

Guidance for Long-Term Care Facilities (LTCF) and Other Class 3A Institutional Dispenser, Limited Facilities (Class 3A Licensees)

The 2014 Drug Enforcement Administration (DEA) Rule allows authorized hospitals/clinics and retail pharmacies to maintain collection receptacles at LTCFs on a voluntary basis.

The New York State Department of Health (DOH) requires institutional facilities without the services of an on-site pharmacy to be licensed as a Class 3A Institutional Dispenser, Limited facility; however, **not every Class 3A licensee meets the qualifications required to be recognized by the DEA as a LTCF.**

“Class 3A Institutional Dispenser, Limited” licensee means nursing homes, convalescent homes, health-related facilities, adult care facilities subject to the provisions of Title 10 NYCRR Parts 487, 488 & 490, dispensaries or clinics not qualifying as institutional dispensers in license Class 3.

“Long Term Care Facility” (LTCF) means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients. (21 CFR 1300.01(b))

1. LTCF disposal (Residents). Mail-back programs and collection receptacles.
 - LTCF residents may participate in DEA authorized collection mail-back programs and collection receptacles in accordance with federal DEA regulations. (21 CFR 1317.70)
 - While LTCFs may not use mail-back packages or administer a mail-back program, LTCF residents may avail themselves of all disposal methods made available under the DEA rule to ultimate users, including participation in authorized mail-back programs.
 - On behalf of an LTCF resident, an LTCF employee may place the resident’s unwanted pharmaceutical controlled substances in a mail-back package, seal it, and deposit it into the facility’s outgoing mail system. (K Issue #5; Federal Register Vol. 79 No. 174)
2. Retail pharmacies and hospitals/clinics with an on-site pharmacy may maintain DEA authorized collection receptacles at LTCFs in accordance with federal DEA regulations. (21 CFR 1317.75) (21 CFR 1317.80)
 - A collection receptacle at a LTCF shall be securely fastened to a permanent structure and located in a secured area regularly monitored by LTCF employees. (21 CFR 1317.75(d)(2))
 - Only those controlled substances listed in Schedule II, III, IV, or V that are lawfully possessed by an ultimate user who resides, or has resided, at the LTCF may be collected. Schedule I controlled substances, controlled substances that are not lawfully possessed by the ultimate user, and other illicit or dangerous substances are not permitted. (21 CFR 1317.30) (21 CFR 1317.70) (21 CFR 1317.75(b)&(c))
 - Mail-back package and collection receptacle disposal of hypodermic syringes and needles is prohibited.
3. DEA regulations allow for, a LTCF to dispose of controlled substances in Schedules II, III, IV, and V on behalf of an ultimate user who resides, or has resided, at such LTCF by transferring those

discontinued pharmaceutical controlled substances into an authorized collection receptacle located at that LTCF.

4. Class 3A Institutional Dispenser, Limited licensees with lawful temporary custody of pharmaceutical controlled substances which are undesired, deteriorated, obsolete, or for any reason no longer needed may surrender for destruction such controlled substances to law enforcement ***pursuant to a DOH approved Law Enforcement Take-Back Event.***
 - Federal, State, tribal, or local law enforcement may collect controlled substances from ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property.
 - Law enforcement shall appoint a law enforcement officer employed by the agency to oversee the collection.
 - Law enforcement officers employed and authorized by the law enforcement agency or law enforcement component of a Federal agency conducting a take back event shall maintain control and custody of the collected substances from the time the substances are collected from the ultimate user or person authorized to dispose of the ultimate user decedent's property until secure transfer, storage, or destruction of the controlled substances has occurred.
 - Each Class 3A Institutional Dispenser, Limited licensee seeking to participate in a DOH approved Law Enforcement Take-Back Event must complete and submit to the applicable DOH Bureau of Narcotic Enforcement regional office a DOH-2340 and DOH-166 identifying all controlled substances to be surrendered. Instructions and forms may be located at https://www.health.ny.gov/professionals/narcotic/licensing_and_certification/destruction.htm