

10A NCAC 26E .0406 DISPOSAL OF UNUSED CONTROLLED SUBSTANCES FROM NURSING HOME *(Effective September 25, 2024)*

Controlled substances dispensed for inpatient administration to individuals residing in a licensed nursing home which for any reason are unused shall be returned to the pharmacy from which they were received. The pharmacist who receives these controlled substances shall return them to their stock or dispose of and destroy them in accordance with 21 CFR 1317.05(a). The pharmacist shall keep a record of the disposal and destruction of unused controlled substances available for a minimum of two years. This record of disposal and destruction shall be kept on the Division form entitled "Record of Ultimate User Controlled Substances Destroyed".

Controlled substances returned to stock must be in a hermetically sealed container or in an otherwise pure uncontaminated condition and be identifiable. A pharmacist may outsource destruction of the unused controlled substances to a reverse distributor in accordance with 21 CFR 1317.05(a)(2), provided the pharmacist must first verify the vendor is registered with the DEA as a reverse distributor and maintains compliance with all applicable federal and State laws and regulations governing reverse distributors and destruction of unused controlled substances. Compliance with this rule is subject to audit by the Director or their designated representative.

<http://reports.oah.state.nc.us/ncac.asp>

Frequently Asked Questions:

1. When does this amended rule regarding disposal of unused controlled substances from nursing homes go into effect?

This emergency amendment goes into effect on September 25th, 2024.

2. What methods of destruction are allowed for controlled substances returned to pharmacies from skilled nursing facilities?

Currently, the following two methods are approved in North Carolina for disposing or destroying unused control substances from nursing homes upon return to the Pharmacy.

- A. When controlled substances are returned to the pharmacy, a representative from the North Carolina Drug Control Unit will conduct an audit. The controlled substances are subsequently secured and sealed in boxes. The box or boxes are then transported to a facility for incineration. This process is witnessed by a Drug Control Unit inspector. The closest identified facility for incineration is currently [Reworld Fairfax](#), located in Lorton, VA.
- B. The pharmacy will utilize a Drug Enforcement Agency (DEA) approved reverse distributor.

3. What is the procedure for scheduling a witnessed incineration of controlled substance returns from skilled nursing facilities?

Currently there are no commercial incinerators in North Carolina that will accept or accommodate witnessed destructions of controlled substances from Long-Term Care Pharmacies. The NC Drug Control Unit has been working on locating an incinerator that

will accept such controlled substances for destruction. [Reworld Fairfax](#) located in Lorton Virginia is a facility that will accept controlled substances for witnessed destruction. Any Long-Term Care Pharmacy wishing to use this approach is responsible for contacting Reworld Fairfax to establish a written agreement and for making all other arrangements needed to use this disposal option in accordance with North Carolina and federal law and regulations.

4. What is the procedure for utilizing a DEA registered reversed distributor for controlled substance returns from skilled nursing facilities?

A Long-Term Care Pharmacy that has controlled substances dispensed for inpatient administration returned to it from skilled nursing facilities may outsource destruction of such unused controlled substances to a currently registered reverse distributor. The reverse distributor must be currently registered with the DEA as a reverse distributor (21 CFR 1317.05). If a pharmacy uses this option, they should provide written notification by email to one of the NCDHHS Drug Control Unit inspectors to indicate that they have elected to use a reverse distributor.

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