

ANDREW M. CUOMO Governor HOWARD A. ZUCKER, M.D., J.D. Commissioner SALLY DRESLIN, M.S., R.N. Executive Deputy Commissioner

October 13, 2016

Dear Class 11 Pharmacy – Automated Dispensing System (ADS) Licensee:

Subject: System Requirements for Continuous Dosing Use

Class 11 Pharmacy – ADS licensees are on notice that the New York State Department of Health, Bureau of Narcotic Enforcement (BNE) is in the process of developing guidelines regarding system requirements for continuous dosing use.

As defined in Title 10 NYCRR Part 80, Section 80.1(g), only those systems which possess capabilities relative to the storage, packaging, counting, labeling, and dispensing of controlled substances will be considered eligible for continuous dosing use.

Pharmacies seeking to utilize an ADS for the continuous dosing of patient-specific prescriptions may not delegate the operations or activities of packaging, counting, labeling, and/or dispensing of controlled substances to non-pharmacy personnel (<u>i.e.</u>, residential health care facility personnel).

Previously approved continuous dosing systems which do not directly package, count, label and dispense patient-specific controlled substances may continue to be recognized as a secure method of storage for controlled substances in sealed emergency medication kits as outlined in Title 10 NYCRR Part 80, Section 80.50(e)(1).

Should you have any questions, please contact BNE at <u>narcotic@health.ny.gov</u>.

Michele Mulloy

Regulatory Compliance Section Manager NYS DOH Bureau of Narcotic Enforcement