Burgos, Alexander N

Subject: FW: [External] RE: 21 NCAC 33 Temporary Rules Requests for Changes - September 2023 RRC

From: Liebman, Brian R <brian.liebman@oah.nc.gov>

Sent: Wednesday, September 20, 2023 11:48 AM

To: Angela Ellis <angela@ncbon.com>

Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Meredith Parris <mparris@ncbon.com>; Anna Baird Choi
 <achoi@hedrickgardner.com>; Kimberly Luisana <kluisana@ncbon.com>; Rules, Oah <oah.rules@oah.nc.gov>
 Subject: RE: [External] RE: 21 NCAC 33 Temporary Rules Requests for Changes - September 2023 RRC

Great, thanks to Meredith and Angela for all their hard work on these.

Alex and Dana, these are the final rules for filing, and I'm recommending approval of all rules.

Brian

Brian Liebman Counsel to the North Carolina Rules Review Commission Office of Administrative Hearings (984)236-1948 <u>brian.liebman@oah.nc.gov</u>

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Burgos, Alexander N

Subject:FW: [External] RE: 21 NCAC 33 Temporary Rules Requests for Changes - September 2023 RRCAttachments:CAC 33 .0101 Administrative Body and Definitions.docx; 21 NCAC 33 .0103 Application.docx; 21NCAC 33 .0104 Provider Collaboration Required.docx; 21 NCAC 33 .0105 Disciplinary Action.docx; 21NCAC 33 .0111 Continuing Education (CE).docx; 21 NCAC 33 .0112 Scope of Practice.docx; 21 NCAC33 .0114 Annual Renewal.docx; 21 NCAC 33 .0115 Inactive Status.docx; 21 NCAC 33 .0116Collaborative Provider Agreement.docx; 21 NCAC 33 .0117 Prescribing Authority Working Doc.docx; 21 NCAC 33 .0118 Birth Outside Hospital Setting.docx

From: Angela Ellis <angela@ncbon.com>

Sent: Wednesday, September 20, 2023 11:11 AM

To: Liebman, Brian R <brian.liebman@oah.nc.gov>

Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Meredith Parris <mparris@ncbon.com>; Anna Baird Choi <achoi@hedrickgardner.com>; Kimberly Luisana <kluisana@ncbon.com>; Rules, Oah <oah.rules@oah.nc.gov> Subject: RE: [External] RE: 21 NCAC 33 Temporary Rules Requests for Changes - September 2023 RRC

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Good morning, Brian!

Thank you for allowing us the extra time to edit the temporary rules. Attached are the final versions for tomorrow's RRC meeting.

I look forward to meeting you in person tomorrow.

Angela Ellis

Angela Ellis Chief Administrative Officer

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4516 Lake Boone Trail Raleigh, NC 27607 P.O. Box 2129 Raleigh, NC 27602

Pronouns: She/Her/Hers





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21 NCAC 33 .0101 is amended under temporary procedures with changes as follows:

3 21 NCAC 33 .0101 **ADMINISTRATIVE BODY AND DEFINITIONS** 4 (a) The responsibility for administering the provisions of G.S. 90, Article 10A, shall be assumed by an administrative 5 body, the Midwifery Joint Committee, hereinafter referred to as the "Committee." The certified nurse midwife shall 6 hereinafter be referred to as "midwife." "CNM." 7 (b) In addition to the definitions set forth in G.S. 90-178.2, the following shall apply to the Rules in this Chapter: 8 "Primary Supervising Physician" means a physician with an active unencumbered license with the 9 North Carolina Medical Board who, by signing the midwife application, shall be held accountable 10 for the on going supervision, consultation, collaboration, and evaluation of the medical acts performed by the midwife, as defined in the site specific written clinical practice guidelines. A 11 physician in a graduate medical education program, whether fully licensed or holding only a 12 13 resident's training license, shall not be named as a primary supervising physician. A physician in a 14 graduate medical education program who is also practicing in a non-training situation may supervise a midwife in the non training situation if he or she is fully licensed. 15 "Back up Primary Supervising Physician" means a physician licensed by the North Carolina 16 (2)Medical Board who, by signing an agreement with the midwife and the primary supervising 17 18 physician or physicians shall be held accountable for the supervision, consultation, collaboration, and evaluation of medical acts by the midwife in accordance with the site specific written clinical 19 practice guidelines when the primary supervising physician is not available. The signed and dated 20 21 agreements for each back up primary supervising physician or physicians shall be maintained at each practice site. A physician in a graduate medical education program, whether fully licensed or 22 23 holding only a resident's training license, shall not be named as a back up primary supervising physician. A physician in a graduate medical education program who is also practicing in a non-24 training situation may be a back up primary supervising physician to a midwife in the non-training 25 situation if he or she is fully licensed and has signed an agreement with the midwife and the primary 26 27 supervising physician. 28 (1)"American Midwifery Certification Board (AMCB)" means the national certifying body for 29 candidates in nurse-midwifery and midwifery who have received their graduate level education in 30 programs accredited by the Accreditation Commission for Midwifery Education. "Accreditation Commission for Midwifery Education (ACME)" means an accreditation agency (2)31 32 established to advance and promote midwifery education. 33 (3)"American College of Nurse-Midwives (ACNM)" means the professional association that 34 represents [certified nurse midwives (CNMs)] CNMs and certified midwives (CMs) in the United 35 States. ACNM sets the standard for midwifery education and practice in the United States. "American College of Obstetricians and Gynecologists (ACOG)" means the professional 36 (4)membership organization for [obstetrician-gynecologist which] obstetrician-gynecologists that 37

1	produces practice guidelines for health care professionals and educational materials for patients,
2	provides practice management and career support, facilitates program and initiatives to improve
3	women's health, and advocates for members and patients.
4	(5) Certified Nurse Midwife (CNM)" means a nurse licensed and registered under Article 9A of this
5	Chapter who has completed a midwifery education program accredited by the Accreditation
6	Commission for Midwifery Education, or its successor, passed a national certification examination
7	administered by the American Midwifery Certification Board, or is successor, and has received the
8	professional designation of "Certified Nurse Midwife" (CNM). Certified Nurse Midwives practice
9	in accordance with the Core Competencies for Basic Midwifery Practice, the Standards for the
10	Practice of Midwifery, the Philosophy of the American College of Nurse Midwives (ACNM), and
11	the Code of Ethics promulgated by the ACNM.
12	(6) "Collaborating provider" means a physician licensed to practice medicine under Article 1 of this
13	Chapter for a minimum of four years and has a minimum of 8,000 hours of practice and who is or
14	has engaged in the practice of obstetrics or a Certified Nurse Midwife who has been approved to
15	practice midwifery under this Article for a minimum of four years and 8,000 hours.
16	(7) "Collaborative provider agreement" means a formal, written agreement between a collaborating
17	provider and a Certified Nurse Midwife with less than 24 months and 4,000 hours of practice as a
18	Certified Nurse Midwife to provide consultation and collaborative assistance or guidance.
19	(8) "Interconceptional care" includes, but is not limited to, the following:
20	(a) Gynecological care, family planning, perimenopause care, and postmenopause care;
21	(b) Screening for cancer of the breast and reproductive tract; and
22	(c) Screening for and management of minor infections of the reproductive organs.
23	(9) —— "Intrapartum care" means care that focuses on the facilitation of the physiologic birth process and
24	includes, but is not limited to, the following:
25	(a) Confirmation and assessment of labor and its progress;
26	(b) Identification of normal and deviations from normal and appropriate interventions,
27	including management of complications, abnormal intrapartum events, and emergencies;
28	(c) Management of spontaneous vaginal birth and appropriate third stage management,
29	including the use of uterotonics;
30	(d) Performing amniotomy;
31	(e) Administering local anesthesia;
32	(f) Performing episiotomy and repair; and
33	(g) Repairing laceration associated with childbirth.
34	(10) "Midwifery" means the act of providing prenatal, intrapartum, postpartum, newborn, and
35	interconceptional care. The term does not include the practice of medicine by a physician licensed
36	to practice medicine when engaged in the practice of medicine as defined by law, the performance
37	of medical acts by a physician assistant or nurse practitioner when performed in accordance with

1		the Rules of the North Carolina Medical Board, the practice of nursing by a RN engaged in the
2		practice of nursing as defined by law, or the performance of abortion, as defined in G.S. 90 21.81.
3	(11)	"Newborn care" means care that focuses on the newborn and includes, but is not limited to, the
4		following:
5		(a) Routine assistance to the newborn to establish respiration and maintain thermal stability;
6		(b) Routine physical assessment including APGAR scoring;
7		(c) Vitamin K administration;
8		(d) Eye prophylaxis for opthalmia neonatorum; and
9		(e) Methods to facilitate newborn adaptation to extrauterine life, including stabilization,
10		resuscitation, and emergency management as indicated.
11	(3) [<mark>(12</mark>)][5] "Obstetrics" means a branch of medical science that deals with birth and with birth, its
12		antecedents antecedents, and sequels, including prenatal, intrapartum, postpartum, newborn or
13		gynecology, and otherwise unspecified primary health services for women.
14	[(13)	"Postpartum care" means care that focuses on management strategies and therapeutics to facilitate
15		a health puerperium and includes, but is not limited to, the following:
16		(a) Management of the normal third stage of labor;
17		(b) Administration of uterotonics after delivery of the infant when indicated;
18		(c) Six weeks postpartum evaluation exam and initiation of family planning; and
19		(d) Management of deviations from normal and appropriate interventions, including
20		management of complications and emergencies.
21	(14)	<u>"Prenatal care" means care that focuses on promotion of a healthy pregnancy using management</u>
22		strategies and therapeutics as indicated and includes, but is not limited to, the following:
23		(a) Obtaining history with ongoing physical assessment of mother and fetus;
24		(b) Obtaining and assessing the results of routine laboratory tests;
25		(c) Confirmation and dating of pregnancy; and
26		(d) <u>Supervising the use of prescription and nonprescription medications, such as prenatal</u>
27		
28		
29	History Note:	Authority G.S. 90-178.4;
30		Eff. February 1, 1984;
31		Amended Eff. July 1, 2000; October 1, 1988;
32		Readopted Eff. November 1, 2018;
33		Amended Eff. April 1, 2020.
34		<u>Temporary [Adoption] Amendment Eff. October 1, 2023.</u>

1 21 NCAC 33 .0103 is amended under temporary procedures <u>with changes</u> as follows:

2		
3	21 NCAC 33 .01	103 <u>ELIGIBILITY AND APPLICATION AND ANNUAL RENEWAL</u>
4	(a) To be eligibl	e for an approval to practice independently as a midwife, CNM, an applicant shall:
5	(1)	submit a completed application for an approval to practice, attesting under oath or affirmation that
6		the information on the application is true and complete, and authorizing the release to the Committee
7		of all information pertaining to the application. [The application is posted on the Board of Nursing's
8		website at www.ncbon.com;]
9	(3)<u>(2)</u>	submit the approval to practice application fee as established in 90-178.4(b)(1); 90-178.4(b)(1) and
10		Rule .0102 of this Section;
11	(3)	have an unencumbered RN license or privilege to practice in all jurisdictions in which a license is
12		or has ever been held.
13	(3) (4)	hold an active, unencumbered North Carolina RN license or privilege to practice;
14	<mark>(4)(5)</mark>	have hold an [active,] unencumbered registered nurse license and midwifery CNM license or an
15		approval to practice in all jurisdictions in which a license/approval license or an approval to practice
16		is or has ever been held;
17	(2)<mark>(5)</mark>(6	submit information on the applicant's education, evidence of the applicant's [maintained]
18		certification by the American College of Nurse Midwives, Midwifery Certification Board or its
19		successor, identification of the physician or physicians who will supervise the applicant, and the
20		sites where the applicant intends to practice midwifery; provide an official copy of the educational
21		transcript and certificate from American Midwifery Certification Board and the full address of the
22		practice location where the applicant intends to practice midwifery;
23	<mark>(6)(7)</mark>	_submit a written explanation and all related documents if the midwife has ever been listed as a nurse
24		aide and if there have ever been any substantiated findings pursuant to G.S. 131E 255. The
25		Committee may take these findings into consideration when determining if an approval to practice
26		should be denied pursuant to G.S. 90 178.6. In the event findings are pending, the Committee may
27		withhold taking any action until the investigation is completed; and submit an attestation of
28		completion of at least 24 months experience and 4,000 practice hours as a CNM. [The clinical
29		experience shall be in collaboration with a collaborating provider.] Documentation of successful
30		<u>completion of this requirement shall be provided to the Committee upon [request;] request; and</u>
31	<mark>(7)[(8)]</mark>	complete a criminal background check in accordance with G.S. 90 171.48. [G.S. 90 171.48; and]
32	(5)<mark>(8)</mark>	have no pending court conditions as a result of any misdemeanor or felony conviction(s). Applicant
33		shall provide a written explanation and any investigative report or court documents evidencing the
34		circumstances of the crime(s) if requested by the Committee. The Committee may use these
35		documents when determining if an approval to practice should be denied pursuant to G.S. 90 178.6
36		<u>G.S. 90-178.6.</u> and 90-171.37; [90-171.37.]

1	In the event that any of the information required in accordance with this Paragraph should indicate a concern			
2	about the applicant's qualifications, an applicant may be required to appear in person for an interview with			
3	the Committee if the Committee determines in its discretion that more information is needed to evaluate the			
4	application.			
5	(b) Each midwife shall annually renew their approval to practice with the Committee no later than the last day of the			
6	midwife's birth month by:			
7	(1) submitting a completed application for renewal, attesting under oath or affirmation that the			
8	information on the application is true and complete, and authorizing the release to the Committee			
9	of all information pertaining to the application. Applications are located on the Board of Nursing's			
10	website at www.ncbon.com;			
11	(2) attest to having completed the requirements of the Certificate Maintenance Program of the American			
12	College of Nurse Midwives, including continuing education requirements, and submit evidence of			
13	completion if requested by the Committee as specified in Rule .0111 of this Section;			
14	(3) submitting the approval to practice renewal fee as established in G.S. 90-178.4(b)(2).			
15	(b) An applicant seeking an approval to practice with less than 24 months experience and 4,000 hours of practice as a			
16	<u>CNM shall:</u>			
17	(1) submit an application for an approval to practice, attesting under oath or affirmation that the			
18	information on the application is true and complete, and authorizing the release to the Committee			
19	of all information pertaining to the application. [The application can be found on the Board of			
20	Nursing's website at www.ncbon.com;]			
21	(2) submit the approval to practice application fee as established in 90-178.4(b) and Rule .0102 of this			
22	Chapter:			
23	(3) hold an [active,] unencumbered [North Carolina RN] license or privilege to [practice;] practice in			
24	all jurisdictions in which a license is or has ever been held:			
25	(4) hold an active, unencumbered [CNM] North Carolina RN license or [an approval to practice in all			
26	jurisdictions in which a license or an approval to practice is or has ever been held;] privilege to			
27	practice;			
28	(5) hold an unencumbered CNM license or an approval to practice in all jurisdictions in which a license			
29	or an approval to practice is or has ever been held;			
30	[(5)][6] [submit information on the applicant's education, evidence of the applicant's maintained certification			
31	by the American Midwifery Certification Board or its successor and the sites where the applicant			
32	intends to practice midwifery;] provide an official copy of the educational transcript and certificate			
33	from American Midwifery Certification Board and the full address of the practice location where			
34	the applicant intends to practice midwifery;			
35	[(6)] submit information identifying the collaborating provider with whom the applicant will collaborate;			
36	[(7) complete a criminal background check in accordance with G.S. 90-171.48;]			

1	(8)	have no pending court conditions as a result of any misdemeanor or felony conviction(s). Applicant
2	· · · ·	shall provide a written explanation and any investigative report or court documents evidencing the
3		circumstances of the crime(s) if requested by the Committee. The Committee may use these
4		documents when determining if an approval to practice should be denied pursuant to [G.S. 90-178.6
5		and 90-171.37.] G.S. 90-178.6.
6	(c) [In the even t	When a CNM seeks independent practice, the CNM shall submit a new application for an approval
7	to practice inde	pendently, attesting under oath or affirmation that the information on the application is true and
8	complete, and a	uthorizing the release to the Committee of all information pertaining to the application and required
9	<u>fee.</u>	
10	(d) Application	s are posted on the Board of Nursing's website at www.nebon.com. The following information shall
11	appear on the ap	plication:
12	(1)	the applicant's name, telephone number and email address;
13	(2)	the applicant's primary address of residence;
14	(3)	the educational degrees obtained by the applicant with the program name and completion date;
15	<u>(4)</u>	the number and expiration date of the applicant's national certification from the AMCB;
16	<u>(5)</u>	other professional or occupational licenses with the license number and jurisdiction in which the
17		license was issued, if applicable;
18	<u>(6)</u>	the name, license number, telephone number, email address, and practice location of the
19		collaborating provider, if applicable; and
20	(7)	the approval to practice number shall be provided on the application if the application is for the
21		renewal or reinstatement of an existing approval to practice.
22	(e) All education	onal transcripts and certification [must] shall be submitted directly to the Board from the primary
23	source.	
24	(f) In the even	t that any information required in accordance with this Rule should indicate a [concern about the
25	applicant's qual	ifications,] discrepancy in the application, an applicant may be required to appear in person for an
26	interview with th	e Committee if the Committee determines in its discretion that more information is needed to evaluate
27	the application.	
28		
29	History Note:	Authority G.S. 90-178.4(b); 90-178.5; <u>90-171.48; <mark>[90-171.37;]</mark></u>
30		Eff. February 1, 1984;
31		Amended Eff. March 1, 2017; January 1, 1989;
32		Readopted Eff. November 1, 2018;
33		Amended Eff. April 1, 2020.
34		<u>Temporary <mark>[Adoption]</mark> Amendment Eff. October 1, 2023.</u>

- 1 2
- 21 NCAC 33 .0104 is amended under temporary procedures with changes as follows:

3	21 NCAC 33 .0104 PHYSICIAN SUPERVISION PROVIDER COLLABORATION REQUIRED
4	The applicant shall furnish the committee evidence that the applicant will perform the acts authorized by the Midwifery
5	Practice Act under the supervision of a physician who is actively engaged in the practice of obstetrics in North
6	Carolina. Such evidence shall include a description of the nature and extent of such supervision and a delineation of
7	the procedures to be adopted and followed by each applicant and the supervising physician responsible for the acts of
8	said applicant for rendering health care services at the sites at which such services will be provided. Such evidence
9	shall include:
10	(1) mutually agreed upon written clinical practice guidelines that define the individual and shared
11	responsibilities of the midwife and the supervising physician or physicians in the delivery of health
12	care services;
13	(2) mutually agreed upon written clinical practice guidelines for ongoing communication that provide
14	for and define appropriate consultation between the supervising physician or physicians and the
15	midwife;
16	(3) periodic and joint evaluation of services rendered, such as chart review, case review, patient
17	evaluation, and review of outcome statistics; and
18	(4) periodic and joint review and updating of the written medical clinical practice guidelines.
19	(a) A CNM who has practiced fewer than 24 months and 4,000 hours of practice as a CNM shall practice in
20	consultation with a collaborating provider in accordance with a collaborative provider agreement in compliance with
21	Rule .0116 of this Chapter.
22	(b) The approval to practice of the CNM practicing under the supervision of a collaborative provider agreement is
23	terminated when the CNM discontinues working within the approved collaborative provider agreement or experiences
24	an interruption in their RN licensure status. The CNM shall notify the Committee in writing within five days of the
25	termination of the collaborative provider agreement.
26	(c) The CNM shall have 90 days to submit a newly-executed collaborative provider agreement with a collaborative
27	provider to the Committee. During this 90-day period, the CNM may continue to practice midwifery in accordance
28	with the Midwifery Practice Act and this Chapter. Should the 90-day period expire without a newly-executed
29	collaborative provider agreement being submitted to the Committee, the approval to practice is rendered inactive and
30	the CNM shall be required to submit an application for reinstatement of the approval to practice consistent with Rule
31	.0103 and Rule .0115 of this Chapter. The Committee will notify the CNM when the application has been approved
32	and the approval to practice is reinstated.
33	(d) To be eligible a collaborative provider [shall] shall:
34	(1) hold an active, unencumbered approval to practice as a CNM [having] and have a minimum of four
35	years and 8,000 hours of practice as a CNM [or] or;
36	(2) hold an active, unencumbered license to practice medicine in North Carolina and be actively
37	engaged in the practice of obstetrics.

1	(e) A CNM who has practiced over 24 months and has 4,000 hours of practice as a CNM may be issued an approval		
2	to practice midwifery independently and shall consult and collaborate with and refer patients to such other health care		
3	providers as may be appropriate for the care of the patient.		
4			
5	History Note:	Authority G.S. 90-178.4(b); <u>90-178.3;</u>	
6		Eff. February 1, 1984;	
7		Amended Eff. July 1, 2000; October 1, 1988; April 1, 1985;	
8		Readopted Eff. November 1, 2018.	
9		<u>Temporary <mark>[Adoption]</mark> Amendment Eff. October 1, 2023.</u>	

21 NCAC 33 .0105 is amended under temporary procedures with changes as follows:

3	21 NCAC 33 .0105	DISCIPLINARY	ACTION
5	H 1110110 00 10100		11011011

(a) The midwife <u>CNM</u> is subject to G.S. 90-171.37; 90-171.48 and 21 NCAC 36 .0217 by virtue of the license to
 practice as a registered nurse. <u>RN.</u>

6 (b) After notice and hearing in accordance with provisions of G. S. 150B, Article 3A, the Committee may take

- 7 <u>disciplinary action [may be taken by the Committee] if it finds</u> one or more of the [following is found:] following:
- 8 (1) practicing without a valid approval to practice as a CNM;
- 9 [(2) immoral or dishonorable conduct pursuant to and consistent with G.S. 90 178.6;]
- 10 [(3)](2) presenting false information to the Committee in procuring or attempting to procure an approval to
 11 practice as a CNM;
- 12 [(4)](3) the CNM is adjudicated mentally incompetent by a court of competent jurisdiction or the CNM's
 13 mental or physical condition renders the CNM unable to safely function as a CNM;
- 14 [(5)](4) unprofessional conduct by reason of deliberate or negligent acts or omissions and contrary to the
 15 prevailing standards for [CNMs;] CNMs as set forth by ACNM;
- 16 [(6)](5) conviction of a criminal offense [which bears on the CNM's ability to practice or that the CNM]
 17 where the CNM has deceived or defrauded the public;
- 18 [(7)](6) soliciting or attempting to solicit payments for the CNM practice with false representations;
- 19
 [(8)](7)
 [lack of professional competence as a CNM;] failure to maintain professional competence as a CNM

 20
 such that the CNM would no longer be eligible for certification by the ACMB or the ACNM;
- 21 [(9)](8) exploiting the patient, including the promotion of the sale of services, appliances, or drugs, for the
 22 financial gain of the CNM or of a third party;
- 23 [(10)](9) failure to respond to inquiries of the Committee for investigation and discipline;
- 24 [(++)](10) the CNM has engaged or attempted to engage in the performance of midwifery acts other than
 25 according to the collaborative provider agreement or without being approved by the Committee to
 26 practice independently;
- 27 [(12) failure to maintain competence as a CNM;]
- 28 [(13)(12)](11) failure to obtain a written, informed consent agreement from a patient;
- [(14)(13)](12)practiced or offered to practice beyond the scope of CNM [practice;] practice as defined in .0112
 of this Chapter;
- 31 [(15)(14)](13) failure to comply with any order of the Committee;
- 32 [(16)(15)](14)violating any term of probation, condition, or limitation imposed on the CNM by the Committee;
- 33 <u>or</u>
- 34 [(17)(16)](15) any violation within this Chapter.
- 35 (b)(c) After an investigation is completed, the Committee may recommend one of the following:
- 36 (1) dismiss the case;
- 37 (2) issue a private letter of concern;

1	(3)	enter into negotiation for a Consent Order; or
2	(4)	a disciplinary hearing in accordance with G.S. 150B, Article 3A.
3	(d) Upon a find	ing of [violation,] a violation of Chapter 90, Article 10A of the North Carolina General Statutes and
4	the rules of this	Subchapter, the Committee may utilize the range of disciplinary options as enumerated in G.S. [90-
5	171.37.] <u>90-178</u>	.6 and 90-178.7.
6		
7	History Note:	Authority G.S. <mark>[90-171.37; 90-171.43; 90-171.44; 90-171.48;] 90-178.6; <u>90-178.7;</u></mark>
8		Eff. February 1, 1985;
9		Amended Eff. August 1, 2002; October 1, 1988;
10		Readopted Eff. November 1, 2018;
11		Amended Eff. April 1, 2020.
12		<u>Temporary [Adoption] Amended Eff. October 1, 2023.</u>

21 NCAC 33 .0111 is amended under temporary procedures with changes as follows:

3 21 NCAC 33 .0111 CONTINUING EDUCATION (CE)

- 4 (a) In order to maintain an approval to practice midwifery, a midwife <u>CNM</u> shall meet the requirements of the
- 5 Certificate Maintenance Program of the American College of Nurse Midwives, Midwifery Certifying Board,
- 6 including continuing education requirements. These requirements are hereby incorporated by reference, including
- 7 subsequent amendments or editions, and may be accessed at no cost at: https://www.amcbmidwife.org/certificate-
- 8 <u>maintenance-program/purpose-objectives.</u> Every midwife who prescribes controlled substances shall complete at
- 9 least one hour of continuing education (CE) hours annually consisting of CE designated specifically to address
- 10 controlled substances prescribing practices, signs of the abuse or misuse of controlled substances, and controlled
- 11 substance prescribing for chronic pain management. Documentation of continuing education shall be maintained by
- 12 the midwife for the previous five calendar years and made available upon request to the Committee.
- 13 (b) Prior to prescribing [controlled substances as the same are defined in 21 NCAC 33 .0117,] Controlled Substances
- 14 (Schedules II, IIN, III, IIIN, IV, V) defined by the State and Federal Controlled Substances Act, CNMs shall have
- 15 <u>completed a minimum of one CE hour within the preceding 12 months on [4] one</u> or more of the following topics:
- 16 (1) Controlled substances prescription practices;
- 17 (2) Prescribing controlled substances for chronic pain management;
- 18 (3) Recognizing signs of controlled substance abuse or misuse; or
- 19 (4) Non-opioid treatment options as an alternative to controlled substances.
- 20 (c) The CNM shall maintain documentation [Documentation] of all CE completed within the previous five years
- 21 [shall be maintained by the CNM] and [made] make available [upon request] to the [Committee.] Committee upon
- 22 <u>request.</u>
- 23
- 24 History Note: Authority: G.S. 90 5.1; 90 14(a)(15); 90 178.5(2); S.L. 2015-241, s. 12F.16(b); G.S. 90-178.3; 90-
- 25 <u>178.5(a)(2):</u>
- 26 *Eff. March 1, 2017;*
- 27 *Readopted Eff. November 1, 2018.*
- 28 <u>Temporary [Adoption]Amendment</u> Eff. October 1, 2023.

23

- 21 NCAC 33 .0112 is adopted under temporary procedures with changes as follows:
- 3 21 NCAC 33 .0112 SCOPE OF PRACTICE
- 4 The CNM's scope of practice is defined by academic educational preparation and national certification and maintained
- 5 competence. A CNM shall be held accountable by the Committee for a broad range of personal health services or
- 6 which the CNM is educationally prepared and for which competency has been maintained once the CNM has been
- 7 authorized to practice midwifery. These services include:] Scope of practice is set by the ACNM at
- 8 https://www.midwife.org/acnm/files/acnmlibrarydata/uploadfilename/00000000266/Definition%20Midwifery%20
- 9 Scope%20of%20Practice_2021.pdf, is available at no cost, and is hereby incorporated by reference, including
- 10 subsequent amendments and editions. Scope of practice includes:
- (1) diagnosing, treating, and managing a full range of primary health care services to the patient
 throughout the lifespan, including gynecologic care, family planning services, preconception care,
 prenatal and postpartum care, childbirth, and care of the newborn;
- 14 (2) promotion and maintenance of health care services for the patient throughout their lifespan;
- 15 [(3)](2) treating patient and their partners for sexually transmitted disease diseases and reproductive health;
- [(4)](3) providing care in diverse settings, which may include settings such as home, hospital, birth center,
 and a variety of ambulatory care settings including private offices and community and public health
 clinics;
- 19 [(5)](4) prescribing, administering, and dispensing therapeutic measures, tests, procedures, and drugs;
- 20[(6)](5)planning for situations beyond the CNMs scope of practice and expertise by collaborating,21consulting with, and referring to other health care providers as appropriate; and
- 22 [(7)](6) evaluating health outcomes.
- 24 *History Note: Authority:* <u>G.S. 90-18.8; 90-178.3;</u>
 25 <u>Temporary Adoption Eff. October 1, 2023.</u>

21 NCAC 33 .0114 is adopted under temporary procedures with changes as follows:

3	21 NCAC 33 .01	14 ANNUAL RENEWAL
4	(a) The CNM sha	all renew the approval to practice shall be renewed annually no later than the last day of the applicant's
5	birth month by:	
6	(1)	maintaining an active, unencumbered North Carolina RN license or privilege to practice;
7	(2)	submitting a completed application as outlined in Rule .0103 of this Chapter for renewal, attesting
8		under oath or affirmation that the information on the application is true and complete, and
9		authorizing the release to the Committee of all information pertaining to the application [as outlined
10		in Rule .0103 of this Chapter.] Applications are located on the Board of Nursing's website at
11		www.nebon.com;
12	(3)	attest attesting to having completed the requirements of the Certificate Maintenance Program of the
13		American Midwifery Certification Board or its successor, including continuing education
14		requirements, and submit evidence of completion if requested by the Committee as specified in Rule
15		.0111 of this Chapter; and
16	(4)	submitting the approval to practice renewal fee as established in G.S. 90-178.4(b)(2) and this
17		Chapter.
18	(b) It shall be the	e duty of the CNM to keep the Committee informed of a current mailing address, telephone number,
19	and email addres	s.
20	(c) If the CNM h	nas not renewed by end of [their] his or her birth month and submitted the annual fee, the approval to
21	practice shall exp	pire.
22		
23	History Note:	Authority: G.S. 90-178.4(b); 90-178.5;
24		<u>Temporary Adoption Eff. October 1, 2023.</u>

- 1 21 NCAC 33 .0115 is adopted under temporary procedures <u>with changes</u> as follows:
- 2

3 21 NCAC 33 .0115 INACTIVE STATUS

4 (a) Any CNM who wishes to place their approval to practice on an inactive status shall notify the Committee in5 writing.

6 (b) A CNM with an inactive approval to practice status shall not practice as a CNM.

7 (c) A CNM with an inactive approval to practice status who reapplies for <u>an</u> approval to practice shall meet the

- 8 qualifications for an approval to practice in Rule. 0103 Rule .0103 of this Chapter and shall not resume practicing
- 9 <u>until receive</u> notification is received from that the Committee has granted the of approval prior to beginning practice
- 10 after the application is approved. application.
- 11 (d) A CNM who has not practiced as a CNM in more than two years shall complete a midwifery refresher course
- 12 approved by the [Commission] Commission. The refresher course shall be based on the American College of Nurse-
- 13 Midwives' reentry to midwifery practice [guidelines] guidelines, which are hereby incorporated by reference,
- 14 including subsequent amendments or editions and are available at no cost at: http://www.midwife.org/Re-entry-

15 <u>Guidelines-for-CNMs/CMs. The refresher course shall be</u> directly related to the CNM's area of academic education

16 and national certification. A midwifery refresher course participant shall be granted an approval to practice that is

- 17 limited to clinical activities required by the refresher course.
- 18

20

19 History Note: Authority G.S. 90-178.3; 90-178.5;

Temporary Adoption Eff. October 1, 2023.

- 1 2
- 21 NCAC 33 .0116 is adopted under temporary procedures with changes as follows:

2		
3	21 NCAC 33 .0	0116 COLLABORATIVE PROVIDER AGREEMENT
4	(a) A CNM wit	h less than 24 months and 4,000 hours of practice as a CNM is required to have a written collaborative
5	provider agreen	nent to practice midwifery. The collaborative provider agreement shall:
6	(1)	be agreed upon, signed, and dated by both the collaborating provider and the CNM, and maintained
7		in each provider site;
8	(2)	be reviewed at least [annually.] annually, to ensure that the CNM and collaborating provider
9		continue to practice under the terms of the agreement, and determine whether any changes to the
10		agreement are necessary. This review shall be acknowledged by a dated signature sheet, signed by
11		both the collaborating provider and the CNM, appended to the collaborative provider agreement,
12		and available for inspection by the Committee;
13	(3)	include mutually agreed upon written clinical practice guidelines for the drugs, devices, medical
14		treatments, tests, and procedures that may be prescribed, ordered, and performed by the CNM; and
15	(4)	include a pre-determined plan for emergency services.
16	(b) The collabor	orating provider and the CNM shall be available to each other for consultation by [direct] in-person
17	communication	or telecommunication.
18	(c) A <u>The CNN</u>	1 shall maintain a copy of the collaborative provider agreement executed within the previous five years
19	shall be mainta	ined by the CNM and made make available upon request of the Committee. to the Committee upon
20	request.	
21		
22	History Note:	Authority G.S. 90-18.8; 90-178.3; 90-178.4; 90-178.5;
23		Temporary Adoption Eff. October 1, 2023.

- 1 2
- 21 NCAC 33 .0117 is adopted under temporary procedures with changes as follows:
- 3 21 NCAC 33 .0117 PRESCRIBING AUTHORITY

4 (a) The prescribing stipulations contained in this rule apply to writing prescriptions and ordering the administration

5 of medications by a CNM.

6 (b) A CNM must possess a valid United States Drug Enforcement Administration ("DEA") registration in order [for]

7 to prescribe controlled substances.

8 (c) [the CNM to] To act as a collaborating provider for [another CNM. The] a CNM, the DEA registration of the

9 collaborating provider shall include the same schedule(s) schedule or schedules of controlled substances as the CNM

- 10 practicing under a collaborative provider agreement.
- 11 [(-+)](d) Prescribing and dispensing stipulations for the CNM authorized to practice under a collaborative provider 12 agreement are as follows:
- 13 (1) Drugs and devices that may be prescribed by the CNM shall be included in the collaborative provider
 14 agreement as outlined in Rule .0116 of this Chapter.
- 15
 (2)(1)
 The collaborative provider agreement outlined in Rule .0116 of this Chapter shall include the Drugs

 16
 drugs and devices that may be prescribed by the CNM shall be included in the collaborative provider

 17
 agreement as outlined in Rule .0116 of this Chapter. may prescribe.
- 18 (A)(2) The CNM has an assigned DEA number that is entered on each prescription for a controlled
 19 substance; substance.
- 20 (B)(3) Refills may be issued consistent with Controlled Substance laws and regulations;
 21 Substances (Schedules II, IIN, III, IIIN, IV, V) defined by the State and Federal Controlled
 22 Substances [Act;] Act. and
- 23 (C)(4) The collaborative provider shall possess a schedule(s) of controlled substances equal to or greater
 24 than the CNM's DEA registration.
- (3)[(2)](5) The CNM may prescribe a drug or device not included in the collaborative provider agreement
 only as follows:
 - (A) Upon a specific written or verbal order obtained from the collaborating provider before the prescription or order is issued by the CNM; and
- 29(B)The written or verbal order as described in Part (c)(3)(A) of this rule shall be entered into30the patient record with a notation that it is issued on the specific order of a collaborating31provider and signed by the CNM and the collaborating provider.
- 32 [(d)](e) All prescribing stipulations requirements shall be written in the patient's chart and shall include the medication
- and dosage, the amount prescribed, the directions for use, the number of refills, and the signature of the CNM.
- 34 [(e)](f) The prescriptions issued by the CNM shall contain:
- 35 (1) the name of the patient;
- 36 (2) the CNM's [name] name, approval to practice number issued by the Committee, and telephone

37 number; and

27

28

1 (3) the CNM's assigned DEA number shall be written on the prescription form when a controlled 2 substance is prescribed. 3 [(f)(g) A CNM shall not prescribe controlled substances for the CNM's own use, the use of the CNM's collaborating 4 provider, the use of the CNM's immediate family, the use of any other person living in the same residence as the 5 CNM, or the use of any person with whom the CNM is having a sexual relationship. As used in this Paragraph, 6 "immediate family" means a spouse, parent, child, sibling, parent-in-law, son-in-law or daughter-in-law, brother-in-7 law or sister-in-law, step-parent, step-child, or step-sibling. 8 9 History Note: Authority G.S. 90-18.8; 90-178.3; 10 Temporary Adoption Eff. October 1, 2023.

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21 NCAC 33 .0118 is adopted under temporary procedures with changes as follows:

-			
3	<u>21 NCAC 33 .(</u>)118 BI	RTH OUTSIDE HOSPITAL SETTING
4	(a) A CNM ap	<mark>proved to</mark>	practice may attend and provide midwifery services for a planned birth outside of a hospital
5	setting for a pre	egnancy c	leemed low-risk by the American College of Obstetricians and Gynecologists (ACOG). Prior
6	to initiating car	e for a pa	atient planning a home birth outside of a hospital setting, the CNM shall be required to:
7	(1)	obtain	a signed, written informed consent agreement with the patient that includes: details:
8		(A)	identifying information of the patient to include name, date of birth, address, phone
9			number, and email address if available;
10		(B)	identifying information of the CNM to include the name, RN license number, approval to
11			practice number, practice name, if applicable, and email address;
12		(C)	information about the procedures, benefits, and risks of planned births outside of hospital
13			settings;
14		(D)	an acknowledgment and understanding of the clear assumption of these risks by the patient;
15		(E)	when and if deemed necessary by the CNM, an acknowledgment by the patient to consent
16			to transfer to a health care facility when and if deemed necessary by the CNM; licensed
17			under Chapter 122C or Chapter 131E of the General Statutes that has at least one operating
18			room; and
19		(F)	a disclosure that the CNM is not covered under a policy of liability insurance, if applicable.
20	(2)	Provid	le the patient with <u>The CNM shall provide</u> a detailed, written plan for transfer of care to a
21		<mark>health</mark>	care facility under emergent and non emergent transfer. Such plan shall be signed and dated
22		<mark>by bot</mark>	the patient and the CNM and shall include:
23		(<u>A)</u>	the name of and distance to the nearest health care facility licensed under Chapter 122C or

- Chapter 131E of the General Statutes that has at least one operating room; 24 25 the procedures for transfer, including modes of transportation and methods for notifying (B) 26 the relevant health care facility of impending transfer; and
- 27 an affirmation that the relevant health care facility has been notified of the plan for 28 emergent and non-emergent transfer by the CNM. consistent with G.S. 90-178.4(a2).
 - (3)After a decision to <u>of</u> non-emergent transfer care has been made, the CNM shall:
 - (A) call the relevant receiving health care facility to notify them of transfer;
 - **(B)** provide a copy of the patient's medical record to the receiving health care facility; and
 - (C) provide a verbal summary of the care provided by the CNM to the patient and newborn, if applicable, to the receiving health care facility.
- 34 (4)In an emergent situation, the CNM shall initiate emergency care as indicated by the situation and 35 immediate immediately transfer of care by making a reasonable effort effort, dependent upon the circumstances and nature of the emergency, to contact the health care professional or facility to 36 37 whom the patient(s) patient or patients will be transferred and to follow the health care professional's

1	instructions; remain with the patient(s) until transfer of care is completed; and continue emergency
2	care as needed while:
3	(A) transporting the patient(s) by private vehicle; or
4	(B) calling 911 and reporting the need for immediate transfer.
5	(b) Copies of the informed consent agreement and emergent and non-emergent transfer of care plans shall be
6	maintained in the patient's record and provided to the Committee upon request.
7	(c) A CNM approved to practice may attend and provide midwifery services for a planned home birth outside of a
8	hospital setting for a pregnancy deemed low-risk by the American College of Obstetricians and Gynecologists
9	(ACOG). No CNM shall attend or provide midwifery services to a patient for a planned home birth outside of a
10	hospital setting for known situations contraindicated by ACOG including specifically fetal malpresentation, multiple
11	gestation, and prior cesarean.
12	
13	History Note: Authority: G.S. 90-18.8; 90-178.3; 90-178.4;
14	Temporary Adoption Eff. October 1, 2023.

Burgos, Alexander N

Subject:FW: [External] RE: 21 NCAC 33 Temporary Rules Requests for Changes - September 2023 RRCAttachments:21 NCAC 33 .0111 Continuing Education (CE) (004).docx; 21 NCAC 33 .0112 Scope of Practice
(004).docx; 21 NCAC 33 .0115 Inactive Status (004).docx

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Wednesday, September 20, 2023 9:44 AM
To: Angela Ellis <angela@ncbon.com>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Meredith Parris <mparris@ncbon.com>; Anna Baird Choi
<achoi@hedrickgardner.com>; Kimberly Luisana <kluisana@ncbon.com>
Subject: RE: [External] RE: 21 NCAC 33 Temporary Rules Requests for Changes - September 2023 RRC

Good morning,

Thanks for all the hard work on these. It's been a pleasure working with both Meredith and Angela on these rules, and I think they're in a place where I can recommend approval of all Rules, with one small caveat. In Rules .0111, .0112, and .0115, I asked for certain ACNM or AMCB documents to be incorporated by reference. To facilitate, I've gone ahead and revised those rules to incorporate the referenced material in a way that complies with the APA. Please review and make sure that the URLs I have added are correct—I had to search the ACNM website for the return to practice guidelines, and I think I found them. Please check. For .0112, I think a similar incorporation is necessary, but I couldn't find the document where the scope was set. The ACNM had a scope of practice document, and then a core competencies document, and both of them seemed to be on point. So I leave it to you to figure out which one is correct, and to insert the URL to the specific document in the Rule, which has been pre-formatted for your convenience.

One more small caveat. I think in Rule .0118, you need to set off the new language ("dependent upon the circumstances and nature of the emergency") in commas. I didn't make that change, but just FYI.

Please review the attached and make any necessary changes. If you need to discuss, I'm available on my cell at 919-455-7142 until around 4:00. Otherwise, please just send the final versions of all revised rules back to me, copying oah.rules@oah.nc.gov and Alex Burgos, and we'll have the final versions filed for RRC review.

Thanks again, Brian

Brian Liebman Counsel to the North Carolina Rules Review Commission Office of Administrative Hearings (984)236-1948 <u>brian.liebman@oah.nc.gov</u>

E-mail correspondence to and from this address may be subject to the North Carolina Public Records Law N.C.G.S. Chapter 132 and may be disclosed to third parties.

21 NCAC 33 .0111 is amended under temporary procedures with changes as follows:

3 21 NCAC 33 .0111 CONTINUING EDUCATION (CE)

- 4 (a) In order to maintain an approval to practice midwifery, a midwife CNM shall meet the requirements of the
- 5 Certificate Maintenance Program of the American College of Nurse Midwives, Midwifery Certifying Board,
- 6 including continuing education requirements. These requirements are hereby incorporated by reference, including
- 7 subsequent amendments or editions, and may be accessed at no cost at: https://www.amcbmidwife.org/certificate-
- 8 <u>maintenance-program/purpose-objectives.</u> Every midwife who prescribes controlled substances shall complete at
- 9 least one hour of continuing education (CE) hours annually consisting of CE designated specifically to address
- 10 controlled substances prescribing practices, signs of the abuse or misuse of controlled substances, and controlled
- 11 substance prescribing for chronic pain management. Documentation of continuing education shall be maintained by
- 12 the midwife for the previous five calendar years and made available upon request to the Committee.
- 13 (b) Prior to prescribing [controlled substances as the same are defined in 21 NCAC 33.0117,] Controlled Substances
- 14 (Schedules II, IIN, III, IIIN, IV, V) defined by the State and Federal Controlled Substances Act, CNMs shall have
- 15 <u>completed a minimum of one CE hour within the preceding 12 months on [4] one</u> or more of the following topics:
- 16 <u>(1) Controlled substances prescription practices;</u>
- 17 (2) Prescribing controlled substances for chronic pain management;
- 18 (3) Recognizing signs of controlled substance abuse or misuse; or
- 19 (4) Non-opioid treatment options as an alternative to controlled substances.
- 20 (c) The CNM shall maintain documentation [Documentation] of all CE completed within the previous five years
- 21 [shall be maintained by the CNM] and [made] make available [upon request] to the [Committee.] Committee upon
- 22 <u>request.</u>
- 23
- 24 History Note: Authority: G.S. 90 5.1; 90 14(a)(15); 90 178.5(2); S.L. 2015-241, s. 12F.16(b); G.S. 90-178.3; 90-
- 25 <u>178.5(a)(2):</u>
- 26 *Eff. March 1, 2017;*
- 27 *Readopted Eff. November 1, 2018.*
- 28 <u>Temporary [Adoption]Amendment</u> Eff. October 1, 2023.

- 1 2
- 21 NCAC 33 .0112 is adopted under temporary procedures with changes as follows:
- 3 21 NCAC 33 .0112 SCOPE OF PRACTICE

4 The CNM's scope of practice is defined by academic educational preparation and national certification and maintained

- competence. A CNM shall be held accountable by the Committee for a broad range of personal health services or 5
- 6 which the CNM is educationally prepared and for which competency has been maintained once the CNM has been
- authorized to practice midwifery. These services include:] Scope of practice is set by the ACNM at [INSERT URL 7
- 8 HERE], is available at no cost, and is hereby incorporated by reference, including subsequent amendments and
- 9 editions. Scope of practice includes:
- 10 diagnosing, treating, and managing a full range of primary health care services to the patient (1)11 throughout the lifespan, including gynecologic care, family planning services, preconception care, 12 prenatal and postpartum care, childbirth, and care of the newborn;
- promotion and maintenance of health care services for the patient throughout their lifespan; 13 (2)
- 14 [(3)](2) treating patient and their partners for sexually transmitted disease diseases and reproductive health;
- 15 $\left[\frac{(4)}{(3)}\right]$ providing care in diverse settings, which may include settings such as home, hospital, birth center, 16 and a variety of ambulatory care settings including private offices and community and public health 17 clinics;
- 18 [(5)](4) prescribing, administering, and dispensing therapeutic measures, tests, procedures, and drugs;
- 19 $\frac{(6)}{(5)}$ planning for situations beyond the CNMs scope of practice and expertise by collaborating, 20 consulting with, and referring to other health care providers as appropriate; and
- 21 [(7)](6) evaluating health outcomes.
- 22

Authority: <u>G.S. 90-18.8; 90-17</u>8.3; 23 History Note: Temporary Adoption Eff. October 1, 2023. 24

- 1 21 NCAC 33 .0115 is adopted under temporary procedures <u>with changes</u> as follows:
- 2

3 21 NCAC 33 .0115 INACTIVE STATUS

4 (a) Any CNM who wishes to place their approval to practice on an inactive status shall notify the Committee in5 writing.

6 (b) A CNM with an inactive approval to practice status shall not practice as a CNM.

7 (c) A CNM with an inactive approval to practice status who reapplies for <u>an</u> approval to practice shall meet the

- 8 qualifications for an approval to practice in Rule. 0103 Rule .0103 of this Chapter and shall not resume practicing
- 9 <u>until receive</u> notification is received from that the Committee has granted the of approval prior to beginning practice
- 10 after the application is approved. application.
- 11 (d) A CNM who has not practiced as a CNM in more than two years shall complete a midwifery refresher course
- 12 approved by the [Commission] Commission. The refresher course shall be based on the American College of Nurse-
- 13 Midwives' reentry to midwifery practice [guidelines] guidelines, which are hereby incorporated by reference,
- 14 including subsequent amendments or editions and are available at no cost at: http://www.midwife.org/Re-entry-

15 <u>Guidelines-for-CNMs/CMs. The refresher course shall be</u> directly related to the CNM's area of academic education

16 and national certification. A midwifery refresher course participant shall be granted an approval to practice that is

- 17 limited to clinical activities required by the refresher course.
- 18

20

19 History Note: Authority G.S. 90-178.3; 90-178.5;

Temporary Adoption Eff. October 1, 2023.

Burgos, Alexander N

Subject: FW: [External] RE: 21 NCAC 33 Temporary Rules Requests for Changes - September 2023 RRC

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Tuesday, September 19, 2023 6:09 PM
To: Angela Ellis <angela@ncbon.com>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Meredith Parris <mparris@ncbon.com>; Anna Baird Choi
<achoi@hedrickgardner.com>; Kimberly Luisana <kluisana@ncbon.com>
Subject: RE: [External] RE: 21 NCAC 33 Temporary Rules Requests for Changes - September 2023 RRC

Hi all,

Thanks for the review and all the hard work. I've reviewed the response document, and everything looks good. Let me read the rules tonight, and I'll let y'all know if everything is indeed good to go.

Best, Brian

Brian Liebman Counsel to the North Carolina Rules Review Commission Office of Administrative Hearings (984)236-1948 <u>brian.liebman@oah.nc.gov</u>

E-mail correspondence to and from this address may be subject to the North Carolina Public Records Law N.C.G.S. Chapter 132 and may be disclosed to third parties.

Burgos, Alexander N

Subject:FW: [External] RE: 21 NCAC 33 Temporary Rules Requests for Changes - September 2023 RRCAttachments:MJC Response to Technical Changes 2.docx; 21 NCAC 33 .0101 Administrative Body and
Definitions.docx; 21 NCAC 33 .0103 Application.docx; 21 NCAC 33 .0104 Provider Collaboration
Required.docx; 21 NCAC 33 .0105 Disciplinary Action.docx; 21 NCAC 33 .0111 Continuing Education
(CE).docx; 21 NCAC 33 .0112 Scope of Practice.docx; 21 NCAC 33 .0114 Annual Renewal.docx; 21
NCAC 33 .0115 Inactive Status.docx; 21 NCAC 33 .0116 Collaborative Provider Agreement.docx; 21
NCAC 33 .0117 Prescribing Authority Working Doc.docx; 21 NCAC 33 .0118 Birth Outside Hospital
Setting.docx

From: Angela Ellis <angela@ncbon.com>
Sent: Tuesday, September 19, 2023 4:12 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Meredith Parris <mparris@ncbon.com>; Anna Baird Choi
<achoi@hedrickgardner.com>; Kimberly Luisana <kluisana@ncbon.com>
Subject: RE: [External] RE: 21 NCAC 33 Temporary Rules Requests for Changes - September 2023 RRC

CAUTION: External email. Do not click links or open attachments unless verified. Report suspicious emails with the Report Message button located on your Outlook menu bar on the Home tab.

Thank you again for all your assistance with these temp rules!

We converted your comments to a Word Doc for easier response. Our responses are highlighted in yellow for each Rule. Along with the response document, please find the resubmitted temporary Rules.

We will await further instruction.

Angela Ellis

Angela Ellis Chief Administrative Officer

Office: (984) 238-7644 Fax: (919) 781-9461

4516 Lake Boone Trail Raleigh, NC 27607 P.O. Box 2129 Raleigh, NC 27602

Pronouns: She/Her/Hers



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Second Response to Technical Changes

<u>Rule. 0101</u>

In (5), p.3, line 13, I still don't understand "unspecified primary health services for women.". I think it can be a whole lot clearer, i.e. whether those services are all related to birth, or whether we're talking lifelong primary care. Given this language, I think maybe you might see my point about the scope of CNM practice in Rule .0112 a little more clearly too, when both obstetricians and CNMs are performing "primary health services".

No changes made to definitions.

Rule .0103

I don't have a change request on this one, since its new language you added, but in new (e), "certification" should be plural. Also change "must" to "shall".

There is only one certification for CNMs. Corrected with "shall"

In (a)(3), line 12, a license for what? Midwifery or to practice as a registered nurse? Any RN license must be unencumbered. Pursuant to the nurse licensure compact, multistate licensure refers to "privilege to practice" (not approval). For clarification, changes were made to reflect these distinctions.

How are (a)(3) and (a)(5) different requirements? They seem to mean the same thing. (a)(3) refers to the RN license, which should not be encumbered in any jurisdiction in which it exists. (a)(5) is specific to CNMs. With the clarification/correction above in (a)(3), the distinction should be clearer.

In (a)(4), line 14, what is a "privilege to practice" and how is it different than a license? See also (b)(3), p.2, line 21.

See response above for (a)(3). Under the Nurse Licensure Compact, the home state in which a nurse resides issues a license. Through the compact, a nurse with a multistate license has a privilege to practice in compact states. Should a compact state take disciplinary action for events occurring in their jurisdiction, they issue discipline on the privilege to practice (and not the license). Privilege to practice is a term understood by our regulated public.

OK, taking all these together, I think I know what you're trying to say, but the Rule language itself is still a little unclear. Seems to me (a)(3) and (4) both refer to nurses, and (5) refers to the CNM privilege to practice. I think (3) either needs to say "license or privilege to practice <u>as an RN</u>" or (3) and (4) need to be combined in whatever way you think best.

(3) refers to any RN license or privilege to practice the applicant has ever held.

(4) the applicant must hold an *active* RN license or privilege to practice at the time they are applying.

(5) if the applicant already has a CNM approval to practice, it also must be unencumbered.

Revised to add "RN" in (3). We purposefully separated (3) and (4) in response to a public comment.

In (a)(6), line 18, what "evidence" are you requiring"? Be specific. See also (b)(5), p.2, line 24. The evidence would be an official copy of the educational transcript and the certificate from the national certifying body.

I think it's important to say that in the Rule then.

Revised to say, "provide an official copy of the educational transcript and certificate from American Midwifery Certification Board and the full address of the practice location where the applicant intends to practice midwifery."

In (a)(6), line 20, what about the "sites" are you asking for? See also (b)(5), p.2, lines 25-26. The sites refer to the practice sites or locations where the CNM intends to practice. I think you need to be more specific. Do you want the city and state? A county? A full address?

Revised to full address of the practice location where the applicant intends to practice midwifery.

On p.3, line 1, what is a "concern"? And who would have the concern? Someone on the committee? A fellow practitioner? A member of the public?

Issues may arise regarding any of the documentation provided, certifications, hours, etc. If there are issues with the application, staff must refer the application to the Committee for a determination of licensure. For example, if a CNM seeks approval, but has reported a criminal conviction within 2 years – staff cannot approve the application; however, the applicant would be referred to the Committee for the determination.

Your statutes say the joint subcommittee is responsible for approving applicants, not staff. Do you have statutory authority to delegate approval of the application to staff? Regardless, I think the key here is the word "concern". I think you need to be more specific about what would trigger the interview requirement. Revised to state, "a discrepancy in the application."

Rule .0105

In (b)(2), line 11, define "immoral" and "dishonorable". These terms, if left undefined, are impermissibly vague and unclear.

This language is consistent with Medical Board and NP Rules. It covers a variety of exhaustive situations that cannot be defined with specificity. Midwifery Statute under G.S. 90-178.6 states "conduct that endangers the public health" and "conduct that deceives, defrauds or harms the public in the course of professional activities or services". This is what is meant by immoral and dishonorable conduct. We added a reference to G.S. 90-178.6.

I think the reference to the statute is good, but the terms "immoral and dishonorable" are still unclear, and **much** broader than what you have in 90-178.6. For instance, adultery is immoral and dishonorable, but it doesn't endanger the public health and doesn't defraud or harm the public in the course of professional activities or services. If what you mean is conduct covered by the statute, I would urge you to just say that, and delete "immoral and dishonorable".

Deleted (2) immoral and dishonorable conduct.

In (b)(4), line 14, who would adjudicate the CNM as mentally incompetent? A judge? In any jurisdiction?

If there is a legal determination where the CNM is found incompetent in any jurisdiction. The CNM would still be afforded due process even if such finding were to be made.

So could the joint subcommittee, in the absence of another jurisdiction's ruling, make a finding that the CNM was mentally incompetent and proceed on discipline on that basis? Because I don't think the subcommittee has that authority. I think this could be fixed by saying "the CNM has been adjudicated mentally incompetent by a court of competent jurisdiction" (no pun intended).

Added, "by a court of competent jurisdiction".

In (b)(5), line 17, what are "prevailing standards"? Are these defined?

Prevailing standards are standards generally accepted within the healthcare profession. Standards of care are taught to CNMs within their general education and nationally defined. These standards would be known to our regulated public.

OK, where are they nationally defined? You need a cross-reference here, because we're talking about the standards by which someone's ability to practice are based on. If you don't say exactly what those standards are, then what stops the joint subcommittee from making a new standard and saying "we think this is a prevailing standard". I'm not saying the joint subcommittee **would** do this, but they **could** under this language.

American College of Nurse Midwives sets the prevailing standards. Added this reference.

In (b)(6), line 18, what criminal offenses "bear on the CNM's ability to practice"? Such examples would include assaults involving patients, fraud, driving while impaired – same as the crimes considered for RN/LPN and physicians.

Again, I think we need some specificity, so the CNM knows what the bounds are. "Deceived or defrauded the public" is one thing, you can look at the elements of a crime, look for fraud or deception, and make that connection. "Bears on the CNM's ability to practice" could mean anything without some kind of definition of what you mean by "ability to practice". Also, "bears on" is very vague. If a CNM is convicted of reckless driving and their license is suspended, but they can still attend births and travel by bus or Uber, did the conviction "bear on" their ability to practice? Consider something like: "the CNM was convicted of a criminal offense based upon any act violative of Chapter 90, Article 10 of the North Carolina General Statutes and the Rules of this Subchapter." If you want to add a "such as" and list particular crimes, I think that'd be OK too.

Revised.

In (b)(8), line 21, where is "professional competence" defined? Also, how is this different from (b)(12)'s requirement to "maintain competence"?

If referencing line 19 instead of 21, professional competence is the standard of competence learned in CNM training and education and is reviewed and maintained with national certification. Professional competence is known to our regulated public.

Doesn't one of the organizations mentioned in Rule .0101 define these standards? I think you need to point to something, even if you're just saying "failure to maintain professional competence as a CNM, such that the CNM would no longer be eligible for certification by the ACMB or the ACNM." Of course,

that language works only if it encompasses the full meaning of "professional competence." That's something I can't answer. Regardless, I think you need to point to the specific standards by which you are judging your CNMs.

Revised with "failure to maintain professional competence as a CNM, such that the CNM would no longer be eligible for certification by the ACMB or the ACNM."

In (d), p.2, lines 2-3, does the Midwifery Committee (or subcommittee) have the statutory authority to exercise power given by statute to the Board of Nursing? Wouldn't the Committee's power to discipline stem from G.S. 90-178.6 and 178.7? If the Committee has the disciplinary authority vested in the Board of Nursing by G.S. 90-171.37, why does G.S. 90-178.6(b) specifically note that "revocation of a license to practice **nursing** pursuant to G.S. 90-171.37 shall automatically result in **comparable** action against the person's approval to practice midwifery under this Article"? Doesn't this indicate that these are separate sources of authority?

The Committee's power does stem from G.S. 90-178.6 and 90-178.7, and we would agree these are separate sources of authority from 90-171.37. If an investigation results in disciplinary action against an RN, the Committee still needs to pursue action against the CNM approval to practice. The Board of Nursing does not have the authority to suspend the CNM approval, so this action would be addressed by the Committee.

Right, so then why is this language necessary? You have explicit statutory authority to take action against a CNM whose license to practice as an RN has been revoked. This rule goes beyond that and says you can take action "as enumerated" by the *Board of Nursing's* discipline statute, upon a finding of a violation of your own rules/statutes. Again, the question is how does the Midwifery Committee have the authority to take action not under its own discipline statutes, but under the Board of Nursing's discipline statute? I don't think you do. You can take action under 178.6 or 178.7, but not under 171.37.

Revised to 90-178.8 and 90-187.7.

Additionally, whatever you do with this language, please clarify whether "violation" means violation of your rules, statutes, or both. Maybe that's picky, but I think it needs to be said.

Revised to a violation of "Chapter 90, Article 10A of the North Carolina General Statutes and the Rules of this Subchapter."

<u>Rule .0111</u>

In (a), lines 5-6, what is this "Program"? Please incorporate it by reference pursuant to 150B-21.6.

The Certificate Maintenance Program is the title of the required program all CNMs must take through their certifying body (American Midwifery Certification Board - AMCB) to maintain their national certification.

Yes, but you didn't incorporate it by reference. If you're requiring adherence to the requirements, you have to incorporate it by reference at the very least. I need to review it to see if it contains anything that would violate the APA.

Revised. Added sentence at the end to state, "The requirements of the Certificate Maintenance Program or its successor may be found at <u>www.amcbmidwife.org."</u>

In (b), line 13, spell out "1".

According to 26 NCAC 02C .0108(9)(c) "if a phrase contains two numbers, only one of which is over nine, figures shall represent both". Please advise.

Thank you for actually reading our formatting rules. This is rare, and made me happy. ⁽³⁾ However, I think by "phrase" it means something like the 12 days of Christmas, if that makes sense ("10 lords a'leaping, 9 ladies dancing..." as opposed to "10 lords a'leaping, nine ladies dancing"). So I think you're fine to spell out "one" here. I'd note you already did do that in "one CE hour" immediately prior to this language, too.

Corrected.

Rule .0112

The sentence at lines 5-6 "The CNM's scope of practice... maintained competence." is impermissibly vague and unclear. What levels of educational preparation are there? What procedures or privileges do they translate to? What if someone has a high level of education but hasn't "maintained competence"? What does that do to the scope of their practice? How does someone "maintain competence"?

Education is understood based on the minimum standard of completing a graduate program (master's or doctorate) as well as passing the national certification exam. The scope and standards are defined as part of their accredited education and nationally recognized profession. The scope is based on educational preparation, national certification, and maintained competence; a CNM cannot have one or the other, they must have all three elements.

I'm afraid I still don't see what the scope of practice is. What you're saying sounds like requirements to practice, not the scope of practice. The way I see it, if education, certification, and maintained competence defined the scope of practice, then someone with a masters and one kind of certification could not do procedures that someone with a doctorate and another kind of certification (I thought there was just the one certification, but I'm trying to understand) could do. And both of them might not be able to perform some procedures that would otherwise be within their scope of practice if they hadn't taken the right kind of CEs. If that's the case, then this rule needs to make it plain who can do what under what educational/certification/competence conditions. If that's not the case, then you need to make clear what it is you're trying to say, because I just don't understand it.

Revised. Added that "scope of practice is set by ACNM found at <u>www.midwife.org</u> and includes:"

At line 6, what does it mean for the CNM to "be held accountable"? Does this mean disciplinary action by the Committee?

Yes. The CNM is responsible for practicing within their scope of practice. Should they exceed their scope of practice, the CNM is subject to disciplinary action by the Committee. So .0105(b)(13) says the CNM can't exceed the scope of practice defined here. This language says

they're to be held accountable for the services the CNM is authorized to practice. This seems like a different concept. Which is why I'm asking what you mean by "held accountable ... for"?

Revised.

At line 8, these services "include" the list of (1)-(7), but what else is included? It is important that there be a discrete list, given that this is where the scope of practice is defined, and it is a disciplinable offense to exceed that scope. How is someone to know if they exceed the scope of practice when it isn't explicitly defined?

A CNM is a nationally recognized healthcare provider who specializes in nurse midwifery. The CNM is an advanced nursing practice nurse role with a specific population focus. Within this population focus, they can provide healthcare as described in 1-7. Like other healthcare disciplines, it would be cumbersome and inaccurate to attempt a list of frequently evolving pharmacotherapeutics, diagnostic tests, and procedures a healthcare provider can order or perform. A CNM's scope of practice is based on a minimum standard of nationally recognized and certified education and training. CNMs provide healthcare as defined by their scope in Rule .0112 and (1) and 2-7 define their practice further within the healthcare continuum.

I agree, it would be cumbersome to list everything a CNM can perform. I guess what I am getting at is that reading this, I don't know what a CNM **can't** do... "diagnosing, treating, and managing a full range of primary health care services throughout the lifespan prescribing, administering, and dispensing therapeutic measures, tests, procedures, and drugs." I **know** you don't mean it to, but I don't see how this stops a CNM from diagnosing ("diagnosing") a 70 year old man ("the patient throughout the lifespan"), with a broken leg ("full range of primary health care services"), and then performing surgery to install plates ("administering . . . therapeutic . . . procedures") in his house ("providing care in diverse setting, such as home...").

In (1), line 9, what are "primary health care services"? Are these defined somewhere? This term is known to our regulated public. It is common knowledge within the healthcare industry that primary health care services are healthcare promotion, maintenance, and disease prevention.

But you already say "promotion and maintenance of health care services" in (2). And it sounds to me like "treating a patient and their partners" for STDs in (3) goes beyond "prevention". So does "prescribing, administering, and dispensing therapeutic measures, tests, procedures, and drugs."

In (1), line 10, what does "throughout the lifespan" mean? Does this mean a midwife functions as a primary care physician for people of all ages?

Lifespan is defined in healthcare as "all ages", and a CNM can provide midwifery care for a newborn to an aging adult. It is also understood that healthcare is not provided in a vacuum, and there will be overlap of care. A midwife is not and cannot be considered a physician because they have different training, titles, and authority. Physicians practice medicine, and CNMs practice nurse midwifery. A CNM is a nurse with additional graduate-level and clinical education that performs medical acts within their scope of training within their population focus. This training includes care which often includes health promotion, maintenance and prevention of illness.

In (2), line 12, what does "promotion and maintenance of health care services" mean? It sounds like you're saying the midwife is responsible for convincing people to seek care with them at risk of "being held accountable".

Promotion and maintenance of health care services refers to educating and coordinating care beyond midwifery practice. The CNM is responsible for practicing within their scope. If what the

patient requires is beyond the CNM's scope of practice, the CNM is accountable to the Committee for informing and educating the patient and coordinating care beyond their service.

I'm going to be honest, I really don't see how I can recommend approval of this rule without major changes. As I said, my main issue is that I can't see what a CNM cannot do. One thing you've said that makes sense to me, and I think you should build from, is that a CNM is a nurse with additional graduate level and clinical education. I am sure there is a statute or rule defining the scope of practice for an RN (given the time constraints, I'm sure you can find it easier than I can). Perhaps a rule saying the scope of practice is anything an RN can do pursuant to [cite to the law or rule] as well as ... and then add a concrete list of whatever it is the CNM can do that an RN cannot.

Made revisions pursuant to our conversation and deleted (2).

Rule .0114

In (a)(2), line 9, what is a "complete" application? Although G.S. 90-174(b)(4) explicitly gives the "joint subcommittee" the authority to "establish the form and contents of the application" by rule, I do not see any rule or part of a rule in which the contents of the application are clearly set out. As the application seems to be on a form provided by the Board of Nursing (see also G.S. 178.5(a)(1)), that form would need to either go through rulemaking itself, or have its contents or substantive requirements described in another rule or a statute.

In correcting the application content requirements under Rule .0103, our intent would be to refer to this rule as the application content would be the same for renewal applications.

I think the cross reference is good, I'd just move it to line 7, so it says "a completed application <u>as outlined</u> in <u>Rule .0103</u>...".

Corrected.

In (c), line 21, please change "their" to "his or her". Gender neutral terminology. I understand, but it's not grammatically accurate. Corrected.

Rule .0115

In (d), line 13-14, what are the American College of Nurse Midwives rentry to practice guidelines? If you are enforcing them via this Rule, they need to be incorporated by reference pursuant to G.S. 150B-21.6.

The American College of Nurse Midwives recommends two components for reentry into CNM practice, didactic content and clinical experience.

OK, these need to be incorporated by reference here.

Changed and broke up into a separate sentence for clarity.

<u>Rule .0116</u>

In (a)(1), lines 7-8, do you mean that a copy of the agreement has to be kept in all provider sites? How does this comport with Rule .0112(4)'s requirement that the CNM be prepared to practice in a variety of different settings?

The physical collaborative provider agreement must be kept by the CNM at their practice location and by the collaborating provider at their practice location (should they differ). Regardless of the practice setting (hospital, birth center, homebirth), the CNM's scope of practice does not change. Rule .0112 speaks to scope of practice which is inclusive of a variety of settings.

I'm not suggesting that the scope of practice changes, I'm suggesting that it sounds like the CNM has to carry the agreement with them when they go to someone's home, but it doesn't say that explicitly.

They don't have to carry the agreement with them, but it needs to exist where the CNM and CP practice.

In (a)(2), line 9, what does a "review" entail?

The agreement must be reviewed by both the CNM and collaborating provider annually to ensure that they are continuing to practice under the terms of the agreement and no changes need to be made. They review the existing CPA and agree to change, or not change the agreement, with acknowledgement by date and signature. This type of review would be consistent with their current practice working with a supervising physician and known to the regulated public.

Why not say this then? "be reviewed at least annually, <u>to ensure that the CNM and collaborating provider</u> <u>continue to practice under the terms of the agreement, and determine whether any changes to the agreement are necessary."</u>

Corrected as suggested above.

In (b), line 15, define "direct communication" and "telecommunication".

Communication can be in person, via internet, phone, email, etc. We would prefer not to limit it to direct, face-to-face communication and provide flexibility for communication as the need arises.

I guess my confusion stems from the dichotomy here. To me a phone call or a text would be "direct" AND "telecommunication", while an email may not be "direct". Maybe "in-person communication or telecommunication" might be closer to what you mean?

Revised to "in-person communication or telecommunication".

<u>Rule .0117</u>

Is this Rule "consistent with the rules established for nurse practitioners under G.S. 90-18.2(b)(1)", as required by G.S. 90-18.8(c)?

G.S. 90-18.8 does not exist; however, the proposed language is consistent with the prescribing requirements for nurse practitioners pursuant to G.S. 90-18.2 and 21 NCAC 36 .0809. G.S. 90-18.8 is created by SL 2023-14, s. 4.3(a). Just FYI.

Got it, thanks! Reviewed, and it is consistent.

In (b), are you requiring both the collaborating provider CNM and the CNM under the agreement to have a DEA registration? There is an inference here (and in (e)(3)), but there's no explicit requirement that a CNM practicing under an agreement or a CNM practicing independently have a DEA registration.

If the CNM is practicing pursuant to a collaborative provider agreement and prescribing controlled substances is part of the CNM's and the collaborating provider's midwifery practice, both the CNM and the collaborating provider must have a DEA registration if the CNM to prescribe controlled substances.

I'm not sure you've answered the whole question. What about an independently practicing CNM, not under a CPA? I think it's obvious they need a DEA registration, but the rule doesn't say that. It only says that a collaborating provider needs a registration. The rule doesn't even say that the CNM under the agreement needs a registration. The only person explicitly required to have a DEA registration is the collaborating provider.

Revised. A DEA number is required only if the CNM prescribes controlled substances.

Where in (e) is the requirement that the CNM write their "identification number" assigned by the joint subcommittee on the prescription? This is required in G.S. 90-18.8(b)(3). G.S. 90-18.2 is Limitations on Nurse Practitioners. Under this statute, there is no requirement that the NP Approval number shall be listed on the prescription. However, to be consistent with prescribing requirements for Nurse Practitioners, we looked to 21 NCAC 36 .0809(b)(2) which lists the same requirements as are contained in this proposed language. G.S. 90-18.8 is created by SL 2023-14, s. 4.3(a). Please review that statute.

Added language to include the approval to practice number issued by the Committee under (f)(2).

Rule .0118

In (a)(4), line 34, define "reasonable effort".

What constitutes a reasonable effort depends on the circumstances of the scenario. An effort must be made to contact the receiving provider or health care facility; however, factors such as the emergent nature of the situation would affect whether one call is reasonable or 10 calls would be considered reasonable

It sounds like the CNM just needs to contact the health care professional or facility. Suggest deleting this phrase and just saying "...immediately transfer care by contacting the health care professional or facility...".

Revised to add "dependent upon the circumstances and nature of the emergency" following reasonable effort.

21 NCAC 33 .0101 is amended under temporary procedures with changes as follows:

3 21 NCAC 33 .0101 **ADMINISTRATIVE BODY AND DEFINITIONS** 4 (a) The responsibility for administering the provisions of G.S. 90, Article 10A, shall be assumed by an administrative 5 body, the Midwifery Joint Committee, hereinafter referred to as the "Committee." The certified nurse midwife shall 6 hereinafter be referred to as "midwife." "CNM." 7 (b) In addition to the definitions set forth in G.S. 90-178.2, the following shall apply to the Rules in this Chapter: 8 "Primary Supervising Physician" means a physician with an active unencumbered license with the 9 North Carolina Medical Board who, by signing the midwife application, shall be held accountable 10 for the on going supervision, consultation, collaboration, and evaluation of the medical acts performed by the midwife, as defined in the site specific written clinical practice guidelines. A 11 physician in a graduate medical education program, whether fully licensed or holding only a 12 13 resident's training license, shall not be named as a primary supervising physician. A physician in a 14 graduate medical education program who is also practicing in a non-training situation may supervise a midwife in the non training situation if he or she is fully licensed. 15 "Back up Primary Supervising Physician" means a physician licensed by the North Carolina 16 (2)Medical Board who, by signing an agreement with the midwife and the primary supervising 17 18 physician or physicians shall be held accountable for the supervision, consultation, collaboration, and evaluation of medical acts by the midwife in accordance with the site specific written clinical 19 practice guidelines when the primary supervising physician is not available. The signed and dated 20 21 agreements for each back up primary supervising physician or physicians shall be maintained at each practice site. A physician in a graduate medical education program, whether fully licensed or 22 23 holding only a resident's training license, shall not be named as a back up primary supervising physician. A physician in a graduate medical education program who is also practicing in a non-24 training situation may be a back up primary supervising physician to a midwife in the non-training 25 situation if he or she is fully licensed and has signed an agreement with the midwife and the primary 26 27 supervising physician. 28 (1)"American Midwifery Certification Board (AMCB)" means the national certifying body for 29 candidates in nurse-midwifery and midwifery who have received their graduate level education in 30 programs accredited by the Accreditation Commission for Midwifery Education. "Accreditation Commission for Midwifery Education (ACME)" means an accreditation agency (2)31 32 established to advance and promote midwifery education. 33 (3)"American College of Nurse-Midwives (ACNM)" means the professional association that 34 represents [certified nurse midwives (CNMs)] CNMs and certified midwives (CMs) in the United 35 States. ACNM sets the standard for midwifery education and practice in the United States. "American College of Obstetricians and Gynecologists (ACOG)" means the professional 36 (4)membership organization for [obstetrician-gynecologist which] obstetrician-gynecologists that 37

1	produces practice guidelines for health care professionals and educational materials for patients,
2	provides practice management and career support, facilitates program and initiatives to improve
3	women's health, and advocates for members and patients.
4	(5) Certified Nurse Midwife (CNM)" means a nurse licensed and registered under Article 9A of this
5	Chapter who has completed a midwifery education program accredited by the Accreditation
6	Commission for Midwifery Education, or its successor, passed a national certification examination
7	administered by the American Midwifery Certification Board, or is successor, and has received the
8	professional designation of "Certified Nurse Midwife" (CNM). Certified Nurse Midwives practice
9	in accordance with the Core Competencies for Basic Midwifery Practice, the Standards for the
10	Practice of Midwifery, the Philosophy of the American College of Nurse Midwives (ACNM), and
11	the Code of Ethics promulgated by the ACNM.
12	(6) "Collaborating provider" means a physician licensed to practice medicine under Article 1 of this
13	Chapter for a minimum of four years and has a minimum of 8,000 hours of practice and who is or
14	has engaged in the practice of obstetrics or a Certified Nurse Midwife who has been approved to
15	practice midwifery under this Article for a minimum of four years and 8,000 hours.
16	(7) "Collaborative provider agreement" means a formal, written agreement between a collaborating
17	provider and a Certified Nurse Midwife with less than 24 months and 4,000 hours of practice as a
18	Certified Nurse Midwife to provide consultation and collaborative assistance or guidance.
19	(8) "Interconceptional care" includes, but is not limited to, the following:
20	(a) Gynecological care, family planning, perimenopause care, and postmenopause care;
21	(b) Screening for cancer of the breast and reproductive tract; and
22	(c) Screening for and management of minor infections of the reproductive organs.
23	(9) —— "Intrapartum care" means care that focuses on the facilitation of the physiologic birth process and
24	includes, but is not limited to, the following:
25	(a) Confirmation and assessment of labor and its progress;
26	(b) Identification of normal and deviations from normal and appropriate interventions,
27	including management of complications, abnormal intrapartum events, and emergencies;
28	(c) Management of spontaneous vaginal birth and appropriate third stage management,
29	including the use of uterotonics;
30	(d) Performing amniotomy;
31	(e) Administering local anesthesia;
32	(f) Performing episiotomy and repair; and
33	(g) Repairing laceration associated with childbirth.
34	(10) "Midwifery" means the act of providing prenatal, intrapartum, postpartum, newborn, and
35	interconceptional care. The term does not include the practice of medicine by a physician licensed
36	to practice medicine when engaged in the practice of medicine as defined by law, the performance
37	of medical acts by a physician assistant or nurse practitioner when performed in accordance with

1		the Rules of the North Carolina Medical Board, the practice of nursing by a RN engaged in the
2		practice of nursing as defined by law, or the performance of abortion, as defined in G.S. 90 21.81.
3	(11)	"Newborn care" means care that focuses on the newborn and includes, but is not limited to, the
4		following:
5		(a) Routine assistance to the newborn to establish respiration and maintain thermal stability;
6		(b) Routine physical assessment including APGAR scoring;
7		(c) Vitamin K administration;
8		(d) Eye prophylaxis for opthalmia neonatorum; and
9		(e) Methods to facilitate newborn adaptation to extrauterine life, including stabilization,
10		resuscitation, and emergency management as indicated.
11	(3) [<mark>(12</mark>)][5] "Obstetrics" means a branch of medical science that deals with birth and with birth, its
12		antecedents antecedents, and sequels, including prenatal, intrapartum, postpartum, newborn or
13		gynecology, and otherwise unspecified primary health services for women.
14	[(13)	"Postpartum care" means care that focuses on management strategies and therapeutics to facilitate
15		a health puerperium and includes, but is not limited to, the following:
16		(a) Management of the normal third stage of labor;
17		(b) Administration of uterotonics after delivery of the infant when indicated;
18		(c) Six weeks postpartum evaluation exam and initiation of family planning; and
19		(d) Management of deviations from normal and appropriate interventions, including
20		management of complications and emergencies.
21	(14)	<u>"Prenatal care" means care that focuses on promotion of a healthy pregnancy using management</u>
22		strategies and therapeutics as indicated and includes, but is not limited to, the following:
23		(a) Obtaining history with ongoing physical assessment of mother and fetus;
24		(b) Obtaining and assessing the results of routine laboratory tests;
25		(c) Confirmation and dating of pregnancy; and
26		(d) <u>Supervising the use of prescription and nonprescription medications, such as prenatal</u>
27		
28		
29	History Note:	Authority G.S. 90-178.4;
30		Eff. February 1, 1984;
31		Amended Eff. July 1, 2000; October 1, 1988;
32		Readopted Eff. November 1, 2018;
33		Amended Eff. April 1, 2020.
34		<u>Temporary [Adoption] Amendment Eff. October 1, 2023.</u>

1 21 NCAC 33 .0103 is amended under temporary procedures <u>with changes</u> as follows:

2		
3	21 NCAC 33 .01	03 ELIGIBILITY AND APPLICATION AND ANNUAL RENEWAL
4	(a) To be eligibl	e for an approval to practice <u>independently</u> as a midwife, <u>CNM,</u> an applicant shall:
5	(1)	submit a completed application for an approval to practice, attesting under oath or affirmation that
6		the information on the application is true and complete, and authorizing the release to the Committee
7		of all information pertaining to the application. [The application is posted on the Board of Nursing's
8		website at www.ncbon.com;]
9	(3)<u>(2)</u>	submit the approval to practice application fee as established in 90-178.4(b)(1); 90-178.4(b)(1) and
10		Rule .0102 of this Section;
11	(3)	have an unencumbered RN license or privilege to practice in all jurisdictions in which a license is
12		or has ever been held.
13	(3) (4)	hold an active, unencumbered North Carolina RN license or privilege to practice;
14	<mark>(4)(5)</mark>	have hold an [active,] unencumbered registered nurse license and midwifery CNM license or an
15		approval to practice in all jurisdictions in which a license/approval license or an approval to practice
16		is or has ever been held;
17	(2)<mark>(5)</mark>(6	submit information on the applicant's education, evidence of the applicant's [maintained]
18		certification by the American College of Nurse Midwives, Midwifery Certification Board or its
19		successor, identification of the physician or physicians who will supervise the applicant, and the
20		sites where the applicant intends to practice midwifery; provide an official copy of the educational
21		transcript and certificate from American Midwifery Certification Board and the full address of the
22		practice location where the applicant intends to practice midwifery.
23	<mark>(6)(7)</mark>	submit a written explanation and all related documents if the midwife has ever been listed as a nurse
24		aide and if there have ever been any substantiated findings pursuant to G.S. 131E 255. The
25		Committee may take these findings into consideration when determining if an approval to practice
26		should be denied pursuant to G.S. 90 178.6. In the event findings are pending, the Committee may
27		withhold taking any action until the investigation is completed; and submit an attestation of
28		completion of at least 24 months experience and 4,000 practice hours as a CNM. [The clinical
29		experience shall be in collaboration with a collaborating provider.] Documentation of successful
30		completion of this requirement shall be provided to the Committee upon [request;] request; and
31	<mark>(7)[(8)]</mark>	complete a criminal background check in accordance with G.S. 90-171.48. [G.S. 90-171.48; and]
32	(5)<mark>(8)</mark>	have no pending court conditions as a result of any misdemeanor or felony conviction(s). Applicant
33		shall provide a written explanation and any investigative report or court documents evidencing the
34		circumstances of the crime(s) if requested by the Committee. The Committee may use these
35		documents when determining if an approval to practice should be denied pursuant to G.S. 90-178.6
36		<u>G.S. 90-178.6.</u> and 90-171.37; [90-171.37.]

1	In the event that any of the information required in accordance with this Paragraph should indicate a concern
2	about the applicant's qualifications, an applicant may be required to appear in person for an interview with
3	the Committee if the Committee determines in its discretion that more information is needed to evaluate the
4	application.
5	(b) Each midwife shall annually renew their approval to practice with the Committee no later than the last day of the
6	midwife's birth month by:
7	(1) submitting a completed application for renewal, attesting under oath or affirmation that the
8	information on the application is true and complete, and authorizing the release to the Committee
9	of all information pertaining to the application. Applications are located on the Board of Nursing's
10	website at www.ncbon.com;
11	(2) attest to having completed the requirements of the Certificate Maintenance Program of the American
12	College of Nurse Midwives, including continuing education requirements, and submit evidence of
13	completion if requested by the Committee as specified in Rule .0111 of this Section;
14	(3) submitting the approval to practice renewal fee as established in G.S. 90-178.4(b)(2).
15	(b) An applicant seeking an approval to practice with less than 24 months experience and 4,000 hours of practice as a
16	<u>CNM shall:</u>
17	(1) submit an application for an approval to practice, attesting under oath or affirmation that the
18	information on the application is true and complete, and authorizing the release to the Committee
19	of all information pertaining to the application. [The application can be found on the Board of
20	Nursing's website at www.ncbon.com;]
21	(2) submit the approval to practice application fee as established in 90-178.4(b) and Rule .0102 of this
22	Chapter:
23	(3) hold an [active,] unencumbered [North Carolina RN] license or privilege to [practice;] practice in
24	all jurisdictions in which a license is or has ever been held:
25	(4) hold an active, unencumbered [CNM] North Carolina RN license or [an approval to practice in all
26	jurisdictions in which a license or an approval to practice is or has ever been held;] privilege to
27	practice;
28	(5) hold an unencumbered CNM license or an approval to practice in all jurisdictions in which a license
29	or an approval to practice is or has ever been held;
30	[(5)][6] [submit information on the applicant's education, evidence of the applicant's maintained certification
31	by the American Midwifery Certification Board or its successor and the sites where the applicant
32	intends to practice midwifery;] provide an official copy of the educational transcript and certificate
33	from American Midwifery Certification Board and the full address of the practice location where
34	the applicant intends to practice midwifery;
35	[(6)] submit information identifying the collaborating provider with whom the applicant will collaborate;
36	[(7) complete a criminal background check in accordance with G.S. 90-171.48;]

1	(8)	have no pending court conditions as a result of any misdemeanor or felony conviction(s). Applicant
2	· · · ·	shall provide a written explanation and any investigative report or court documents evidencing the
3		circumstances of the crime(s) if requested by the Committee. The Committee may use these
4		documents when determining if an approval to practice should be denied pursuant to [G.S. 90-178.6
5		and 90-171.37.] G.S. 90-178.6.
6	(c) [In the even t	When a CNM seeks independent practice, the CNM shall submit a new application for an approval
7	to practice inde	pendently, attesting under oath or affirmation that the information on the application is true and
8	complete, and a	uthorizing the release to the Committee of all information pertaining to the application and required
9	<u>fee.</u>	
10	(d) Application	s are posted on the Board of Nursing's website at www.nebon.com. The following information shall
11	appear on the ap	plication:
12	(1)	the applicant's name, telephone number and email address;
13	(2)	the applicant's primary address of residence;
14	(3)	the educational degrees obtained by the applicant with the program name and completion date;
15	<u>(4)</u>	the number and expiration date of the applicant's national certification from the AMCB;
16	<u>(5)</u>	other professional or occupational licenses with the license number and jurisdiction in which the
17		license was issued, if applicable;
18	<u>(6)</u>	the name, license number, telephone number, email address, and practice location of the
19		collaborating provider, if applicable; and
20	(7)	the approval to practice number shall be provided on the application if the application is for the
21		renewal or reinstatement of an existing approval to practice.
22	(e) All education	onal transcripts and certification [must] shall be submitted directly to the Board from the primary
23	source.	
24	(f) In the even	t that any information required in accordance with this Rule should indicate a [concern about the
25	applicant's qual	ifications,] discrepancy in the application, an applicant may be required to appear in person for an
26	interview with the	e Committee if the Committee determines in its discretion that more information is needed to evaluate
27	the application.	
28		
29	History Note:	Authority G.S. 90-178.4(b); 90-178.5; <u>90-171.48; <mark>[90-171.37;]</mark></u>
30		Eff. February 1, 1984;
31		Amended Eff. March 1, 2017; January 1, 1989;
32		Readopted Eff. November 1, 2018;
33		Amended Eff. April 1, 2020.
34		<u>Temporary <mark>[Adoption]</mark> Amendment Eff. October 1, 2023.</u>

- 1 2
- 21 NCAC 33 .0104 is amended under temporary procedures with changes as follows:

3	21 NCAC 33 .0104 PHYSICIAN SUPERVISION PROVIDER COLLABORATION REQUIRED
4	The applicant shall furnish the committee evidence that the applicant will perform the acts authorized by the Midwifery
5	Practice Act under the supervision of a physician who is actively engaged in the practice of obstetrics in North
6	Carolina. Such evidence shall include a description of the nature and extent of such supervision and a delineation of
7	the procedures to be adopted and followed by each applicant and the supervising physician responsible for the acts of
8	said applicant for rendering health care services at the sites at which such services will be provided. Such evidence
9	shall include:
10	(1) mutually agreed upon written clinical practice guidelines that define the individual and shared
11	responsibilities of the midwife and the supervising physician or physicians in the delivery of health
12	care services;
13	(2) mutually agreed upon written clinical practice guidelines for ongoing communication that provide
14	for and define appropriate consultation between the supervising physician or physicians and the
15	midwife;
16	(3) periodic and joint evaluation of services rendered, such as chart review, case review, patient
17	evaluation, and review of outcome statistics; and
18	(4) periodic and joint review and updating of the written medical clinical practice guidelines.
19	(a) A CNM who has practiced fewer than 24 months and 4,000 hours of practice as a CNM shall practice in
20	consultation with a collaborating provider in accordance with a collaborative provider agreement in compliance with
21	Rule .0116 of this Chapter.
22	(b) The approval to practice of the CNM practicing under the supervision of a collaborative provider agreement is
23	terminated when the CNM discontinues working within the approved collaborative provider agreement or experiences
24	an interruption in their RN licensure status. The CNM shall notify the Committee in writing within five days of the
25	termination of the collaborative provider agreement.
26	(c) The CNM shall have 90 days to submit a newly-executed collaborative provider agreement with a collaborative
27	provider to the Committee. During this 90-day period, the CNM may continue to practice midwifery in accordance
28	with the Midwifery Practice Act and this Chapter. Should the 90-day period expire without a newly-executed
29	collaborative provider agreement being submitted to the Committee, the approval to practice is rendered inactive and
30	the CNM shall be required to submit an application for reinstatement of the approval to practice consistent with Rule
31	.0103 and Rule .0115 of this Chapter. The Committee will notify the CNM when the application has been approved
32	and the approval to practice is reinstated.
33	(d) To be eligible a collaborative provider [shall] shall:
34	(1) hold an active, unencumbered approval to practice as a CNM [having] and have a minimum of four
35	years and 8,000 hours of practice as a CNM [or] or;
36	(2) hold an active, unencumbered license to practice medicine in North Carolina and be actively
37	engaged in the practice of obstetrics.

1	(e) A CNM who	has practiced over 24 months and has 4,000 hours of practice as a CNM may be issued an approval	
2	to practice midwi	ifery independently and shall consult and collaborate with and refer patients to such other health care	
3	providers as may be appropriate for the care of the patient.		
4			
5	History Note:	Authority G.S. 90-178.4(b); <u>90-178.3;</u>	
6		Eff. February 1, 1984;	
7		Amended Eff. July 1, 2000; October 1, 1988; April 1, 1985;	
8		Readopted Eff. November 1, 2018.	
9		<u>Temporary <mark>[Adoption</mark>] Amendment Eff. October 1, 2023.</u>	

21 NCAC 33 .0105 is amended under temporary procedures with changes as follows:

3	21 NCAC 33 .0105	DISCIPLINARY ACTION
2		

(a) The midwife <u>CNM</u> is subject to G.S. 90-171.37; 90-171.48 and 21 NCAC 36 .0217 by virtue of the license to
 practice as a registered nurse. <u>RN.</u>

6 (b) After notice and hearing in accordance with provisions of G. S. 150B, Article 3A, the Committee may take

- 7 <u>disciplinary action [may be taken by the Committee] if it finds</u> one or more of the [following is found:] following:
- 8 (1) practicing without a valid approval to practice as a CNM;
- 9 [(2) immoral or dishonorable conduct pursuant to and consistent with G.S. 90 178.6;]
- 10 [(3)](2) presenting false information to the Committee in procuring or attempting to procure an approval to
 11 practice as a CNM;
- 12 [(4)](3) the CNM is adjudicated mentally incompetent by a court of competent jurisdiction or the CNM's
 13 mental or physical condition renders the CNM unable to safely function as a CNM;
- 14 [(5)](4) unprofessional conduct by reason of deliberate or negligent acts or omissions and contrary to the
 15 prevailing standards for [CNMs;] CNMs as set forth by ACNM;
- 16 [(6)](5) conviction of a criminal offense [which bears on the CNM's ability to practice or that the CNM]
 17 where the CNM has deceived or defrauded the public;
- 18 [(7)](6) soliciting or attempting to solicit payments for the CNM practice with false representations;
- [(8)](7) [lack of professional competence as a CNM;] failure to maintain professional competence as a CNM
 such that the CNM would no longer be eligible for certification by the ACMB or the ACNM;
- 21 [(9)](8) exploiting the patient, including the promotion of the sale of services, appliances, or drugs, for the
 22 financial gain of the CNM or of a third party;
- 23 [(10)](9) failure to respond to inquiries of the Committee for investigation and discipline;
- 24 [(++)](10) the CNM has engaged or attempted to engage in the performance of midwifery acts other than
 25 according to the collaborative provider agreement or without being approved by the Committee to
 26 practice independently;
- 27 [(12) failure to maintain competence as a CNM;]
- 28 [(13)(12)](11) failure to obtain a written, informed consent agreement from a patient;
- [(14)(13)](12)practiced or offered to practice beyond the scope of CNM [practice;] practice as defined in .0112
 of this Chapter;
- 31 [(15)(14)](13) failure to comply with any order of the Committee;
- 32 [(16)(15)](14)violating any term of probation, condition, or limitation imposed on the CNM by the Committee;
- 33 <u>or</u>
- 34 [(17)(16)](15) any violation within this Chapter.
- 35 (b)(c) After an investigation is completed, the Committee may recommend one of the following:
- 36 (1) dismiss the case;
- 37 (2) issue a private letter of concern;

1	(3)	enter into negotiation for a Consent Order; or
2	(4)	a disciplinary hearing in accordance with G.S. 150B, Article 3A.
3	(d) Upon a find	ing of [violation,] a violation of Chapter 90, Article 10A of the North Carolina General Statutes and
4	the rules of this	Subchapter, the Committee may utilize the range of disciplinary options as enumerated in G.S. [90-
5	171.37.] <u>90-178</u>	.6 and 90-178.7.
6		
7	History Note:	Authority G.S. <mark>[90-171.37; 90-171.43; 90-171.44; 90-171.48;] 90-178.6; <u>90-178.7;</u></mark>
8		Eff. February 1, 1985;
9		Amended Eff. August 1, 2002; October 1, 1988;
10		Readopted Eff. November 1, 2018;
11		Amended Eff. April 1, 2020.
12		<u>Temporary [Adoption] Amended Eff. October 1, 2023.</u>

- 1 2
- 21 NCAC 33 .0111 is amended under temporary procedures with changes as follows:

3 21 NCAC 33 .0111 CONTINUING EDUCATION (CE)

- 4 (a) In order to maintain an approval to practice midwifery, a midwife CNM shall meet the requirements of the
- 5 Certificate Maintenance Program of the American College of Nurse Midwives, Midwifery Certifying Board,
- 6 including continuing education requirements. Every midwife who prescribes controlled substances shall complete at
- 7 least one hour of continuing education (CE) hours annually consisting of CE designated specifically to address
- 8 controlled substances prescribing practices, signs of the abuse or misuse of controlled substances, and controlled
- 9 substance prescribing for chronic pain management. Documentation of continuing education shall be maintained by
- 10 the midwife for the previous five calendar years and made available upon request to the Committee. The requirements
- 11 of the Certificate Maintenance Program or its successor may be found at www.amcbmidwife.org.
- 12 (b) Prior to prescribing [controlled substances as the same are defined in 21 NCAC 33 .0117,] Controlled Substances
- 13 (Schedules II, IIN, III, IIIN, IV, V) defined by the State and Federal Controlled Substances Act, CNMs shall have
- 14 <u>completed a minimum of one CE hour within the preceding 12 months on [4] one</u> or more of the following topics:
- 15 (1) Controlled substances prescription practices;
- 16 (2) Prescribing controlled substances for chronic pain management;
- 17 (3) Recognizing signs of controlled substance abuse or misuse; or
- 18 (4) Non-opioid treatment options as an alternative to controlled substances.
- 19 (c) The CNM shall maintain documentation [Documentation] of all CE completed within the previous five years
- 20 [shall be maintained by the CNM] and [made] make available [upon request] to the [Committee.] Committee upon
- 21 <u>request.</u>
- 22
- 23 History Note: Authority: G.S. 90 5.1; 90 14(a)(15); 90 178.5(2); S.L. 2015-241, s. 12F.16(b); G.S. 90-178.3; 90-24
 24 178.5(a)(2);
- 25 *Eff. March 1, 2017;*
- 26 Readopted Eff. November 1, 2018.
- 27 Temporary [Adoption] Amendment Eff. October 1, 2023.

21 NCAC 33 .0112	SCO

3 PE OF PRACTICE

4 The CNM's scope of practice is defined by academic educational preparation and national certification and maintained

competence. A CNM shall be held accountable by the Committee for a broad range of personal health services or 5

- 6 which the CNM is educationally prepared and for which competency has been maintained once the CNM has been
- authorized to practice midwifery. These services include: Scope of practice is set by the ACNM and posted on its 7

8 website at www.midwife.org and includes:

- 9 (1)diagnosing, treating, and managing a full range of primary health care services to the patient 10 throughout the lifespan, including gynecologic care, family planning services, preconception care, 11 prenatal and postpartum care, childbirth, and care of the newborn;
- promotion and maintenance of health care services for the patient throughout their lifespan; 12 (2)
- 13 $\frac{(3)}{(2)}$ treating patient and their partners for sexually transmitted disease diseases and reproductive health;
- 14 [(4)](3) providing care in diverse settings, which may include settings such as home, hospital, birth center, 15 and a variety of ambulatory care settings including private offices and community and public health 16 clinics;
- 17 [(5)](4) prescribing, administering, and dispensing therapeutic measures, tests, procedures, and drugs;
- 18 [(6)](5) planning for situations beyond the CNMs scope of practice and expertise by collaborating, 19 consulting with, and referring to other health care providers as appropriate; and
- 20 [(7)](6) evaluating health outcomes.
- 21 22
- Authority: G.S. 90-18.8; 90-178.3; History Note:
- 23 Temporary Adoption Eff. October 1, 2023.

21 NCAC 33 .0114 is adopted under temporary procedures with changes as follows:

3 21 NCAC 33 .0114 ANNUAL RENEWAL 4 (a) The CNM shall renew the approval to practice shall be renewed annually no later than the last day of the applicant's 5 birth month by: 6 (1) maintaining an active, unencumbered North Carolina RN license or privilege to practice; 7 (2)submitting a completed application as outlined in Rule .0103 of this Chapter for renewal, attesting 8 under oath or affirmation that the information on the application is true and complete, and 9 authorizing the release to the Committee of all information pertaining to the application as a set of all information pertaining to the application as a set of a set 10 in Rule .0103 of this Chapter.]Applications are located on the Board of Nursing's website at 11 www.ncbon.com; 12 (3) attest attesting to having completed the requirements of the Certificate Maintenance Program of the 13 American Midwifery Certification Board or its successor, including continuing education 14 requirements, and submit evidence of completion if requested by the Committee as specified in Rule 15 .0111 of this Chapter; and (4) 16 submitting the approval to practice renewal fee as established in G.S. 90-178.4(b)(2) and this 17 Chapter. 18 (b) It shall be the duty of the CNM to keep the Committee informed of a current mailing address, telephone number, 19 and email address. 20 (c) If the CNM has not renewed by end of [their] his or her birth month and submitted the annual fee, the approval to 21 practice shall expire. 22 23 History Note: Authority: G.S. 90-178.4(b); 90-178.5; 24 Temporary Adoption Eff. October 1, 2023.

- 1 21 NCAC 33 .0115 is adopted under temporary procedures <u>with changes</u> as follows:
- 2

3 21 NCAC 33 .0115 INACTIVE STATUS

4 (a) Any CNM who wishes to place their approval to practice on an inactive status shall notify the Committee in5 writing.

6 (b) A CNM with an inactive approval to practice status shall not practice as a CNM.

7 (c) A CNM with an inactive approval to practice status who reapplies for <u>an</u> approval to practice shall meet the

- 8 qualifications for an approval to practice in Rule. 0103 Rule .0103 of this Chapter and shall not resume practicing
- 9 <u>until receive</u> notification is received from that the Committee has granted the of approval prior to beginning practice
- 10 after the application is approved. application.
- 11 (d) A CNM who has not practiced as a CNM in more than two years shall complete a midwifery refresher course
- 12 approved by the [Commission] Commission. The refresher course shall be based on the American College of Nurse-
- 13 Midwives' reentry to midwifery practice [guidelines] guidelines, contain didactic content and clinical experience, and
- 14 <u>be</u> directly related to the CNM's area of academic education and national certification. A midwifery refresher course
- 15 participant shall be granted an approval to practice that is limited to clinical activities required by the refresher course.
- 16
- 17 History Note: Authority G.S. 90-178.3; 90-178.5;
- 18 Temporary Adoption Eff. October 1, 2023.

- 1 2
- 21 NCAC 33 .0116 is adopted under temporary procedures with changes as follows:

2		
3	21 NCAC 33 .(0116 COLLABORATIVE PROVIDER AGREEMENT
4	(a) A CNM wit	h less than 24 months and 4,000 hours of practice as a CNM is required to have a written collaborative
5	provider agreen	nent to practice midwifery. The collaborative provider agreement shall:
6	(1)	be agreed upon, signed, and dated by both the collaborating provider and the CNM, and maintained
7		in each provider site;
8	(2)	be reviewed at least [annually.] annually, to ensure that the CNM and collaborating provider
9		continue to practice under the terms of the agreement, and determine whether any changes to the
10		agreement are necessary. This review shall be acknowledged by a dated signature sheet, signed by
11		both the collaborating provider and the CNM, appended to the collaborative provider agreement,
12		and available for inspection by the Committee;
13	(3)	include mutually agreed upon written clinical practice guidelines for the drugs, devices, medical
14		treatments, tests, and procedures that may be prescribed, ordered, and performed by the CNM; and
15	(4)	include a pre-determined plan for emergency services.
16	(b) The collab	orating provider and the CNM shall be available to each other for consultation by [direct] in-person
17	communication	or telecommunication.
18	(c) A The CNN	1 shall maintain a copy of the collaborative provider agreement executed within the previous five years
19	shall be mainta	ined by the CNM and made make available upon request of the Committee. to the Committee upon
20	<u>request.</u>	
21		
22	History Note:	Authority G.S. 90-18.8; 90-178.3; 90-178.4; 90-178.5;
23		Temporary Adoption Eff. October 1, 2023.

- 1 2
- 21 NCAC 33 .0117 is adopted under temporary procedures with changes as follows:
- 3 21 NCAC 33 .0117 PRESCRIBING AUTHORITY
- 4 (a) The prescribing stipulations contained in this rule apply to writing prescriptions and ordering the administration
- 5 of medications by a CNM.
- 6 (b) A CNM must possess a valid United States Drug Enforcement Administration ("DEA") registration in order [for]

7 to prescribe controlled substances.

- 8 (c) [the CNM to] To act as a collaborating provider for [another CNM. The] a CNM, the DEA registration of the
- 9 collaborating provider shall include the same schedule(s) schedule or schedules of controlled substances as the CNM
- 10 practicing under a collaborative provider agreement.
- 11 [(-+)](d) Prescribing and dispensing stipulations for the CNM authorized to practice under a collaborative provider 12 agreement are as follows:
- 13 (1) Drugs and devices that may be prescribed by the CNM shall be included in the collaborative provider
 14 agreement as outlined in Rule .0116 of this Chapter.
- 15
 (2)(1)
 The collaborative provider agreement outlined in Rule .0116 of this Chapter shall include the Drugs

 16
 drugs and devices that may be prescribed by the CNM shall be included in the collaborative provider

 17
 agreement as outlined in Rule .0116 of this Chapter. may prescribe.
- 18 (A)(2) The CNM has an assigned DEA number that is entered on each prescription for a controlled
 19 substance; substance.
- 20 (B)(3) Refills may be issued consistent with Controlled Substance laws and regulations;
 21 Substances (Schedules II, IIN, III, IIIN, IV, V) defined by the State and Federal Controlled
 22 Substances [Act;] Act, and
- 23 (C)(4) The collaborative provider shall possess a schedule(s) of controlled substances equal to or greater
 24 than the CNM's DEA registration.
- (3)[(2)](5) The CNM may prescribe a drug or device not included in the collaborative provider agreement
 only as follows:
 - (A) Upon a specific written or verbal order obtained from the collaborating provider before the prescription or order is issued by the CNM; and
- 29(B)The written or verbal order as described in Part (c)(3)(A) of this rule shall be entered into30the patient record with a notation that it is issued on the specific order of a collaborating31provider and signed by the CNM and the collaborating provider.
- 32 [(d)](e) All prescribing stipulations requirements shall be written in the patient's chart and shall include the medication
- and dosage, the amount prescribed, the directions for use, the number of refills, and the signature of the CNM.
- 34 [(e)](f) The prescriptions issued by the CNM shall contain:
- 35 (1) the name of the patient;
- 36 (2) the CNM's [name, approval to practice number issued by the Committee, and telephone

37 number; and

27

28

1 (3) the CNM's assigned DEA number shall be written on the prescription form when a controlled 2 substance is prescribed. 3 [(f)(g) A CNM shall not prescribe controlled substances for the CNM's own use, the use of the CNM's collaborating 4 provider, the use of the CNM's immediate family, the use of any other person living in the same residence as the 5 CNM, or the use of any person with whom the CNM is having a sexual relationship. As used in this Paragraph, 6 "immediate family" means a spouse, parent, child, sibling, parent-in-law, son-in-law or daughter-in-law, brother-in-7 law or sister-in-law, step-parent, step-child, or step-sibling. 8 9 History Note: Authority G.S. 90-18.8; 90-178.3; 10 Temporary Adoption Eff. October 1, 2023.

21 NCAC 33 .0118 is adopted under temporary procedures <u>with changes</u> as follows:

2 3 <u>21</u>

21 NCAC 33 .0118 BIRTH OUTSIDE HOSPITAL SETTING

4	(a) <mark>A CNM app</mark>	roved to	practice may attend and provide midwifery services for a planned birth outside of a hospital
5	setting for a preg	gnancy c	leemed low-risk by the American College of Obstetricians and Gynecologists (ACOG). Prior
6	to initiating care	for a pa	atient planning a home birth outside of a hospital setting, the CNM shall be required to:
7	(1)	obtain	a signed, written informed consent agreement with the patient that includes: details:
8		(A)	identifying information of the patient to include name, date of birth, address, phone
9			number, and email address if available;
10		(B)	identifying information of the CNM to include the name, RN license number, approval to
11			practice number, practice name, if applicable, and email address;
12		(C)	information about the procedures, benefits, and risks of planned births outside of hospital
13			settings;
14		(D)	an acknowledgment and understanding of the clear assumption of these risks by the patient;
15		(E)	when and if deemed necessary by the CNM, an acknowledgment by the patient to consent
16			to transfer to a health care facility when and if deemed necessary by the CNM; licensed
17			under Chapter 122C or Chapter 131E of the General Statutes that has at least one operating
18			room; and
19		(F)	a disclosure that the CNM is not covered under a policy of liability insurance, if applicable.
20	(2)	Provid	le the patient with <u>The CNM shall provide</u> a detailed, written plan for transfer of care to a
21		<mark>health</mark>	care facility under emergent and non emergent transfer. Such plan shall be signed and dated
22		<mark>by bot</mark>	h the patient and the CNM and shall include:
23		(A)	the name of and distance to the nearest health care facility licensed under Chapter 122C or
24			Chapter 131E of the General Statutes that has at least one operating room;
25		(B)	the procedures for transfer, including modes of transportation and methods for notifying
26			the relevant health care facility of impending transfer; and
27		<mark>(C)</mark>	an affirmation that the relevant health care facility has been notified of the plan for
28			emergent and non-emergent transfer by the CNM. consistent with G.S. 90-178.4(a2).
29	(3)	After a	a decision <mark>to of</mark> non-emergent transfer care has been made, the CNM shall:
30		(A)	call the relevant receiving health care facility to notify them of transfer;
31		(B)	provide a copy of the patient's medical record to the receiving health care facility; and
32		(C)	provide a verbal summary of the care provided by the CNM to the patient and newborn, if
33			applicable, to the receiving health care facility.
34	(4)	In an	emergent situation, the CNM shall initiate emergency care as indicated by the situation and
35		i <mark>mmee</mark>	liate <u>immediately</u> transfer <mark>of</mark> care by making a reasonable effort <mark>dependent upon the</mark>
55			
36		<u>circun</u>	nstances and nature of the emergency to contact the health care professional or facility to

1	instructions; remain with the patient(s) until transfer of care is completed; and continue emergency		
2	care as needed while:		
3	(A) transporting the patient(s) by private vehicle; or		
4	(B) calling 911 and reporting the need for immediate transfer.		
5	(b) Copies of the informed consent agreement and emergent and non-emergent transfer of care plans shall be		
6	maintained in the patient's record and provided to the Committee upon request.		
7	(c) A CNM approved to practice may attend and provide midwifery services for a planned home birth outside of a		
8	hospital setting for a pregnancy deemed low-risk by the American College of Obstetricians and Gynecologists		
9	(ACOG). No CNM shall attend or provide midwifery services to a patient for a planned home birth outside of a		
10	hospital setting for known situations contraindicated by ACOG including specifically fetal malpresentation, multiple		
11	gestation, and prior cesarean.		
12			
13	History Note: Authority: G.S. 90-18.8; 90-178.3; 90-178.4;		
14	Temporary Adoption Eff. October 1, 2023.		

Burgos, Alexander N

Subject: FW: [External] RE: 21 NCAC 33 Temporary Rules Requests for Changes - September 2023 RRC

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Tuesday, September 19, 2023 11:28 AM
To: Meredith Parris <mparris@ncbon.com>; Angela Ellis <angela@ncbon.com>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: [External] RE: 21 NCAC 33 Temporary Rules Requests for Changes - September 2023 RRC

Sounds good. If you're running late and want to just switch to 4 instead, let me know.

Brian Liebman Counsel to the North Carolina Rules Review Commission Office of Administrative Hearings (984)236-1948 <u>brian.liebman@oah.nc.gov</u>

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From: Meredith Parris <<u>mparris@ncbon.com</u>>
Sent: Tuesday, September 19, 2023 11:26 AM
To: Liebman, Brian R <<u>brian.liebman@oah.nc.gov</u>>; Angela Ellis <<u>angela@ncbon.com</u>>
Cc: Burgos, Alexander N <<u>alexander.burgos@oah.nc.gov</u>>
Subject: RE: [External] RE: 21 NCAC 33 Temporary Rules Requests for Changes - September 2023 RRC

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I'm hoping the meeting at 1 will be very straightforward and can end by 2pm. I'll do my best to call you then and make sure we are off the phone by 2:50. Thank you! Meredith

Meredith Parris JD

Director, Legal

Office: (984) 238-7627 Fax: (919) 781-9461

4516 Lake Boone Trail Raleigh, NC 27607 P.O. Box 2129 Raleigh, NC 27602

Pronouns: She/Her/Hers



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From: Liebman, Brian R <<u>brian.liebman@oah.nc.gov</u>>
Sent: Tuesday, September 19, 2023 11:23 AM
To: Meredith Parris <<u>mparris@ncbon.com</u>>; Angela Ellis <<u>angela@ncbon.com</u>>
Cc: Burgos, Alexander N <<u>alexander.burgos@oah.nc.gov</u>>
Subject: RE: [External] RE: 21 NCAC 33 Temporary Rules Requests for Changes - September 2023 RRC

Hi Meredith,

I could do a call before 3, with the caveat that I'll have to be off the phone by 2:50, so I can prepare for my meeting. I'd prefer to do it then, to give you the extra time, but if y'all want to wait till 4 that works too. Let me know.

Brian

Brian Liebman Counsel to the North Carolina Rules Review Commission Office of Administrative Hearings (984)236-1948 brian.liebman@oah.nc.gov

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From: Meredith Parris <<u>mparris@ncbon.com</u>>
Sent: Tuesday, September 19, 2023 11:16 AM
To: Liebman, Brian R <<u>brian.liebman@oah.nc.gov</u>>; Angela Ellis <<u>angela@ncbon.com</u>>
Cc: Burgos, Alexander N <<u>alexander.burgos@oah.nc.gov</u>>
Subject: RE: [External] RE: 21 NCAC 33 Temporary Rules Requests for Changes - September 2023 RRC

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Hey, Brian.

We are working diligently to respond to your questions. I have a meeting starting at 1, and I know you are unavailable from 3-4. Would it be possible to try and call you in between or should we set a time to speak at 4? I think talking through some of the content will be helpful for us both. Just let me know what works best for you!

Thanks, Meredith

Meredith Parris JD

Director, Legal

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Burgos, Alexander N

Subject:FW: [External] RE: 21 NCAC 33 Temporary Rules Requests for Changes - September 2023 RRCAttachments:21 NCAC 33 .0104 Provider Collaboration Required.docx

From: Angela Ellis <angela@ncbon.com>
Sent: Tuesday, September 19, 2023 7:40 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Meredith Parris <mparris@ncbon.com>
Subject: RE: [External] RE: 21 NCAC 33 Temporary Rules Requests for Changes - September 2023 RRC

CAUTION: External email. Do not click links or open attachments unless verified. Report suspicious emails with the Report Message button located on your Outlook menu bar on the Home tab.

Good morning, Brian!

My apologies. Attached is .0104.

We will review your comments this morning and re-submit. Thank you!

Angela Ellis

Angela Ellis Chief Administrative Officer

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hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. Please contact the sender by reply e-mail and destroy all copies of the original.

- 1 2
- 21 NCAC 33 .0104 is amended under temporary procedures with changes as follows:

3	21 NCAC 33 .0104 PHYSICIAN SUPERVISION PROVIDER COLLABORATION REQUIRED				
4	The applicant shall furnish the committee evidence that the applicant will perform the acts authorized by the Midwifery				
5	Practice Act under the supervision of a physician who is actively engaged in the practice of obstetrics in North				
6	Carolina. Such evidence shall include a description of the nature and extent of such supervision and a delineation of				
7	the procedures to be adopted and followed by each applicant and the supervising physician responsible for the acts of				
8	said applicant for rendering health care services at the sites at which such services will be provided. Such evidence				
9	shall include:				
10	(1) mutually agreed upon written clinical practice guidelines that define the individual and shared				
11	responsibilities of the midwife and the supervising physician or physicians in the delivery of health				
12	care services;				
13	(2) mutually agreed upon written clinical practice guidelines for ongoing communication that provide				
14	for and define appropriate consultation between the supervising physician or physicians and the				
15	midwife;				
16	(3) periodic and joint evaluation of services rendered, such as chart review, case review, patient				
17	evaluation, and review of outcome statistics; and				
18	(4) periodic and joint review and updating of the written medical clinical practice guidelines.				
19	(a) A CNM who has practiced fewer than 24 months and 4,000 hours of practice as a CNM shall practice in				
20	consultation with a collaborating provider in accordance with a collaborative provider agreement in compliance with				
21	Rule .0116 of this Chapter.				
22	(b) The approval to practice of the CNM practicing under the supervision of a collaborative provider agreement is				
23	terminated when the CNM discontinues working within the approved collaborative provider agreement or experiences				
24	an interruption in their RN licensure status. The CNM shall notify the Committee in writing within five days of the				
25	termination of the collaborative provider agreement.				
26	(c) The CNM shall have 90 days to submit a newly-executed collaborative provider agreement with a collaborative				
27	provider to the Committee. During this 90-day period, the CNM may continue to practice midwifery in accordance				
28	with the Midwifery Practice Act and this Chapter. Should the 90-day period expire without a newly-executed				
29	collaborative provider agreement being submitted to the Committee, the approval to practice is rendered inactive and				
30	the CNM shall be required to submit an application for reinstatement of the approval to practice consistent with Rule				
31	.0103 and Rule .0115 of this Chapter. The Committee will notify the CNM when the application has been approved				
32	and the approval to practice is reinstated.				
33	(d) To be eligible a collaborative provider [shall] shall:				
34	(1) hold an active, unencumbered approval to practice as a CNM [having] and have a minimum of four				
35	years and 8,000 hours of practice as a CNM [or] or;				
36	(2) hold an active, unencumbered license to practice medicine in North Carolina and be actively				
37	engaged in the practice of obstetrics.				

1	(e) A CNM who	has practiced over 24 months and has 4,000 hours of practice as a CNM may be issued an approval			
2	to practice midwifery independently and shall consult and collaborate with and refer patients to such other health care				
3	providers as may be appropriate for the care of the patient.				
4					
5	History Note:	Authority G.S. 90-178.4(b); <u>90-178.3;</u>			
6		Eff. February 1, 1984;			
7		Amended Eff. July 1, 2000; October 1, 1988; April 1, 1985;			
8		Readopted Eff. November 1, 2018.			
9		<u>Temporary <mark>[Adoption</mark>] Amendment Eff. October 1, 2023.</u>			

Subject: FW: [External] RE: 21 NCAC 33 Temporary Rules Requests for Changes - September 2023 RRC

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Tuesday, September 19, 2023 1:02 AM
To: Angela Ellis <angela@ncbon.com>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Meredith Parris <mparris@ncbon.com>
Subject: RE: [External] RE: 21 NCAC 33 Temporary Rules Requests for Changes - September 2023 RRC

Angela,

Thanks for making these changes. I have some follow ups. First, though, I don't think you sent the right version of .0104. I don't see any changes there.

My comments below, in blue, for the other rules.

Rule. 0101

In (5), p.3, line 13, I still don't understand "unspecified primary health services for women". I think it can be a whole lot clearer, i.e. whether those services are all related to birth, or whether we're talking lifelong primary care. Given this language, I think maybe you might see my point about the scope of CNM practice in Rule .0112 a little more clearly too, when both obstetricians and CNMs are performing "primary health services".

Rule .0103

I don't have a change request on this one, since its new language you added, but in new (e), "certification" should be plural. Also change "must" to "shall".

In (a)(3), line 12, a license for what? Midwifery or to practice as a registered nurse? Any RN license must be unencumbered. Pursuant to the nurse licensure compact, multistate licensure refers to "privilege to practice" (not approval). For clarification, changes were made to reflect these distinctions.

How are (a)(3) and (a)(5) different requirements? They seem to mean the same thing. (a)(3) refers to the RN license, which should not be encumbered in any jurisdiction in which it exists. (a)(5) is specific to CNMs. With the clarification/correction above in (a)(3), the distinction should be clearer.

In (a)(4), line 14, what is a "privilege to practice" and how is it different than a license? See also (b)(3), p.2, line 21.

See response above for (a)(3). Under the Nurse Licensure Compact, the home state in which a nurse resides issues a license. Through the compact, a nurse with a multistate license has a privilege to practice in compact states. Should a compact state take disciplinary action for events occurring in their jurisdiction, they issue discipline on the privilege to practice (and not the license). Privilege to practice is a term understood by our regulated public.

OK, taking all these together, I think I know what you're trying to say, but the Rule language itself is still a little unclear. Seems to me (a)(3) and (4) both refer to nurses, and (5) refers to the CNM privilege to practice. I think (3) either needs to say "license or privilege to practice <u>as an RN</u>" or (3) and (4) need to be combined in whatever way you think best.

In (a)(6), line 18, what "evidence" are you requiring"? Be specific. See also (b)(5), p.2, line 24.

The evidence would be an official copy of the educational transcript and the certificate from the national certifying body.

I think it's important to say that in the Rule then.

In (a)(6), line 20, what about the "sites" are you asking for? See also (b)(5), p.2, lines 25-26. The sites refer to the practice sites or locations where the CNM intends to practice. I think you need to be more specific. Do you want the city and state? A county? A full address?

On p.3, line 1, what is a "concern"? And who would have the concern? Someone on the committee? A fellow practitioner? A member of the public?

Issues may arise regarding any of the documentation provided, certifications, hours, etc. If there are issues with the application, staff must refer the application to the Committee for a determination of licensure. For example, if a CNM seeks approval, but has reported a criminal conviction within 2 years – staff cannot approve the application; however, the applicant would be referred to the Committee for the determination.

Your statutes say the joint subcommittee is responsible for approving applicants, not staff. Do you have statutory authority to delegate approval of the application to staff? Regardless, I think the key here is the word "concern". I think you need to be more specific about what would trigger the interview requirement.

Rule .0105

In (b)(2), line 11, define "immoral" and "dishonorable". These terms, if left undefined, are impermissibly vague and unclear.

This language is consistent with Medical Board and NP Rules. It covers a variety of exhaustive situations that cannot be defined with specificity. Midwifery Statute under G.S. 90-178.6 states "conduct that endangers the public health" and "conduct that deceives, defrauds or harms the public in the course of professional activities or services". This is what is meant by immoral and dishonorable conduct. We added a reference to G.S. 90-178.6.

I think the reference to the statute is good, but the terms "immoral and dishonorable" are still unclear, and **much** broader than what you have in 90-178.6. For instance, adultery is immoral and dishonorable, but it doesn't endanger the public health and doesn't defraud or harm the public in the course of professional activities or services. If what you mean is conduct covered by the statute, I would urge you to just say that, and delete "immoral and dishonorable".

In (b)(4), line 14, who would adjudicate the CNM as mentally incompetent? A judge? In any jurisdiction? If there is a legal determination where the CNM is found incompetent in any jurisdiction. The CNM would still be afforded due process even if such finding were to be made.

So could the joint subcommittee, in the absence of another jurisdiction's ruling, make a finding that the CNM was mentally incompetent and proceed on discipline on that basis? Because I don't think the subcommittee has that authority. I think this could be fixed by saying "the CNM has been adjudicated mentally incompetent by a court of competent jurisdiction" (no pun intended).

In (b)(5), line 17, what are "prevailing standards"? Are these defined?

Prevailing standards are standards generally accepted within the healthcare profession. Standards of care are taught to CNMs within their general education and nationally defined. These standards would be known to our regulated public.

OK, where are they nationally defined? You need a cross-reference here, because we're talking about the standards by which someone's ability to practice are based on. If you don't say exactly what those standards are, then what stops the joint subcommittee from making a new standard and saying "we think this is a prevailing standard". I'm not saying the joint subcommittee **would** do this, but they **could** under this language.

In (b)(6), line 18, what criminal offenses "bear on the CNM's ability to practice"?

Such examples would include assaults involving patients, fraud, driving while impaired – same as the crimes considered for RN/LPN and physicians.

Again, I think we need some specificity, so the CNM knows what the bounds are. "Deceived or defrauded the public" is one thing, you can look at the elements of a crime, look for fraud or deception, and make that connection. "Bears on

the CNM's ability to practice" could mean anything without some kind of definition of what you mean by "ability to practice". Also, "bears on" is very vague. If a CNM is convicted of reckless driving and their license is suspended, but they can still attend births and travel by bus or Uber, did the conviction "bear on" their ability to practice? Consider something like: "the CNM was convicted of a criminal offense based upon any act violative of Chapter 90, Article 10 of the North Carolina General Statutes and the Rules of this Subchapter." If you want to add a "such as" and list particular crimes, I think that'd be OK too.

In (b)(8), line 21, where is "professional competence" defined? Also, how is this different from (b)(12)'s requirement to "maintain competence"?

If referencing line 19 instead of 21, professional competence is the standard of competence learned in CNM training and education and is reviewed and maintained with national certification. Professional competence is known to our regulated public.

Doesn't one of the organizations mentioned in Rule .0101 define these standards? I think you need to point to something, even if you're just saying "failure to maintain professional competence as a CNM, such that the CNM would no longer be eligible for certification by the ACMB or the ACNM." Of course, that language works only if it encompasses the full meaning of "professional competence." That's something I can't answer. Regardless, I think you need to point to the specific standards by which you are judging your CNMs.

In (d), p.2, lines 2-3, does the Midwifery Committee (or subcommittee) have the statutory authority to exercise power given by statute to the Board of Nursing? Wouldn't the Committee's power to discipline stem from G.S. 90-178.6 and 178.7? If the Committee has the disciplinary authority vested in the Board of Nursing by G.S. 90-171.37, why does G.S. 90-178.6(b) specifically note that "revocation of a license to practice nursing pursuant to G.S. 90-171.37 shall automatically result in **comparable** action against the person's approval to practice midwifery under this Article"? Doesn't this indicate that these are separate sources of authority? The Committee's power does stem from G.S. 90-178.6 and 90-178.7, and we would agree these are separate sources of authority from 90-171.37. If an investigation results in disciplinary action against an RN, the Committee still needs to pursue action against the CNM approval to practice. The Board of Nursing does not have the authority to suspend the CNM approval, so this action would be addressed by the Committee. Right, so then why is this language necessary? You have explicit statutory authority to take action against a CNM whose license to practice as an RN has been revoked. This rule goes beyond that and says you can take action "as enumerated" by the *Board of Nursing's* discipline statute, upon a finding of a violation of your own rules/statutes. Again, the question is how does the Midwifery Committee have the authority to take action not under its own discipline statutes, but under the Board of Nursing's discipline statute? I don't think you do. You can take action under 178.6 or 178.7, but not under 171.37.

Additionally, whatever you do with this language, please clarify whether "violation" means violation of your rules, statutes, or both. Maybe that's picky, but I think it needs to be said.

<u>Rule .0111</u>

In (a), lines 5-6, what is this "Program"? Please incorporate it by reference pursuant to 150B-21.6. The Certificate Maintenance Program is the title of the required program all CNMs must take through their certifying body (American Midwifery Certification Board - AMCB) to maintain their national certification. Yes, but you didn't incorporate it by reference. If you're requiring adherence to the requirements, you have to incorporate it by reference at the very least. I need to review it to see if it contains anything that would violate the APA.

In (b), line 13, spell out "1".

According to 26 NCAC 02C .0108(9)(c) "if a phrase contains two numbers, only one of which is over nine, figures shall represent both". Please advise.

Thank you for actually reading our formatting rules. This is rare, and made me happy. 😕 However, I think by "phrase" it means something like the 12 days of Christmas, if that makes sense ("10 lords a'leaping, 9 ladies dancing..." as opposed to "10 lords a'leaping, nine ladies dancing"). So I think you're fine to spell out "one" here. I'd note you already did do that in "one CE hour" immediately prior to this language, too.

Rule .0112

The sentence at lines 5-6 "The CNM's scope of practice... maintained competence." is impermissibly vague and unclear. What levels of educational preparation are there? What procedures or privileges do they translate to? What if someone has a high level of education but hasn't "maintained competence"? What does that do to the scope of their practice? How does someone "maintain competence"?

Education is understood based on the minimum standard of completing a graduate program (master's or doctorate) as well as passing the national certification exam. The scope and standards are defined as part of their accredited education and nationally recognized profession. The scope is based on educational preparation, national certification, and maintained competence; a CNM cannot have one or the other, they must have all three elements.

I'm afraid I still don't see what the scope of practice is. What you're saying sounds like requirements to practice, not the scope of practice. The way I see it, if education, certification, and maintained competence defined the scope of practice, then someone with a masters and one kind of certification could not do procedures that someone with a doctorate and another kind of certification (I thought there was just the one certification, but I'm trying to understand) could do. And both of them might not be able to perform some procedures that would otherwise be within their scope of practice if they hadn't taken the right kind of CEs. If that's the case, then this rule needs to make it plain who can do what under what educational/certification/competence conditions. If that's not the case, then you need to make clear what it is you're trying to say, because I just don't understand it.

At line 6, what does it mean for the CNM to "be held accountable"? Does this mean disciplinary action by the Committee?

Yes. The CNM is responsible for practicing within their scope of practice. Should they exceed their scope of practice, the CNM is subject to disciplinary action by the Committee.

So .0105(b)(13) says the CNM can't *exceed* the scope of practice defined here. This language says they're to be held accountable for the services the CNM is authorized to practice. This seems like a different concept. Which is why I'm asking what you mean by "held accountable ... for"?

At line 8, these services "include" the list of (1)-(7), but what else is included? It is important that there be a discrete list, given that this is where the scope of practice is defined, and it is a disciplinable offense to exceed that scope. How is someone to know if they exceed the scope of practice when it isn't explicitly defined? A CNM is a nationally recognized healthcare provider who specializes in nurse midwifery. The CNM is an advanced nursing practice nurse role with a specific population focus. Within this population focus, they can provide healthcare as described in 1-7. Like other healthcare disciplines, it would be cumbersome and inaccurate to attempt a list of frequently evolving pharmacotherapeutics, diagnostic tests, and procedures a healthcare provider can order or perform. A CNM's scope of practice is based on a minimum standard of nationally recognized and certified education and training. CNMs provide healthcare as defined by their scope in Rule .0112 and (1) and 2-7 define their practice further within the healthcare continuum.

I agree, it would be cumbersome to list everything a CNM can perform. I guess what I am getting at is that reading this, I don't know what a CNM **can't** do... "diagnosing, treating, and managing a full range of primary health care services throughout the lifespan prescribing, administering, and dispensing therapeutic measures, tests, procedures, and drugs." I **know** you don't mean it to, but I don't see how this stops a CNM from diagnosing ("diagnosing") a 70 year old man ("the patient throughout the lifespan"), with a broken leg ("full range of primary health care services"), and then performing surgery to install plates ("administering . . . therapeutic . . . procedures") in his house ("providing care in diverse setting, such as home...").

In (1), line 9, what are "primary health care services"? Are these defined somewhere?

This term is known to our regulated public. It is common knowledge within the healthcare industry that primary health care services are healthcare promotion, maintenance, and disease prevention.

But you already say "promotion and maintenance of health care services" in (2). And it sounds to me like "treating a patient and their partners" for STDs in (3) goes beyond "prevention". So does "prescribing, administering, and dispensing therapeutic measures, tests, procedures, and drugs."

In (1), line 10, what does "throughout the lifespan" mean? Does this mean a midwife functions as a primary care physician for people of all ages?

Lifespan is defined in healthcare as "all ages", and a CNM can provide midwifery care for a newborn to an aging adult. It is also understood that healthcare is not provided in a vacuum, and there will be overlap of care. A midwife is not and cannot be considered a physician because they have different training, titles, and authority. Physicians practice medicine, and CNMs practice nurse midwifery. A CNM is a nurse with additional graduate-level and clinical education that performs medical acts within their scope of training within their population focus. This training includes care which often includes health promotion, maintenance and prevention of illness.

In (2), line 12, what does "promotion and maintenance of health care services" mean? It sounds like you're saying the midwife is responsible for convincing people to seek care with them at risk of "being held accountable".

Promotion and maintenance of health care services refers to educating and coordinating care beyond midwifery practice. The CNM is responsible for practicing within their scope. If what the patient requires is beyond the CNM's scope of practice, the CNM is accountable to the Committee for informing and educating the patient and coordinating care beyond their service.

I'm going to be honest, I really don't see how I can recommend approval of this rule without major changes. As I said, my main issue is that I can't see what a CNM cannot do. One thing you've said that makes sense to me, and I think you should build from, is that a CNM is a nurse with additional graduate level and clinical education. I am sure there is a statute or rule defining the scope of practice for an RN (given the time constraints, I'm sure you can find it easier than I can). Perhaps a rule saying the scope of practice is anything an RN can do pursuant to [cite to the law or rule] as well as ... and then add a concrete list of whatever it is the CNM can do that an RN cannot.

<u>Rule .0114</u>

In (a)(2), line 9, what is a "complete" application? Although G.S. 90-174(b)(4) explicitly gives the "joint subcommittee" the authority to "establish the form and contents of the application" by rule, I do not see any rule or part of a rule in which the contents of the application are clearly set out. As the application seems to be on a form provided by the Board of Nursing (see also G.S. 178.5(a)(1)), that form would need to either go through rulemaking itself, or have its contents or substantive requirements described in another rule or a statute.

In correcting the application content requirements under Rule .0103, our intent would be to refer to this rule as the application content would be the same for renewal applications.

I think the cross reference is good, I'd just move it to line 7, so it says "a completed application as outlined in Rule .0103...".

In (c), line 21, please change "their" to "his or her". Gender neutral terminology. I understand, but it's not grammatically accurate.

Rule .0115

In (d), line 13-14, what are the American College of Nurse Midwives rentry to practice guidelines? If you are enforcing them via this Rule, they need to be incorporated by reference pursuant to G.S. 150B-21.6. The American College of Nurse Midwives recommends two components for reentry into CNM practice, didactic content and clinical experience.

OK, these need to be incorporated by reference here.

Rule .0116

In (a)(1), lines 7-8, do you mean that a copy of the agreement has to be kept in all provider sites? How does this comport with Rule .0112(4)'s requirement that the CNM be prepared to practice in a variety of different settings?

The physical collaborative provider agreement must be kept by the CNM at their practice location and by the collaborating provider at their practice location (should they differ). Regardless of the practice setting

(hospital, birth center, homebirth), the CNM's scope of practice does not change. Rule .0112 speaks to scope of practice which is inclusive of a variety of settings.

I'm not suggesting that the scope of practice changes, I'm suggesting that it sounds like the CNM has to carry the agreement with them when they go to someone's home, but it doesn't say that explicitly.

In (a)(2), line 9, what does a "review" entail?

The agreement must be reviewed by both the CNM and collaborating provider annually to ensure that they are continuing to practice under the terms of the agreement and no changes need to be made. They review the existing CPA and agree to change, or not change the agreement, with acknowledgement by date and signature. This type of review would be consistent with their current practice working with a supervising physician and known to the regulated public.

Why not say this then? "be reviewed at least annually, to ensure that the CNM and collaborating provider continue to practice under the terms of the agreement, and determine whether any changes to the agreement are necessary."

In (b), line 15, define "direct communication" and "telecommunication".

Communication can be in person, via internet, phone, email, etc. We would prefer not to limit it to direct, face-to-face communication and provide flexibility for communication as the need arises. I guess my confusion stems from the dichotomy here. To me a phone call or a text would be "direct" AND "telecommunication", while an email may not be "direct". Maybe "in-person communication or telecommunication" might be closer to what you mean?

Rule .0117

Is this Rule "consistent with the rules established for nurse practitioners under G.S. 90-18.2(b)(1)", as required by G.S. 90-18.8(c)?

G.S. 90-18.8 does not exist; however, the proposed language is consistent with the prescribing requirements for nurse practitioners pursuant to G.S. 90-18.2 and 21 NCAC 36.0809. G.S. 90-18.8 is created by SL 2023-14, s. 4.3(a). Just FYI.

In (b), are you requiring both the collaborating provider CNM and the CNM under the agreement to have a DEA registration? There is an inference here (and in (e)(3)), but there's no explicit requirement that a CNM practicing under an agreement or a CNM practicing independently have a DEA registration.

If the CNM is practicing pursuant to a collaborative provider agreement and prescribing controlled substances is part of the CNM's and the collaborating provider's midwifery practice, both the CNM and the collaborating provider must have a DEA registration if the CNM to prescribe controlled substances.

I'm not sure you've answered the whole question. What about an independently practicing CNM, not under a CPA? I think it's obvious they need a DEA registration, but the rule doesn't say that. It only says that a collaborating provider needs a registration. The rule doesn't even say that the CNM under the agreement needs a registration. The only person explicitly required to have a DEA registration is the collaborating provider.

Where in (e) is the requirement that the CNM write their "identification number" assigned by the joint subcommittee on the prescription? This is required in G.S. 90-18.8(b)(3).

G.S. 90-18.2 is Limitations on Nurse Practitioners. Under this statute, there is no requirement that the NP Approval number shall be listed on the prescription. However, to be consistent with prescribing requirements for Nurse Practitioners, we looked to 21 NCAC 36 .0809(b)(2) which lists the same requirements as are contained in this proposed language.

G.S. 90-18.8 is created by SL 2023-14, s. 4.3(a). Please review that statute.

Rule .0118

In (a)(4), line 34, define "reasonable effort".

What constitutes a reasonable effort depends on the circumstances of the scenario. An effort must be made to contact the receiving provider or health care facility; however, factors such as the emergent nature of the situation would affect whether one call is reasonable or 10 calls would be considered reasonable

It sounds like the CNM just needs to contact the health care professional or facility. Suggest deleting this phrase and just saying "...immediately transfer care by contacting the health care professional or facility...".

I'll be available most of the day tomorrow if you have questions, except for between 3:00 and 4:00 p.m.

Best, Brian

Brian Liebman Counsel to the North Carolina Rules Review Commission Office of Administrative Hearings (984)236-1948 <u>brian.liebman@oah.nc.gov</u>

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Burgos, Alexander N

Subject: FW: [External] RE: 21 NCAC 33 Temporary Rules Requests for Changes - September 2023 RRC

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Friday, September 15, 2023 2:05 PM
To: Angela Ellis <angela@ncbon.com>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Meredith Parris <mparris@ncbon.com>
Subject: RE: [External] RE: 21 NCAC 33 Temporary Rules Requests for Changes - September 2023 RRC

Thanks! I will take a look and let you know what I think ASAP.

Best, Brian

Brian Liebman Counsel to the North Carolina Rules Review Commission Office of Administrative Hearings (984)236-1948 brian.liebman@oah.nc.gov

E-mail correspondence to and from this address may be subject to the North Carolina Public Records Law N.C.G.S. Chapter 132 and may be disclosed to third parties.

From: Angela Ellis <angela@ncbon.com>
Sent: Friday, September 15, 2023 1:41 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Meredith Parris <mparris@ncbon.com>
Subject: [External] RE: 21 NCAC 33 Temporary Rules Requests for Changes - September 2023 RRC

CAUTION: External email. Do not click links or open attachments unless verified. Report suspicious emails with the Report Message button located on your Outlook menu bar on the Home tab.

Hi Brian,

Thank you for all your assistance with these temporary rules!

The following documents are attached:

- Request for Technical Change document with responses
- 21 NCAC 33 Rules
- Substantial Compliance Memo

Anna Choi, General Counsel for the NC Board of Nursing, Kimberly Luisana and I will attend the RRC meeting in person on September 21st.

Please let me know if you need anything further. We have blocked out time on our calendars Monday afternoon and Tuesday for any additional requests in preparation for the RRC meeting. Have a great weekend!

Angela Ellis

Angela Ellis Chief Administrative Officer

Office: (984) 238-7644 Fax: (919) 781-9461

4516 Lake Boone Trail Raleigh, NC 27607 P.O. Box 2129 Raleigh, NC 27602

Pronouns: She/Her/Hers



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Memorandum

To the Rules Review Commission On Behalf of the Midwifery Joint Committee

Re: Request for Approval of Temporary Rules Based on Substantial Compliance

September 21, 2023

Senate Bill 20 / Session Law 2023-14 was enacted on May 16, 2023 and required the Midwifery Joint Committee (MJC) to adopt rules for when portions of this law become effective on October 1, 2023. With this law and it's effective date, the MJC had approximately three months to promulgate rules, and thus, the MJC began working towards temporary rulemaking.

While the MJC works with the Board of Nursing (BON) pursuant to a Memorandum of Understanding, rulemaking was not contemplated in this agreement. An emergency meeting was called on June 8, 2023, and the MJC voted to approve an Addendum to the existing Memorandum of Understanding to engage BON staff in the rulemaking process and implementation of Senate Bill 20. The MJC, which meets annually in November, convened on July 12, 2023 and July 17, 2023, to work diligently towards adoption of the proposed temporary rules as mandated by the legislature. On August 29, 2023, the MJC adopted six new rules and amended five existing rules to meet the requirements of Senate Bill 20.

Although the MJC voted to adopt the rules two business days short of the required 30 days, the MJC has substantially complied with G.S. 150B-18 and requests the Commission approve these rules. Neither the MJC nor the BON have made previous requests for the Commission to consider substantial compliance when promulgating rules. These proposed temporary rules provide structure and clarity to CNMs while protecting the health and safety of the public in accordance with the October 1, 2023 effective date. The MJC intends to promulgate permanent rules at its upcoming annual meeting in November.

Temporary Rulemaking Timeline

- July 12, 2023 and July 17, 2023: The MJC called a meeting to discuss proposed rules drafted in response to Senate Bill 20. Following discussion, the MJC voted to proceed with temporary rulemaking.
- July 20, 2023: The MJC submitted proposed temporary rules to the Codifier. Emails to interested parties were sent July 20th with social media posts on all platforms (FB, Instagram and LinkedIn). The BON website was updated on July 20th as well.
- July 26, 2023: The temporary rules were posted on July 26, 2023.
- August 8, 2023: Public Hearing held.
- August 17, 2023: Public comment period ends. Public comment was held for 20 days, 5 days more than required.

- August 29, 2023: Called MJC meeting held for adoption of temporary rules. A public comment was received by the Board of Nursing before noon the same day of the meeting. The comment was distributed to and accepted by the MJC prior to a vote to adopt the proposed temporary rules. No additional comments have been submitted since.

We acknowledge our calculation error when scheduling the required 30 calendar days after the July 20, 2023 submission date, and we agree with RRC counsel that these rules were adopted 2 days earlier than the 30 calendar day period required by statute. However, the MJC asserts that it has substantially complied with the statutory requirements, as referenced in G.S. 150B-18, and thus the temporary rules should be approved by the Commission. A decision to reject these rules based upon this unintentional error, when all other statutory requirements were met and in fact, the period of public comment was longer than the minimum required by statute, would run contrary to the legislative mandate requiring that the Board adopt rules necessary to administer the provisions of this Article by the October 1st deadline.

AGENCY: North Carolina Board of Nursing

RULE CITATION: All Rules and Forms

DEADLINE FOR RECEIPT: Friday, September 15, 2023.

<u>PLEASE NOTE:</u> This request may extend to several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

G.S. 150B-21.1(a3)(1) requires an agency to submit its rules to the Codifier "at least 30 business days prior" to adoption. According to your Temporary Rulemaking Findings of Need form, these rules were submitted on July 20, 2023, and adopted less than 30 business days later, on August 29, 2023. By my calculations, 30 business days after July 20 would have been August 31. Can you confirm the timeline? See Memo Regarding Statutory Compliance.

G.S. 90-178.4 creates a "joint subcommittee of the North Carolina Medical Board and the Board of Nursing" to "administer the provisions of this Article and the rules adopted pursuant to this Article." The statute gives the rulemaking authority to the "joint subcommittee". That said, does the Medical Board have to submit these Rules, as well as the Board of Nursing?

The Midwifery Joint Committee Rules are listed under Chapter 33 and administered by the Board of Nursing. The Medical Board serves on the MJC to assist in promulgation of Rules. Neither the Board of Nursing nor Medical Board have Midwifery related Rules in our Chapters.

Many of your rules request the CNM to make submissions to the Committee. I don't see a contact rule anywhere in Chapter 33, so consider adding one and referring to it throughout, so your regulated public knows how and where to submit applications, requests, etc.

We intend to draft this Rule and submit through permanent rulemaking later this year.

Throughout these rules, the Committee often refers to a CNM's level of experience (i.e. more than 24 months and 4,000 hours of practice). Must this experience be gathered in the State of North Carolina? Or does out of state practice count? Out of state practice counts as level of experience.

Please conform your introductory statements on each Rule to the rule formatting examples for temporary rules to be published in the NCAC, which can be found on our website at: <u>https://www.oah.nc.gov/rule-format-examples</u>. Corrected.

AGENCY: North Carolina Board of Nursing

RULE CITATION: 21 NCAC 33 .0101

DEADLINE FOR RECEIPT: Friday, September 15, 2023.

<u>PLEASE NOTE:</u> This request may extend to several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

Throughout the Rule, there are several instances where you use the phrase "certified nurse midwife" and then add the acronym in parentheses. However, the acronym is used inconsistently, and in many cases you use the phrase "Certified Nurse Midwife" with the words capitalized. Only add the acronym in parentheses at the first usage, and then consistently use the acronym. Otherwise, delete the acronym and just use the full phrase. In any event, please choose one form between "CNM", "certified nurse midwife", or "Certified Nurse Midwife" and be consistent. Please be mindful of the sentence in (a), lines 6-7 if you choose to just eliminate the acronym. Corrected throughout.

Many of these definitions are verbatim copies of statutory definitions from G.S. 90-178.2. Repetition of verbatim statutory language subjects your rule to objection under G.S. 150B-21.9(a)(3) for lack of necessity. To avoid a staff opinion recommending objection, I suggest deleting the following definitions: (5), (6), (7), (8), (9), (10), (11), (13), and (14). I am including requests for changes for these definitions below, but even if these changes are made, I will still be inclined to issue a staff opinion if these definitions continue to be included.

Deleted 5, 6, 7, 8, 9, 10, 11, 13, and 14.

Throughout, please delete "but is not limited to" as it follows "including" or "includes". Corrected throughout.

Throughout, wherever the phrase "including" is used to set off a list, what else would fall within the definition? For instance, in (b)(8), "interconceptional care" includes the care in (a), (b), and (c), but what else would fall within this care? Elsewhere in your Rules I have observed that midwives fill a primary care provider role. That doesn't seem to be captured in (b)(8), however. Deleted 8.

In (b)(4), p.2, line 2, "obstetrician-gynecologist" should be plural. Also on that line, please change "which" to "that". Corrected.

In (b)(5), line 9, change "or is successor" to "or <u>its</u> successor". Deleted.

In (b)(5), lines 9-10, from whom would the CNM receive this designation? Additionally, this definition seems somewhat circular in this respect, as it essentially says a CNM is someone who has received the designation CNM. Deleted.

In (b)(5), lines 10-13, what are these documents (?) referenced in the Rule? What does it mean that CNMs "practice in accordance with" them? Would violation of any of these standards be grounds for the Commission to discipline a midwife? At the very least, I think these need to be incorporated by reference pursuant to G.S. 150B-21.6. Deleted.

In (b)(8)(c), line 24, what is a "minor" infection? **Deleted**.

In (b)(10), p.3, line 1, where is the practice of medicine "defined by law"? **Deleted.**

In (b)(10), line 2, what is a "medical act"? **Deleted**.

In (b)(10), line 4, where is the practice of nursing "defined by law"? **Deleted**.

In (b)(11)(a) and (b), lines 7 and 8, define "routine". Deleted.

In (b)(11)(b), line 8, what else is included in the "physical assessment" besides APGAR scoring? Deleted.

In (b)(12), line 13, delete "and with", and insert commas on either side of "its antecedents" to make a proper list. Corrected.

In (b)(12), line 14, should "care" be inserted after "newborn"? "Birth, its antecedents, and sequels," encompasses the listed categories of care.

In (b)(12), lines 14-15, what does "otherwise unspecified primary health services" mean?

"Otherwise, unspecified primary health services for women" aligns with the American College of Nurse Midwives definition of midwifery and scope of practice. Midwives have

> Brian Liebman Commission Counsel Date submitted to agency: September 7, 2023

the education and training to provide a provision of care which includes health promotion, disease prevention, risk assessment and management, and individualized wellness education and counseling. This is known to our regulated public based on their training and experience.

In (b)(13), line 17, what is "a health puerperium"? **Deleted**.

In (b)(13)(a), what is "the normal third stage" of labor? **Deleted**.

In (b)(13)(b), what are "uterotonics"? **Deleted**.

In (b)(13)(b), clarify when uterotonics would be "indicated". **Deleted**.

In (b)(13)(d), what are "normal and appropriate" interventions? **Deleted.**

In (b)(13)(d), what else would be included in "management of deviations" besides "complications and emergencies"? **Deleted**.

In (b)(14), line 23-24, what are "management strategies"? **Deleted**.

In (b)(14), line 24, when are strategies and therapeutics "indicated"? **Deleted.**

In (b)(14)(a), what are the contents of a "physical assessment"? **Deleted**.

In (b)(14)(b), what are "routine" lab tests? **Deleted**.

AGENCY: North Carolina Board of Nursing

RULE CITATION: 21 NCAC 33 .0103

DEADLINE FOR RECEIPT: Friday, September 15, 2023.

<u>PLEASE NOTE:</u> This request may extend to several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

In (a), line 5, is "approval to practice" a noun? I've seen it used that way throughout these Rules. If it's used that way, that's fine, but just wanted to confirm. I noted that in (b), p.2, line 13, the Rule says "seeking an approval to practice" rather than "an approval to practice". Please be consistent.

"Approval to Practice" is a noun. We will correct and be consistent with "an approval to practice" when appropriate.

In (a)(1), line 6, what is a "complete" application? Although G.S. 90-174(b)(4) explicitly gives the "joint subcommittee" the authority to "establish the form and contents of the application" by rule, I do not see any rule or part of a rule in which the contents of the application are clearly set out. As the application seems to be on a form provided by the Board of Nursing (see also G.S. 178.5(a)(1)), that form would need to either go through rulemaking itself, or have its contents or substantive requirements described in another rule or a statute. See also (b)(1) and (c) on p.2 with respect to references to applications.

This rule has been reformatted to include the contents of the application under (d) and where the application can be found.

In (a)(1), line 8, add "The" before "Application" and put "Application" in lowercase. Corrected.

In (a)(3), line 12, a license for what? Midwifery or to practice as a registered nurse? Any RN license must be unencumbered. Pursuant to the nurse licensure compact, multistate licensure refers to "privilege to practice" (not approval). For clarification, changes were made to reflect these distinctions.

How are (a)(3) and (a)(5) different requirements? They seem to mean the same thing. (a)(3) refers to the RN license, which should not be encumbered in any jurisdiction in which it exists. (a)(5) is specific to CNMs. With the clarification/correction above in (a)(3), the distinction should be clearer.

> Brian Liebman Commission Counsel Date submitted to agency: September 7, 2023

In (a)(4), line 14, what is a "privilege to practice" and how is it different than a license? See also (b)(3), p.2, line 21.

See response above for (a)(3). Under the Nurse Licensure Compact, the home state in which a nurse resides issues a license. Through the compact, a nurse with a multistate license has a privilege to practice in compact states. Should a compact state take disciplinary action for events occurring in their jurisdiction, they issue discipline on the privilege to practice (and not the license). Privilege to practice is a term understood by our regulated public.

In (a)(4), line 14, where is the statutory requirement that the nurse be a RN, as opposed to an LPN? Is it G.S. 90-178.2(1), which defines a CNM as "a nurse licensed and registered under Article 9A"?

It is factually impossible for an LPN to meet the educational requirements to enter a CNM program. A CNM must hold an RN license in order to practice midwifery.

In (a)(6), line 18, what "evidence" are you requiring"? Be specific. See also (b)(5), p.2, *line 24.*

The evidence would be an official copy of the educational transcript and the certificate from the national certifying body.

In (a)(6), line 20, what about the "sites" are you asking for? See also (b)(5), p.2, lines 25-26.

The sites refer to the practice sites or locations where the CNM intends to practice.

In (a)(7), line 26, are you requiring the attestation to be "under oath or affirmation" as in (a)(1)?Yes. Corrected.

In (a)(8), line 30, where is your statutory authority to require a criminal background check under the Board of Nursing's statutes? G.S. 90-171.48 applies only to applicants for licensure as a nurse.

Deleted reference to criminal background checks for CNMs.

In (b)(5), p.2, line 24, add a comma following "education". Corrected.

In (b)(6), line 27, what "information" are you requiring? Identifying information to include name, license number, email address and practice locations. Simplified in (d) under Application contents.

On p.3, lines 1-3, is this supposed to be part of (c), or a new paragraph (d)? Revised to add a new paragraph.

On p.3, line 1, what is a "concern"? And who would have the concern? Someone on the committee? A fellow practitioner? A member of the public? Issues may arise regarding any of the documentation provided, certifications, hours, etc. If there are issues with the application, staff must refer the application to the

> Brian Liebman **Commission Counsel** Date submitted to agency: September 7, 2023

Committee for a determination of licensure. For example, if a CNM seeks approval, but has reported a criminal conviction within 2 years – staff cannot approve the application; however, the applicant would be referred to the Committee for the determination.

On p.3, line 2, when "may" the applicant not be required to appear even if a concern is raised?

Not all information reported during the application process requires an appearance. For example, if an applicant reports disciplinary action on the RN license from 15 years ago that isn't consistent with a violation of the NC Nursing Practice Act, this applicant would not be required to appear. By contrast, if it's discipline which occurred within 1 year of the submission and related to the practice of nursing, the Committee would need to review.

I don't understand the reference to G.S. 90-171.37 in your History Note. Please explain how the Board of Nursing's disciplinary authority is relevant here. Deleted.

AGENCY: North Carolina Board of Nursing

RULE CITATION: 21 NCAC 33 .0104

DEADLINE FOR RECEIPT: Friday, September 15, 2023.

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The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

In (b), line 24, what do you mean by "discontinues working within the . . . agreement"? Does this mean that the CNM stops working with the collaborating provider? Or does it mean that the CNM violates the terms of the agreement?

Situations arise where the CNM and collaborating provider discontinue working with one another for a variety of reasons (move, change in practice location, retirement, etc.). If the relationship no longer exists and supervision is required, the CNM's approval to practice is terminated until such time as they have a new collaborating provider on file with the Committee. The Committee does not get involved in the "why" behind the dissolution of the collaborating relationship unless a violation of the midwifery practice act is alleged and an investigation is warranted.

In (d), line 34, consider breaking this paragraph into a list as follows:

- (d) A collaborative provider shall:
 - (1) hold an active, unencumbered approval to practice as a CNM and have a minimum of four years and 8,000 hours of practice as a CNM or;
 - (2) hold an active, unencumbered license to practice medicine in North Carolina and be actively engaged in the practice of obstetrics.

Corrected.

In (d), line 36, add "be" before "actively". Corrected.

In (d), line 36, define "actively engaged in the field of obstetrics". The collaborating provider must be a CNM or a physician working in the field of obstetrics. For example, a physician who worked in obstetrics 20 years ago but currently practices as orthopedist would not be considered actively engaged in obstetrics.

In (e), p.2, line 1, add "has" before "4,000". Added.

Brian Liebman Commission Counsel Date submitted to agency: September 7, 2023 In (e), lines 2-3, what are you requiring with "shall consult and collaborate with and refer patients to such other health care providers as may be appropriate for the care of the patient"? Is this not required of a CNM practicing under a collaborative agreement? Collaboration is the foundation of advanced practice. Because of their training and education, a CNM may need to collaborate with others having additional knowledge as the needs of the patient arise. While it is specifically required under a collaborative provider agreement, the agreement speaks to a formalized relationship. CNMs practicing independently will still need to collaborate with other health care providers as appropriate for care; however, this collaboration is not required to exist in a formalized agreement.

AGENCY: North Carolina Board of Nursing

RULE CITATION: 21 NCAC 33 .0105

DEADLINE FOR RECEIPT: Friday, September 15, 2023.

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In reviewing this Rule, the staff recommends the following changes be made:

In (b), lines 8-9, consider re-writing in the active tense: "the Committee may take disciplinary action if it finds one or more of the following:" *Revised.*

In (b)(2), line 11, define "immoral" and "dishonorable". These terms, if left undefined, are impermissibly vague and unclear.

This language is consistent with Medical Board and NP Rules. It covers a variety of exhaustive situations that cannot be defined with specificity. Midwifery Statute under G.S. 90-178.6 states "conduct that endangers the public health" and "conduct that deceives, defrauds or harms the public in the course of professional activities or services". This is what is meant by immoral and dishonorable conduct. We added a reference to G.S. 90-178.6.

In (b)(4), line 14, who would adjudicate the CNM as mentally incompetent? A judge? In any jurisdiction?

If there is a legal determination where the CNM is found incompetent in any jurisdiction. The CNM would still be afforded due process even if such finding were to be made.

In (b)(4), line 14, who determines whether the CNM's mental or physical condition renders them unable to safely function? What does it mean to "safely function" in this context?

The Committee would make this determination at hearing based on the evidence provided. A CNM must be able to perform their duties consistent with the minimum practice standards set out by the midwifery practice act, which speaks to their ability to safely function.

In (b)(5), line 17, what are "prevailing standards"? Are these defined?

Prevailing standards are standards generally accepted within the healthcare profession. Standards of care are taught to CNMs within their general education and nationally defined. These standards would be known to our regulated public.

In (b)(6), line 18, what criminal offenses "bear on the CNM's ability to practice"? Such examples would include assaults involving patients, fraud, driving while impaired – same as the crimes considered for RN/LPN and physicians.

In (b)(8), line 21, where is "professional competence" defined? Also, how is this different from (b)(12)'s requirement to "maintain competence"?

If referencing line 19 instead of 21, professional competence is the standard of competence learned in CNM training and education and is reviewed and maintained with national certification. Professional competence is known to our regulated public.

In (b)(10), line 24, how long does the CNM have to respond to inquiries before he or she is judged to have failed to respond?

This depends on the allegation and investigation. Typically, this violation is alleged after an investigation has concluded, and the licensee has not communicated with the investigator or fails to attend a hearing after being noticed appropriately.

In (b)(12), line 28, to the extent this is different than (b)(8), where is "competence" defined?

Deleted (b)(12). Professional competence is known to our regulated public.

In (b)(14), line 30, where is "the scope of CNM practice" defined? *Added reference to .0112.*

In (c), line 36, what is a "private letter of concern"?

A letter which indicates the investigation concludes with a minor practice violation that does not arise to disciplinary action or the need for remediation via an order. These letters alert the practitioner to these minor deficiencies and refer to remedial courses available. The courses, however, are not mandated by the Committee.

In (d), p.2, lines 2-3, does the Midwifery Committee (or subcommittee) have the statutory authority to exercise power given by statute to the Board of Nursing? Wouldn't the Committee's power to discipline stem from G.S. 90-178.6 and 178.7? If the Committee has the disciplinary authority vested in the Board of Nursing by G.S. 90-171.37, why does G.S. 90-178.6(b) specifically note that "revocation of a license to practice **nursing** pursuant to G.S. 90-171.37 shall automatically result in **comparable** action against the person's approval to practice midwifery under this Article"? Doesn't this indicate that these are separate sources of authority?

The Committee's power does stem from G.S. 90-178.6 and 90-178.7, and we would agree these are separate sources of authority from 90-171.37. If an investigation results in disciplinary action against an RN, the Committee still needs to pursue action against the CNM approval to practice. The Board of Nursing does not have the authority to suspend the CNM approval, so this action would be addressed by the Committee. In your History Note, please explain the relevance of the references to the portions of G.S. 90-171 that have been added. Deleted these references as they are the authority for RN discipline.

AGENCY: North Carolina Board of Nursing

RULE CITATION: 21 NCAC 33 .0111

DEADLINE FOR RECEIPT: Friday, September 15, 2023.

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In reviewing this Rule, the staff recommends the following changes be made:

In (a), lines 5-6, what is this "Program"? Please incorporate it by reference pursuant to 150B-21.6. The Certificate Maintenance Program is the title of the required program all CNMs must take through their certifying body (American Midwifery Certification Board - AMCB) to maintain their national certification.

In (b), line 12, Rule .0117 does not define "controlled substances". Added language for the various schedules of Controlled Substances which is consistent with the NP prescribing rules and how Controlled Substances are referenced.

In (b), line 13, spell out "1". According to 26 NCAC 02C .0108(9)(c) "if a phrase contains two numbers, only one of which is over nine, figures shall represent both". Please advise.

In (c), please consider rewriting in the active tense. Corrected.

AGENCY: North Carolina Board of Nursing

RULE CITATION: 21 NCAC 33 .0112

DEADLINE FOR RECEIPT: Friday, September 15, 2023.

<u>PLEASE NOTE:</u> This request may extend to several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

The sentence at lines 5-6 "The CNM's scope of practice... maintained competence." is impermissibly vague and unclear. What levels of educational preparation are there? What procedures or privileges do they translate to? What if someone has a high level of education but hasn't "maintained competence"? What does that do to the scope of their practice? How does someone "maintain competence"?

Education is understood based on the minimum standard of completing a graduate program (master's or doctorate) as well as passing the national certification exam. The scope and standards are defined as part of their accredited education and nationally recognized profession. The scope is based on educational preparation, national certification, and maintained competence; a CNM cannot have one or the other, they must have all three elements.

At line 6, what does it mean for the CNM to "be held accountable"? Does this mean disciplinary action by the Committee?

Yes. The CNM is responsible for practicing within their scope of practice. Should they exceed their scope of practice, the CNM is subject to disciplinary action by the Committee.

At line 8, these services "include" the list of (1)-(7), but what else is included? It is important that there be a discrete list, given that this is where the scope of practice is defined, and it is a disciplinable offense to exceed that scope. How is someone to know if they exceed the scope of practice when it isn't explicitly defined?

A CNM is a nationally recognized healthcare provider who specializes in nurse midwifery. The CNM is an advanced nursing practice nurse role with a specific population focus. Within this population focus, they can provide healthcare as described in 1-7. Like other healthcare disciplines, it would be cumbersome and inaccurate to attempt a list of frequently evolving pharmacotherapeutics, diagnostic tests, and procedures a healthcare provider can order or perform. A CNM's scope of practice is based on a minimum standard of nationally recognized and certified education and training. CNMs provide healthcare as defined by their scope in Rule .0112 and (1) and 2-7 define their practice further within the healthcare continuum.

In (1), line 9, what are "primary health care services"? Are these defined somewhere? This term is known to our regulated public. It is common knowledge within the healthcare industry that primary health care services are healthcare promotion, maintenance, and disease prevention.

In (1), line 10, what does "throughout the lifespan" mean? Does this mean a midwife functions as a primary care physician for people of all ages?

Lifespan is defined in healthcare as "all ages", and a CNM can provide midwifery care for a newborn to an aging adult. It is also understood that healthcare is not provided in a vacuum, and there will be overlap of care. A midwife is not and cannot be considered a physician because they have different training, titles, and authority. Physicians practice medicine, and CNMs practice nurse midwifery. A CNM is a nurse with additional graduate-level and clinical education that performs medical acts within their scope of training within their population focus. This training includes care which often includes health promotion, maintenance and prevention of illness.

In (2), line 12, what does "promotion and maintenance of health care services" mean? It sounds like you're saying the midwife is responsible for convincing people to seek care with them at risk of "being held accountable".

Promotion and maintenance of health care services refers to educating and coordinating care beyond midwifery practice. The CNM is responsible for practicing within their scope. If what the patient requires is beyond the CNM's scope of practice, the CNM is accountable to the Committee for informing and educating the patient and coordinating care beyond their service.

In (3), line 13, "disease" should be plural. Corrected.

In (4), what other "settings" must the CNM provide care in? Consider "providing care in diverse settings such as home. . ." Corrected.

In (7), line 19, do you mean evaluating health outcomes of specific patients? Or are you requiring the CNM to conduct longitudinal studies of their treatment profiles? This would be terminology known to our regulated public. It is well understood that part of providing healthcare within the continuum of care is the ability and responsibility of a healthcare provider to evaluate patient outcomes (specifically or generally, in the clinical setting, quality control, or in a research setting). This could be the immediate effects of a medication (treating a sexually transmitted infection and follow up to evaluate for side effects or complication) or the longitudinal outcomes in providing health maintenance (providing preventative care and education to a women like breast cancer screening).

AGENCY: North Carolina Board of Nursing

RULE CITATION: 21 NCAC 33 .0114

DEADLINE FOR RECEIPT: Friday, September 15, 2023.

<u>PLEASE NOTE:</u> This request may extend to several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

In (a), line 6, please consider rewriting in the active tense. Corrected.

In (a)(2), line 9, what is a "complete" application? Although G.S. 90-174(b)(4) explicitly gives the "joint subcommittee" the authority to "establish the form and contents of the application" by rule, I do not see any rule or part of a rule in which the contents of the application are clearly set out. As the application seems to be on a form provided by the Board of Nursing (see also G.S. 178.5(a)(1)), that form would need to either go through rulemaking itself, or have its contents or substantive requirements described in another rule or a statute.

In correcting the application content requirements under Rule .0103, our intent would be to refer to this rule as the application content would be the same for renewal applications.

In (3), line 13, add "-ing" to "attest". Corrected.

In (c), line 21, please change "their" to "his or her". Gender neutral terminology.

In (c), line 21, when you say "has not renewed" do you mean the CNM has to submit the application to renew, or do you mean that the Committee has to have granted the application by the end of the birth month?

Complete applications submitted by the CNM renew same day, so the CNM has to submit them by the last day of their birth month. If, however, the application is incomplete for any reason, the approval to practice expires on the last day of their birth month.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Brian Liebman Commission Counsel Date submitted to agency: September 7, 2023

AGENCY: North Carolina Board of Nursing

RULE CITATION: 21 NCAC 33 .0115

DEADLINE FOR RECEIPT: Friday, September 15, 2023.

<u>PLEASE NOTE:</u> This request may extend to several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

In (a), line 7, would an email satisfy the "in writing" requirement? Yes

In (c), line 10, move the period after "Rule" to just before "0103". Corrected.

In (c) line 10, consider revising in the active tense: "and <u>shall not resume practicing</u> <u>until he or she receives</u> notification <u>that the Committee has granted his or her</u> <u>application</u>."

Corrected and edited to be gender neutral.

In (c), line 10, what application are you referring to? Nothing in Rule .0103 governs applications to come out of inactive status.

Rule .0103 has been corrected to include reinstatement applications and should address this comment.

In (d), line 13, add "the" before "American". Corrected.

In (d), line 13-14, what are the American College of Nurse Midwives rentry to practice guidelines? If you are enforcing them via this Rule, they need to be incorporated by reference pursuant to G.S. 150B-21.6.

The American College of Nurse Midwives recommends two components for reentry into CNM practice, didactic content and clinical experience.

What does the last sentence in (d) mean? Why would the approval to practice be limited only to clinical activities required by the refresher course? The CNM can't practice in areas that they do not need a refresher on?

No, the CNM would not have hold an approval to practice as they haven't completed the retraining. The CNM would be granted has a limited approval to practice to perform the

Brian Liebman Commission Counsel Date submitted to agency: September 7, 2023 clinical activities at the preceptor and clinical site listed in the refresher course. When the refresher course is completed, they would be eligible for an approval to practice.

AGENCY: North Carolina Board of Nursing

RULE CITATION: 21 NCAC 33 .0116

DEADLINE FOR RECEIPT: Friday, September 15, 2023.

<u>PLEASE NOTE:</u> This request may extend to several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

In (a)(1), lines 7-8, do you mean that a copy of the agreement has to be kept in all provider sites? How does this comport with Rule .0112(4)'s requirement that the CNM be prepared to practice in a variety of different settings?

The physical collaborative provider agreement must be kept by the CNM at their practice location and by the collaborating provider at their practice location (should they differ). Regardless of the practice setting (hospital, birth center, homebirth), the CNM's scope of practice does not change. Rule .0112 speaks to scope of practice which is inclusive of a variety of settings.

In (a)(2), line 9, what does a "review" entail?

The agreement must be reviewed by both the CNM and collaborating provider annually to ensure that they are continuing to practice under the terms of the agreement and no changes need to be made. They review the existing CPA and agree to change, or not change the agreement, with acknowledgement by date and signature. This type of review would be consistent with their current practice working with a supervising physician and known to the regulated public.

In (b), line 15, define "direct communication" and "telecommunication". Communication can be in person, via internet, phone, email, etc. We would prefer not to limit it to direct, face-to-face communication and provide flexibility for communication as the need arises.

In (c), please consider revising in the active tense. Corrected.

AGENCY: North Carolina Board of Nursing

RULE CITATION: 21 NCAC 33 .0117

DEADLINE FOR RECEIPT: Friday, September 15, 2023.

<u>PLEASE NOTE:</u> This request may extend to several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

Is this Rule "consistent with the rules established for nurse practitioners under G.S. 90-18.2(b)(1)", as required by G.S. 90-18.8(c)?

G.S. 90-18.8 does not exist; however, the proposed language is consistent with the prescribing requirements for nurse practitioners pursuant to G.S. 90-18.2 and 21 NCAC 36.0809.

In (b), are you requiring both the collaborating provider CNM and the CNM under the agreement to have a DEA registration? There is an inference here (and in (e)(3)), but there's no explicit requirement that a CNM practicing under an agreement or a CNM practicing independently have a DEA registration.

If the CNM is practicing pursuant to a collaborative provider agreement and prescribing controlled substances is part of the CNM's and the collaborating provider's midwifery practice, both the CNM and the collaborating provider must have a DEA registration if the CNM to prescribe controlled substances.

In (b), line 9, please delete the "(s)" and say either "schedules" or "schedule or schedules". Corrected.

To my reading, (c)(1) and (c)(2) say the exact same thing. Please correct. Deleted (c)(1).

Consider rewriting (c)(1)/(2) in the active tense: "The collaborative provider agreement outlined in Rule .0116 of this Chapter shall include the drugs and devices that the CNM may prescribe." Corrected.

Beyond that, is (c)(1)/(2) really necessary? Rule .0116 already says this.

Yes. This language is necessary as it is specific to a CNM who holds a DEA license and the required documentation related to that level of prescriptive authority.

In (c)(2), why are (A)-(C) underneath (c)(2). These seem to be independent requirements that should be (3), (4), (5), to my reading.

They are 3 independent requirements related to prescribing controlled substances while working with a collaborating provider. Reformatted as suggested.

In (c)(2)(B), what are the "Controlled Substance laws and regulations"? Are these state level statutes and rules? Federal statutes and regulations? Make a specific reference to the laws/rules/regulations you are requiring compliance with. Reference to Controlled Substance Act above (.0104)

Added language for the various schedules of Controlled Substances which is consistent with the nurse practitioner prescribing rule and how Controlled Substances are referenced.

In (c)(2)(C), does this not say a slightly different thing than the second sentence of (b)? What does "equal or greater than" mean?

A CNM who practices with a collaborating provider cannot have more prescriptive authority when compared to their collaborating provider. The collaborating provider may possess a schedule of controlled substances greater than/higher than the CNMs, but they must both have the same schedule of controlled substances for the CNM to prescribe.

In (d), line 29, what is a "prescribing stipulation" in this context? Changed language to "prescribing requirements".

Where in (e) is the requirement that the CNM write their "identification number" assigned by the joint subcommittee on the prescription? This is required in G.S. 90-18.8(b)(3).

G.S. 90-18.2 is Limitations on Nurse Practitioners. Under this statute, there is no requirement that the NP Approval number shall be listed on the prescription. However, to be consistent with prescribing requirements for Nurse Practitioners, we looked to 21 NCAC 36 .0809(b)(2) which lists the same requirements as are contained in this proposed language.

AGENCY: North Carolina Board of Nursing

RULE CITATION: 21 NCAC 33 .0118

DEADLINE FOR RECEIPT: Friday, September 15, 2023.

<u>PLEASE NOTE:</u> This request may extend to several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

In (a), do these rules only apply if the patient is planning the birth at their "home"? No. This applies to any birth outside of a hospital. After further review of approved temp rule by MJC on August 29th, staff moved 1st sentence of (a) to (c) as approved by the Committee.

In (a)(1), line 8, does the agreement "include" anything else beyond what is delineated here? Instead of "include" replace with "details" Corrected.

In (a)(1)(C), line 13, what information are you requiring? This speaks to the intent of SB20 so there is documentation between the CNM and the patient informing the patient of all of the benefits and risks of procedures, and documenting this in their informed consent agreement.

In (a)(1)(E), line 16, is "health care facility" defined anywhere? It seems like (a)(2)(A) specifies what kind of health care facility is acceptable, consider moving that here. Corrected. The specified health care facility is defined based on these cited statutes.

Are (a)(2) and (a)(2)(A)-(C) verbatim repetitions of G.S. 90-178.4(a2)? If so consider revising to eliminate the repetition of statutory language and just say that the CNM has to provide a detailed written plan of care consistent with G.S. 90-178.4(a2). Delete (A)-(C)

Corrected and deleted.

In (a)(2)(C), line 26, how and when must the health care facility be notified? Can the CNM satisfy this request by leaving a voicemail for the hospital administrator? Deleted (a)(2) (C).

In (a)(3), line 28, there appears to be a grammatical error: "a decision to non-emergent transfer care". Changed from "to" to "of".

In (a)(3), line 28, what is a "non emergent" transfer of care? A non-emergent transfer of care refers to a situation that does not call for prompt and urgent action and is a commonly known term to our regulated public.

In (a)(3)(B), line 30, does the patient have to agree to a release of their medical records? Is that part of the consent agreement? Standard practice is the medical record follows the patient and does not require patient consent. This is understood by our regulated public.

In (a)(4), line 33, what is an "emergent situation"? An emergent situation is one that calls for prompt and urgent action and is understood by our regulated public.

In (a)(4), line 34, "immediate" should be "immediately". Corrected.

In (a)(4), line 34, delete "of" between "transfer" and "care". Corrected.

In (a)(4), line 34, define "reasonable effort". What constitutes a reasonable effort depends on the circumstances of the scenario. An effort must be made to contact the receiving provider or health care facility; however, factors such as the emergent nature of the situation would affect whether one call is reasonable or 10 calls would be considered reasonable.

In (a)(4), lines 35 and 36, and in (a)(4)(A), p.2, line 1, delete the (s) and either make the word plural or say "patient or patients". Corrected.

In (b), p.2, line 3, I think you meant "emergent and non-emergent transfer of care $\frac{plans}{2}$ ".

If referring to (b), p. 2, line 2, this has been corrected.

In (c), line 7, under what guidelines is this assessment made? Please incorporate them by reference under G.S. 150B-21.6.

It is understood by our regulated public that the assessment of whether patient(s) have the ACOG contraindications is determined by any healthcare provider trained to identify these contraindications.

In (c), line 8, what other known situations are contraindicated by ACOG? Where are these documented? Please incorporate them by reference under G.S. 150B-21.6. Changed "including" to "specifically". ACOG would list the contraindications referenced in SB20 under G.S. 90-178.4(a3). Currently, ACOG only lists these three known situations, which is why they are specified in this list.

1 2 21 NCAC 33 .0101 is amended under temporary procedures with changes as follows:

3 21 NCAC 33 .0101 **ADMINISTRATIVE BODY AND DEFINITIONS** 4 (a) The responsibility for administering the provisions of G.S. 90, Article 10A, shall be assumed by an administrative 5 body, the Midwifery Joint Committee, hereinafter referred to as the "Committee." The certified nurse midwife shall 6 hereinafter be referred to as "midwife." "CNM." 7 (b) In addition to the definitions set forth in G.S. 90-178.2, the following shall apply to the Rules in this Chapter: 8 "Primary Supervising Physician" means a physician with an active unencumbered license with the 9 North Carolina Medical Board who, by signing the midwife application, shall be held accountable 10 for the on going supervision, consultation, collaboration, and evaluation of the medical acts performed by the midwife, as defined in the site specific written clinical practice guidelines. A 11 physician in a graduate medical education program, whether fully licensed or holding only a 12 13 resident's training license, shall not be named as a primary supervising physician. A physician in a 14 graduate medical education program who is also practicing in a non-training situation may supervise a midwife in the non training situation if he or she is fully licensed. 15 "Back up Primary Supervising Physician" means a physician licensed by the North Carolina 16 (2)Medical Board who, by signing an agreement with the midwife and the primary supervising 17 18 physician or physicians shall be held accountable for the supervision, consultation, collaboration, and evaluation of medical acts by the midwife in accordance with the site specific written clinical 19 practice guidelines when the primary supervising physician is not available. The signed and dated 20 21 agreements for each back up primary supervising physician or physicians shall be maintained at each practice site. A physician in a graduate medical education program, whether fully licensed or 22 23 holding only a resident's training license, shall not be named as a back up primary supervising physician. A physician in a graduate medical education program who is also practicing in a non-24 training situation may be a back up primary supervising physician to a midwife in the non-training 25 situation if he or she is fully licensed and has signed an agreement with the midwife and the primary 26 27 supervising physician. 28 (1)"American Midwifery Certification Board (AMCB)" means the national certifying body for 29 candidates in nurse-midwifery and midwifery who have received their graduate level education in 30 programs accredited by the Accreditation Commission for Midwifery Education. "Accreditation Commission for Midwifery Education (ACME)" means an accreditation agency (2)31 32 established to advance and promote midwifery education. 33 (3)"American College of Nurse-Midwives (ACNM)" means the professional association that 34 represents [certified nurse midwives (CNMs)] CNMs and certified midwives (CMs) in the United 35 States. ACNM sets the standard for midwifery education and practice in the United States. "American College of Obstetricians and Gynecologists (ACOG)" means the professional 36 (4)membership organization for [obstetrician-gynecologist which] obstetrician-gynecologists that 37

1	produces practice guidelines for health care professionals and educational materials for patients,
2	provides practice management and career support, facilitates program and initiatives to improve
3	women's health, and advocates for members and patients.
4	(5) Certified Nurse Midwife (CNM)" means a nurse licensed and registered under Article 9A of this
5	Chapter who has completed a midwifery education program accredited by the Accreditation
6	Commission for Midwifery Education, or its successor, passed a national certification examination
7	administered by the American Midwifery Certification Board, or is successor, and has received the
8	professional designation of "Certified Nurse Midwife" (CNM). Certified Nurse Midwives practice
9	in accordance with the Core Competencies for Basic Midwifery Practice, the Standards for the
10	Practice of Midwifery, the Philosophy of the American College of Nurse Midwives (ACNM), and
11	the Code of Ethics promulgated by the ACNM.
12	(6) "Collaborating provider" means a physician licensed to practice medicine under Article 1 of this
13	Chapter for a minimum of four years and has a minimum of 8,000 hours of practice and who is or
14	has engaged in the practice of obstetrics or a Certified Nurse Midwife who has been approved to
15	practice midwifery under this Article for a minimum of four years and 8,000 hours.
16	(7) "Collaborative provider agreement" means a formal, written agreement between a collaborating
17	provider and a Certified Nurse Midwife with less than 24 months and 4,000 hours of practice as a
18	Certified Nurse Midwife to provide consultation and collaborative assistance or guidance.
19	(8) "Interconceptional care" includes, but is not limited to, the following:
20	(a) Gynecological care, family planning, perimenopause care, and postmenopause care;
21	(b) Screening for cancer of the breast and reproductive tract; and
22	(c) Screening for and management of minor infections of the reproductive organs.
23	(9) "Intrapartum care" means care that focuses on the facilitation of the physiologic birth process and
24	includes, but is not limited to, the following:
25	(a) Confirmation and assessment of labor and its progress;
26	(b) Identification of normal and deviations from normal and appropriate interventions,
27	including management of complications, abnormal intrapartum events, and emergencies;
28	(c) Management of spontaneous vaginal birth and appropriate third stage management,
29	including the use of uterotonics;
30	(d) Performing amniotomy;
31	(e) Administering local anesthesia;
32	(f) Performing episiotomy and repair; and
33	(g) Repairing laceration associated with childbirth.
34	(10) "Midwifery" means the act of providing prenatal, intrapartum, postpartum, newborn, and
35	interconceptional care. The term does not include the practice of medicine by a physician licensed
36	to practice medicine when engaged in the practice of medicine as defined by law, the performance
37	of medical acts by a physician assistant or nurse practitioner when performed in accordance with

1		the Rules of the North Carolina Medical Board, the practice of nursing by a RN engaged in the
2		practice of nursing as defined by law, or the performance of abortion, as defined in G.S. 90 21.81.
3	(11)	"Newborn care" means care that focuses on the newborn and includes, but is not limited to, the
4		following:
5		(a) Routine assistance to the newborn to establish respiration and maintain thermal stability;
6		(b) Routine physical assessment including APGAR scoring;
7		(c) Vitamin K administration;
8		(d) Eye prophylaxis for opthalmia neonatorum; and
9		(e) Methods to facilitate newborn adaptation to extrauterine life, including stabilization,
10		resuscitation, and emergency management as indicated.
11	(3) [(12)	p](5) "Obstetrics" means a branch of medical science that deals with birth and with birth, its
12		antecedents antecedents, and sequels, including prenatal, intrapartum, postpartum, newborn or
13		gynecology, and otherwise unspecified primary health services for women.
14	[(13)	"Postpartum care" means care that focuses on management strategies and therapeutics to facilitate
15		a health puerperium and includes, but is not limited to, the following:
16		(a) Management of the normal third stage of labor;
17		(b) Administration of uterotonics after delivery of the infant when indicated;
18		(c) Six weeks postpartum evaluation exam and initiation of family planning; and
19		(d) Management of deviations from normal and appropriate interventions, including
20		management of complications and emergencies.
21	(14)	<u>"Prenatal care" means care that focuses on promotion of a healthy pregnancy using management</u>
22		strategies and therapeutics as indicated and includes, but is not limited to, the following:
23		(a) Obtaining history with ongoing physical assessment of mother and fetus;
24		(b) Obtaining and assessing the results of routine laboratory tests;
25		(c) <u>Confirmation and dating of pregnancy; and</u>
26		(d) <u>Supervising the use of prescription and nonprescription medications, such as prenatal</u>
27		
28		
29	History Note:	Authority G.S. 90-178.4;
30		Eff. February 1, 1984;
31		Amended Eff. July 1, 2000; October 1, 1988;
32		Readopted Eff. November 1, 2018;
33		Amended Eff. April 1, 2020.
34		<u>Temporary [Adoption] Amendment Eff. October 1, 2023.</u>

1 21 NCAC 33 .0103 is amended under temporary procedures <u>with changes</u> as follows:

2		
3	21 NCAC 33 .01	103 <u>ELIGIBILITY AND APPLICATION AND ANNUAL RENEWAL</u>
4	(a) To be eligibl	e for an approval to practice independently as a midwife, CNM, an applicant shall:
5	(1)	submit a completed application for an approval to practice, attesting under oath or affirmation that
6		the information on the application is true and complete, and authorizing the release to the Committee
7		of all information pertaining to the application. [The application is posted on the Board of Nursing's
8		website at www.ncbon.com;]
9	(3)<u>(2)</u>	submit the approval to practice application fee as established in 90-178.4(b)(1); 90-178.4(b)(1) and
10		Rule .0102 of this Section;
11	<u>(3)</u>	have an unencumbered license or privilege to practice in all jurisdictions in which a license is or has
12		ever been held.
13	<mark>(3)</mark> (4)	hold an active, unencumbered North Carolina RN license or privilege to practice;
14	<mark>(4)(5)</mark>	have hold an [active,] unencumbered registered nurse license and midwifery CNM license or an
15		approval to practice in all jurisdictions in which a license/approval license or an approval to practice
16		is or has ever been held;
17	(2)<mark>(5)</mark>(6)submit information on the applicant's education, evidence of the applicant's <u>maintained</u> certification
18		by the American College of Nurse Midwives, Midwifery Certification Board or its successor,
19		identification of the physician or physicians who will supervise the applicant, and the sites where
20		the applicant intends to practice midwifery;
21	<mark>(6)(</mark> 7)	_submit a written explanation and all related documents if the midwife has ever been listed as a nurse
22		aide and if there have ever been any substantiated findings pursuant to G.S. 131E 255. The
23		Committee may take these findings into consideration when determining if an approval to practice
24		should be denied pursuant to G.S. 90 178.6. In the event findings are pending, the Committee may
25		withhold taking any action until the investigation is completed; and submit an attestation of
26		completion of at least 24 months experience and 4,000 practice hours as a CNM. [The clinical
27		experience shall be in collaboration with a collaborating provider.] Documentation of successful
28		completion of this requirement shall be provided to the Committee upon [request;] request; and
29	<mark>(7)[(8)]</mark>	complete a criminal background check in accordance with G.S. 90-171.48. [G.S. 90-171.48; and]
30	(5)<mark>(8)</mark>	have no pending court conditions as a result of any misdemeanor or felony conviction(s). Applicant
31		shall provide a written explanation and any investigative report or court documents evidencing the
32		circumstances of the crime(s) if requested by the Committee. The Committee may use these
33		documents when determining if an approval to practice should be denied pursuant to G.S. 90-178.6
34		<u>G.S. 90-178.6.</u> and 90-171.37; [90-171.37.]
35	In the e	vent that any of the information required in accordance with this Paragraph should indicate a concern
36	about t h	ne applicant's qualifications, an applicant may be required to appear in person for an interview with

1	the Committee if the Committee determines in its discretion that more information is needed to evaluate the
2	application.
3	(b) Each midwife shall annually renew their approval to practice with the Committee no later than the last day of the
4	midwife's birth month by:
5	(1) submitting a completed application for renewal, attesting under oath or affirmation that the
6	information on the application is true and complete, and authorizing the release to the Committee
7	of all information pertaining to the application. Applications are located on the Board of Nursing's
8	website at www.ncbon.com;
9	(2) attest to having completed the requirements of the Certificate Maintenance Program of the American
10	College of Nurse Midwives, including continuing education requirements, and submit evidence of
11	completion if requested by the Committee as specified in Rule .0111 of this Section;
12	(3) submitting the approval to practice renewal fee as established in G.S. 90 178.4(b)(2).
13	(b) An applicant seeking an approval to practice with less than 24 months experience and 4,000 hours of practice as a
14	CNM shall:
15	(1) submit an application for an approval to practice, attesting under oath or affirmation that the
16	information on the application is true and complete, and authorizing the release to the Committee
17	of all information pertaining to the application. [The application can be found on the Board of
18	Nursing's website at www.ncbon.com;]
19	(2) submit the approval to practice application fee as established in 90-178.4(b) and Rule .0102 of this
20	Chapter;
21	(3) hold an [active,] unencumbered [North Carolina RN] license or privilege to [practice;] practice in
22	all jurisdictions in which a license is or has ever been held;
23	(4) hold an active, unencumbered [CNM] North Carolina RN license or [an approval to practice in all
24	jurisdictions in which a license or an approval to practice is or has ever been held;] privilege to
25	practice;
26	(5) hold an unencumbered CNM license or an approval to practice in all jurisdictions in which a license
27	or an approval to practice is or has ever been held;
28	[(5)](6) submit information on the applicant's [education] education, evidence of the applicant's maintained
29	certification by the American Midwifery Certification Board or its successor and the sites where the
30	applicant intends to practice midwifery;
31	[(6)](7) submit information identifying the collaborating provider with whom the applicant will collaborate;
32	[(7) complete a criminal background check in accordance with G.S. 90-171.48;]
33	(8) have no pending court conditions as a result of any misdemeanor or felony conviction(s). Applicant
34	shall provide a written explanation and any investigative report or court documents evidencing the
35	circumstances of the crime(s) if requested by the Committee. The Committee may use these
36	documents when determining if an approval to practice should be denied pursuant to [G.S. 90-178.6
37	and 90-171.37.] G.S. 90-178.6.

1	(a) $\prod_{n \in \mathbb{N}} f_{n} f_{n}$	t] When a CNM seeks independent practice, the CNM shall submit a new application for an approval
1	• • -	
2	-	pendently, attesting under oath or affirmation that the information on the application is true and
3	complete, and a	uthorizing the release to the Committee of all information pertaining to the application and required
4	<u>fee.</u>	
5	(d) Application	s are posted on the Board of Nursing's website at www.ncbon.com. The following information shall
6	appear on the ap	plication:
7	<u>(1)</u>	the applicant's name, telephone number and email address;
8	(2)	the applicant's primary address of residence;
9	<u>(3)</u>	the educational degrees obtained by the applicant with the program name and completion date;
10	(4)	the number and expiration date of the applicant's national certification from the AMCB;
11	<u>(5)</u>	other professional or occupational licenses with the license number and jurisdiction in which the
12		license was issued, if applicable;
13	<u>(6)</u>	the name, license number, telephone number, email address, and practice location of the
14		collaborating provider, if applicable; and
15	<u>(7)</u>	the approval to practice number shall be provided on the application if the application is for the
16		renewal or reinstatement of an existing approval to practice.
17	(e) All educatio	nal transcripts and certification must be submitted directly to the Board from the primary source.
18	(f) In the even	t that any information required in accordance with this Rule should indicate a concern about the
19	applicant's quali	ifications, an applicant may be required to appear in person for an interview with the Committee if the
20	Committee deter	rmines in its discretion that more information is needed to evaluate the application.
21		
22	History Note:	Authority G.S. 90-178.4(b); 90-178.5; <u>90-171.48; <mark>[90-171.37;]</mark></u>
23		Eff. February 1, 1984;
24		Amended Eff. March 1, 2017; January 1, 1989;
25		Readopted Eff. November 1, 2018;
26		Amended Eff. April 1, 2020.
27		<u>Temporary <mark>[Adoption] Amendment</mark> Eff. October 1, 2023.</u>

21 NCAC 33 .0104 is amended as a temporary rule, without changes, as published on the OAH website on July 26,
 2023 as follows:

3 4

21 NCAC 33 .0104 PHYSICIAN SUPERVISION PROVIDER COLLABORATION REQUIRED

The applicant shall furnish the committee evidence that the applicant will perform the acts authorized by the Midwifery 5 6 Practice Act under the supervision of a physician who is actively engaged in the practice of obstetrics in North Carolina. Such evidence shall include a description of the nature and extent of such supervision and a delineation of 7 8 the procedures to be adopted and followed by each applicant and the supervising physician responsible for the acts of 9 said applicant for rendering health care services at the sites at which such services will be provided. Such evidence 10 shall include: 11 (1)mutually agreed upon written clinical practice guidelines that define the individual and shared responsibilities of the midwife and the supervising physician or physicians in the delivery of health 12 13 care services; 14 mutually agreed upon written clinical practice guidelines for ongoing communication that provide (2)15 for and define appropriate consultation between the supervising physician or physicians and the midwife; 16 periodic and joint evaluation of services rendered, such as chart review, case review, patient 17 (3)18 evaluation, and review of outcome statistics; and 19 periodic and joint review and updating of the written medical clinical practice guidelines. (4)(a) A CNM who has practiced fewer than 24 months and 4,000 hours of practice as a CNM shall practice in 20 21 consultation with a collaborating provider in accordance with a collaborative provider agreement in compliance with 22 Rule .0116 of this Chapter. 23 (b) The approval to practice of the CNM practicing under the supervision of a collaborative provider agreement is 24 terminated when the CNM discontinues working within the approved collaborative provider agreement or experiences 25 an interruption in their RN licensure status. The CNM shall notify the Committee in writing within five days of the 26 termination of the collaborative provider agreement. (c) The CNM shall have 90 days to submit a newly-executed collaborative provider agreement with a collaborative 27 28 provider to the Committee. During this 90-day period, the CNM may continue to practice midwifery in accordance 29 with the Midwifery Practice Act and this Chapter. Should the 90-day period expire without a newly-executed 30 collaborative provider agreement being submitted to the Committee, the approval to practice is rendered inactive and 31 the CNM shall be required to submit an application for reinstatement of the approval to practice consistent with Rule 32 .0103 and Rule .0115 of this Chapter. The Committee will notify the CNM when the application has been approved 33 and the approval to practice is reinstated. 34 (d) To be eligible a collaborative provider shall hold an active, unencumbered approval to practice as a CNM having a minimum of four years and 8,000 hours of practice as a CNM or an active, unencumbered license to practice 35 medicine in North Carolina and actively engaged in obstetrics. 36

1	(e) A CNM who	has practiced over 24 months and 4,000 hours of practice as a CNM may be issued an approval to
2	practice midwife	ry independently and shall consult and collaborate with and refer patients to such other health care
3	providers as may	be appropriate for the care of the patient.
4		
5	History Note:	Authority G.S. 90-178.4(b); <u>90-178.3;</u>
6		Eff. February 1, 1984;
7		Amended Eff. July 1, 2000; October 1, 1988; April 1, 1985;
8		Readopted Eff. November 1, 2018.
9		Temporary Adoption Eff. October 1, 2023.

21 NCAC 33 .0105 is amended under temporary procedures with changes as follows:

3	21 NCAC 33 .0105	DISCIPLINARY ACTION

4	(a) The midwif	e <u>CNM</u> is subject to G.S. 90-171.37; 90-171.48 and 21 NCAC 36 .0217 by virtue of the license to
5	practice as a reg	istered nurse. RN.
6	(b) After notice	e and hearing in accordance with provisions of G. S. 150B, Article 3A, the Committee may take
7	disciplinary action	on [<mark>may be taken by the Committee</mark>] if <mark>it finds</mark> one or more of the <mark>[following is found:</mark>] following:
8	<u>(1)</u>	practicing without a valid approval to practice as a CNM;
9	(2)	immoral or dishonorable [conduct;] conduct pursuant to and consistent with G.S. 90-178.6;
10	(3)	presenting false information to the Committee in procuring or attempting to procure an approval to
11		practice as a CNM:
12	(4)	the CNM is adjudicated mentally incompetent or the CNM's mental or physical condition renders
13		the CNM unable to safely function as a CNM;
14	<u>(5)</u>	unprofessional conduct by reason of deliberate or negligent acts or omissions and contrary to the
15		prevailing standards for CNMs;
16	(6)	conviction of a criminal offense which bears on the CNM's ability to practice or that the CNM has
17		deceived or defrauded the public;
18	(7)	soliciting or attempting to solicit payments for the CNM practice with false representations;
19	(8)	lack of professional competence as a CNM;
20	<u>(9)</u>	exploiting the patient, including the promotion of the sale of services, appliances, or drugs, for the
21		financial gain of the CNM or of a third party;
22	<u>(10)</u>	failure to respond to inquiries of the Committee for investigation and discipline;
23	<u>(11)</u>	the CNM has engaged or attempted to engage in the performance of midwifery acts other than
24		according to the collaborative provider agreement or without being approved by the Committee to
25		practice independently:
26	[(12)	failure to maintain competence as a CNM;]
27	[(13)](12)	failure to obtain a written, informed consent agreement from a patient;
28	[(14)](13)	practiced or offered to practice beyond the scope of CNM [practice;] practice as defined in .0112 of
29		this Chapter:
30	[(15)] <u>(14)</u>	failure to comply with any order of the Committee;
31	[(16)] <u>(15)</u>	violating any term of probation, condition, or limitation imposed on the CNM by the Committee; or
32	[(17)] <u>(16)</u>	any violation within this Chapter.
33	(b)(c) After an i	investigation is completed, the Committee may recommend one of the following:
34	(1)	dismiss the case;
35	(2)	issue a private letter of concern;
36	(3)	enter into negotiation for a Consent Order; or
37	(4)	a disciplinary hearing in accordance with G.S. 150B, Article 3A.

1	(d) Upon a find	ling of violation, the Committee may utilize the range of disciplinary options as enumerated in G.S.
2	<u>90-171.37.</u>	
3		
4	History Note:	Authority G.S. <mark>[90-171.37; 90-171.43; 90-171.44; 90-171.48;] 90-178.6; <u>90-178.7;</u></mark>
5		Eff. February 1, 1985;
6		Amended Eff. August 1, 2002; October 1, 1988;
7		Readopted Eff. November 1, 2018;
8		Amended Eff. April 1, 2020.
9		<u>Temporary [Adoption] Amendmend Eff. October 1, 2023.</u>

- 1 2
- 21 NCAC 33 .0111 is amended under temporary procedures with changes as follows:

3 21 NCAC 33 .0111 CONTINUING EDUCATION (CE)

- 4 (a) In order to maintain an approval to practice midwifery, a midwife CNM shall meet the requirements of the
- 5 Certificate Maintenance Program of the American College of Nurse Midwives, Midwifery Certifying Board,
- 6 including continuing education requirements. Every midwife who prescribes controlled substances shall complete at
- 7 least one hour of continuing education (CE) hours annually consisting of CE designated specifically to address
- 8 controlled substances prescribing practices, signs of the abuse or misuse of controlled substances, and controlled
- 9 substance prescribing for chronic pain management. Documentation of continuing education shall be maintained by
- 10 the midwife for the previous five calendar years and made available upon request to the Committee.
- 11 (b) Prior to prescribing [controlled substances as the same are defined in 21 NCAC 33 .0117,] Controlled Substances
- 12 (Schedules II, IIN, III, IIIN, IV, V) defined by the State and Federal Controlled Substances Act, CNMs shall have

13 completed a minimum of one CE hour within the preceding 12 months on 1 or more of the following topics:

- 14 (1) Controlled substances prescription practices;
- 15 (2) Prescribing controlled substances for chronic pain management;
- 16 (3) Recognizing signs of controlled substance abuse or misuse; or
- 17 (4) Non-opioid treatment options as an alternative to controlled substances.
- 18 (c) <u>The CNM shall maintain documentation</u> [Documentation] of all CE completed within the previous five years
- 19 [shall be maintained by the CNM] and [made] make available [upon request] to the [Committee.] Committee upon
- 20 <u>request.</u>
- 21 22

23

- History Note: Authority: G.S. 90 5.1; 90 14(a)(15); 90 178.5(2); S.L. 2015-241, s. 12F.16(b); G.S. 90-178.3; 90-
- <u>178.5(a)(2);</u>
- 24 Eff. March 1, 2017;
- 25 *Readopted Eff. November 1, 2018.*
- 26 <u>Temporary [Adoption] Amendment</u> Eff. October 1, 2023.

21 NCAC 33 .0112 is adopted under temporary procedures with changes as follows:

3 21 NCAC 33 .0112 SCOPE OF PRACTICE

The CNM's scope of practice is defined by academic educational preparation and national certification and maintained competence. A CNM shall be held accountable by the Committee for a broad range of personal health services or which the CNM is educationally prepared and for which competency has been maintained once the CNM has been authorized to practice midwifery. These services include:

8 (1)diagnosing, treating, and managing a full range of primary health care services to the patient 9 throughout the lifespan, including gynecologic care, family planning services, preconception care, 10 prenatal and postpartum care, childbirth, and care of the newborn; promotion and maintenance of health care services for the patient throughout their lifespan; 11 (2)12 (3) treating patient and their partners for sexually transmitted disease diseases and reproductive health; 13 (4) providing care in diverse settings, which may include settings such as home, hospital, birth center, 14 and a variety of ambulatory care settings including private offices and community and public health 15 clinics; 16 (5) prescribing, administering, and dispensing therapeutic measures, tests, procedures, and drugs; 17 (6)planning for situations beyond the CNMs scope of practice and expertise by collaborating, 18 consulting with, and referring to other health care providers as appropriate; and 19 (7)evaluating health outcomes. 20 21 History Note: Authority: <u>G.S. 90-18.8; 90-178.3;</u> 22 Temporary Adoption Eff. October 1, 2023.

21 NCAC 33 .0114 is adopted under temporary procedures with changes as follows:

2			
3	21 NCAC 33 .0	114 ANNUAL RENEWAL	
4	(a) The CNM <u>sh</u>	nall renew the approval to practice shall be renewed annually no later than the last day of the applicant's	
5	birth month by:		
6	(1)	maintaining an active, unencumbered North Carolina RN license or privilege to practice;	
7	(2)	submitting a completed application for renewal, attesting under oath or affirmation that the	
8		information on the application is true and complete, and authorizing the release to the Committee	
9		of all information pertaining to the application as outlined in Rule .0103 of this Chapter.	
10		Applications are located on the Board of Nursing's website at www.nebon.com;	
11	(3)	attest attesting to having completed the requirements of the Certificate Maintenance Program of the	
12		American Midwifery Certification Board or its successor, including continuing education	
13		requirements, and submit evidence of completion if requested by the Committee as specified in Rule	
14		.0111 of this Chapter; and	
15	(4)	submitting the approval to practice renewal fee as established in G.S. 90-178.4(b)(2) and this	
16		Chapter.	
17	(b) It shall be the duty of the CNM to keep the Committee informed of a current mailing address, telephone number,		
18	and email address.		
19	(c) If the CNM	has not renewed by end of their birth month and submitted the annual fee, the approval to practice	
20	shall expire.		
21			
22	History Note:	Authority: G.S. 90-178.4(b); 90-178.5;	
23		Temporary Adoption Eff. October 1, 2023.	

- 1 21 NCAC 33 .0115 is adopted under temporary procedures <u>with changes</u> as follows:
- 2

3 21 NCAC 33 .0115 INACTIVE STATUS

4 (a) Any CNM who wishes to place their approval to practice on an inactive status shall notify the Committee in5 writing.

6 (b) A CNM with an inactive approval to practice status shall not practice as a CNM.

7 (c) A CNM with an inactive approval to practice status who reapplies for <u>an</u> approval to practice shall meet the

- 8 qualifications for an approval to practice in Rule. 0103 Rule .0103 of this Chapter and shall not resume practicing
- 9 <u>until receive</u> notification is received from that the Committee has granted the of approval prior to beginning practice
- 10 after the application is approved. application.
- 11 (d) A CNM who has not practiced as a CNM in more than two years shall complete a midwifery refresher course
- 12 approved by the Commission based on the American College of Nurse-Midwives' reentry to midwifery practice
- 13 guidelines and directly related to the CNM's area of academic education and national certification. A midwifery
- 14 refresher course participant shall be granted an approval to practice that is limited to clinical activities required by the
- 15 refresher course.
- 16
- 17 History Note: Authority G.S. 90-178.3; 90-178.5;
- 18 Temporary Adoption Eff. October 1, 2023.

1 21 NCAC 33 .0116 is adopted under temporary procedures <u>with changes</u> as follows:

2			
3	21 NCAC 33 .0	116 COLLABORATIVE PROVIDER AGREEMENT	
4	(a) A CNM wit	h less than 24 months and 4,000 hours of practice as a CNM is required to have a written collaborative	
5	provider agreen	nent to practice midwifery. The collaborative provider agreement shall:	
6	(1)	be agreed upon, signed, and dated by both the collaborating provider and the CNM, and maintained	
7		in each provider site;	
8	(2)	be reviewed at least annually. This review shall be acknowledged by a dated signature sheet, signed	
9		by both the collaborating provider and the CNM, appended to the collaborative provider agreement,	
10		and available for inspection by the Committee;	
11	(3)	include mutually agreed upon written clinical practice guidelines for the drugs, devices, medical	
12		treatments, tests, and procedures that may be prescribed, ordered, and performed by the CNM; and	
13	(4)	include a pre-determined plan for emergency services.	
14	(b) The collabo	rating provider and the CNM shall be available to each other for consultation by direct communication	
15	or telecommuni	cation.	
16	(c) A The CNM shall maintain a copy of the collaborative provider agreement executed within the previous five years		
17	shall be mainta	ined by the CNM and made make available upon request of the Committee. to the Committee upon	
18	request.		
19			
20	History Note:	Authority G.S. 90-18.8; 90-178.3; 90-178.4; 90-178.5;	
21		Temporary Adoption Eff. October 1, 2023.	

- 1 2
- 21 NCAC 33 .0117 is adopted under temporary procedures with changes as follows:
- 3 21 NCAC 33 .0117 PRESCRIBING AUTHORITY

4 (a) The prescribing stipulations contained in this rule apply to writing prescriptions and ordering the administration
 5 of medications by a CNM.

- 6 (b) A CNM must possess a valid United States Drug Enforcement Administration ("DEA") registration in order for
- 7 the CNM to act as a collaborating provider for another CNM. The DEA registration of the collaborating provider shall

8 include the same schedule(s) schedule or schedules of controlled substances as the CNM practicing under a

9 collaborative provider agreement.

- (c) Prescribing and dispensing stipulations for the CNM authorized to practice under a collaborative provider
 agreement are as follows:
- 12 (1) Drugs and devices that may be prescribed by the CNM shall be included in the collaborative provider
 13 agreement as outlined in Rule .0116 of this Chapter.
- 14
 (2)(1)
 The collaborative provider agreement outlined in Rule .0116 of this Chapter shall include the Drugs

 15
 drugs and devices that may be prescribed by the CNM shall be included in the collaborative provider

 16
 agreement as outlined in Rule .0116 of this Chapter. may prescribe.
- 17 (A)(2) The CNM has an assigned DEA number that is entered on each prescription for a controlled
 18 substance; substance.
- 19
 (B)(3)
 Refills may be issued consistent with Controlled Substance laws and regulations;

 20
 Substances (Schedules II, IIN, III, IIIN, IV, V) defined by the State and Federal Controlled

 21
 Substances [Aet;] Act. and
- 22 (C)(4) The collaborative provider shall possess a schedule(s) of controlled substances equal to or greater
 23 than the CNM's DEA registration.
- (3)[(2)](5) The CNM may prescribe a drug or device not included in the collaborative provider agreement
 only as follows:
- 26(A)Upon a specific written or verbal order obtained from the collaborating provider before the27prescription or order is issued by the CNM; and
- (B) The written or verbal order as described in Part (c)(3)(A) of this rule shall be entered into
 the patient record with a notation that it is issued on the specific order of a collaborating
 provider and signed by the CNM and the collaborating provider.

31 (d) All prescribing stipulations requirements shall be written in the patient's chart and shall include the medication

32 and dosage, the amount prescribed, the directions for use, the number of refills, and the signature of the CNM.

- 33 (e) The prescriptions issued by the CNM shall contain:
- 34 (1) the name of the patient;
- 35 (2) the CNM's name and telephone number; and
- 36 (3) the CNM's assigned DEA number shall be written on the prescription form when a controlled
 37 substance is prescribed.

(f) A CNM shall not prescribe controlled substances for the CNM's own use, the use of the CNM's collaborating
provider, the use of the CNM's immediate family, the use of any other person living in the same residence as the
CNM, or the use of any person with whom the CNM is having a sexual relationship. As used in this Paragraph,
"immediate family" means a spouse, parent, child, sibling, parent-in-law, son-in-law or daughter-in-law, brother-inlaw or sister-in-law, step-parent, step-child, or step-sibling.

7

8

History Note: Authority G.S. 90-18.8; 90-178.3; Temporary Adoption Eff. October 1, 2023.

21 NCAC 33 .0118 is adopted under temporary procedures with changes as follows:

3	21 NCAC 33.	0118 BI	IRTH OUTSIDE HOSPITAL SETTING
4	(a) <mark>A CNM ap</mark>	proved to	o practice may attend and provide midwifery services for a planned birth outside of a hospital
5	setting for a pro	egnancy (deemed low-risk by the American College of Obstetricians and Gynecologists (ACOG). Prior
6	to initiating car	re for a pa	atient planning a home birth outside of a hospital setting, the CNM shall be required to:
7	(1)	obtain	a signed, written informed consent agreement with the patient that includes: details:
8		(A)	identifying information of the patient to include name, date of birth, address, phone
9			number, and email address if available;
0		(B)	identifying information of the CNM to include the name, RN license number, approval to
1			practice number, practice name, if applicable, and email address;
2		(C)	information about the procedures, benefits, and risks of planned births outside of hospital
3			settings;
4		(D)	an acknowledgment and understanding of the clear assumption of these risks by the patient;
5		(E)	when and if deemed necessary by the CNM, an acknowledgment by the patient to consent
6			to transfer to a health care facility when and if deemed necessary by the CNM; licensed
7			under Chapter 122C or Chapter 131E of the General Statutes that has at least one operating
8			room; and
9		(F)	a disclosure that the CNM is not covered under a policy of liability insurance, if applicable.
0	(2)	<mark>Provic</mark>	le the patient with <u>The CNM shall provide</u> a detailed, written plan for transfer of care to a
1		<mark>health</mark>	care facility under emergent and non emergent transfer. Such plan shall be signed and dated
2		<mark>by bo</mark> t	th the patient and the CNM and shall include:
3		<mark>(A)</mark>	
4			Chapter 131E of the General Statutes that has at least one operating room;
5		(B)	the procedures for transfer, including modes of transportation and methods for notifying
6			the relevant health care facility of impending transfer; and
7		<mark>(C)</mark>	an affirmation that the relevant health care facility has been notified of the plan for
8			emergent and non-emergent transfer by the CNM. consistent with G.S. 90-178.4(a2).
9	(3)	After	a decision <mark>to <u>of</u> non-emergent transfer care has been made, the CNM shall:</mark>
0		(A)	call the relevant receiving health care facility to notify them of transfer;
1		(B)	provide a copy of the patient's medical record to the receiving health care facility; and
2		(C)	provide a verbal summary of the care provided by the CNM to the patient and newborn, if
3			applicable, to the receiving health care facility.
4	(4)	In an	emergent situation, the CNM shall initiate emergency care as indicated by the situation and
5		i <mark>mme</mark>	diate immediately transfer of care by making a reasonable effort to contact the health care
6		profes	ssional or facility to whom the patient(s) patient or patients will be transferred and to follow

1	the health care professional's instructions; remain with the patient(s) until transfer of care is
2	completed; and continue emergency care as needed while:
3	(A) transporting the patient(s) by private vehicle; or
4	(B) calling 911 and reporting the need for immediate transfer.
5	(b) Copies of the informed consent agreement and emergent and non-emergent transfer of care plans shall be
6	maintained in the patient's record and provided to the Committee upon request.
7	(c) A CNM approved to practice may attend and provide midwifery services for a planned home birth outside of a
8	hospital setting for a pregnancy deemed low-risk by the American College of Obstetricians and Gynecologists
9	(ACOG). No CNM shall attend or provide midwifery services to a patient for a planned home birth outside of a
10	hospital setting for known situations contraindicated by ACOG including specifically fetal malpresentation, multiple
11	gestation, and prior cesarean.
12	
13	History Note: Authority: G.S. 90-18.8; 90-178.3; 90-178.4;
14	Temporary Adoption Eff. October 1, 2023.

Subject: FW: [External] Midwifery Rules and Technical Changes

From: Liebman, Brian R
Sent: Tuesday, September 12, 2023 3:24 PM
To: Meredith Parris <<u>mparris@ncbon.com</u>>
Cc: Angela Ellis <<u>angela@ncbon.com</u>>; Burgos, Alexander N <<u>alexander.burgos@oah.nc.gov</u>>
Subject: RE: [External] Midwifery Rules and Technical Changes

Hi Meredith and Angela,

As we discussed earlier, your application rule needs to state with some specificity—enough that the applicant should be able to tell what the agency would consider a complete application without having to ask—the contents or substantive requirements of the application form. Here's an example of a rule from the Radiation Protection Committee that I reviewed that contains the requirements of an application form:

10a ncac 15 .1301.pdf (state.nc.us)

Also, with respect to the substantial compliance issue, just be aware that regardless of whatever explanation you submit, I will have to prepare a staff opinion on the issue. So don't be alarmed when you see that.

Glad to talk earlier, and let me know if I can be of further assistance.

Best, Brian

Brian Liebman Counsel to the North Carolina Rules Review Commission Office of Administrative Hearings (984)236-1948 <u>brian.liebman@oah.nc.gov</u>

E-mail correspondence to and from this address may be subject to the North Carolina Public Records Law N.C.G.S. Chapter 132 and may be disclosed to third parties.

Subject: FW: [External] Midwifery Rules and Technical Changes

From: Meredith Parris <mparris@ncbon.com>
Sent: Tuesday, September 12, 2023 6:20 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Angela Ellis <angela@ncbon.com>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: [External] Midwifery Rules and Technical Changes

CAUTION: External email. Do not click links or open attachments unless verified. Report suspicious emails with the Report Message button located on your Outlook menu bar on the Home tab.

Thanks, Brian.

We really appreciated your call this afternoon and the additional examples you provided. I will get a memo to you as soon as I am able regarding our substantial compliance argument, but my priority is getting these responses to you ASAP!

Best, Meredith

Meredith Parris JD

Director, Legal

Office: (984) 238-7627 Fax: (919) 781-9461

4516 Lake Boone Trail Raleigh, NC 27607 P.O. Box 2129 Raleigh, NC 27602

Pronouns: She/Her/Hers



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Subject: FW: [External] Midwifery Rules and Technical Changes

From: Meredith Parris <mparris@ncbon.com>
Sent: Tuesday, September 12, 2023 11:17 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Angela Ellis <angela@ncbon.com>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: [External] Midwifery Rules and Technical Changes

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Will do! Thanks!

Meredith Parris JD

Director, Legal

Office: (984) 238-7627 Fax: (919) 781-9461

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From: Liebman, Brian R <<u>brian.liebman@oah.nc.gov</u>>
Sent: Tuesday, September 12, 2023 11:16 AM
To: Meredith Parris <<u>mparris@ncbon.com</u>>
Cc: Angela Ellis <<u>angela@ncbon.com</u>>; Burgos, Alexander N <<u>alexander.burgos@oah.nc.gov</u>>
Subject: RE: [External] Midwifery Rules and Technical Changes

Sure, 1 PM on my office phone would be great. Talk to you then.

Brian Liebman Counsel to the North Carolina Rules Review Commission Office of Administrative Hearings (984)236-1948 brian.liebman@oah.nc.gov

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From: Meredith Parris <<u>mparris@ncbon.com</u>>
Sent: Tuesday, September 12, 2023 11:15 AM
To: Liebman, Brian R <<u>brian.liebman@oah.nc.gov</u>>
Cc: Angela Ellis <<u>angela@ncbon.com</u>>; Burgos, Alexander N <<u>alexander.burgos@oah.nc.gov</u>>
Subject: RE: [External] Midwifery Rules and Technical Changes

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Great! Thanks, Brian.

Would 1pm work for you? I think Angela can hop on at that time, too. I can call your office number directly if that works for you. I'm otherwise free until 4.

Best, Meredith

Meredith Parris JD

Director, Legal

Office: (984) 238-7627 Fax: (919) 781-9461

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From: Liebman, Brian R <<u>brian.liebman@oah.nc.gov</u>>
Sent: Tuesday, September 12, 2023 11:00 AM
To: Meredith Parris <<u>mparris@ncbon.com</u>>
Cc: Angela Ellis <<u>angela@ncbon.com</u>>; Burgos, Alexander N <<u>alexander.burgos@oah.nc.gov</u>>
Subject: RE: [External] Midwifery Rules and Technical Changes

Hi Ms. Parris,

I'd be more than happy to speak with you today. When would be convenient for you?

Best, Brian

Brian Liebman Counsel to the North Carolina Rules Review Commission Office of Administrative Hearings (984)236-1948 <u>brian.liebman@oah.nc.gov</u>

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From:	Angela Ellis <angela@ncbon.com></angela@ncbon.com>
Sent:	Friday, September 8, 2023 9:09 AM
То:	Liebman, Brian R
Cc:	Burgos, Alexander N; Meredith Parris
Subject:	[External] RE: 21 NCAC 33 Temporary Rules Requests for Changes - September 2023 RRC

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Hi Brian,

This is to confirm receipt of the Request for Changes. We will review and respond by the deadline date identified.

Have a great weekend!

Angela Ellis

Angela Ellis Chief Administrative Officer

Office: (984) 238-7644 Fax: (919) 781-9461

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From: Liebman, Brian R <brian.liebman@oah.nc.gov> Sent: Thursday, September 7, 2023 4:49 PM To: Angela Ellis <angela@ncbon.com> Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov> Subject: 21 NCAC 33 Temporary Rules Requests for Changes - September 2023 RRC

Good afternoon,

I'm the attorney who reviewed the Rules submitted by the Board for the September 2023 RRC meeting. The RRC will formally review these Rules at its meeting on Thursday, September 21, 2023, at 9:00 a.m. The meeting will be a hybrid of in-person and WebEx attendance, and an evite should be sent to you as we get closer to the meeting. If there are any other representatives from your agency who will want to attend virtually, let me know prior to the meeting, and we will get evites out to them as well.

Please submit the revised Rules and forms to me via email, no later than <u>5 p.m. on Friday, September 15, 2023.</u>

In the meantime, please do not hesitate to reach out via email with any questions or concerns.

Thanks,

Brian

Brian Liebman Counsel to the North Carolina Rules Review Commission Office of Administrative Hearings (984)236-1948 <u>brian.liebman@oah.nc.gov</u>

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