

G.S. 150B-21.3A Report for 10A NCAC SUBCHAPTER 26E, MANUFACTURERS: DISTRIBUTORS: DISPENSERS AND RESEARCHERS OF CONTROLLED SUBSTANCES

Agency - DHHS - Commission for Mental Health, Developmental Disabilities and Substance Abuse Services

Comment Period - September 12, 2015 - November 11, 2015

Date Submitted to APO - Filled in by RRC staff

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SECTION .0100 - REGISTRATION OF MANUFACTURERS: DISTRIBUTORS: AND DISPENSERS OF CONTROLLED SUBSTANCES	10A NCAC 26E .0101	SCOPE	Eff. June 30, 1978	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 26E .0102	DEFINITIONS	Amended Eff. February 1, 2005	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 26E .0103	ADDITIONAL INFORMATION	Amended Eff. May 15, 1979	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 26E .0104	PERSONS REQUIRED TO REGISTER	Amended Eff. February 23, 2005	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 26E .0105	SEPARATE REGISTRATION FOR INDEPENDENT ACTIVITIES	Amended Eff. February 1, 2005	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 26E .0106	TRAINING AND QUALIFICATION REQUIREMENTS FOR DOG HANDLERS	Eff. February 1, 2005	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 26E .0107	APPROVAL OF CANINE CERTIFICATION ASSOCIATIONS BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES	Eff. February 1, 2005	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 26E .0108	SEPARATE REGISTRATION FOR SEPARATE LOCATIONS	Recodified from 10A NCAC 26E .0106 Eff. February 1, 2005	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	21 CFR .1301.12	No	Necessary without substantive public interest
	10A NCAC 26E .0109	EXEMPTION OF AGENTS AND EMPLOYEES: AGENTS OF MANUFACTURERS	Recodified from 10A NCAC 26E .0107 Eff. February 1, 2005	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	21 CFR .1301.22	No	Necessary without substantive public interest
	10A NCAC 26E .0110	EXEMPTION OF INDIVIDUAL PRACTITIONERS	Recodified from 10A NCAC 26E .0108 Eff. February 1, 2005	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	21 CFR .1301.22	No	Necessary without substantive public interest
10A NCAC 26E .0111	EXEMPTION OF LAW ENFORCEMENT OFFICIALS	Recodified from 10A NCAC 26E .0109 Eff. February 1, 2005	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	21 CFR .1301.23; 21 CFR .1301.24	No	Necessary without substantive public interest	

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	10A NCAC 26E .0112	TIME FOR APPLICATION FOR REGISTRATION: EXPIRATION DATE	Recodified from 10A NCAC 26E .0110 Eff. February 1, 2005	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 26E .0113	APPLICATION FORMS: CONTENTS: SIGNATURE	Recodified from 10A NCAC 26E .0111 Eff. February 1, 2005	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	21 CFR .1301.11	No	Necessary without substantive public interest
	10A NCAC 26E .0114	FILING OF APPLICATION: JOINT FILINGS	Recodified from 10A NCAC 26E .0112 Eff. February 1, 2005	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 26E .0115	ACCEPTANCE FOR FILING: DEFECTIVE APPLICATIONS	Recodified from 10A NCAC 26E .0113 Eff. February 1, 2005	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 26E .0116	ADDITIONAL INFORMATION	Recodified from 10A NCAC 26E .0114 Eff. February 1, 2005	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 26E .0117	AMENDMENTS TO AND WITHDRAWAL OF APPLICATIONS	Recodified from 10A NCAC 26E .0115 Eff. February 1, 2005	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 26E .0118	ADMINISTRATION REVIEW GENERALLY	Recodified from 10A NCAC 26E .0116 Eff. February 1, 2005	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10 NCAC 26E .0119	CERTIFICATE OF REGISTRATION: DENIAL OF REGISTRATION	Recodified from 10A NCAC 26E .0117 Eff. February 1, 2005	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	21 CFR .1301.35	No	Necessary without substantive public interest
	10A NCAC 26E .0120	SUSPENSION OR REVOCATION OF REGISTRATION	Recodified from 10A NCAC 26E .0118 Eff. February 1, 2005.	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	21 CFR .1301.36	No	Necessary without substantive public interest
	10A NCAC 26E .0121	SUSPENSION OF REGISTRATION PENDING FINAL ORDER	Recodified from 10A NCAC 26E .0119 Eff. February 1, 2005	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	21 CFR .1301.36	No	Necessary without substantive public interest
	10A NCAC 26E .0122	EXTENSION OF REGISTRATION PENDING FINAL ORDER	Recodified from 10A NCAC 26E .0120 Eff. February 1, 2005	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	21 CFR .1301.36	No	Necessary without substantive public interest

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	10A NCAC 26E .0123	ORDER TO SHOW CAUSE	Recodified from 10A NCAC 26E .0121 Eff. February 1, 2005	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 26E .0124	HEARINGS GENERALLY	Recodified from 10A NCAC 26E .0122 Eff. February 1, 2005	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	21 CFR .1301.41	No	Necessary without substantive public interest
	10A NCAC 26E .0125	MODIFICATION IN REGISTRATION	Recodified from 10A NCAC 26E .0123 Eff. February 1, 2005	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	21 CFR .1301.51	No	Necessary without substantive public interest
	10A NCAC 26E .0126	TERMINATION OF REGISTRATION	Recodified from 10A NCAC 26E .0124 Eff. February 1, 2005	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	21 CFR .1301.52	No	Necessary without substantive public interest
	10A NCAC 26E .0127	TRANSFER OF REGISTRATION	Recodified from 10A NCAC 26E .0125 Eff. February 1, 2005	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	21 CFR .1301.52	No	Necessary without substantive public interest
	10A NCAC 26E .0128	EXEMPTION FROM REGISTRATION	Recodified from 10A NCAC 26E .0126 Eff. February 1, 2005	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 26E .0129	SECURITY REQUIREMENTS GENERALLY	Recodified from 10A NCAC 26E .0127 Eff. February 1, 2005	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	21 CFR .1301.71	No	Necessary without substantive public interest
SECTION .0200 - LABELING AND PACKAGING CONTROLLED SUBSTANCES: RECORDS OF REGISTRANTS	10A NCAC 26E .0201	LABELING AND PACKAGING REQUIREMENTS GENERALLY	Amended Eff. September 30, 1978	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	21 CFR .1302.14; 21 CFR .1306.24; 21 CFR .1306.14	No	Necessary without substantive public interest
	10A NCAC 26E .0202	RECORD AND INVENTORY REQUIREMENTS GENERALLY	Amended Eff. May 1, 1990	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	21 CFR .1304	No	Necessary without substantive public interest
SECTION .0300 - PRESCRIPTIONS	10A NCAC 26E .0301	PRESCRIPTION REQUIREMENTS GENERALLY	Amended Eff. August 1, 1987	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	21 CFR .1304; 21 CFR .1306	No	Necessary without substantive public interest
	10A NCAC 26E .0302	NONPRESCRIPTION REQUIREMENTS GENERALLY	Eff. June 30, 1978	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	21 CFR .1306	No	Necessary without substantive public interest
	10A NCAC 26E .0303	USE OF CONTROLLED SUBSTANCES IN SCHEDULE VI	Amended Eff. September 15, 1980	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	21 CFR .1306	No	Necessary without substantive public interest
	10A NCAC 26E .0304	HOSPITALS HAVING 24-HOUR PHARMACY SERVICE	Eff. June 30, 1978	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 26E .0305	HOSPITALS NOT HAVING 24-HOUR PHARMACY SERVICE	Amended Eff. May 1, 1990	Necessary without substantive public interest	No		No	Necessary without substantive public interest

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	10A NCAC 26E .0306	SUPPLYING OF METHADONE IN TREATMENT PROGRAMS BY RN	Amended Eff. August 1, 2002	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 26E .0307	PREPRINTED PRESCRIPTION BLANKS PROHIBITED	Eff. April 1, 1983	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 26E .0308	USE OF SYNTHETIC CANNABINOIDS IN SCHEDULE II	Amended Eff. December 1, 1987	Necessary without substantive public interest	No		No	Necessary without substantive public interest
SECTION .0400 - MISCELLANEOUS	10A NCAC 26E .0401	DEFINITIONS	Eff. June 30, 1978	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 26E .0402	APPLICATION OF OTHER STATE LAW AND FEDERAL LAW	Eff. June 30, 1978	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 26E .0403	DISTRIBUTION TO SUPPLIER	Amended Eff. September 30, 1978	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 26E .0404	DISCONTINUANCE OR TRANSFER OF BUSINESS	Amended Eff. May 15, 1979	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 26E .0405	PROCEDURE FOR DISPOSING OF CONTROLLED SUBSTANCES	Amended Eff. July 1, 1994	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	21 cfr .1307	No	Necessary without substantive public interest
	10A NCAC 26E .0406	DISPOSAL OF UNUSED CONTROLLED SUBSTANCES FROM NURSING HOME	Amended Eff. September 15, 1980	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 26E .0407	DISPOSAL BY REGISTRANTS AND PRACTITIONERS: SCHEDULES II-V	Amended Eff. July 1, 1982	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	21 CFR .1317.05; 21 CFR .1317.90; 21 CFR .1317.95	No	Necessary without substantive public interest
	10A NCAC 26E .0408	SPECIAL CONTROLLED SUBSTANCES EMERGENCY KIT	Amended Eff. April 1, 2001	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 26E .0409	DISPOSAL OF UNUSED PORTIONS OF INJECTABLE: SCHEDULES II-V	Amended Eff. May 15, 1979	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 26E .0410	RECORD OF ALL CONTROLLED SUBSTANCES DISPENSED	Eff. September 15, 1980	Necessary without substantive public interest	No		No	Necessary without substantive public interest
SECTION .0500 - ADMINISTRATIVE FUNCTIONS: PRACTICES AND PROCEDURES	10A NCAC 26E .0501	SCOPE	Eff. June 30, 1978	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 26E .0502	DEFINITIONS	Amended Eff. August 1, 1990	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 26E .0503	AUTHORITY TO MAKE INSPECTIONS	Amended Eff. August 1, 1990	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	21 CFR .1316.03	No	Necessary without substantive public interest

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	10A NCAC 26E .0504	EXCLUSION FROM INSPECTION	Eff. June 30, 1978	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	21 CFR .1316.04	No	Necessary without substantive public interest
	10A NCAC 26E .0505	ENTRY	Amended Eff. May 15, 1979	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	21 CFR .1316.05	No	Necessary without substantive public interest
	10A NCAC 26E .0506	NOTICE OF INSPECTION	Amended Eff. August 1, 1990	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	21 CFR .1316.06	No	Necessary without substantive public interest
SECTION .0600 - Controlled Substances Reporting System	10A NCAC 26E .0601	SCOPE	Eff. April 1, 2007	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 26E .0602	DEFINITIONS	Eff. April 1, 2007	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	10A NCAC 26E .0603	REQUIREMENTS FOR TRANSMISSION OF DATA	Amended Eff. January 1, 2012	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	45 CFR 164	No	Necessary without substantive public interest