Naloxone – Safety Update

- On July 23, 2020, the FDA announced that in order to reduce the risk of death from opioid overdose, healthcare providers should discuss the availability of naloxone and consider prescribing it to patients who are prescribed opioid pain relievers, patients who are prescribed medicines to treat opioid use disorder (OUD), and for other patients at increased risk of opioid overdose.

- Naloxone is an FDA-approved medicine used to treat an opioid emergency such as an overdose or possible overdose. There are three FDA-approved forms of naloxone: a nasal spray, an injectable, and an autoinjector. Naloxone is sold under the brand names Narcan® and Evzio®, and also as generics.

- Healthcare providers should routinely discuss the availability of naloxone with all patients when prescribing or renewing an opioid analgesic or medicine to treat OUD and consider prescribing naloxone to patients prescribed medicines to treat OUD and patients prescribed opioid analgesics who are at increased risk of opioid overdose.

- Health care professionals should also consider prescribing naloxone when a patient has household members, including children, or other close contacts at risk for accidental ingestion or opioid overdose.

- Health care professionals should educate patients and caregivers on how to recognize respiratory depression and how to administer naloxone. Patients should be informed about their options for obtaining naloxone as permitted by their individual state dispensing and prescribing requirements or guidelines for naloxone. Patients should seek emergency medical help, even if naloxone is administered.

- Patients should discuss the benefits of naloxone with their health care provider and how to obtain it. In most states, and the District of Columbia, patients can obtain naloxone from a pharmacy under a standing order that takes the place of an individual prescription. Some states also allow patients to obtain naloxone without a prescription from a community-based program or pharmacy. Patients may refer to their respective State Health Department for more information.

- The FDA is requiring the drug manufacturers for all opioid pain relievers and medicines to treat OUD to add new recommendations about naloxone to the prescribing information. This will help ensure that health care professionals discuss the availability of naloxone and assess each patient's need for a naloxone prescription when opioid pain relievers or medicines to treat OUD are being prescribed or renewed. The patient Medication Guides will also be updated.