

The Changing Landscape of the Fight Against Opioid and Heroin Addiction and the Availability of Naloxone

October 17, 2016 – Dorsey Health Law

by Nicole Burgmeier and Edwin N. McIntosh

In recent months, the Obama administration and many health and pharmaceutical players at the state and local levels have focused their attention on the national opioid epidemic. Based on recent findings from the National Center for Injury Prevention and Control, approximately 40 Americans die each day from overdoses involving prescription opioids. Additionally, according to the National Institute of Drug Abuse, in 2014 approximately 10,000 Americans died from heroin overdose.

To shed light on the matter, the White House declared a week last month as Prescription Opioid and Heroin Epidemic Awareness Week. Additionally, forty-six governors have agreed to take steps to address the nation's opioid addiction by signing the NGA Compact to Fight Opioid Addiction which seeks to reduce inappropriate prescribing of opioids and changing the nation's understanding of opioids and addiction, and ensuring a path to recovery for individuals suffering from addiction. The DEA continues to expand its Prescription Take-Back programs, with the next one being held on October 22, 2016.

However, many have recognized that in addition the need for awareness and policies to reduce the chances that an individual becomes addicted to opioids, there is also a need for the wider availability of the life-saving drug, naloxone, for those currently suffering from opioid addiction.

As a result of this need, the FDA recently launched a 2016 Naloxone App competition aimed at developing a mobile phone application that can connect opioid users, family members, and bystanders with nearby carriers of naloxone in an emergency overdose situation.

Likewise, at the state and local level, governments have been revising state laws to authorize the dispensing of naloxone without a prescription; such changes have allowed more and more pharmacies to dispense naloxone without a prescription, greatly increasing access to the lifesaving drug. Rite Aid, for example, recently announced that naloxone is now available without a prescription in its pharmacies in 17 states; CVS and

Related Capabilities

- Healthcare & Life Sciences
- Healthcare Transactions & Regulations
- Healthcare Litigation
- Medical Devices

Walgreens have implemented similar policies. Midwest states that have implemented regulations or policies regarding administration of naloxone by pharmacies include: Illinois, Missouri, Wisconsin, Nebraska, Minnesota and South Dakota (note: Minnesota and South Dakota allow dispensing of naloxone under a protocol or collaborative practice agreement).

The effort to make naloxone available to those in need has expanded to some pharmacy manufacturers who have also been donating naloxone to state agencies, community pharmacies, treatment centers, and health care providers. For example, Mallinckrodt Pharmaceuticals recently announced the donation of 30,000 drug deactivation pouches in Hennepin County, Minnesota.

Additionally, state officials have expanded their plans to distribute naloxone to a number of different agencies. Colorado, for example, recently announced plans to distribute naloxone to first responders in seventeen counties with high rates of drug overdoses. Many other states have announced similar plans.

Yet, even with so many industry players, lawmakers, and the public agreeing that greater action to curb opioid abuse and make naloxone more easily available to those in need, there continues to be disagreements and difficult questions that must be addressed. Recently, for example, a joint FDA advisory panel split on whether the injectable .4mg dose of naloxone should remain the current standard, or whether that dosage standard should be raised.

For now, given the daily changes in policy and laws related to naloxone dispensing, the pharmacy industry should continue to monitor applicable state and federal law, and, if a pharmacy determines that it can, and will, dispense naloxone without a prescription, it should adopt appropriate protocols and policies at the corporate and store level to ensure any required record keeping, reporting, or counseling requirements are met. Additionally, retail pharmacies should consider adopting policies and procedures for emergency situations involving an individual presenting themselves at the store for naloxone while experiencing an overdose. The pharmacies' legal counsel should be involved in drafting and reviewing these policies to ensure compliance with state and federal laws.