

Note from the Codifier: The OAH website includes notices and the text of proposed temporary rules as required by G.S. 150B-21.1(a1). Prior to the agency adopting the temporary rule, the agency must hold a public hearing no less than five days after the rule and notice have been published and must accept comments for at least 15 business days. For questions, you may contact the Office of Administrative Hearings at 984-236-1850 or email oah.postmaster@oah.nc.gov.

TITLE 10A – DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice is hereby given in accordance with G.S. 150B-21.1 that the Commission for Mental Health/DD/SAS intends to amend the rule cited as 10A NCAC 26E .0406.

Codifier of Rules approved this rule as an emergency rule effective September 25, 2024 and received for publication the following notice and proposed temporary rule on: September 17, 2024.

Public Hearing:

Date: October 8, 2024

Time: 10:00 a.m.

Location: Microsoft Teams Join the meeting now Meeting ID: 248 612 694 Passcode: 7QL7mh Dial in by phone +1 984-204-1487.. 85608728# United States, Raleigh Phone conference ID: 856 087 28# Join on a video conference device Tenant key: ncgov@m.webex.com Video ID 118 798 209 6

Reason for Proposed Temporary Action: A serious and unforeseen threat to the public health, safety or welfare. On July 26, 2024, Stericycle, the owners of the only incinerator in North Carolina that is capable of destroying controlled substances to the point that they are non-retrievable, notified long-term care pharmacies in North Carolina that they will no longer accept bookings for witnessed destruction of controlled substances. Stericycle's business decision to no longer provide long-term care pharmacies the option of destruction of unused controlled substances from nursing homes by an incinerator within the State was not foreseen by the Department. Amendment of Rule 10A NCAC 26E .0406 is proposed for emergency, and simultaneously, temporary procedures to provide immediate clarity regarding the use of federally recognized options for disposing of and destroying unused controlled substances from nursing homes, including outsourcing the destruction to reverse distributors, in order to help ensure safe, secure, and timely disposal and destruction of unused controlled substances in North Carolina. The proposed emergency and temporary rules are in the public's best interest to avoid the threat of unused controlled substances accumulating at nursing homes or long-term care pharmacies, and the related diversion risks.

Comment Procedures: Comments from the public shall be directed to: Denise Baker, 3001 Mail Service Center, Raleigh, NC 27699-3001; email dmhdsasrules@dhhs.nc.gov. The comment period begins September 30, 2024 and ends October 18, 2024.

CHAPTER 26 - MENTAL HEALTH, GENERAL

SUBCHAPTER 26E - MANUFACTURERS: DISTRIBUTORS: DISPENSERS AND RESEARCHERS OF CONTROLLED SUBSTANCES

SECTION .0400 - MISCELLANEOUS

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

Controlled substances dispensed for inpatient administration to individuals residing in ~~to~~ 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 ~~his~~ their stock or dispose of and destroy them in accordance with ~~the procedure outlined by the director and~~ 21 CFR 1317.05(a). The pharmacist shall keep a record of this 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 "Controlled Record of Ultimate User Controlled Substances Destroyed". Destruction Record Nursing Homes. 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.

Authority G.S. 90-100; ~~143B-210(9);~~ 143B-147.