

10A NCAC 26E .0406 DISPOSAL OF UNUSED CONTROLLED SUBSTANCES FROM NURSING HOME

A pharmacy that has dispensed controlled substances for inpatient administration to individuals residing in a licensed nursing home shall be responsible for either returning unused controlled substances to its stock, or disposing of and destroying any unused controlled substances in accordance with 21 CFR 1317.05(a) or (c), and other applicable federal regulations governing U.S. Drug Enforcement Administration (DEA) registrant collection, disposal, and destruction of unused controlled substances in licensed nursing homes, including 21 U.S.C. 822(g), 21 CFR 1317.10, 21 CFR 1317.15, 21 CFR 1317.80, 21 CFR 1304.22, and 21 CFR Part 1317 Subpart C. The pharmacy 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 of Mental Health, Developmental Disabilities, and Substance Use Services (Division) Form entitled "Record of Controlled Substances Destroyed Pursuant to Rule 10A NCAC 26E .0406". This form is available upon request at Drug Control Unit 3008 Mail Service Center Raleigh, NC 27699-3008 or nccsareg@dhhs.nc.gov. Controlled substances returned to stock must be in a hermetically sealed container or in a pure uncontaminated condition and be identifiable with the original manufacturer's labelling legible. A pharmacy may outsource destruction of the unused controlled substances to a reverse distributor in accordance with 21 CFR 1317.05(a)(2), provided the pharmacy must first verify the reverse distributor 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 per 21 CFR 1317.15. Pharmacies that are authorized by the DEA as collectors may install, manage, and maintain collection receptacles at nursing homes for the purpose of collection, disposal, and destruction of unused controlled substances from nursing homes, in accordance with 21 CFR 1317.05(c), 21 CFR 1317.40, and other applicable federal regulations governing the use of collection receptacles by authorized pharmacy collectors in nursing homes, including 21 CFR 1301.51, 21 CFR 1316.02, 21 CFR 1317.05(c)(2)(iv), 21 CFR 1317.60, 21 CFR 1317.75, and 21 CFR 1317.80. Compliance with this Rule is subject to audit by the Division Director or their designated representative.

*History Note: Authority G.S. 90-100; 143B-147;
Eff. June 30, 1978;
Amended Eff. September 15, 1980; May 15, 1979;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Emergency Amendment Eff. September 30, 2024;
Temporary Amendment Eff. January 2, 2025;
Amended Eff. November 1, 2025.*