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UC Comments on California Department of Justice Notice of Modification to Text of Proposed Regulations regarding the Controlled Substance Utilization Review and Evaluation System (CURES) at Title 11, Division 1, Chapter 8.5 Issued on January 16, 2020

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OFFICE OF THE VICE PRESIDENT - RESEARCH AND INNOVATION

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January 31, 2020

Ross Daley and Haylee James
California Department of Justice
Justice Data and Investigative Services Bureau
4949 Broadway
Sacramento, CA 95820
E-mail: CURESregulations@doj.ca.gov

RE: Department of Justice Notice of Modification to Text of Proposed Regulations regarding the Controlled Substance Utilization Review and Evaluation System (CURES) at Title 11, Division 1, Chapter 8.5 Issued on January 16, 2020

Dear Mr. Daley and Ms. James:

I write on behalf of the University of California (UC) system with regard to the Notice of Modification to Text of Proposed Regulations specific to the Controlled Substance Utilization Review and Evaluation System (CURES) at Title 11, Division 1, Chapter 8.5 issued by the Department of Justice (Department) on January 16, 2020.

The UC system has more than 800 research centers, institutes, laboratories, and programs that span 10 campuses, 6 medical schools, a Division of Agriculture and Natural Resources, and 3 affiliated U.S. Department of Energy national laboratories. UC has established an unparalleled reputation for research and innovation that contributes to the state and nation through discoveries and new technologies that improve health, quality of life, and public safety. With regard to research involving CURES data, UC conducts epidemiological evaluations utilizing healthcare records and other state-managed databases to assess the effectiveness of treatments for substance use disorders, examines gender-related factors in substance abuse and treatment, and identifies predictors likely to lead to dose escalation and/or overdose of prescribed medications. These efforts reflect more than \$8 million in current active funding for opioid research and have included multiple research projects conducted in collaboration with the Department.

This letter serves to comment on Sections **826(f)(3)(K)(vii)(a)**, **826(f)(3)(K)(vii)**, and **826(f)(5)** of the proposed modified regulations specific to access and use of Identified Individual-Level Data. In order to continue to ensure researchers' access to this vital information, UC strongly urges the Department to restore Sections 826(f)(3)(K)(vii)(a) and 826(f)(5) originally included in the Proposed Regulations published on October 4, 2019, but removed in the Modified Regulations published on January 16, 2020. In addition, UC urges the Department to remove language in Section 826(f)(3)(K)(vii) mandating researchers to obtain prior written consent of any individual for whom Identified Individual-Level Data is being requested. More information is provided below:

I. Reinstatement 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 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 procedures that allow them to request identifiable data for research, as well as requirements that must be met to ensure security of that data.

Other aspects of the Proposed Regulations also provide protection for patient privacy and data safety. In particular, Section 826 provides for the following protections for individuals whose identifiable data may be used in research:

- Limitations on researchers' permissible use of such data;
- Submission to the Department of any draft publication for review and prior approval;
- Non-disclosure of any identifying data by the researcher;
- Prohibition on sale of data;
- Requirement of background checks on the research team;
- Written verification of approval by the CPHS or IRB;
- Submission to the Department of a data request application including significant information on the research team, project outline stating how the data will be used in the research, detailed security measures, and signature by the investigator attesting to compliance;
- Certification of human subjects protection training;
- Renewal reports including new information;

- Secure transfer of data from the government to the Bona Fide Researcher; and
- A detailed certificate of destruction of data.

Due to the rigor of these and other privacy, security and human subjects protections required by law, we believe that maintaining access to statewide identified individual-level CURES data would involve minimal risk of patient harm or a privacy or security breach.

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.

Recommendation: UC strongly recommends the following text be reinstated:

“(vii) If the Research Requestor is a Bona Fide Researcher and is requesting Identified Individual-Level Data, the Data Request Application must contain written verification of compliance with Civil Code section 1798.24, subdivision (t), or 1798.24, subdivision (b).

a. Compliance with Civil Code section 1798.24, subdivision (t), which is applicable only to a nonprofit entity, requires the Research Requestor to obtain formal approval for the use of Identified Individual-Level Data, as specified in and consistent with the Data Request Application, by the Committee for the Protection of Human Subjects for the California Health and Human Services Agency. This requirement may be satisfied if formal approval is secured from the Research Requestor’s institutional review board, if that institutional review board has a written agreement with the Committee for the Protection of Human Subjects for that institutional review board to provide the data security approvals required by Civil Code section 1798.24, subdivision (t). The Research Requestor must provide written verification to the Department’s Research Center of formal approvals by the Committee for the Protection of Human Subjects, or, if applicable, by the institutional review board, for the request of Identified Individual-Level Data from CURES. The written verification must include the Committee for the Protection of Human Subjects’ or institutional review board’s review and determination that the data security approvals required by Civil Code section 1798.24, subdivision (t), have been satisfied.”

II. 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 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.

Recommendation: UC strongly recommends that language added in Section 826(f)(3)(K)(vii) shown below be removed:

If the Bona Fide Researcher is requesting Identified Individual-Level Data, the Bona Fide Researcher must provide the prior written voluntary consent of any individual for whom Identified

Individual-Level Data is being requested on the Data Request Application, in accordance with the requirements of this section and Civil Code section 1798.24, subdivision (b). 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. The individual's written consent must be retained for at least as long as the individual's Identified Individual-Level Data is retained by the Bona Fide Researcher. The 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. A Bona Fide Researcher must not obtain an individual's Identified Individual-Level Data from CURES outside of that 30 days, or the time limit agreed to by the individual in the individual's written consent, unless the individual has provided a renewed written voluntary consent.

III. Reinstatement 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.

Recommendation: Allow the Department to restrict viewing of CURES data to its Secure Lab at the Department's discretion, as originally proposed. UC therefore recommends reinstatement of the text below:

“(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 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.”

IV. General Comments

In addition to our specific comments above, UC would also like to point out that the statutory language governing access to CURES data for research, as established in 1997 (AB 3042 Takasugi) and noted below, remains unchanged:

“Data may be provided to public or private entities, as approved by DOJ, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision, shall not be disclosed, sold, or transferred to any third party.”

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 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.

We would like to thank you and your team for your diligent efforts to meet the concerns of institutions of higher education while developing regulations to ensure the security of sensitive data concerning controlled substance use. The UC system looks forward to continuing its collaborations with the Department to pursue academic research beneficial to stakeholders within the State of California and beyond. We welcome any opportunity to further discuss the comments of this letter.

Sincerely,

A handwritten signature in black ink, reading "Lourdes G. DeMattos". The signature is fluid and cursive, with the first name "Lourdes" being more prominent and the last name "DeMattos" following in a similar style.

Lourdes G. DeMattos
Acting Executive Director
Research Policy Analysis & Coordination