research and public health purposes should continue to be available to researchers at state agencies, the University of California, and other bona fide research agencies. Now is not the time to create new restrictions that will prevent CDPH, researchers, and other state agencies from working with CA Department of Justice (DOJ) to work on all fronts to reduce deaths due to overdose and addiction. To this end, we recommend that sections §826(f)(3)K(3)(vii)(a) and §826(f)(5) , which have been deleted in the modified proposed regulations, be restored in the final published regulations. These provisions guarantee access to identified individual-level CURES data as required under Civil Code 1798.24(t) and stipulate the mechanism for accessing such data via DOJ's secure data lab…. If DOJ has already determined to make the above-mentioned changes, we would request that DOJ include an exemption from the new regulations for CDPH (and possibly all CA state agencies)."	No changes has been made in response to this comment. The Department received diametrically opposed comments on this topic. The Department has decided to err on the side of privacy and thus has decided not to make this change. As currently drafted, the regulations authorize, among other things, release of (i) Identified Individual-Level Data to a Bona Fide Researcher with the prior written voluntary consent of the individual for whom such data is being requested, and (ii) De-Identified Individual-Level Data without such consent. Bona Fide Researchers may continue to benefit from such access. The Department is committed to ensuring beneficial access to CURES information for educational, peer review, statistical, and research purposes. But the Department is also committed to ensuring patient privacy. As such, the Department intends to continue to monitor researcher needs for information in the CURES database and possibly to propose additional, future regulations. The Department encourages the commenters to submit this and other comments in future rulemaking proceedings.

15.01	Objection No. 15.01 [Proposed modifications to Article 2. § 826(f) Procedures for Requesting Identified Individual-Level Data and De-Identified Individual-Level Data from CURES] "[T]he requirement that patients and, conceivably, prescribers consent individually to the Department of Justice's (DOJ) releasing their CURES records would, effectively, make it impossible for researchers to access identified individual-level data. The proposed change would be severely detrimental to public health research and is entirely unnecessary. It is detrimental to public health research because identified individual-level data is necessary to conduct research vital to combat the prescription opioid epidemic in California. And it is unnecessary because the safeguards DOJ requires as a condition for releasing identified data are wholly sufficient to safeguard patients' and prescribers' legitimate privacy concerns. Section §826(f)(3)(K)(3)(vii) of the proposed regulations stipulates that 'Identified Individual-Level Data may be disclosed under Civil Code section 1798.24, subdivision (b), only with the prior written voluntary consent of the individual to whom the data pertains.' (Section §820(aa) appears to circumscribe Identified Individual-Level Data only to patients, defining these data as 'individually disaggregated data that includes the PII [personally identifying information] of any *patient* to which that data relates' [emphasis added]. However, a plain reading of §826(f)(3)(K)(3)(vii) also seems to include prescribers within the purview of identified data.) Clearly, the requirement that all individuals submit written voluntary consent would make all research involving identified data—save, perhaps, a handful of small clinical studies—infeasible…. Of course, patients (and doctors) have legitimate apprehensions about sensitive, private data being released—especially given the socially fraught nature of opioid use. Yet adequate data protocols can address these concerns completely, combining elements from the new proposal with others already on the books, while also affording researchers access to identified data. DOJ could (and already does, in some instances) require all research using identified data to be carried out in its secure data lab; see, e.g., current §826(5), which requires all researchers to submit to background checks and provide	No change has been made in response to this comment. The Department received diametrically opposed comments on this topic. The Department has decided to err on the side of privacy and thus has decided not to make this change. As currently drafted, the regulations authorize, among other things, release of (i) Identified Individual-Level Data to a Bona Fide Researcher with the prior written voluntary consent of the individual for whom such data is being requested, and (ii) De-Identified Individual-Level Data without such consent. Bona Fide Researchers may continue to benefit from such access. The Department is committed to ensuring beneficial access to CURES information for educational, peer review, statistical, and research purposes. But the Department is also committed to ensuring patient privacy. As such, the Department intends to continue to monitor researcher needs for information in the CURES database and possibly to propose additional, future regulations. The Department encourages the commenters to submit this and other comments in future rulemaking proceedings.

	biometric information. In addition, data could be encrypted and provided to researchers who comply with all the security measures outlined in §826(f)(3)(K)(i)(f) of the proposed changes, which include encryption methods, anti-virus software, secure networks, and elimination of individual identifiers, among others. Finally, the proposed CURES regulations prevent publications from inadvertently revealing individual identities by requiring researchers to provide DOJ with advance copies of all articles submitted for publication (§826(d)(3)) and prohibiting researchers from disseminating documents in which indirect identification is a 'reasonable possibility' (§826(d)(7)). CDPH, of course, complies with all these requisites: we have a secure local storage system, data encryption methods, secure local computers subject to strict password protocols, and rigorous data de-identification standards that prohibit data re-identification. In short, the proposed change requiring individual consent for releasing identified data is a solution in search of a problem. The sanctity of individual data privacy may be kept intact, even as DOJ advances crucial public health research by allowing researchers to access identified data."	
16.01	Objection No. 16.01 [Proposed modifications to Article 1. § 820(e) "Bona Fide Research" Defined] "We appreciate and support the Department's acceptance of this amendment in the 15-Day Modification."	Because no further recommendation is made, the Department considers this comment resolved.
16.02	Objection No. 16.02 [Proposed modifications to Article 1. § 820(f) "Bona Fide Researcher" Defined] "We appreciate and support the Department's acceptance of this amendment in the 15-Day Modification."	Because no further recommendation is made, the Department considers this comment resolved.
16.03	Objection No. 16.03 [Proposed modifications to Article 1. § 820(b) / (p) "Aggregated Data" / "De-Identified Individual-Level Data" Defined]	No change has been made in response to this comment. The definitions of De-Identified Individual-Level Data and Aggregated Data

	"In the 15-Day Modification, the Department continues to define 'Aggregated Data' to mean data that does not include PII or Personal Identifying Information as set forth in Penal Code section 530.55, subdivision (b), and is presented in summary counts. Additionally, the Department defines 'De-Identified Individual-Level Data' to mean individually disaggregated data that does not include any PII, or Personal Identifying Information as set forth in Penal Code section 530.55, subdivision (b). Given that the Department is citing PII, which covers identifying information that differs from the data elements contained in HIPAA, and given the risk for re-identification even when deidentified, CMA reiterates its request that the Department provide specificity regarding the methodology it intends to employ for data exclusion (e.g., data fields, summary counts, etc.)."	have appropriate safeguards in place to protect the privacy of patients. Moreover, the Department does not make De-Identified Individual-Level Data or Identified Individual-Level Data publically available; its provision is restricted to qualifying Bona Fide Researchers who satisfy all the requirements of these regulations. Furthermore, the Department has broadly defined Personal Identifying Information (PII) in order to be intentionally over-inclusive of identifying information. Thus, the list of information included in the Department's definition of PII encompasses the identifiers listed in HIPAA. However, in response to comments from the directly affected public, the Department revised section 826, subdivision (d)(6), to further specify the conditions of release, disclosure, or dissemination of data or documents from CURES that may have a reasonable possibility of directly or indirectly identifying any individual. These revisions include the addition of section 826, subdivision (d)(6)(A)(xi), which directly lists HIPAA identifiers. Access to De-Identified Individual-Level Data and Aggregated Data is necessary for research endeavors. However, the Department believes that protecting patient privacy is of the utmost importance. In light of this, the Department has made considerable revisions to section 826 to help ensure patient privacy.

16.04	Objection No. 16.04 [Proposed modifications to Article 1. § 820(eee) "Research Requestor" Defined] "In our previous comments, we expressed concerns regarding the definition of 'research requestors,' in addition to Bona Fide Researchers, who could request data from CURES. While we appreciate that the 15-Day revision no longer includes references to 'research requestors,' the proposed regulations now reference 'public or private' entities and we are concerned that there are still no parameters or restrictions placed upon what constitutes a public or private entity for purposes of accessing aggregated CURES data. As expressed earlier, given the probability for re-identifying deidentified data and lack of detail on the Department's procedures to aggregate CURES data, CMA is concerned that there are not sufficient checks in place to prevent or limit the potential to violate patient privacy. Particularly as more third-party data companies assemble and track statistical health information, CMA suggests the Department be mindful that even aggregated information can be used in ways that many patients did not ever consent to nor consider. CMA urges the Department clarify the definition of a public or private entity."	No change has been made in response to this comment. The Department believes there are appropriate safeguards in place to protect the privacy of patients. The terminology of "public or private entities" is introduced by our governing statutes. Health and Safety Code section 11165, subdivision (c)(2)(A), provides that "[d]ata may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, if patient information, including any information that may identify the patient, is not compromised." The Department believes that the safeguards it has established to provide data to public or private entities for educational, peer review, statistical, or research purposes are appropriate to protect patient privacy and prevent identification. Such safeguards include the restriction that public or private entities that do not qualify as a Bona Fide Researcher are limited to accessing or obtaining Aggregated Data from CURES. Due to the strict limitations on access to data from CURES applicable to public or private entities that do not qualify as a Bona Fide Researcher, it is unnecessary to further define the qualifying parameters of a public or private entity. With no relation to this comment, the Department, in an effort to clarify the text of the proposed regulations, has removed section 820,

		subdivision (eee), "Research Requestor," and made revisions to section 826 to better specify which subdivisions are applicable to public or private entities, Bona Fide Researchers, or Team Members.
16.05	Objection No. 16.05 [Proposed modifications to Article 1. § 820(nnn) / (ooo) "Under His or Her Care" / "Under the Care of" Defined] "CMA continues to disagree with the Department's establishment of the provider-patient relationship (inclusive of, and hereinafter referred to as the 'physician-patient relationship'), in the context of accessing information in CURES…. In the 15-Day Modification, the Department has defined Subdivision (nnn) 'Under His or Her the Practitioner's Care' or referred to as Subdivision (ooo) 'Under the Care of' to encompass any of the following situations: ▪ The patient has had a professional medical consultation with the 'Prescriber-User,' or physician, and has an ongoing physician-patient relationship; ▪ The patient has an appointment for a professional medical consultation with the physician; or, ▪ The patient has not had a professional medical consultation with the physician, but the physician is part of the patient's 'organized health care arrangement' and the patient has a physician-patient relationship with the physician. ▪ The patient presents to an emergency department for treatment and the Prescriber-User or Interstate Prescriber is involved in or oversees the intake or professional medical consultation of that patient within the emergency department. According to the Initial Statement of Reasons, the Department states that this definition is necessary because it provides specificity to the vague language used in statute as a condition of CURES access. The Department asserts that clearly defining the circumstances under which a physician may consider a patient to be 'Under His or Her	No change has been made in response to this comment. Contrary to the suggestion of the commenter, these regulations do not define the establishment of the provider-patient relationship. These regulations seek to clarify and make specific the primary statutory limitation on the circumstances under which a Prescriber or Pharmacist may access a patient's records—namely, that the patient must be under "the practitioner's care" or "the pharmacist's care." CURES users have minimal guidance, if any, in understanding or applying this statutory constraint as applied to the access of patient information in CURES. Regulations are an appropriate vehicle to provide this clarity. These regulations provide specific, authorizing scenarios when a patient is under the care of a Prescriber or Pharmacist. While a provider-patient relationship is one of the necessary conditions for access to patient information in two of the four authorizing scenarios, the Department makes no attempt to define the provider-patient relationship in this context, or any other. Because the existence of this relationship is a factually and legally complex

	Care' provides the medical community, regulatory entities and affected public with a defined standard under which use of CURES is justifiable. CMA, as part of the medical community, wholeheartedly disagrees with the Department's justification to define 'Under His or Her Care.' Establishment of the physician-patient relationship is a complex legal question that has major implications for determining when a physician has a duty to treat, when a physician may be sued for malpractice, when a physician has 'abandoned' a patient and other serious matters. In fact, California courts have yet to decide when a physician–patient relationship has been established in many particular circumstances…. It is not within the purview of the Department to define the context of the physician-patient relationship, on a matter that has not yet been decided within California, and which is beyond the scope of the Department's rulemaking authority conferred to the Department." CMA continues to urge the Department to withdraw its proposed definitions for 'Under His or Her Care' and 'Under the Care Of' and leave the meaning as defined in the statute, Health & Safety Code §11165.1(a)(1)(A)(i)."	question, these regulations recognize that the licensed clinicians and their institutions, not the CURES Program, must determine if and when that relationship exists. Furthermore, clarifying the circumstances under which a Prescriber or Pharmacist may access patient information, the Department helps to inform patients regarding the point at which they should expect that providers will have access to their patient information.
16.06	Objection No. 16.06 [Proposed modifications to Article 2. § 821(c)(2) Data Accessible to a Prescriber-User in CURES] "In the original regulations, per §821(c)(2), the Department proposed that a Prescriber-User may access patient information in CURES for a search period not to exceed 12 months from the date of the search. According to the Initial Statement of Reasons, this subdivision is 'necessary to limit the temporal scope of information that a Prescriber-User may access, to only that information which the Department has determined is authorized and is necessary to assist a Prescriber-User in appropriately prescribing to a patient Under His or Her Care.' The Department claimed that limiting the search period to 12 months was necessary to ensure that a Prescriber-User is only permitted to access to data for patients currently Under His or Her Care, pursuant to Health & Safety Code	No change has been made in response to this comment. In response to comment 4.06, among other public comments, the Department revised section 821, subdivision (c)(2), to replace "12 months" with "24 months." Until now, there has been minimal interest expressed in extending this access period. In response to these public comments, the Department has doubled the original access period to allow practitioners access to additional information that may better inform their ability to make appropriate prescribing decisions. However, in appearing to reject any temporal constraints, this comment

	§11165.1 The 15-Day Modification proposes extending the time period to 24 months from the date of the search. While this is a small improvement over 12 months, there is still no adequate justification provided as to why the Department should limit how much prescription data history is necessary for a clinician to make appropriate prescribing decisions. PDMPs can be a useful tool to support safer prescribing and dispensing practices for scheduled medications. An American Medical Association survey found that 87 percent of responding physicians supported PDMPs because they help prescribers become more informed about a patient's prescription history. PDMPs may also be a helpful tool to identify patients who merit an assessment for a substance use disorder. The course of a patient's treatment may see them on multiple medications and visiting several doctors over the treatment time line, whether it's an acute condition or chronic disease; PDMPs are a useful decision support tool for prescribers when considering whether to prescribe a controlled substance or a medication that could have harmful drug-drug interactions with a controlled substance prescribed or dispensed by another party. The Department has limited the search term to access patient data to 24 months for Prescriber-Users and Pharmacist-Users; however, both authorized Regulatory Agencies and Law Enforcement Entities are permitted to access patient data for the full scope of the patient history, with no temporal limitations at all. In many ways, the Department is inappropriately setting forth a standard of care – is the expectation that a Prescriber-User would only need to review 24 months of prescription data history to ensure they are making 'appropriate prescribing' decisions? As mentioned earlier, CURES is also a clinical-decision making tool and should be prioritized as such. CMA urges the Department to consult with clinicians to determine the most appropriate time frame for patient prescription data history that supports and optimizes health care delivery at the point of care. At a minimum, CMA requests the Department to explain its methodology in determining why 24 months is now the appropriate search term for physicians to access patient prescription history in making 'appropriate prescribing' decisions – particularly when it appears that the technological	fails to consider patient privacy as a countervailing interest when establishing the access period for practitioners to search CURES. Protecting patient privacy is of the utmost importance to the Department. As such, the Department believes it is appropriate to impose reasonable limitations on the search period for practitioners accessing patient information. Furthermore, the Department's revised access period aligns more closely with the access periods of other state prescription drug monitoring programs.

	capability is there for others to search the full patient history, such as with Regulatory Agencies and Law Enforcement Entities."	
16.07	Objection No. 16.07 [Proposed modifications to Article 2. § 821(d)(1)(A) Restrictions on Accessing Patient Information in CURES] "Some of the complications stated earlier in defining "Under the Care of" similarly arise in this Subdivision. The Department has proposed that a Prescriber-User must only access patient information to 'Treat a patient Under the Care of the Prescriber-User.' Again, this brings up legal issues related to establishment of the physician-patient relationship that have not yet been settled in California. Even the term 'treat' raises concerns as it supposes that there is a duty to treat and diagnose a patient in that context. Equally concerning, the Department is proposing a time limit upon when the CURES database must be consulted prior to providing medical treatment…. In attempting to put parameters on accessing patient information in CURES when an 'appointment for a professional medical consultation' has been established, the Department has overstepped its authority. Not even the duty to consult mandate in statute considers such – for purposes of compliance, the requirement states that a physician must consult CURES no earlier than 24 hours or the previous business day, prior to the prescribing, ordering, administering, or furnishing of a controlled substance to the patient. (Health & Safety Code §11165.4(a)(2); S.B. 482, Stats. 2016, ch. 708.). However, this is prior to the act of prescribing, ordering, administering, or furnishing of a controlled substance to the patient, and it certainly doesn't preclude a physician from checking CURES outside of the 24 hour window. Moreover, there are many instances when a physician may consider taking on a complex patient within their panel, but may need to access the patient prescription history to properly inform the medical examination. Obtaining a full medical history will be the basis for a risk assessment between the clinician and patient, and this process is typically done prior to the actual physical examination. In the original proposed regulations, the Department proposed that access to CURES information on any prospective patients may occur no earlier than 24 hours prior to the appointment. The 15-Day Modification	No change has been made in response to this comment. In response to comment 4.07, among other public comments, the Department revised section 821, subdivision (c)(2), to replace "24 hours, or the previous business day" with "7 days." Appointments are sometimes scheduled months in advance. Some of those appointments will be canceled before the scheduled visit. The Department believes that access to a patient's information should have a reasonable proximity to the consultation wherein that patient will be treated when there is no preexisting provider-patient relationship. Furthermore, this restriction is intended to provide patients with guidelines that provide them a reasonable expectation as to when a Health Care Practitioner may access their data. The Department considered disallowing access to a patient's records until the patient had appeared at the consultation and signed relevant disclosure forms. However, the Department believed that this would be too restrictive in many scenarios, and took this modified approach. In response to this comment the Department has further extended this period to 7 days, which the Department believes is an appropriate amount of time for a Health Care

	amends this provision to state that the Prescriber-User must not access the patient's information CURES earlier than 7 days before the appointment. While this is an improvement over the previous 24-hour requirement, it is still unclear why this requirement is necessary and it may still have a negative impact on clinician workflow and how medical practices structure their patient assessments. Similar to our request for Subdivision (nnn) 'Under His or Her Care' and Subdivision (ooo) 'Under the Care of,' CMA strongly suggests that the Department withdraw Subdivision (d)(1)(A) and Subdivision (d)(1)(A)(i)."	Practitioner to consult CURES in this circumstance, while still balancing patient privacy. This would allow a Health Care Practitioner to consult CURES a week prior to an appointment, though the Department would note that in order for a Health Care Practitioner to satisfy the duty to consult CURES as set forth in Health and Safety Code section 11165.4, the Health Care Practitioner would be required to consult CURES no earlier than 24 hours, or the previous business day, before the Health Care Practitioner prescribes, orders, administers, or furnishes a Controlled Substance to the patient. Regarding the comment that inclusion of the term "treat" is problematic, the Department notes that this term is introduced by our governing statutes. Health and Safety Code section 11165.1, subdivision (a)(1)(B), provides that "a subscriber may be suspended, for reasons which include, but are not limited to, the following . . . [a]ccessing information for a reason other than to diagnose or treat a patient, or to document compliance with the law." Regarding the comment relating to the "under the care of" terminology, see comment 4.05 for more information.
16.08	Objection No. 16.08 [Proposed modifications to Article 2. § 821(g)(3)(A) Delegate Use of CURES]	Because no further recommendation is made, the Department considers this comment resolved.

	"We appreciate and support the amendment to Subdivision (g)(3)(A) that now states that Delegates may access the Web-Based Application, but are not limited to only using the Web-Based Application."	
16.09	Objection No. 16.09 [Proposed modifications to Article 2. § 823(a) Eligibility for Access to Data from CURES by Interstate Prescribers and Interstate Pharmacists] "Currently, the CURES database contains information related to controlled substances prescriptions dispensed within California. Consequently, when a physician consults a patient activity report in CURES prior to writing a prescription, the patient's prescription history does not reflect prescriptions written in other states. Many states already participate in one of several interstate data sharing hubs that allow for the exchange of prescription information across state lines. CMA is supportive of a comprehensive CURES database, but we have concerns that there is a lack of adequate privacy protections for the protected health information contained in CURES, and thus, sharing of such data across state lines could weaken the state's ability to meet a patient's reasonable expectation of privacy. Historically, the Department's patient privacy and data security policies for CURES have not been sufficiently subject to public input or adequately memorialized to hold up as a standard for other states accessing data in CURES. As it stands, the proposed regulations provide little specificity regarding the terms and conditions contained within the memoranda of understanding that is to be entered into between the Interstate Prescriber or Interstate Pharmacist's PDMP and the Department, and the memoranda of understanding between the authorized interstate data sharing hub and the Department, as specified in Subdivision (a)(1)(A) and Subdivision (a)(1)(C). CMA strongly encourages the Department to mandate the memoranda of understanding terms via regulations that address breach liability, jurisdiction over a contract breach and enforcement of these terms. Furthermore, in the Initial Statement of Reasons, the Department refers to Health & Safety Code §11165(h) as authorizing interstate data sharing. Health & Safety Code §11165(h)(3) specifies that any agreement entered into for interstate data sharing must ensure that access to CURES data is handled consistent with California law, including	No change has been made in response to this comment. The access and handling restrictions that will be included in such interstate data sharing agreements will conform to California law, as required by Health and Safety Code section 11165, subdivision (h)(3), and section 823, subdivision (a)(1), of these proposed regulations. However, probable variances in the applicability of federal laws to other state PDMPs do not permit enumeration. For example, HIPAA will be applicable to all Interstate Prescribers and Interstate Pharmacists, but it may govern only a few, if any, state PDMPs. A list of all laws applicable to interstate PDMPs is likely to be over-inclusive for some state PDMPs, and under-inclusive for other state PDMPs.

	regulations, and meet the same patient privacy, audit and data security standards employed and required for direct access to CURES. In §823(a)(1)(C), the proposed regulation is specific about what laws an Interstate Prescriber or Interstate Pharmacist must comply with, including but not limited to the Confidentiality of Medical Information Act, HIPAA and Health & Safety Code §11165(a). However, in §823(a)(1)(D), the section on Interstate Prescriber or Interstate Pharmacist's PDMP and its applicable privacy, confidentiality and security standards, the Department has omitted specific references to California and federal law. Doing such creates ambiguity and it is not clear why there is dissimilar language for both the Interstate Prescriber or Interstate Pharmacist and Interstate Prescriber or Interstate Pharmacist's PDMP. Having less prescriptive language for PDMPs is concerning as they are large databases with volumes of sensitive patient health information, and the scale of risk and impact involved if there was a breach is quite high. CMA urges the Department to specifically list the same federal and State privacy, confidentiality and security laws and regulations for Interstate Prescriber or Pharmacist's PDMPs as it does for Interstate Prescribers or Interstate Pharmacists."	
16.10	Objection No. 16.10 [Proposed modifications to Article 2. § 824(d)(1) Restrictions on Use or Disclosure of Data Obtained from CURES by Law Enforcement] "In §824(d)(1), the proposed regulation lists all of the purposes for which a Regulatory Agency can access CURES data. As noted in the Initial Statement of Reasons, this Subdivision is necessary to ensure that information contained in CURES is used solely for the purposes in which it was intended and are based upon a Regulatory Agency's efforts to control the Diversion and Resultant Abuse of Schedule II, Schedule III and Schedule IV Controlled Substances. While CMA agrees that it is within the purview of a Regulatory Agency to investigate licensees as specified, §824(d)(1)(A) - §824(d)(1)(E) includes language that is overly-broad and outside the scope of the statute that permits enforcement action by Regulatory Agencies, or licensing boards. (Business & Professions Code §2240.) While the term 'to investigate' is within the authority of Regulatory Agencies, it is not clear to us that to	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 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

	'evaluate compliance by a licensee with any State or federal law or regulation…' is within the purview of these entities as well. Furthermore, the Regulatory Agencies' authority is limited to enforcing state laws, but §824(d)(1)(A) provides that they can access CURES data to investigate or evaluate compliance with 'any state or federal law…' CMA requests that the language must be limited to investigations of violations that are within the power of the Regulatory Agency to enforce. As such, CMA suggests the Department amend §824(d)(1)(A) - §824(d)(1)(E) to remove the words 'evaluate' and remove reference to 'federal' in §824(d)(1)(A)."	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 by the board or by any other state or federal regulatory agency." Moreover, the Department disagrees with the commenter's suggestion that the term "evaluate," in contrast to the term "investigate," exceeds the statutory authority granted to Regulatory Agencies.
16.11	Objection No. 16.11 [Proposed modifications to Article 2. § 824(d)(3) / (d)(5) Restrictions on Use or Disclosure of Data Obtained from CURES by Law Enforcement] "CMA applauds the Department for memorializing a search warrant or court order requirement as a condition for accessing a Patient Activity Report, per §825(d)(3). As indicated in the Initial Statement of Reasons, including a higher evidentiary threshold to access CURES data is necessary as it contains patient information and it ensures that Law Enforcement Officials cannot access it outside of their statutorily-mandated duties	No change has been made in response to this comment. Regarding the first concern raised by the commenter, there are meaningful distinctions between Patient Activity Reports and Prescriber or Pharmacy History Reports that account for a divergence in the application of the search

	related to CURES. Unlike a search warrant issued by a neutral magistrate upon a finding of probable cause, permitting access to prescription history at a much lower standard is concerning as it can be issued by the government when an agent merely believes that the records will be 'relevant or material' to an investigation. Further, recent data as compiled by the Department indicates that hundreds of law enforcement officials have faced accusations of misusing computer databases - the last 10 years have resulted in over 1,000 cases of computer database misuse being confirmed. This is concerning as prescription drug records can reveal highly sensitive information that will often disclose a patient's underlying medical condition. CMA continues to have two specific concerns regarding law enforcement access of CURES that were raised with regard to the original proposed regulations, but have not been addressed by the Department: 1. As defined earlier in the proposed regulations, Prescriber History Reports are reports generated by CURES of the controlled substances prescribing history of a prescriber. This same evidentiary threshold for a search warrant or court order for a Patient Activity Report is not similarly applied in §825(d)(2), regarding access to a Prescriber History Report or a Pharmacy History Report for which the regulations does not require a search warrant or court order, but only an investigation (e.g., case number and violation code or crime code). A comparison between the data fields for the Patient Activity Report and Prescriber History Report indicate many commonalities (similar data fields that appear in both reports are bolded). In fact, many of the same sensitive patient information and data fields may be accessed via Prescriber History Reports, which is problematic if the goal is to ensure patient privacy and that Law Enforcement Officials cannot access this information outside of statutorily-mandated duties related to CURES…. 2. As found at §825(d)(5), the proposed regulation provides a number of exceptions to the search warrant or court order requirement for law enforcement as it concerns Patient Activity Reports. For example, §825(d)(5)(C) states that law	warrant or court order policy requirement. Prescriber 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 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 or Pharmacy History Reports would need to be generated, consolidated, and sorted to obtain the same information produced by a single Patient Activity Report. Regarding the commenter's second concern, each of the exceptions to the search warrant or court order requirement is based either on the preemptive effect of federal law or specific circumstances in which a patient's privacy interests benefit from other procedural protections or have been diminished (for example, when the patient is deceased). The commenter specifically questioned the basis for section 825, subdivision (d)(5)(C), which states that law enforcement officials may access a Patient Activity Report if they provide the CURES PDMP with an administrative subpoena issued under 21 United States Code section 876 of the Controlled Substances Act. This exception is consistent with federal law. The

	enforcement officials may access a Patient Activity Report if they provide the CURES PDMP with an administrative subpoena issued under 21 U.S.C. §876 of the Controlled Substances Act. While the Initial Statement of Reasons provides justification as to why search warrants or court orders are necessary in §825(d)(3), the same justification regarding why these exceptions to the search warrant or court order requirement is not considered. Instead, the reasoning for why exceptions are provided pursuant to §825(d)(5) is merely that they are based 'upon circumstances that the Department has encountered' and 'are necessary because they delineate the mechanisms other than a search warrant of court order that call for the release of CURES data.' CMA has repeatedly underscored the importance of confidentiality of medical information as an indispensable component of quality medical care that patients have a privacy interest in their medical information maintained in CURES, particularly in the digital age where technology has facilitated the government's ability to store and mine large amounts of data In *Lewis v. Superior Court* (Medical Board of California) (2017) 3 Cal.5th 561 the California Supreme Court concluded that the Medical Board did not violate California's constitutional right to privacy when it obtained CURES data as a routine part of its investigations, and that the government interest in protecting the public outweighed any potential privacy interest. However, writing both for the majority and in a concurring opinion, Justice Liu clearly articulated that patients have a reasonable expectation of privacy in their prescription records. Moreover, the majority indicated that its analysis might have been different if the plaintiff had asserted the protection from unreasonable search and seizure. (*Lewis*, 3 Cal.5th at 578). The existence of a reasonable expectation of privacy in their prescription records requires a showing of probable cause by Law Enforcement Official prior to searching those records. Accordingly, CMA urges the Department to delete the provisions in §825(d)(5), which would create significant, unjustified and potentially unlawful exceptions to the warrant or court order requirement in (d)(3)(C). Similarly, we urge the Department to add to §825(d)(2) the requirement for a search warrant or court order in (d)(3)(C) in order to adequately protect patient prescription records that may be derived from a Prescriber History Report"	Ninth Circuit U.S. Court of Appeals has held that under Title 21, United States Code section 876, the Drug Enforcement Administration 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). As to both concerns, a premise advanced is that "recent data as compiled by the Department indicates that hundreds of law enforcement officials have faced accusations of misusing computer databases - the last 10 years have resulted in over 1,000 cases of computer database misuse being confirmed." This information is incorrect. Outside agencies have obtained individual CLETS "Misuse Reports" submitted by individual law enforcement agencies and have independently compiled and interpreted data from those reports that pertain to both sworn and nonsworn personnel. None of these accusations concerns access to the CURES PDMP or CURES PDMP data.

17.01	Objection No. 17.01 [Proposed modifications to Article 2. § 826(f) Procedures for Requesting Identified Individual-Level Data and De-Identified Individual-Level Data from CURES] "Specifically, sections §826(f)(3)K(vii) and §826(f)(3)K(vii)(a) of the original proposed regulations included specifications for access to and use of identifiable data by researchers. However, the January 16, 2020 modification effectively removes the possibility of ever using identifiable data due to the prohibitive requirement that researchers obtain written patient consent for use of such data. This is a highly unusual standard, which other state and federal agencies (DHCS, CDPH, OSHPD, etc.) do not require for use of their health care datasets (with identifiable data). Please restore the *option* for DOJ to permit bona fide researchers to access identifiable, individual-level data from CURES without patient consent. The original proposed regulations effectively covered security protocols. Completely removing the *option* to use this important dataset to its fullest value substantially undermines the ability to create evidence-based, public health policies and programs that will reduce opioid overdose and related deaths. To wit, restoring the original draft language (§826(f)(5)) regarding the CDOJ secure data lab, which is housed on CDOJ premises, would reinforce appropriately strict security and privacy protocols, which would address other commenters' concerns about privacy and security. This secure lab is another layer of security, beyond IRB approvals and institutional applicant-confirmed security protocols and standards, that ensures patient privacy while allowing the exploration of effectiveness of policies and interventions regarding opioid overdoses and deaths. I believe this serious restriction on access to data is antithetical to the legislative intent of CURES, which states that: CDOJ may make available data for educational, statistical, or research purposes; data should be protected pursuant to, state and federal privacy and security laws and regulations; and that 'CDOJ shall establish policies, procedures, and regulations regarding the use, access, evaluation, management, implementation, operation, storage, disclosure, and security of the information within CURES, *consistent*	No changes are being made in response to this comment. The Department received diametrically opposed comments on this topic. The Department has decided to err on the side of privacy and thus has decided not to make this change. As currently drafted, the regulations authorize, among other things, release of (i) Identified Individual-Level Data to a Bona Fide Researcher with the prior written voluntary consent of the individual for whom such data is being requested, and (ii) De-Identified Individual-Level Data without such consent. Bona Fide Researchers may continue to benefit from such access. The Department is committed to ensuring beneficial access to CURES information for educational, peer review, statistical, and research purposes. But the Department is also committed to ensuring patient privacy. As such, the Department intends to continue to monitor researcher needs for information in the CURES database and possibly to propose additional, future regulations. The Department encourages the commenters to submit this and other comments in future rulemaking proceedings.

	with this subdivision' (H&SC section 11165(c)(2)(A)). Simply put, aggregated data and de-identified data are the weakest tools a researcher can use; although they may be sufficient to describe problems, they cannot help answer questions about "why" or "how" which are integral to informing change in public policy or clinical practice, and, ultimately, health outcomes. In health services research parlance, the limited datasets can indicate a correlation at best; however, they cannot determine causation. Effectively prohibiting this type of rigorous research is inconsistent with one of the legislature's primary purposes for initiating CURES: to make data available for educational, statistical and research purposes. The effective prohibition on access to identifiable CURES data (through the patient consent requirement) also countermands major federal and state efforts to reverse the opioid epidemic. As you are aware, huge amounts of money are being doled out to learn about what works and what doesn't in helping prevent opioid use disorder and overdose. Without access to proper data, these efforts by UC and CSU physician researchers, and others will be stymied. Finally, physician researchers and other researchers are supported by their institution's rigorous privacy and security protocols and standards; they respect these rules and take them seriously from personal perspective and professional perspective. CDOJ already has strict standards to which researchers must adhere before accessing sensitive data, including the secure data lab. Under the modified proposed regulations, DOJ sorely limits its ability to meet its public obligation as stated in the regulations: *evaluate or identify a resolution of a problem in a research field.* Furthermore, the new language limits *contributions to the basic knowledge of a research field;* it prohibits *the utilization of* rigorous *scientific methods and research methodologies.* The modified rules also seriously undermine *the reasonable expectation that the final research product may support publication in a peer-reviewed journal, program evaluation and quality improvement, public health surveillance, or policy development.* The methodological rigor expected of peer-review level research will simply not be present without identifiable, individual level data; nor will conclusions that can help change the pattern of substance use disorder in California.	

	Please restore the language from the original proposed regulation regarding access and use of identifiable (individual-level) CURES data without patient consent. This will ensure that DOJ remains a responsible steward of public information by achieving an appropriately balanced protection of public health and privacy."	
18.01	Objection No. 18.01 [Proposed modifications to Article 2. § 821(g)(3)(A) Delegate Use of CURES] "Changing 'must only' to 'may' does not offer clarification on the permitted use of CURES by delegates. As nowhere else in the text does it state or imply that they may use the integrated HIT system, it is unclear whether they are simply permitted to use the web-based application, or are permitted to use either the web-based application or the integrated HIT system. If the desired clarification is to allow the use of either system—which is strongly recommended—then we suggest adding additional text to confirm this. Based on our previously expressed concerns of requiring them to exit their workflow, we hope this clarification will be addressed and the permission to use either system is made clear."	No change has been made in response to this comment. In response to comments from the directly affected public, the Department revised section 821, subdivision (g)(3)(A), from "must only" to "may." This subdivision does not restrict delegate access. This subdivision is located in a Delegate's "Procedures for Use of CURES" section and is therefore intended to be descriptive rather than proscriptive.
19.01	Objection No. 19.01 [Proposed modifications to Article 2. § 826(f) Procedures for Requesting Identified Individual-Level Data and De-Identified Individual-Level Data from CURES] "We urge the DOJ to restore §826(f)(3)K(vii)(a), §826(f)(5), and the language in §826(f)(3)K(vii) allowing Bona Fide Researchers data access under Civil Code section 1798.24, subdivision (t) to the final version of the CURES regulations (with necessary minor stylistic changes to ensure consistency with other parts of the final regulations). These sections were included in the initial draft of the regulations but were deleted in the revised version published on January 16…. We also respectfully request that the recently added language in §826(f)(3)(K)(vii) mandating prior written voluntary individual consent as the only avenue for a Bona Fide Researcher to obtain Identified Individual-Level Data be deleted….	No changes are being made in response to this comment. The Department received diametrically opposed comments on this topic. The Department has decided to err on the side of privacy and thus has decided not to make this change. As currently drafted, the regulations authorize, among other things, release of (i) Identified Individual-Level Data to a Bona Fide Researcher with the prior written voluntary consent of the individual for whom such data is being requested, and (ii) De-Identified Individual-Level Data without such consent. Bona Fide Researchers may continue to benefit from such access. The Department is committed to ensuring beneficial access to CURES information for educational, peer

	If our recommendations are not adopted, the CURES regulations will block important research that will improve the health and safety of Californians. However, restoring research access under California Civil Code Section 17.98.24(t) will further the stated purpose of the CURES regulations…. Removing access to data for research under 1798.24(t) is not required by California Law, and DOJ would still have discretion to deny research requests that are frivolous or not likely to improve the health or safety of Californians. Furthermore, DOJ is clearly permitted by statute to disclose personal identifying information to the University of California and researchers from other non-profit research institutions for research under California Civil Code Section 1798.24(t). DOJ has provided access to statewide individual-level identified CURES data in the past under these laws, and so clearly continuing to do so would not violate California law. In addition, maintaining access by restoring §826(f)(3)K(vii) and §826(f)(5) would still give DOJ wide discretion about which research requests to approve and would not require DOJ to provide data for requests that were frivolous or lacked scientific merit. The only potential counterargument against restoring these regulations we can envision are related to patient privacy concerns. However, we believe existing statues and other aspects of the proposed regulations provide ample protection for patient privacy and data safety…. Given that California is in the midst of an ongoing opioid and stimulant crisis and more people are dying of opioid-related and stimulant-related overdoses every day, we respectfully submit that there should be increased availability of CURES for research, not less, so that DOJ, researchers, and state agencies can use every tool possible to combat the ongoing opioid crisis and reduce prescription drug overdose and addiction in California.”	review, statistical, and research purposes. But the Department is also committed to ensuring patient privacy. As such, the Department intends to continue to monitor researcher needs for information in the CURES database and possibly to propose additional, future regulations. The Department encourages the commenters to submit this and other comments in future rulemaking proceedings.

20.01	Objection No. 20.01 [Proposed modifications to Article 2. § 826(f) Procedures for Requesting Identified Individual-Level Data and De-Identified Individual-Level Data from CURES] "Reinstate language concerning use of Identified Individual-Level Data, as described at Section 826(f)(3)(K)(vii)(a). 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 deletion of Section 826(f)(3)(K)(vii)(a) will severely hinder research access to statewide CURES data, and in effect, stifle, or even halt, population-level public health and safety research intended to advance the very purpose of the legislation driving this regulatory change: the need for data-driven solutions to prevent prescription drug abuse and diversion. The CURES database is comprised of tens of millions of patients who have been prescribed controlled substances in California. If the Modified Regulations put forth on January 16, 2020 are adopted as written, researchers would be required to obtain patients' individual consent to access identified CURES data. Locating and contacting these individuals after care has been provided would be an infeasible, if not impossible, task. The Modified Regulations will thus have the effect of precluding access to identified individual-level CURES data. In turn, researchers conducting studies related to public health, public policy, epidemiology, or other fields that examine population-level antecedents or consequences of prescribing controlled substance cannot continue their work. This holds particularly true for those studies requiring the ability to link CURES data with data acquired from outside sources. For example, the ability to link death certificate data to CURES data is important for identifying whether decedents did or did not receive opioid prescriptions prior to their deaths. While this can be accomplished by coroners for individual cases, linking these data at the population level is critical for identifying public health trends and for producing information the	No changes are being made in response to this comment. The Department received diametrically opposed comments on this topic. The Department has decided to err on the side of privacy and thus has decided not to make this change. As currently drafted, the regulations authorize, among other things, release of (i) Identified Individual-Level Data to a Bona Fide Researcher with the prior written voluntary consent of the individual for whom such data is being requested, and (ii) De-Identified Individual-Level Data without such consent. Bona Fide Researchers may continue to benefit from such access. The Department is committed to ensuring beneficial access to CURES information for educational, peer review, statistical, and research purposes. But the Department is also committed to ensuring patient privacy. As such, the Department intends to continue to monitor researcher needs for information in the CURES database and possibly to propose additional, future regulations. The Department encourages the commenters to submit this and other comments in future rulemaking proceedings.

	Department and other state agencies can use to guide future policy changes as well as decisions concerning resource allocations. We are unclear as to the Department's rationale for deleting Section 826(f)(3)(K)(vii)(a) following the initial Notice of Proposed Rulemaking published on October 4, 2019. We also believe the Modified Regulations would place the Department's regulations at odds with California Civil Code Section 1798.24(t), which specifically authorizes UC and other non-profit educational institutions to use personally identifiable information for research purposes, subject to review by the California Health and Human Services Agency's Committee for the Protection of Human Subjects (CPHS) or a local Institutional Review Board (IRB). Under California Civil Code Section 1798.24(t), researchers are given explicit statutory low them to request identifiable data for research, as well as requirements that must be met to ensure security of that data…. UC, therefore, believes that maintaining access to statewide Identified Individual-Level Data from CURES, without requiring researchers to obtain explicit prior written consent, would not conflict with existing statute or otherwise imperil patient privacy in any meaningful way. Restoring Sections 826(f)(3)(K)(vii)(a) and 826(f)(5) would still afford the Department wide discretion to approve research requests and would not require the Department to provide data for requests that are frivolous or lack scientific merit."	
20.02	Objection No. 20.02 [Proposed modifications to Article 2. § 826(f)(3)(K)(vii) Procedures for Requesting Identified Individual-Level Data and De-Identified Individual-Level Data from CURES] "Remove Language in Section 826(f)(3)(K)(vii) Requiring Researchers to Obtain Prior Written Consent. UC respectfully requests that the recently added language in §826(f)(3)(K)(vii) mandating prior written individual consent as the only avenue for a Bona Fide Researcher to obtain Identified Individual-Level Data be deleted. As described above, obtaining prior written consent of every individual listed in the CURES database will stifle population-level research. Researchers simply have no ability to obtain individual	See response 20.01.

	consent from the tens of millions of patients who have been prescribed controlled substances in California. Consequently, this requirement would effectively eliminate the ability of researchers to access identified individual-level CURES data for population-level research focused on public health, public safety, and other important topics needed to advance the health and safety of Californians who use controlled substances."	
20.03	Objection No. 20.03 [Proposed modifications to Article 2. § 826(f)(5) Procedures for Requesting Identified Individual-Level Data and De-Identified Individual-Level Data from CURES] "Reinstate language authorizing the Department to restrict the review of Identified Individual-Level Data to the Department's Secure Lab at Section 826(f)(5). Section 826(f)(5) as written in the Proposed Regulations published on October 4, 2019, the Department, at its discretion, can restrict the viewing or access of CURES data by any Bona Fide Researcher following a criminal history background check. We believe the Department's Data Request Application process described elsewhere in Section 826, coupled with the aforementioned security practices, will allow the Department sufficient authority and discretion to (1) deny any research requests the Department deems frivolous or unlikely to improve the health or safety of Californians, and (2) ensure the security of Identified Individual-Level Data for research requests determined to hold strong scientific merit."	See response 20.01.
20.04	Objection No. 20.04 [Proposed modifications to Article 2. § 826 Research] "We believe that if our recommendations are not adopted, the CURES regulations will block important research that will improve the health and safety of Californians. Given that California is in the midst of an ongoing opioid and stimulant crisis where more people are dying of opioid-related and stimulant-related overdoses every day, UC believes it is imperative that state agencies use every tool available to combat the ongoing opioid crisis in their efforts to reduce prescription drug addiction and overdose in California. Restoring research access to Identified Individual-Level Data as permitted under California Civil Code Section 1798.24(t) will provide the research community	See response 20.01.

	valuable means by which the Department and other agencies can further the stated purpose of the CURES regulations. In the event the Department remains concerned about reinsertion of the Sections 826(f)(3)(K)(vii)(a) and 826(f)(5), UC respectfully requests that the Department extend the comment period to allow additional comment from the research community. A truncated comment period adversely affects our ability to provide meaningful comments to the Department."	