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Assembly California Legislature



EVAN LOW
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January 7, 2019

The Honorable Xavier Becerra
Attorney General, State of California
California Department of Justice
1300 I Street
Sacramento, CA 95814

Re: Implementation of Assembly Bill 1753

Dear Attorney General Becerra:

I write in regards to the implementation of legislation I authored, Assembly Bill 1753 (Chapter 479, Statutes of 2018). This bill was part of a comprehensive package introduced by the Assembly last year in a bipartisan effort to address the devastating opioid crisis. I appreciate the technical assistance your office provided in drafting the statutory language enacted through this legislation.

Since the Governor signed AB 1753 into law, I have heard from numerous impacted stakeholders that there is a persistent lack of clarity about how the legislation is being implemented. This has led to apprehension and uncertainty within the prescribing and dispensing communities. My hope with this letter is to elucidate the intent of the legislation I authored and urge the state agencies entrusted with carrying out its provisions to take care not to place any undue burden on patients.

As you know, the Department of Justice's Security Prescription Printers Program regulates the manufacturing of special tamper-resistant forms required for all paper prescriptions for controlled substances. AB 1753 enhanced the regulation of these forms by requiring unique serialization and improving how lost or stolen prescription pads are identified and tracked. The bill was supported by a broad coalition representing law enforcement, health professionals, and patient advocates.

The language in the bill was intentionally crafted to delegate significant discretion to the Department of Justice in determining how to most smoothly and effectively implement the new requirements. Specifically, the newly mandated serial number field is described only in broad terms by statute, simply stating that this field is to be adopted "in a manner prescribed by the Department of Justice." Additionally, the phrase "if applicable" was affixed to the inclusion of the serial number in statute's prescription reporting requirements to further allow for flexibility.

Throughout the passage of AB 1753, I shared an understanding with other engaged stakeholders that the wide latitude afforded to your department would allow for the serialization requirements to be developed and disseminated through a measured timeline that would facilitate a comfortable transition for the impacted health community. However, it appears your department only recently issued guidance regarding specifications for serialization and indicated that the number would be an immediate requirement for all prescriptions written or filled after January 1 of this year. Compliant forms were made available to prescribers less than two weeks prior to this deadline.

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This unanticipated situation has reportedly already been problematic for health professionals. Physicians and other prescribers who have not had access to the new serialized forms are faced with the dilemma of whether to write prescriptions for needed medication on outdated prescription pads or prolong a patient's access to treatment. Meanwhile, I have been informed that numerous pharmacies have already turned away individuals holding prescriptions written on unserialized forms that are otherwise valid; in the face of possible discipline, dispensers are forced to decide between denying care to their patients and risking action against their licenses.

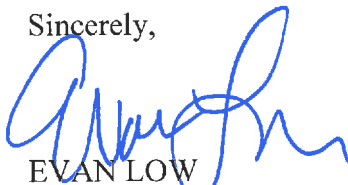
Our offices have been in communication as to whether the Department of Justice can and should promulgate regulations to incorporate greater transparency and stakeholder consultation to how the serial number requirement is being instituted. I would like to reiterate that such rulemaking, including potential language formally delaying part of AB 1753's requirements, would align with the author's intent to provide your department with implementation discretion. I further encourage the Department of Justice to be generally cognizant of how its decision-making may result in regulatory obstacles to the delivery of treatments to patients.

Additionally, I urge the regulatory boards with jurisdiction over licensed prescribers and dispensers to appropriately assess their enforcement priorities to allow for health professionals to confidently write and fill prescriptions that are in the best interest of patients without fear of reprisal as remaining uncertainties around AB 1753's implementation are reconciled. The priority for all agencies involved with carrying out the bill's provisions must be to ensure that legitimate medication needs are not obstructed. This urgency has been communicated to both the Board of Pharmacy and the Medical Board, and I am encouraged by their indication that licensees who otherwise exercise good judgment will not be unduly disciplined as a result of the present situation.

I believe that responsible action by state regulators is ultimately the best avenue for resolving the recent confusion regarding security prescription form requirements. I hope that your office will continue to work with its client agencies and other impacted stakeholders to resolve the outstanding conflicts. In the event that administrative solutions cannot be identified or enacted, I am committed to seeing that legislative action is taken to clarify statute as determined necessary.

Please continue your current practice of open communication and responsiveness in regards to how the Department of Justice is engaged on the issues described above. I greatly appreciate your leadership and remain available to assist in any way I can. If you have any questions, please contact my Chief of Staff, Gina Frisby, at (916) 319-2028.

Sincerely,



EVAN LOW
Assembly District 28

cc: Dean Grafilo, Director, Department of Consumer Affairs
California State Board of Pharmacy
Medical Board of California