

12-14-16

480-34-0.31-11

Naloxone.

(1) Effective December 14, 2016, O.C.G.A. §16-13-71(b)(635) is hereby removed from the list of dangerous drugs of the Georgia Dangerous Drugs Act.

(2) This Rule places Naloxone, including any drugs, chemicals, or substances; salts, isomers, esters, ethers, or derivatives of such drugs, chemicals, or substances that have the same pharmacological action; all other salts, isomers, esters, ethers, and compounds of such drugs, chemicals, or substances under Schedule V of the Georgia Controlled Substances Act, O.C.G.A. §16-13-29(7).

(3) This Rule is based on the following findings of the Board:

(a) That the Board reviewed information from the Office of the Governor requesting that the Board consider scheduling naloxone as a Schedule V to assist in the protection of the public health, safety, and welfare and to combat Georgia's rising opioid abuse epidemic. Such information stated that naloxone has no pharmacological activity in the absence of opioids or other opioid antagonists according to the large volume of research that exists regarding the drug;

(b) That the Board reviewed information from the Georgia Prescription Drug Monitoring Program that revealed that there are over one hundred (100) counties in Georgia that have a ratio of narcotic prescriptions per person exceeding a ratio of 1:1 for the year 2015-2016 and that between forty-five (45) and fifty (50) million opioids dispensed each month throughout the State of Georgia for the past five months;

(c) That the Board reviewed information from the Department of Public Health indicating that the steady and sharp increase in the number of overdoses and deaths due to prescription and illegal forms of opioid drugs poses an imminent threat to the public health, safety, and welfare; that such an increase may legitimately be termed a public health emergency; and that naloxone is critical in assisting persons at risk of overdose;

(d) That the Board reviewed information from the Georgia Bureau of Investigation that indicates in some counties, there has been an increase in opioid deaths from 2010-2016;

(e) That the drug has a lower potential for abuse relative to the drugs or other substances in Schedule V;

(f) That the drug has a currently accepted medical use in treatment in the United States; and

(g) That the drug has come to be considered an important and life-saving tool in treating opioid overdoses.

(4) Pursuant to Official Code of Georgia Annotated (O.C.G.A.) §16-13-29.2, the Georgia Board of Pharmacy authorizes pharmacists and pharmacy interns and externs under the supervision of a licensed pharmacist to dispense naloxone pursuant either to a prescription by a licensed practitioner or to the standing order of Dr. Brenda Fitzgerald, Commissioner of the Department of Public Health. The pharmacy shall keep a copy of the standing order issued by the Commissioner of the Department of Public Health and shall keep a record of each prescription of naloxone issued pursuant to the standing order. Such record shall include the name of each purchaser, date of birth, address, city, state, and zip code. This record shall be maintained by the pharmacy for two (2) years. Nothing herein shall prevent this record from being maintained electronically.

(5) Dispensers shall not be required to submit information regarding each naloxone prescription dispensed to the Prescription Drug Monitoring Program.

(6) Pharmacies are not required to maintain naloxone in their biennial inventories.

(7) This Rule shall not be construed to require hospital pharmacies to treat naloxone as a controlled substance for purposes of its recordkeeping and distribution system.