From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Thursday, March 16, 2017 8:06 AM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: SynchroMed II and SynchroMed EL Implantable Drug Infusion Pumps by Medtronic: Class I Recall - Failure of Priming Bolus

AUDIENCE: Risk Manager, Patient

ISSUE: Medtronic is recalling the SynchroMed Implantable Infusion Pumps because a software problem may cause unintended delivery of drugs during a priming bolus procedure, used to quickly deliver large dose of medication from the device to the patient's spine. During this procedure, patients may receive the drug unintentionally at a high rate of infusion in the cerebrospinal fluid followed by a period of reduced drug delivery after the priming bolus. This can result in a drug overdose or under dose which can lead to serious adverse health consequences such as respiratory depression, coma or death.

BACKGROUND: The SynchroMed II and SynchroMed EL Implantable Drug Infusion Pumps (SynchroMed Implantable Infusion Pumps) are programed to deliver prescribed drugs to a specific site inside the patient's body. The SynchroMed pumps are used to treat primary or metastatic cancer, chronic pain, and severe spasticity.

RECOMMENDATION: In September 2016, Medtronic sent an Urgent Medical Device Correction notice to affected customers. The notice provided a description of the software change, description of labeling changes, 8870 software card recommendations, and new priming bolus recommendations. The notice also asked customers to:

- Continue to use the current software card and its displayed tubing volume until the Medtronic Representative has exchanged the current card with the new software card (new version is AAU0).

Medtronic Representatives began visiting affected customers on October 3, 2016 to replace software application cards with the updated version (AAU01).

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Read the MedWatch safety alert, including a link to the FDA recall notice, at:

https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm546623.htm