

FINDING OF EMERGENCY

Pursuant to the Legislature's finding of emergency and statutory direction, the Board of Pharmacy ("the Board") adds a new section to current regulations which sets out a protocol for pharmacists to furnish naloxone hydrochloride ("naloxone") without a prescription.

These emergency regulations are adopted pursuant to the procedure set forth in Business & Professions Code §4052.01(e).

DESCRIPTION OF SPECIFIC FACTS WHICH CONSTITUTE THE EMERGENCY

1. The Legislature enacted, and the Governor signed, Assembly Bill (AB)1535 (Chapter 326, Statutes of 2014), which allows pharmacists to furnish naloxone without a prescription under a protocol to be developed by the Medical Board and the Board of Pharmacy. The protocol set forth in this regulation has been developed in consultation with the California Society of Addiction Medicine, the California Pharmacists' Association and other entities. The final regulation has been approved by both the Medical Board and the Board of Pharmacy.

2. Delay in the implementation of these regulations would conflict with the statutory directive found in §4052.01(e) of the Business and Professions Code, which calls for emergency regulations to be adopted:

“(e) The board may adopt emergency regulations to establish the standardized procedures or protocols. The adoption of regulations pursuant to this subdivision shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The emergency regulations authorized by this subdivision are exempt from review by the Office of Administrative Law. The emergency regulations authorized by this subdivision shall be submitted to the Office of Administrative Law for filing with the Secretary of State and shall remain in effect until the earlier of 180 days following their effective date or the effective date of regulations adopted pursuant to subdivision (a).”

3. These emergency regulations ensure that pharmacists can begin as soon as possible to furnish naloxone. Naloxone is an “opioid antagonist,” that reverses the effects of opioid medications, including oxycodone, oxymorphone, Vicodin, Percocet, methadone, and heroin. Increasing public access to naloxone will prevent drug overdose deaths.

4. The Board will also pursue the nonemergency rulemaking process set out in the Administrative Procedure Act. However, the Legislature instructed the Board to implement emergency regulations so that pharmacists can begin furnishing naloxone as soon as possible in hopes of saving lives. Individuals wishing to receive notice of that process should contact: Karen Halbo, Board of Pharmacy, 1625 N. Market Blvd., N219, Sacramento, CA 95834, email: Karen.Halbo@DCA.ca.gov, phone: (916)574-7948, fax: (916)574-8618.

5. Therefore, in order to preserve the peace, health, safety and general welfare of the State of California, the Board has adopted these regulations on an emergency basis, in accordance with Business & Professions Code §4052.01(e).

In order to provide additional background to affected parties, this notice contains information for the public benefit consistent with that provided in a traditional emergency rulemaking Finding of Emergency.

AUTHORITY AND REFERENCE

Authority: Business & Professions Code §4005 and §4052.01. Reference: Business & Professions Code §4052.01.

INFORMATIVE DIGEST

Effective January 1, 2015, the Legislature, via Business & Professions Code §4052.01, instructed the Medical Board and the Board of Pharmacy to collaborate on a protocol setting out procedures for pharmacists to follow in order to furnish naloxone, a low-cost generic medication only available by prescription, to members of the public. Prescription drug overdose is the leading cause of death in California, and increasing the public's access to naloxone will help combat the epidemic of opioid overdose in California. The Board of Pharmacy, in conjunction with the Medical Board and in consultation with the California Society of Addiction Medicine, the California Pharmacists' Association and other entities, has developed 16 CCR §1746.3, the naloxone protocol. This protocol, set out in 16 CCR §1746.3, has been approved by both the Medical Board and the Board of Pharmacy. The procedures set out in the protocol require a pharmacist to provide a consultation to ensure the education of the person to whom the drug is furnished, and the person to whom the drug is furnished may not waive this consultation. The pharmacist must notify the patient's primary care provider, where possible. The procedure also requires a pharmacist to complete a training program on the use of opioid antagonists prior to attempting to furnish naloxone pursuant to the protocol.

Until the Legislature enacted, and the Governor signed, Senate Bill 493, (Chapter 469, Statutes of 2013), the board of pharmacy was unable to address the problem of restricted public access to naloxone as it was categorized as a controlled substance that required a doctor's prescription. The Board has worked diligently to draft the naloxone protocol in conjunction with other agencies, and while the Board will seek to adopt the naloxone protocol through the regular rulemaking process, these emergency regulations are needed to begin saving lives as soon as possible. The only other California law concerning naloxone is Assembly Bill 635, (Chapter 707, Statutes of 2013) which insulates physicians from civil liability when they prescribe naloxone to a family member, friend, or other person in a position to assist a person experiencing or suspected of experiencing an opioid overdose (Civil Code 1714.22).

Consistency and Compatibility with Existing State Regulations: During the process of developing these regulations and amendments, the Board has conducted a search of any

similar regulations on this topic and has concluded that these regulations are neither inconsistent nor incompatible with existing state regulations.

Mandate on Local Agencies or School Districts: This regulatory action does not impose a mandate on local agencies or school districts.

FISCAL IMPACT

- A. Cost or Savings to any state agency: NONE
- B. Cost to any local agency required to be reimbursed under Part 7 (commencing with Section 17500) of Division 4: NONE
- C. Cost to any school district required to be reimbursed under Part 7 (commencing with Section 17500) of Division 4: NONE
- D. Other nondiscretionary cost or savings imposed on local agencies: NONE
- E. Cost or savings in federal funds to the state: NONE

Technical or Theoretical, Or Empirical Studies, Reports, or Documents Relied on:

Scott Burris, et al., “Stopping an Invisible Epidemic: Legal Issues in the Provision of Naloxone To Prevent Opioid Overdose,” DREXEL L. REV. 1(2):273-339, 326 (2009). (*This law review article recommends fostering naloxone distribution through pharmacies, and using EC statutes as a model*).

Substance Abuse and Mental Health Services Administration, “Opioid Overdose Toolkit,” available at <http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2014/SMA14-4742>. (*This resource provides materials to develop policies to prevent opioid overdose*).

The Network for Public Health Law, “Legal Interventions To Reduce Overdose Mortality: Naloxone Access and Overdose Good Samaritan Laws” (Aug. 2014), available at https://www.networkforphl.org/_asset/qz5pvn/naloxone-FINAL.pdf. (*This article describes naloxone access nationwide*).

Harm Reduction Coalition, “Guide to Developing and Managing Overdose Prevention and Take-Home Naloxone Projects” (2012), available at <http://harmreduction.org/issues/overdose-prevention/tools-best-practices/manuals-best-practice/od-manual/> (*This manual outlines the process of developing an overdose prevention program, including with a take-home naloxone component*).

Northeast Behavioral Health, “Opioid Overdose Prevention and Reversal via Peer-Administered Narcan” (2012), available at <http://harmreduction.org/wp-content/uploads/2012/02/od-train-the-trainer-parents.pdf>. (*This PowerPoint presentation provides information to educate peers on opioid prevention and reversal*).

CA Department of Health Care Services, “Pharmacist Protocol for Furnishing Naloxone for the Prevention of Opioid Overdose” (last updated Oct. 29, 2014). (*This draft protocol was consulted in development of the Board’s recommended protocol*).

World Health Organization, “Community Management of Opioid Overdose” (2014). (*This resource provides materials to develop policies to prevent opioid overdose*).

Drug Policy Alliance, “What Is Naloxone?” (Aug. 2014), *available at* <http://www.drugpolicy.org/resource/what-naloxone>. (*This fact sheet provides comprehensive information on naloxone*).

Massachusetts Department of Health and Human Services, “Dispensing of Naloxone by Standing Order” (2014), *available at* <http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/dhpl/pharmacy/dispensing-of-naloxone-by-standing-order-.html>. (*This site contains a pamphlet recommended as the base for the Board’s factsheet*).

N. Zaller, et al., “The Feasibility of Pharmacy-Based Naloxone Distribution Interventions: A Qualitative Study with Injection Drug Users and Pharmacy Staff in Rhode Island,” 48 SUBST. USE MISUSE 8 (2013). (*This research supports pharmacy-based naloxone intervention, but notes barriers including misinformation and costs*).

Traci C. Green, et al., “Responding to Opioid Overdose in Rhode Island: Where the Medical Community Has Gone and Where We Need To Go,” R.I. MED. J. 29-33 (Oct. 2014), *available at* <http://www.rimed.org/rimedicaljournal/2014/10/2014-10-29-dadt-green.pdf>. (*This article gives an overview of opioid overdose, provides guidance resources, and emphasizes the importance of Good Samaritan Laws*).