

G.S. 150B-21.3A Report for 21 NCAC 46, BOARD OF PHARMACY									
Agency - Board of Pharmacy									
Comment Period - February 21, 2017 to May 1, 2017									
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]	Implements or Conforms to Federal Regulation [150B-21.3A(e)]	Federal Regulation Citation	Public Comment Received [150B-21.3A(c)(1)]	Agency Determination Following Public Comment [150B-21.3A(c)(1)]
	SECTION .1200 - ORGANIZATION OF THE BOARD	21 NCAC 46 .1201	GENERAL PURPOSE OF THE BOARD	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1202	ELECTION OF OFFICERS OF THE BOARD	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1203	MEETINGS OF THE BOARD	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1205	FISCAL YEAR	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1206	FEES	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	SECTION .1300 - GENERAL DEFINITIONS	21 NCAC 46 .1317	DEFINITIONS	Amended Eff. March 1, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	SECTION .1400 - HOSPITALS: OTHER HEALTH FACILITIES	21 NCAC 46 .1401	REGISTRATION AND PERMITS	Amended Eff. May 1, 1997	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1410	PERSONNEL	Eff. May 1, 1997	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1411	RESPONSIBILITIES OF THE PHARMACIST-MANAGER	Amended Eff. March 1, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1412	PHYSICAL REQUIREMENTS	Amended Eff. January 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1413	ABSENCE OF PHARMACIST	Amended Eff. March 1, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1414	DRUG DISTRIBUTION AND CONTROL	Amended Eff. March 1, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1415	MEDICATION IN HEALTH CARE FACILITY EMERGENCY DEPARTMENTS	Amended Eff. March 1, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1416	REPACKAGING	Eff. May 1, 1997	Necessary without substantive public interest	No		No	Necessary without substantive public interest

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		21 NCAC 46 .1417	REMOTE MEDICATION ORDER PROCESSING SERVICES	Amended Eff. December 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1418	SUPERVISION OF UNIT DOSE MEDICATION SYSTEMS	Eff. June 18, 2011	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	SECTION .1500 - ADMISSION REQUIREMENTS: EXAMINATIONS	21 NCAC 46 .1501	APPLICATION	Amended Eff. July 1, 2005	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1502	AGE	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1503	EXPERIENCE IN PHARMACY	Amended Eff. March 1, 2004	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1504	EDUCATION	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1505	EXAMINATION	Amended Eff. May 1, 2017	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
		21 NCAC 46 .1506	RULES OF EXAMINATION CONDUCT	Amended Eff. May 1, 1989	Unnecessary	No		No	Unnecessary
	SECTION .1600 - LICENSES AND PERMITS	21 NCAC 46 .1601	PHARMACY PERMITS	Amended Eff. November 1, 2012	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1602	LICENSE BY RECIPROCITY	Amended Eff. February 1, 2006	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1603	WHEN NEW PERMIT REQUIRED	Amended Eff. March 1, 2004	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1604	WHEN NEW PERMIT NOT REQUIRED	Amended Eff. June 1, 2004	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1605	CHARGE FOR VERIFICATION FOR REINSTATEMENT	Amended Eff. February 1. 2006	Unnecessary	No		No	Unnecessary

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		21 NCAC 46 .1606	REQUIREMENT OF PERSONAL APPEARANCE	Amended Eff. April 1, 2003	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1607	OUT-OF-STATE PHARMACIES	Amended Eff. March 1, 2006	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1608	DEVICE AND MEDICAL EQUIPMENT PERMITS	Amended Eff. April 1, 2007	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1609	PERMIT RENEWAL	Eff. September 1, 1995	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1610	REINSTATEMENT OF FORFEITED LICENSING PRIVILEGES	Eff. September 1, 1995	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1611	FEE FOR SUBMITTAL OF DISHONORED AND RETURNED CHECK	Amended Eff. February 1, 2006	Unnecessary	No		No	Unnecessary
		21 NCAC 46 .1612	REINSTATEMENT OF LICENSES AND PERMITS	Amended Eff. March 1, 2006	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1613	EXTENSION PERIOD FOR CERTAIN MEMBERS OF THE ARMED FORCES	Eff. April 1, 2010	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1614	SUSPENSION OF AUTHORITY TO EXPEND FUNDS	Eff. August 1, 2010	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	SECTION .1700 - DRUGS DISPENSED BY NURSE OR PHYSICIAN'S ASSISTANT	21 NCAC 46 .1703	DRUGS TO BE DISPENSED	Amended Eff. April 1, 1999	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1706	RETROSPECTIVE REVIEW AND CONSULTATION	Eff. April 1, 1999	Necessary without substantive public interest	No		No	Necessary without substantive public interest

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	SECTION .1800 - PRESCRIPTIONS	21 NCAC 46 .1801	EXERCISE OF PROFESSIONAL JUDGMENT IN FILLING PRESCRIPTIONS	Amended Eff. August 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1802	PRESCRIPTION REFILLS	Amended Eff. September 1, 1993	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1803	PRESCRIPTION RECORDS	Eff. April 1, 1983	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1804	PRESCRIPTION: RECEIVING AND DISPENSING	Amended Eff. April 1, 2004	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
		21 NCAC 46 .1805	DISPENSING DRUGS WITHOUT A PRESCRIPTION	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1806	TRANSFER OF PRESCRIPTION INFORMATION	Amended Eff. June 1, 2004	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1808	REPACKAGED PHARMACEUTICALS	Eff. December 1, 1991	Unnecessary	No		No	Unnecessary
		21 NCAC 46 .1809	EMERGENCY PRESCRIPTION REFILLS	Amended Eff. April 1, 1999	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1811	EXCESSIVE DISPENSING OF PRESCRIPTION DRUGS	Eff. July 1, 1996	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1812	CHANGES IN PRESCRIPTION ORDERS	Eff. April 1, 1997	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1813	TRANSMISSION OF PRESCRIPTION ORDERS	Amended Eff. March 1, 2004	Necessary without substantive public interest	No		No	Necessary without substantive public interest

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		21 NCAC 46 .1814	AUTOMATED DISPENSING OR DRUG SUPPLY DEVICES	Amended Eff. March 1, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1815	EMERGENCY PRESCRIPTION REFILL DUE TO INTERRUPTION OF MEDICAL SERVICES	Eff. August 1, 2000	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1816	PROCEDURES FOR CENTRALIZED PROCESSING OF PRESCRIPTION ORDERS	Eff. August 1, 2000	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1817	PROOF OF IDENTIFICATION	Eff. August 1, 2002	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1818	PRESCRIPTION LABELS	Eff. January 1, 2006	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	SECTION .1900 - FORMS	21 NCAC 46 .1901	DEFINITION	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1902	APPLICATION FOR PHARMACIST'S LICENSE	Amended Eff. May 1, 1989	Unnecessary	No		No	Unnecessary
		21 NCAC 46 .1903	APPLICATION FOR PHARMACY PERMIT	Eff. April 1, 1983	Unnecessary	No		No	Unnecessary
		21 NCAC 46 .1904	RENEWAL OF PHARMACIST'S LICENSE	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1905	REPLACEMENT OF CERTIFICATES	Eff. April 1, 1983	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1906	RECIPROCITY DATA QUESTIONNAIRE	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1907	APPLICATION FOR RECIPROCITY	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest

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		21 NCAC 46 .1908	REGISTRATION FOR PRACTICAL PHARMACY TRAINING	Eff. April 1, 1983	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1909	PRACTICAL PHARMACY EXPERIENCE	Eff. April 1, 1983	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .1911	CERTIFICATE OF GRADUATION	Amended Eff. May 1, 1989	Unnecessary	No		No	Unnecessary
		21 NCAC 46 .1912	APPLICATION FOR REGISTRATION AS A DISPENSING PHYSICIAN	Eff. February 1, 1991	Unnecessary	No		No	Unnecessary
		21 NCAC 46 .1913	APPLICATION FOR DEVICE DISPENSING PERMIT	Eff. February 1, 1991	Unnecessary	No		No	Unnecessary
	SECTION .2000 - ADMINISTRATIVE PROVISIONS	21 NCAC 46 .2001	RIGHT TO HEARING	Amended Eff. October 1, 1990	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2004	REQUEST FOR HEARING	Amended Eff. August 1, 2002	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2005	GRANTING OR DENYING HEARING REQUEST	Eff. July 1, 1988	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2006	NOTICE OF HEARING	Amended Eff. September 1, 1995	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2007	WHO SHALL HEAR CONTESTED CASES	Amended Eff. September 1, 1995	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2008	INFORMAL PROCEDURES	Amended Eff. April 1, 2001	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2009	PETITION FOR INTERVENTION	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest

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		21 NCAC 46 .2010	TYPES OF INTERVENTION	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2011	DISQUALIFICATION OF BOARD MEMBERS	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2013	SUBPOENAS	Eff. September 1, 1988	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2014	WITNESSES	Eff. July 1, 1988	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2015	FINAL DECISION	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2016	PROPOSALS FOR DECISIONS	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	SECTION .2100 - ELECTIONS	21 NCAC 46 .2102	ELIGIBILITY TO VOTE	Amended Eff. May 1, 2017	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
		21 NCAC 46 .2103	GEOGRAPHIC REPRESENTATIONS	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2104	COMMITTEE ON NOMINATIONS	Amended Eff. May 1, 2017	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
		21 NCAC 46 .2105	NOMINATION BY PETITION	Amended Eff. May 1, 2017	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
		21 NCAC 46 .2106	CONSENT TO NOMINATION	Eff. April 1, 1983	Necessary without substantive public interest	No		No	Necessary without substantive public interest

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		21 NCAC 46 .2107	BALLOTS: CASTING AND COUNTING	Amended Eff. May 1, 2017	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
		21 NCAC 46 .2108	DETERMINATION OF ELECTION RESULTS	Amended Eff. May 1, 2017	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
		21 NCAC 46 .2109	DEVICE AND MEDICAL EQUIPMENT COMMITTEE REPRESENTATIVES	Amended Eff. April 1, 2003	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	SECTION .2200 - CONTINUING EDUCATION	21 NCAC 46 .2201	HOURS: RECORDS: PROVIDERS: CORRESPONDENCE: RECIPROCITY	Amended Eff. January 1, 2018	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
	SECTION .2300 - PRESCRIPTION INFORMATION AND RECORDS	21 NCAC 46 .2301	PRESCRIPTION: DRUG ORDER REQUIREMENTS	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2302	RECORDS OF DISPENSING	Amended Eff. March 1, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2303	RECORDS OF PRESCRIPTION FILLING AND REFILLING	Amended Eff. March 1, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2304	AUTOMATED DATA PROCESSING SYSTEMS	Amended Eff. March 1, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2305	SECURITY	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	SECTION .2400 - DISPENSING IN HEALTH DEPARTMENT	21 NCAC 46 .2401	MEDICATION IN HEALTH DEPARTMENTS	Amended Eff. September 1, 2016	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2402	TRAINING OF HEALTH DEPARTMENT NURSES	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest

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		21 NCAC 46 .2403	DRUGS AND DEVICES TO BE DISPENSED	Amended Eff. September 1, 2016	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	SECTION .2500 - MISCELLANEOUS PROVISIONS	21 NCAC 46 .2501	SUPERVISION	Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2502	RESPONSIBILITIES OF PHARMACIST-MANAGER	Amended Eff. April 1, 2006	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2503	RESEARCH PARTICIPATION	Eff. May 1, 1989	Unnecessary	No		No	Unnecessary
		21 NCAC 46 .2504	PATIENT COUNSELING	Amended Eff. June 1, 2004	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	Omnibus Budget and Reconciliation Act of 1990, P.L. 101-508	No	Necessary without substantive public interest
		21 NCAC 46 .2505	VETERINARY PRESCRIPTION DRUGS	Eff. September 1, 1995	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2506	EXCEPTIONS TO HEALTH CARE PRACTITIONERS IDENTIFICATION REQUIREMENTS	Eff. August 1, 2002	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2507	ADMINISTRATION OF VACCINES BY PHARMACISTS	Amended Eff. September 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2508	ELECTRONIC RECORDS	Eff. March 1, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2509	AVAILABILITY OF PHARMACY RECORDS	Eff. March 1, 2004	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2510	WAIVER OF ENFORCEMENT	Eff. July 1, 2004	Necessary without substantive public interest	No		No	Necessary without substantive public interest

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		21 NCAC 46 .2511	CHARGE FOR STATUS AFFIDAVIT	Eff. March 1, 2006	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2512	PHARMACIST WORK CONDITIONS	Eff. April 1, 2007	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2513	DRUG, SUPPLIES AND MEDICAL DEVICE REPOSITORY PROGRAM	Eff. June 1, 2010	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	SECTION .2600 – DEVICES	21 NCAC 46 .2601	DISPENSING AND DELIVERY	Amended Eff. March 1, 2006	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2602	ORDERS	Amended Eff. April 1, 1997	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2603	EDUCATION AND TRAINING	Amended Eff. September 1, 1995	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2604	RECORDS	Amended Eff. April 1, 1999	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2605	REGISTRATION OF NON-PHARMACISTS	Amended Eff. April 1, 2004	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2606	CONVEYING WARNINGS	Amended Eff. September 1, 1995	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2607	AVAILABILITY OF RECORDS	Amended Eff. February 1, 2007	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2608	DISPENSING OF MEDICAL OXYGEN	Eff. September 1, 1995	Necessary without substantive public interest	No		No	Necessary without substantive public interest

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		21 NCAC 46 .2609	REHABILITATION EQUIPMENT	Amended Eff. April 1, 1999	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2610	MEDICAL GAS, OXYGEN AND RESPIRATORY RELATED EQUIPMENT	Eff. September 1, 1995	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2611	MEDICAL EQUIPMENT	Amended Eff. April 1, 1999	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2612	STORAGE OF DEVICES AND MEDICAL EQUIPMENT	Amended Eff. November 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2613	DEVICES AND MEDICAL EQUIPMENT IN POSSESSION OF PERMIT HOLDERS	Eff. April 1, 2007	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	SECTION .2700 - NUCLEAR PHARMACY	21 NCAC 46 .2701	REQUIREMENTS	Eff. October 1, 1990	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2702	DEFINITIONS	Amended Eff. February 1, 2005	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2703	OBTAINING A NUCLEAR PHARMACY PERMIT	Amended Eff. February 1, 2005	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2704	REQ FOR PHARMACIES PROVIDING RADIOPHARMACEUTICAL SERVICES	Amended Eff. February 1, 2005	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2705	LABELING REQUIREMENTS OF RADIOPHARMACEUTICALS	Eff. January 1, 2005	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .2706	PROHIBITIONS	Eff. January 1, 2005	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	SECTION .2800 – COMPOUNDING	21 NCAC 46 .2801	COMPOUNDING	Amended Eff. January 1, 2015	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	21 U.S.C. § 353a	No	Necessary without substantive public interest

G.S. 150B-21.3A Report for 21 NCAC 46, BOARD OF PHARMACY									
Agency - Board of Pharmacy									
Comment Period - February 21, 2017 to May 1, 2017									
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]	Implements or Conforms to Federal Regulation [150B-21.3A(e)]	Federal Regulation Citation	Public Comment Received [150B-21.3A(c)(1)]	Agency Determination Following Public Comment [150B-21.3A(c)(1)]
	SECTION .2900 - PRODUCT SELECTION	21 NCAC 46 .2901	RETURN OF OUTDATED DRUGS	Amended Eff. July 1, 2011	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	SECTION .3000 - DISPOSAL OF UNWANTED DRUGS	21 NCAC 46 .3001	PROCEDURE FOR DISPOSING OF DRUGS	Eff. October 1, 1993	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	SECTION .3100 – GENERAL DEFINITIONS	21 NCAC 46 .3101	CLINICAL PHARMACIST PRACTITIONER	Amended Eff. July 1, 2016	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
	SECTION .3200 – PEER REVIEW AGREEMENTS	21 NCAC 46 .3201	DEFINITIONS	Eff. April 1, 2001	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .3202	PEER REVIEW AGREEMENTS	Amended Eff. March 1, 2004	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .3203	DUE PROCESS	Amended Eff. March 1, 2004	Unnecessary	No		No	Unnecessary
		21 NCAC 46 .3204	RECEIPT AND USE OF INFORMATION OF SUSPECTED IMPAIRMENT	Amended Eff. March 1, 2004	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .3205	INTERVENTION AND REFERRAL	Amended Eff. March 1, 2004	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .3206	MONITORING TREATMENT	Eff. April 1, 2001	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .3207	MONITORING REHABILITATION AND PERFORMANCE	Amended Eff. March 1, 2004	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .3208	MONITORING POST-TREATMENT SUPPORT	Eff. April 1, 2001	Necessary without substantive public interest	No		No	Necessary without substantive public interest

G.S. 150B-21.3A Report for 21 NCAC 46, BOARD OF PHARMACY									
Agency - Board of Pharmacy									
Comment Period - February 21, 2017 to May 1, 2017									
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]	Implements or Conforms to Federal Regulation [150B-21.3A(e)]	Federal Regulation Citation	Public Comment Received [150B-21.3A(c)(1)]	Agency Determination Following Public Comment [150B-21.3A(c)(1)]
		21 NCAC 46 .3209	REPORTS OF INDIVIDUAL CASES TO THE BOARD	Amended Eff. March 1, 2004	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .3210	PERIODIC REPORTING OF STATISTICAL INFORMATION	Eff. April 1, 2001	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .3211	CONFIDENTIALITY	Eff. April 1, 2001	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .3301	REGISTRATION	Amended Eff. July 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	SECTION .3400 – AUTOMATED DISPENSING ON DruG SUPPLY DEVICES	21 NCAC 46 .3401	DEFINITIONS	Amended Eff. December 1, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .3402	GENERAL REQUIREMENTS FOR THE USE OF AUTOMATED MEDICATION SYSTEMS	Amended Eff. December 1, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 46 .3404	STOCKING OR RESTOCKING OF AN AUTOMATED MEDICATION SYSTEM	Amended Eff. December 1, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	SECTION .3500 – CONTROLLED SUBSTANCES REPORTING SYSTEM	21 NCAC 46 .3501	REPORTS FROM THE CONTROLLED SUBSTANCES REPORTING SYSTEM	Eff. March 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest

Introduction:

In response to its request for comments on its Periodic Rule Review Report, the Board of Pharmacy received comments from a total of four commenters, commenting on four rules (or related series of rules). All of these comments are attached in their entirety. None of the four commenters addressed the Periodic Rule Review Report, the Board's categorization of any rule in the Periodic Rule Review Report, any of the standards for review by the Commission set forth in G.S. 150B-21.9(a), or anything else pertinent to the rule review process. Instead, all four commenters are best characterized as submitting belated public comments on rulemaking proceedings that were completed within the preceding year (and most of those comments are about a version of a rule that has not even taken effect yet). Therefore, nothing in the comments leads the Board to conclude that it should change the characterization of any rule in the Periodic Rule Review Report.

21 NCAC 46 .1505

Comment:

I fully support limiting the number of attempts to pass the North American Pharmacist Licensure Examination and Multistate Pharmacy Jurisprudence Examination and codifying a cap on the number of attempts. I believe the standards for practicing pharmacy should be high to ensure appropriate pharmaceutical care for patients. Learning that persons can have 5 attempts to pass examinations is very concerning. I hope the board will consider further reducing the number of attempts one person can have to pass examination. I support reducing the number of attempts to 3 which I think is very generous. If a person is not able to pass the exam after 3 attempts, I believe that they have chosen the wrong profession.

Response:

This comment does not appear to address the existing rule review process or any the standards for review by the Commission set forth in G.S. 150B-21.9(a). Instead, this is a belated public comment for a rule amendment that was approved by the Commission at its meeting on April 20, 2017 and that, to the Board's knowledge, has not yet been entered into the Code. Moreover, the commenter merely expresses his general agreement with the substance of the rule, along with his policy position that the rule amendment should have been even more restrictive than it is.

21 NCAC 46 .2102, .2104, .2105, .2107 and .2108

Comment:

I fully support this proposal as pharmacist participation in elections is very low as reported in your newsletter. Participation is likely to increase with pharmacists logging into the North Carolina Board of Pharmacy website for renewals and then seeing election information at that time.

Response:

This comment does not appear to address the existing rule review process or any the standards for review by the Commission set forth in G.S. 150B-21.9(a). Instead, this is a belated public comment for a set of rule amendments that was approved by the Commission at its meeting on April 20, 2017 and that, to the Board's knowledge, has not yet been entered into the Code. Moreover, the commenter merely expresses his policy agreements with the substance of the rule amendments.

21 NCAC 46 .2201

Comment:

I've been working pediatrics evening shift at UNC Hospitals for the past 20 years. Most local/regional pediatric conferences are run by nursing educational organizations - like SEHEC, Moses Cone, or UNC. All conferences I've attended over the years do cover drug therapy in pediatrics. However, they aren't registered with AACP or other pharmacy agencies for CE because there aren't many RPh attending. The audiences are mostly RNs, NPs, and MDs. I'd like to continue attending these as they ARE VERY USEFUL to my practice, are affordable (~\$180 for all day), and require me to only take one day off from work because I can drive to them. I hope there is some way to work out an exception - they always issue a certificate at the end - I could save handouts to prove content if audited as well. There aren't many AACP approved pediatric conferences in our state.

This is an example of the pediatric conferences offered locally I described in my previous email.

From: UNC-CH, Center for Lifelong Learning [Nursing_cll@unc.edu]

Sent: Wednesday, February 22, 2017 15:40

To: Sebastian, Georganne

Subject: Practice, Research, and Teaching Institutes open for registration!

You are receiving this email because you are subscribed to the following lists - SON Day-long Programs.

Nursing_cll@unc.edu



CAROLINA NURSING
CENTER FOR LIFELONG LEARNING

Experience lifelong learning-- integrating practice, research, and teaching.

**Practice, Research, and Teaching
Institutes open for registration!**

Registration Open

March 11, 2017
[28th Annual PACU and
Ambulatory Surgery](#)

Excellence in Teaching for Nurse Educators

When: Monday, May 22, 2017 8:00 AM - Friday, June 2, 2017 4:30 PM

Where: Chapel Hill, NC

What: This five day institute was strategically planned to be split over two weeks. Participants will attend the first three days of didactic content on May 22, 23, and 24 to build skills in inclusive excellence in teaching, strategies to help students thrive, and ways to incorporate reflective practice into students' learning.

You will return on June 1 and 2 with time for each group to finalize your case study with your UNC mentor on Thursday and prepare to present it on Friday. The case study is designed to synthesize your learning from the week, and to encourage critical thinking in your students.

Learning Outcomes:

- Describe the process of teaching and role of the nurse educator
- Apply innovative strategies for teaching and evaluation to promote higher-level learning
- Apply principles for developing learning outcomes, test questions, and case studies
- Discuss strategies for facilitating success of the nursing student
- Examine the use of simulation in nursing education
- Demonstrate strategies to manage student incivility and conflict
- Analyze teaching tools and strategies for clinical faculty

Click here for more information: [Click here for the event summary](#)
Register early to receive the JMJ RN Scholarship discount. Funds are limited! [Register Now!](#)

Instrumentation: Development, Testing, & Revision

Conference

March 24, 2017

New! [2017 Pediatric Pharmacology Update](#)

March 27-31, 2017

[Adult/Adolescent Sexual Assault Nurse Examiner Training](#)

March 31, 2017

[Assessment and Management of Addictions: Overview and Update for Healthcare Professionals](#)

April 28, 2017

[Excellence in Nursing Leadership](#)

June 2, 2017

New! [Psychiatric Pharmacology: Revolutions in Clinical Practice](#)

Summer Institutes

May 22, 23, 24 &

June 1, 2, 2017

[Excellence in Teaching for Nurse Educators](#)

July 31 - August 4, 2017

[Instrumentation: Development, Testing, & Revision](#)

August 1, 2, & 3, 2017

[History Taking and Physical Assessment](#)

When: Monday, July 31, 2017 8:00 AM - Friday, August 4, 2017 5:00 PM

Where: Chapel Hill, NC

What: Blending real life examples and humor with theoretical knowledge, Dr. Lynn has designed this invaluable four-and-a-half-day institute for doctorally-prepared researchers and educators, post-doctoral fellows and doctoral students to advance their knowledge in instrument development and testing beyond that typically taught in graduate research courses.

This material is equally applicable to instrument adaptation and enhancement. Participants will learn the similarities and differences in instrument development using traditional and qualitative approaches, along with exploring how each are used in instrument revision.

Learning Outcomes:

- Discuss and differentiate the concepts of reliability and validity beyond that traditionally taught in graduate research courses
- Evaluate the relative contributions of reliability and validity to the assessment of various types of instruments
- Describe the steps that should be taken/decisions to be made in instrument development and adaptation
- Contrast instrument development from qualitative data and traditional approaches
- Explore the uses of exploratory and confirmatory factor analysis in instrument development and revision
- Assess the extent to which the “textbook” steps in instrument development have been taken for instruments in common use
- Describe the measurement concerns in mailed/Internet-based data collection, norming, cross-cultural instrument use, and collecting data from special populations

Click here for more information: [Click here for the event summary](#)

Register early to receive the JMJ RN Scholarship discount. Funds are limited!

[Register Now!](#)

Registration Opening Soon!

September 11-15, 2017

Pediatric Sexual Assault
Nurse Examiner Training

September 8, 2017

Management of Budgets

September 22, 2017

Management of HR Issues

September 29, 2017

Emerging Trends in Nursing
Education: Virtual
Simulation

October 13, 2017

9th Annual Excellence in
Maternity Care

October 27, 2017

Innovative Care of
Individuals with Diabetes

November 3, 2017

Pain Management: Looking
Through an Inclusive Lens

November 10, 2017

Compliance & Billing for
Nurse Practitioners

December 8, 2017

Pharmacology Update

About Us

We provide opportunities and resources for nurses with different educational and experiential backgrounds to maintain and expand their knowledge, skills, and competencies to meet their current and future needs in

History Taking and Physical Assessment

When: Tuesday, August 1, 2017 8:00 AM - Thursday, August 3, 2017 5:00 PM

Where: Chapel Hill, NC

What: An advanced History Taking and Physical Assessment course designed just for me? Yes! Taught by expert Laura Nasir, PhD, RN, FNP-BC, FHEA, *this 44 CNE hour* hybrid course is designed to fit your busy schedule. It will boost your confidence and assessment skills so that you can provide better client care in existing or new positions or help you prepare for graduate school. Practicing APRNs and PAs wishing to refresh their examination skills are also invited to attend. There will be designated lab sections for practicing APRNs and PAs. Just register as a practicing APRN or PA.

Immersive lab practice will be held at the UNC at Chapel Hill School of Nursing August 1-3, 2017.

Online Modules:

- History Taking and Skin Assessment
- Head, Ears, Eyes, Neck & Throat (HEENT)
- Assessment Cardiovascular & Respiratory
- Assessment Abdomen & Lymphatic System
- Assessment Musculoskeletal & Neurological
- Assessment Genitalia & Breast Assessment
- Putting it All Together: Head-to-Toe Assessment

Click here for more information: [Click here for the event summary](#)

Register early to receive the JMJ RN Scholarship discount. Funds

are limited!

[Register Now!](#)

practice, education, and research.

Center for Lifelong

Learning

<http://nursing.unc.edu/lifelong/>

The University of North Carolina at Chapel Hill School of Nursing is accredited as a provider of continuing nursing education (CNE) by the American Nurses Credentialing Center's Commission on Accreditation (ANCC).

Response:

This comment does not appear to address the existing rule review process or any the standards for review by the Commission set forth in G.S. 150B-21.9(a). Instead, this is a belated public comment for a rule amendment that was approved by the Commission at its meeting on February 16, 2017 and that will not go into effect until January 2018. Moreover, the commenter supports the version of 21 NCAC 46.2201 that is currently in effect and is the subject of the periodic rule review and, instead, presents policy arguments against the judgments made in the version of 21 NCAC 46.2201 that will not go into effect until January 2018.

Comment:

Dear Director Campbell and Board,

Regarding the proposed changes to reporting/documentation of CE -- please Nooooo! The changes would do away with the 2 features I (and many others) love most about the current system in NC: the ability to carry over credits, and the ability to use a variety of sources as CE.

I know many pharmacists (including myself) who might complete a module for maintenance of board certification or attend a national conference and earn 20-25 credits in one year, but then do not or cannot do the same the next year. Under the current system, at least some of those excess credits are usable as carryover, but under the proposed system they would be simply be lost and go to waste.

I also love that NC recognizes many forms of professional education as CE, such as BLS/ACLS/PALS education, which are vital in the hospital setting.

I find it surprising and disappointing that so many pharmacists apparently complain about having to enter their credits into the BOP website -- it only takes about 1 minute per item, and most pharmacists I have discussed this with actually LIKE entering them because it's very helpful for our own ability to track our CE! Especially since the website determines and marks the carryover credits.

Thank you for your consideration of my opinion. I have discussed this with many coworkers and have heard mostly strong agreement with these views.

Response:

This comment does not appear to address the existing rule review process or any the standards for review by the Commission set forth in G.S. 150B-21.9(a). Instead, this is a belated public comment for a rule amendment that was approved by the Commission at its meeting on February 16, 2017 and that will not go into effect until January 2018. Moreover, the commenter supports the version of 21 NCAC 46.2201 that is currently in effect and is the subject of the periodic rule review and, instead, presents policy arguments against the judgments made in the version of 21 NCAC 46.2201 that will not go into effect until January 2018.

Comment:

I am very pleased with the current system for tracking continuing credits. I understand that you receive some complaints each year from some pharmacists. With any system, it is very likely some people will disagree with the system. My hope is that you will know there are likely very many pharmacists who are happy with the current system and do not wish to see it change. I am one of those pharmacists.

Response:

This comment does not appear to address the existing rule review process or any the standards for review by the Commission set forth in G.S. 150B-21.9(a). Instead, this is a belated public comment for a rule amendment that was approved by the Commission at its meeting on February 16, 2017 and that will not go into effect until January 2018. Moreover, to the extent that a position can be ascertained, the commenter appears to support the version of 21 NCAC 46. 2201 that is currently in effect and is the subject of the periodic rule review and, instead, presents policy arguments against the judgments made in the version of 21 NCAC 46 .2201 that will not go into effect until January 2018.

21 NCAC 46 .3101

Comment:

Greetings!

I would like to comment on 21 NCAC 46 .3101

While CPP has been a great thing for pharmacists, prescribers, and patient's alike in NC, the rules and structure around it fits the outpatient world in which it was conceived. I work as an inpatient pharmacist within a large health system in NC. We are trying to create a safe and efficient structure by which inpatient hospital pharmacists can practice at the top of their license. On the inpatient side multiple pharmacists would need to have multiple agreements with different physicians. Current structure of rules and agreements may not quite support that. It would be great if we could create templated agreements wherein multiple pharmacists and MDs could sign, that delineate clearly the competencies and activities which said pharmacists could engage.

I hope that makes sense. I'd be glad to discuss the thoughts if it would help. Have put multiple contacts below.

Thanks for all you guys do!

Response:

This comment does not appear to address the existing rule review process or any the standards for review by the Commission set forth in G.S. 150B-21.9(a). Instead, this is a belated public comment for a rule amendment that was approved by the Commission at its meeting on April 21, 2016. To the extent that the commenter believes that the rule prohibits "agreements wherein multiple pharmacists and MDs could sign," that is a misunderstanding of the substance of the rule, which does in fact permit multiple pharmacists and physicians to sign Clinical Pharmacist Practitioner agreements. And, even if the view were correct, the comment would merely state a policy difference with 21 NCAC 46. 3101. Finally, to the extent that the commenter believes that the Board should provide "template" agreements to assist the public in carrying out the rule, that comment would not address the substance of the rule at all, and the Board has already created such templates.