

G.S. 150B-21.3A Report for 10A NCAC 26E, MANUFACTURERS: DISTRIBUTORS: DISPENSERS AND RESEARCHERS OF CONTROLLED SUBSTANCES							
Agency - DHHS - Commission for Mental Health, Developmental Disabilities and Substance Abuse Services							
Comment Period - September 16, 2025 - November 15, 2025							
Date Submitted to APO - Filled in by RRC staff							
Subchapter	Rule Section	Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]	Required to Implement or Conform to Federal Regulation [150B-21.3A(d1)]	Federal Regulation Citation
SUBCHAPTER 26E - MANUFACTURERS: DISTRIBUTORS: DISPENSERS AND RESEARCHERS OF CONTROLLED SUBSTANCES	SECTION .0100 - REGISTRATION OF MANUFACTURERS: DISTRIBUTORS: AND DISPENSERS OF CONTROLLED SUBSTANCES	10A NCAC 26E .0101	SCOPE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1301.01
		10A NCAC 26E .0102	DEFINITIONS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1300.01
		10A NCAC 26E .0103	ADDITIONAL INFORMATION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No	
		10A NCAC 26E .0104	PERSONS REQUIRED TO REGISTER	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1301.11
		10A NCAC 26E .0105	SEPARATE REGISTRATION FOR INDEPENDENT ACTIVITIES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1309.13
		10A NCAC 26E .0106	TRAINING AND QUALIFICATION REQUIREMENTS FOR DOG HANDLERS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No	
		10A NCAC 26E .0107	APPROVAL OF CANINE CERTIFICATION ASSOCIATIONS BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No	
		10A NCAC 26E .0108	SEPARATE REGISTRATION FOR SEPARATE LOCATIONS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1301.12
		10A NCAC 26E .0109	EXEMPTION OF AGENTS AND EMPLOYEES: AGENTS OF MANUFACTURERS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1301.22
		10A NCAC 26E .0110	EXEMPTION OF INDIVIDUAL PRACTITIONERS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1301.22
		10A NCAC 26E .0111	EXEMPTION OF LAW ENFORCEMENT OFFICIALS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1309.26
		10A NCAC 26E .0112	TIME FOR APPLICATION FOR REGISTRATION: EXPIRATION DATE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1309.31
		10A NCAC 26E .0113	APPLICATION FORMS: CONTENTS: SIGNATURE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1309.32
		10A NCAC 26E .0114	FILING OF APPLICATION: JOINT FILINGS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1309.33
		10A NCAC 26E .0115	ACCEPTANCE FOR FILING: DEFECTIVE APPLICATIONS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1309.34
		10A NCAC 26E .0116	ADDITIONAL INFORMATION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1309.35
		10A NCAC 26E .0117	AMENDMENTS TO AND WITHDRAWAL OF APPLICATIONS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1309.36

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		10A NCAC 26E .0118	ADMINISTRATION REVIEW GENERALLY	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1309.41
		10A NCAC 26E .0119	CERTIFICATE OF REGISTRATION: DENIAL OF REGISTRATION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1309.42
		10A NCAC 26E .0120	SUSPENSION OR REVOCATION OF REGISTRATION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1309.43
		10A NCAC 26E .0121	SUSPENSION OF REGISTRATION PENDING FINAL ORDER	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1309.44
		10A NCAC 26E .0122	EXTENSION OF REGISTRATION PENDING FINAL ORDER	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1309.45
		10A NCAC 26E .0123	ORDER TO SHOW CAUSE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1301.37
		10A NCAC 26E .0124	HEARINGS GENERALLY	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1301.41
		10A NCAC 26E .0125	MODIFICATION IN REGISTRATION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1313.51
		10A NCAC 26E .0126	TERMINATION OF REGISTRATION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1301.52
		10A NCAC 26E .0127	TRANSFER OF REGISTRATION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1301.52
		10A NCAC 26E .0128	EXEMPTION FROM REGISTRATION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No	
		10A NCAC 26E .0129	SECURITY REQUIREMENTS GENERALLY	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1301.71-1301.77
	SECTION .0200 - LABELING AND PACKAGING CONTROLLED SUBSTANCES: RECORDS OF REGISTRANTS	10A NCAC 26E .0201	LABELING AND PACKAGING REQUIREMENTS GENERALLY	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1302; 1306.14; 1306.24
		10A NCAC 26E .0202	RECORD AND INVENTORY REQUIREMENTS GENERALLY	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1304.03-1304.26
	SECTION .0300 - PRESCRIPTIONS	10A NCAC 26E .0301	PRESCRIPTION REQUIREMENTS GENERALLY	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1306.11; 1306.21
		10A NCAC 26E .0302	NONPRESCRIPTION REQUIREMENTS GENERALLY	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1306.01
		10A NCAC 26E .0303	USE OF CONTROLLED SUBSTANCES IN SCHEDULE VI	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1308.11

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		10A NCAC 26E .0304	HOSPITALS HAVING 24-HOUR PHARMACY SERVICE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1306.6
		10A NCAC 26E .0305	HOSPITALS NOT HAVING 24-HOUR PHARMACY SERVICE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1306.6
		10A NCAC 26E .0306	SUPPLYING OF METHADONE IN TREATMENT PROGRAMS BY RN	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1306.07
		10A NCAC 26E .0307	PREPRINTED PRESCRIPTION BLANKS PROHIBITED	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1306.05
		10A NCAC 26E .0308	USE OF SYNTHETIC CANNABINOIDS IN SCHEDULE II	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No	
	SECTION .0400 - MISCELLANEOUS	10A NCAC 26E .0401	DEFINITIONS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No	
		10A NCAC 26E .0402	APPLICATION OF OTHER STATE LAW AND FEDERAL LAW	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1307.02
		10A NCAC 26E .0403	DISTRIBUTION TO SUPPLIER	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No	
		10A NCAC 26E .0404	DISCONTINUANCE OR TRANSFER OF BUSINESS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1301.52
		10A NCAC 26E .0405	PROCEDURE FOR DISPOSING OF CONTROLLED SUBSTANCES	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR Part 1317 Subpart A
		10A NCAC 26E .0406	DISPOSAL OF UNUSED CONTROLLED SUBSTANCES FROM NURSING HOME	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1317.80
		10A NCAC 26E .0407	DISPOSAL BY REGISTRANTS AND PRACTITIONERS: SCHEDULES II-V	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR Part 1317 Subpart C
		10A NCAC 26E .0408	SPECIAL CONTROLLED SUBSTANCES EMERGENCY KIT	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No	
		10A NCAC 26E .0409	DISPOSAL OF UNUSED PORTIONS OF INJECTABLE: SCHEDULES II-V	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1317.90
		10A NCAC 26E .0410	RECORD OF ALL CONTROLLED SUBSTANCES DISPENSED	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1304.22 c
	SECTION .0500 - ADMINISTRATIVE FUNCTIONS: PRACTICES AND PROCEDURES	10A NCAC 26E .0501	SCOPE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1316.01
		10A NCAC 26E .0502	DEFINITIONS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No	

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		10A NCAC 26E .0503	AUTHORITY TO MAKE INSPECTIONS	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No	
		10A NCAC 26E .0504	EXCLUSION FROM INSPECTION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No	
		10A NCAC 26E .0505	ENTRY	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	Yes If yes, include the citation to the federal law	21 CFR 1316.05
		10A NCAC 26E .0506	NOTICE OF INSPECTION	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No	
	SECTION .0600 - CONTROLLED SUBSTANCES REPORTING SYSTEM	10A NCAC 26E .0601	SCOPE	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No	
		10A NCAC 26E .0602	DEFINITIONS	Amended Eff. November 1, 2022	Necessary	No	
		10A NCAC 26E .0603	REQUIREMENTS FOR TRANSMISSION OF DATA	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016	Necessary	No	
		10A NCAC 26E .0604	REPORTING REQUIREMENTS	Eff. November 1, 2022	Necessary	No	
		10A NCAC 26E .0605	PENALTIES	Eff. November 1, 2022	Necessary	No	