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Final Regulation
Agency Background Document

Agency name	Boards of Nursing and Medicine, Department of Health Professions
Virginia Administrative Code (VAC) Chapter citation(s)	18VAC90-70
VAC Chapter title(s)	Regulations Governing the Practice of Licensed Certified Midwives
Action title	New regulations for licensed certified midwives
Date this document prepared	September 12, 2023

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

Chapter 200 of the 2021 Acts of Assembly required the Boards of Nursing and Medicine to promulgate regulations governing the practice of licensed certified midwives. The resulting licensure statute, Virginia Code § 54.1- 2957.04, specifies the credential that will be considered as qualification for licensure and renewal, the requirement for a practice agreement, and the prescriptive authority for the profession. The Boards have adopted additional requirements similar to other licensed professions for a fee structure, renewal or reinstatement, continuing competency, and standards of practice.

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the "Definitions" section of the regulation.

PMP: Prescription Monitoring Program, including the PMP database of prescribed medication.
MME: Morphine Milligram Equivalent.

Statement of Final Agency Action

Provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

On August 4, 2023, the Board of Medicine voted to amend the Regulations Governing the Practice of Licensed Certified Midwives. On September 12, 2023, the Board of Nursing voted to amend the Regulations Governing the Practice of Licensed Certified Midwives.

Mandate and Impetus

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding the mandate for this regulatory change, and any other impetus that specifically prompted its initiation. If there are no changes to previously reported information, include a specific statement to that effect.

Chapter 200 of the 2021 Acts of the Assembly, Special Session I, mandates that the Boards promulgate regulations for the licensure of certified midwives. That legislation held that:

> The Boards of Medicine and Nursing shall jointly adopt regulations for the licensure of licensed certified midwives, which shall include criteria for licensure and renewal of a license as a certified midwife that shall include a requirement that the applicant provide evidence satisfactory to the Boards of current certification as a certified midwife by the American Midwifery Certification Board and that shall be consistent with the requirements for certification as a certified midwife established by the American Midwifery Certification Board.

To comply with this mandate, the Boards have adopted a new chapter, 18VAC90-70-10 *et seq.*, Regulations Governing the Practice of Licensed Certified Midwives.

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia and Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

Regulations of the Boards of Nursing and Medicine are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Virginia Code § 54.1-2400(6) specifically states that the general powers and duties of health regulatory boards shall be "[t]o promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) that are reasonable and necessary to administer effectively the regulatory system."

The specific legislative authority for this action can be found in Chapter 200 of the 2021 Acts of Assembly, Special Session I. That action amended Virginia Code § 54.1-2900 to create a definition of a licensed certified midwife as an individual licensed as a certified midwife by the Boards of Medicine and Nursing. Virginia Code § 54.1-2900 was further amended to include a definition of the practice of licensed certified midwifery. Virginia Code § 54.1-2957.04 provided another directive to the Boards of Medicine and Nursing to promulgate regulations to license certified midwives. Virginia Code § 54.1-3005 was amended to specify that the Board of Nursing was to promulgate regulations with the Board of Medicine regarding the licensure of licensed certified midwives. Finally, the act amended both Virginia Code §§ 54.1-3303 and 54.1-3408 to clarify that licensed certified midwives have prescriptive authority.

Purpose

Explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety, or welfare of citizens, and (3) the goals of the regulatory change and the problems it is intended to solve.

(1) The rationale of the regulatory change is to comply with a legislative mandate to license certified midwives and to do so while protecting the health and safety of citizens of the Commonwealth.

(2) The Boards have promulgated regulations to establish qualifications for licensure and renewal of licensure that ensure minimal competency to protect the health and safety of patients who receive the services of licensed certified midwives. The regulations promulgated are also necessary to provide standards for confidentiality, patient records, dual relationships, and informed consent to protect public health and safety.

(3) The goal of the regulatory change is to comply with a legislative mandate. The problem the regulatory change is intended to solve is the licensure of licensed certified midwives in the Commonwealth, which is not currently a licensure category but which the General Assembly has determined will be licensed.

Substance

Briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of Changes" section below.

Because certified midwives are not currently a regulated health profession in Virginia, the Boards created a new chapter of regulations for licensed certified midwives. That chapter includes requirements for licensure and practice as required in Virginia Code § 54.1-2957.04, standard fees related to administrative and disciplinary costs that are levied on all licensees, requirements for renewal and reinstatement, continuing competency requirements, and unprofessional conduct violations.

Issues

Identify the issues associated with the regulatory change, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, include a specific statement to that effect.

1) The primary advantage to private citizens is that licensed certified midwives will be available to

provide care to patients while being regulated by the Boards, thereby ensuring the safety of patients who receive care from a licensed certified midwife. There are no disadvantages to the public.

2) There are no primary advantages or disadvantages to the agency or the Commonwealth.
3) The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. Any restraint on competition as a result of promulgating these regulations is a foreseeable, inherent, and ordinary result of the statutory obligation of the Board to protect the safety and health of citizens of the Commonwealth. The Board is authorized under § 54.1-2400 "[t]o promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) which are reasonable and necessary to administer effectively the regulatory system . . . Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title." The promulgated regulations do not conflict with the purpose or intent of Chapters 1 or 25 of Title 54.1.

Requirements More Restrictive than Federal

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any requirement of the regulatory change which is more restrictive than applicable federal requirements. If there are no changes to previously reported information, include a specific statement to that effect.

There are no applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any other state agencies, localities, or other entities that are particularly affected by the regulatory change. If there are no changes to previously reported information, include a specific statement to that effect.

Other State Agencies Particularly Affected – none

Localities Particularly Affected – none

Other Entities Particularly Affected – none

Public Comment

Summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency's response. Include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency. If no comment was received, enter a specific statement to that effect.

Commenter	Comment	Agency response
Karen Kelly, CNM	Supports regulations and licensure of licensed certified midwives, will allow practitioners like her to practice as she was trained.	The Boards appreciate the support.

14 commenters on Town Hall	Comments were supportive of the proposed regulations and the licensure of licensed certified midwives by the Commonwealth as an avenue to expand access to care in Virginia.	The Boards appreciate the support.
12 commenters on Town Hall	Comments were supportive of licensed certified midwives generally.	The Boards appreciate the support.
12 commenters on Town Hall	Comments were supportive of the regulations as written.	The Boards appreciate the support.
7 commenters on Town Hall	Comments were generally supportive of midwives as a whole.	The Boards appreciate the support.
Erin Baird, Exec. Medical Director of Women's and Children's Services, Centra Medical Group Women's Center, via Town Hall Linsay Hillar, via Town Hall	Both comments referred to certified professional midwives and their need to carry and administer medications.	Certified professional midwives are a category of licensee solely regulated by the Board of Medicine. These regulations create a new licensure category for licensed certified midwives, an advanced level practitioner with prescriptive authority.

Detail of Changes Made Since the Previous Stage

*List all changes made to the text since the previous stage was published in the Virginia Register of Regulations and the rationale for the changes. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Put an asterisk next to any substantive changes.*

Current chapter-section number	New chapter-section number, if applicable	New requirement from previous stage	Updated new requirement since previous stage	Change, intent, rationale, and likely impact of updated requirements
70-260		No new requirement.	Language amended to reflect ability of agency subordinate to hear credentials cases, pursuant to Ch. 191 of the 2023 General Assembly.	Will allow agency subordinates to hear informal cases involving nonroutine applications to practice. This change has been or is being made for all boards consistent with the statutory change.

Detail of All Changes Proposed in this Regulatory Action

*List all changes proposed in this action and the rationale for the changes. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Put an asterisk next to any substantive changes.*

Current chapter-section number	New chapter-section number, if applicable	Change, intent, rationale, and likely impact of updated requirements
70-10	Sets out definitions for words and terms used in the chapter.	Includes definitions, particularly for acronyms used in the chapter, which are useful in interpreting and understanding regulatory requirements. Words and terms defined in Virginia Code §§ 54.1-2900 and 54.1-2957.04 are also referenced.
70-20	Delegation of authority to Board of Nursing.	This section allows the Virginia Board of Nursing to manage the issuance of licensure for licensed certified midwives and to maintain all records of licensed certified midwives. This regulation is necessary because the profession will be jointly regulated by the Boards of Medicine and Nursing. This is consistent with treatment of records and licensure for nurse practitioners, who are also jointly regulated by the Boards.
70-30	Use of the Committee of the Joint Boards of Nursing and Medicine.	This section states that the Committee of the Joint Boards of Nursing and Medicine shall administer the provisions of this chapter. The Committee of the Joint Boards administers all chapters of license categories jointly regulated by the Boards of Nursing and Medicine.
70-40	Establishes fees for licensed certified midwives.	These fees are identical to the fees imposed on nurse practitioners pursuant to 18VAC90-30-50.
70-50	General licensure requirement.	This regulation specifically restricts practice as a certified midwife to an individual licensed as a licensed certified midwife by the Boards.
70-60	Qualifications for initial licensure.	This regulation lays out the criteria for initial licensure as a licensed certified midwife. The regulatory advisory panel and the Boards believe these qualifications establish minimal competency for licensure. Virginia Code § 54.1-2957.04 requires that a licensed certified midwife hold a current certification as a certified midwife from the American Midwifery Certification Board. The statute also requires that licensure qualifications be consistent with qualifications of a certified midwife established by the American Midwifery Certification Board. Therefore, the Boards have included a requirement that the applicant hold a graduate degree from a program in midwifery approved by the Accreditation Commission for Midwifery Education or its successor (*see* definition of "approved program" in 70-10) because that is also required by the American Midwifery Certification Board.
70-70	Qualifications for licensure by endorsement.	This regulation is similar to that for initial licensure in that a current certification by the American Midwifery Certification Board is required. However, instead of submitting evidence of a graduate degree from an approved program, an applicant for licensure by endorsement can submit evidence of current licensure as a certified midwife in another jurisdiction.

70-80	Renewal requirements.	This regulation establishes that licenses will be renewed biennially, and that renewal notifications will be sent to the last known address of record for each licensed certified midwife. Subsection C requires that the licensee attest to current certification as a certified midwife by the American Midwifery Certification Board, as required by Virginia Code § 54.1-2957.04. Subsection D specifies that practice with an expired license is prohibited and may constitute grounds for discipline.
70-90	Sets out continuing competency requirements.	Subsection A specifies that a licensed certified midwife must maintain certification as a certified midwife by the American Midwifery Certification Board. Subsection B requires that a licensed certified midwife obtain eight hours of continuing education in pharmacology or pharmacotherapeutics for each biennium. Nurse practitioners must complete the same number of hours in the same topics. (*See* 18VAC90-40-55(B).) The Boards believe this is necessary to protect public health and safety because licensed certified midwives have the ability to prescribe Schedules II-VI as part of their scope of practice. Subsection C requires licensees to maintain evidence of compliance with the requirements of the section, and Subsection D authorizes random audits for continued competency compliance. Subsections E and F provide the boards flexibility to give extensions or exemptions for certain portions of the requirements.
70-100	Establishes requirements for reinstatement of license.	The requirements for late renewal, reinstatement, or reactivation are similar to those of nurse practitioners. *See* 18VAC90-30-110. Requirements are provided for late renewal within the first two years, after two years has lapsed, and following suspension or revocation.
70-110	Establishes standards of practice of licensed certified midwives.	Subsections A, B, and C establish requirements for use of a practice agreement, what the practice agreement must address, and how it must be maintained by the licensed certified midwife. Subsection D specifies that a licensed certified midwife must practice in accordance with the standard of care of the profession. Subsection E requires the licensed certified midwife include a signature of the practitioner and the DEA number of the practitioner on each prescription. This requirement is identical to 18VAC90-40-110(A), which applies to nurse practitioners. Subsection F requires that the licensed certified midwife disclose his or her licensure type to patients at an initial encounter, identical to the requirement for nurse practitioners in 18VAC90-40-110(B).

		Subsection G requires the licensed certified midwife to disclose certain risks when providing services to patients outside of a hospital or birthing center. This is required by Virginia Code § 54.1-2957.04(F). Subsection H requires the licensed certified midwife to disclose the name and contact information for the consulting physician upon request of a patient or patient's representative. This requirement is identical to 18VAC90-40-110(C), which applies to nurse practitioners.
70-120	Establishes requirements for prescribing for self or family.	These requirements are identical to requirements for prescribing for self or family of nurse practitioners (18VAC90-40-121) and the prescribing professions under the Board of Medicine (18VAC85-20-25 (MDs, DOs, DPMs), 18VAC85-50-176 (physician assistants)).
70-130	Waiver for electronic prescribing.	This section is consistent with Virginia Code § 54.1-3408.02(C) and similar regulations for other prescribing professions. *See, e.g.*, 18VAC90-40-122.
70-140	Establishes rules for evaluation of a patient for acute pain treatment.	This requirement is identical to 18VAC90-40-150 governing nurse practitioners. The intent of the section is to ensure that licensed certified midwives prescribe opioids only when absolutely necessary, rather than as a routine treatment and that the prescription be limited in quantity and dosage. Prior to prescribing a controlled substance for pain, the licensed certified midwife has legal obligations in the establishment of a practitioner/patient relationship and in checking the PMP and also a professional obligation to assess the patient's risk.
70-150	Establishes the requirements for treatment of acute pain with opioids.	This requirement is identical to 18VAC90-40-160 governing nurse practitioners. The Board of Medicine, when it initially promulgated regulations related to prescribing opioids and which this section of the regulations is based on, determined that a consistent seven-day limit to acute pain prescribing was advisable. If post-surgical pain is being treated, the limit is increased to 14 days. In each case, the prescriber can document circumstances that would warrant prescribing outside the limits. A specified limitation on days of prescribing has reduced the amount of unused or unnecessary opioids available for abuse or diversion. It also encourages practitioners to prescribe non-opioid controlled substances that may be just as effective but not addictive. Since there are many controlled substances containing opioids, the acceptable limitation on dosage is translated into morphine milligram equivalency (MME). Typically, a patient should not be prescribed a dosage in excess of 50 MME per day. If a prescriber exceeds 120 MME per day for a patient, there must be a clear justification or consultation with or referral to a pain specialist. Naloxone, an overdose antidote, should always be prescribed under the conditions listed in subsection B. A specified standard in regulation should assist

		practitioners in determining dosages that are consistent with the standard of care in prescribing for pain. Subsection C lists drugs for which there is a high risk of overdose if co-prescribed with an opioid. Regulations require documentation of the circumstances necessitating co-prescribing and the tapering plan in place. Buprenorphine is not allowed for treatment of pain outside of the practice of a waivered prescriber because of a high risk of abuse.
70-160	Establishes requirements for medical records of treatment of acute pain with opioids.	This requirement is identical to 18VAC90-40-170 governing nurse practitioners. Requirements for the medical record in the treatment of a patient with are consistent with the establishment of a bona fide practitioner-patient relationship.
70-170	Establishes the requirements for treatment of acute pain with opioids.	This requirement is identical to 18VAC90-40-180 governing nurse practitioners. Prescribing for chronic pain with a substance containing an opioid for longer than 30 days requires a more in-depth evaluation of the patient because of the high risk of addiction. In addition to a thorough evaluation of the patient's physical and mental status, the prescriber must obtain a urine drug screen or serum medication level to determine what drugs, illicit or prescribed, are in the patient's system, and must check the PMP to determine what other drugs may have been prescribed. A urine drug screen may cost as little as $50, but it is an essential test to determine the risk of abuse or addiction if a practitioner is going to initiate prescribing of opioids for chronic pain. Subsection B requires the practitioner to discuss risks and benefits of opioid treatment, the responsibilities of the patient, and an exit strategy for discontinuation if necessary. Those patient responsibilities should include securing the drug and properly disposing of any unwanted or unused drug to prevent affecting other people or the environment.
70-180	Establishes guidelines for treating chronic pain with opioids.	This requirement is identical to 18VAC90-40-190 governing nurse practitioners. Upon initial promulgation of opioid prescribing regulations in 2017, the Boards carefully considered guidelines for treating pain with opioids from the Centers for Disease Control and Prevention and other sources familiar with pain management. The Boards determined that 50 MME/day was a reasonable dosage for chronic pain. However, the practitioner can exercise reasonable professional judgment based on factors unique to the patient and exceed the 50 MME/day dosage if the prescription is documented and justified in the medical record. Likewise, any decision to exceed 120 MME/day should be documented and justified and the prescriber should refer to or consult with a pain management specialist.

		Any prescribing of doses in excess of 120 MME/day or concomitant benzodiazepenes heightens the risk of overdose, so the rules require prescribing of naloxone in addition to the opioid.
70-190	Establishes the requirement for a treatment plan when treating chronic pain with opioids.	This requirement is identical to 18VAC90-40-200 governing nurse practitioners. This section details what a practitioner should include in a treatment plan and what should be documented in the patient record, including the presence or absence of indicators for medication abuse, misuse, abuse, or diversion. The intent is to ensure a practitioner considers and documents a plan for monitoring the effectiveness of opioid prescribing and is alert to signs of abuse, diversion, misuse, or addiction. A patient who is compliant with the plan should not be concerned about being denied pain medication, and a prescriber who is fully documenting and monitoring should not be concerned about compliance with law and regulation.
70-200	Establishes requirements for informed consent and agreement to treatment of chronic pain with opioids.	This requirement is identical to 18VAC90-40-210 governing nurse practitioners. Section 210 protects both the patient and the practitioner. A clearly documented treatment plan and informed consent provides the patient with clear expectations for continued treatment with opioids and provides the practitioner a roadmap to follow in the management of the patient's chronic pain.
70-210	Establishes requirements for using opioid therapy to treat chronic pain.	This requirement is identical to 18VAC90-40-220 governing nurse practitioners. Requirements in this section ensure that the practitioner is carefully considering the effects of prescribing opioids, evaluating the patient's progress, considering other modalities for pain control, monitoring the patient's prescribing history to check for evidence of drugs from other sources, and evaluating the patient for opioid use disorder. This evaluation must occur at least every three months to detect problems before addiction or diversion is in evidence. The only method of assurance that the drug is being taken by the patient as prescribed and that there are no other drugs in the patient's system is by the use of a urine drug screen or serum medication level. The type of testing will be determined by the provider, but the regulation requires testing every three months during the first year of treatment and every six months thereafter.
70-220	Establishes requirements to refer patients for additional consultations as needed.	This requirement is identical to 18VAC90-40-230 governing nurse practitioners. Requires practitioners to refer patients for additional evaluation and treatment when required to achieve treatment goals or when the practitioner makes a diagnosis of opioid use disorder.
70-230	Establishes requirements for the content of medical records when treating	This requirement is identical to 18VAC90-40-240 governing nurse practitioners.

	chronic pain with opioids.	Requirements for the medical record in the treatment of a chronic pain patient with opioids are consistent with the establishment of a bona fide practitioner-patient relationship and the requirements for a complete record of the treatment plan and goals, informed consent, evaluations and consultations, and periodic reviews as specified in other sections of this chapter.
70-240	Establishes grounds for disciplinary action against licensed certified midwives.	The grounds for disciplinary action or denial of licensure are similar to those for nurse practitioners. *See* 18VAC90-30-220. This regulation differs from the nurse practitioner disciplinary regulation in that the competency disciplinary provision mirrors the provision for physician assistants rather than nurse practitioners, which is more vague. *Compare* 18VAC85-50-179(A)(1) (governing physician assistants) and 18VAC90-30-220(3) (governing nurse practitioners). Additionally, this regulation makes it a violation of regulation to practice in the Commonwealth as a licensed certified midwife if the individual's national certification by the American Midwifery Certification Board has lapsed. The midwives and certified nurse midwives participating in the regulatory advisory panel believed that this requirement was necessary to protect the public.
70-250	Sets out requirements for administrative hearings.	This regulation is identical to 18VAC90-30-230 governing nurse practitioners. This regulation states that the Virginia Administrative Process Act, Va. Code § 2.2-4000 *et seq.*, governs disciplinary proceedings related to licensed certified midwives. The regulation further states that the Committee of the Joint Boards of Nursing and Medicine will conduct all disciplinary proceedings on behalf of the two boards.
70-260	Criteria for delegation of disciplinary proceedings to an agency subordinate.	This regulation is similar to 18VAC90-30-240 governing nurse practitioners. The only change is addressed in the chart above. The language of the regulation has been amended from the proposed stage to address legislative changes which allow a board to delegate credentials cases and disciplinary cases, rather than just disciplinary cases, to an agency subordinate. The regulation sets out the criteria used for delegation of a disciplinary proceeding to an agency subordinate.