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ADVISORY

To: Massachusetts Controlled Substance Registrants

FROM: David Johnson, Director, Drug Control Program

DATE: November 6, 2024

RE: Sale, Transfer or Trade of Prescription Grade Intravenous (IV) IV Fluids During FDA Declared Shortage

The recent hurricanes affecting the southeastern United States have disrupted the usual modes of manufacture and distribution of several kinds of medical grade IV fluids. As a result, the FDA added certain IV fluids to its drug shortage list. That list currently includes multiple kinds of IV fluids, and the FDA acknowledges that additional IV fluids may need to be added to this list as additional information regarding storm damage becomes available.¹ The FDA further acknowledges that it may need to take additional action to alleviate these shortages.

For the duration of the FDA's acknowledgement of IV fluid scarcity due to hurricane related supply chain disruptions, the Drug Control Program will consider that any sale, transfer or trade of commercially available preparations of the IV fluids included on the FDA's shortage list, made by one Registrant to another Registrant, is being made for emergency medical reasons as that term is used in FDA regulation 21 CFR 203.3(m) and 203.3(cc)(5). The Drug Control Program will consider that all such sales, transfers or trades are not distribution and therefore do not require a Distributor MCSR. The Drug Control Program will rescind this Advisory when the hurricane related supply chain disruptions are sufficiently resolved.

Questions should be addressed to the Drug Control Program at: dcp.dph@mass.gov

¹ [Hurricane Helene: Baxter's manufacturing recovery in North Carolina | FDA](#); [Drug Shortages | FDA](#); and [Temporary Policies for Compounding Certain Parenteral Drug Products | FDA](#)