Date of Hearing: June 27, 2023

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Marc Berman, Chair
SB 667 (Dodd) – As Amended May 24, 2023

SENATE VOTE: 40-0

SUBJECT: Healing arts: pregnancy and childbirth

SUMMARY: Makes various clarifications and changes to the practice and supervision of certified nurse-midwives (CNMs).

EXISTING LAW:

1) Regulates and licenses the practice of nursing under the Nursing Practice Act, which is administered and enforced by the Board of Registered Nursing (BRN). (Business and Professions Code (BPC) §§ 2700-2838.4)

2) Establishes the following related to nursing scope of practice:

    a) Defines "the practice of nursing" as those functions, including basic health care, that help people cope with difficulties in daily living that are associated with their actual or potential health or illness problems or the relevant treatment, and that require a substantial amount of scientific knowledge or technical skill, including all of the following:

        i) Direct and indirect patient care services that ensure the safety, comfort, personal hygiene, and protection of patients; and the performance of disease prevention and restorative measures. (BPC § 2725(b)(1))

        ii) Direct and indirect patient care services, including, but not limited to, the administration of medications and therapeutic agents, necessary to implement a treatment, disease prevention, or rehabilitative regimen ordered by and within the scope of licensure of a physician, dentist, podiatrist, or clinical psychologist, as defined. (BPC § 2725(b)(2))

        iii) The performance of skin tests, immunization techniques, and the withdrawal of human blood from veins and arteries. (BPC § 2725(b)(3))

        iv) Observation of signs and symptoms of illness, reactions to treatment, general behavior, or general physical condition, and (A) determination of whether the signs, symptoms, reactions, behavior, or general appearance exhibit abnormal characteristics, and (B) implementation, based on observed abnormalities, of appropriate reporting, or referral, or standardized procedures, or changes in treatment regimen in accordance with standardized procedures, or the initiation of emergency procedures. (BPC § 2725(b)(4))

    b) Defines "standardized procedures" as either of the following:

i) Policies and protocols developed by a licensed health facility through collaboration among administrators and health professionals including physicians and nurses. (BPC § 2725(c)(1))

ii) Policies and protocols developed through collaboration among administrators and health professionals, including physicians and nurses, by an organized health care system which is not a licensed health facility, subject to any guidelines for standardized procedures established by the Medical Board of California and the BRN. (BPC § 2725(c)(2))

c) Establishes standardized procedure guidelines jointly promulgated by the Medical Board of California and the BRN. (California Code of Regulations (CCR), Title 16, § 1474)

d) Requires standardized procedures to include a written description of the method used during development and approval. (CCR, tit. 16, § 1474(a))

e) Specifies the required form and content of standardized procedures, including that they be in writing and signed, specify the authorized functions, establish procedure protocols, detail education and training requirements, provide for evaluation and of authorized nurses, provide for the maintenance of records of authorized nurses, establish the scope of physician supervision, set forth circumstances requiring physician consultation, state limitations on settings, specify patient record keeping requirements, and provide for periodic review of the standardized procedures. (CCR, tit. 16, § 1474(b))

3) Requires the BRN to issue a certificate to practice nurse-midwifery to anyone who meets the statutory requirements for CNMs and meets the BRN's educational standards. (BPC §§ 2746, 2746.1, 2746.2(a))

4) Establishes the following related to CNM scope of practice:

a) Authorizes a CNM to attend cases of low-risk pregnancy and childbirth and to provide prenatal, intrapartum, and postpartum care, including interconception care, family planning care, and immediate care for the newborn, consistent with the Core Competencies for Basic Midwifery Practice adopted by the American College of Nurse-Midwives, or its successor national professional organization, as approved by the BRN. (BPC § 2746.5(a))

b) Defines "low-risk pregnancy" as a pregnancy in which all of the following conditions are met:

i) There is a single fetus. (BPC § 2746.5(a)(1))

ii) There is a cephalic presentation at onset of labor. (BPC § 2746.5(a)(2))

iii) The gestational age of the fetus is greater than or equal to 37 weeks and zero days and less than or equal to 42 weeks and zero days at the time of delivery. (BPC § 2746.5(a)(3))

iv) Labor is spontaneous or induced. (BPC § 2746.5(a)(4))

v) The patient has no preexisting disease or condition, whether arising out of the pregnancy or otherwise, that adversely affects the pregnancy and that the CNM is not qualified to independently address. (BPC § 2746.5(a)(5))

c) Authorizes a CNM to provide specified services in cases of non-low-risk pregnancy and childbirth under mutually agreed-upon policies and protocols that delineate the parameters for consultation, collaboration, referral, and transfer of a patient's care, signed by both the CNM and a physician and surgeon and specifies various conditions and requirements when providing those services. (BPC §§ 2746.5(b)-(c))

d) Authorizes a CNM to order, furnish, and dispense drugs or devices incidental to the provision of care and services for low-risk pregnancy and childbirth and specifies the conditions under which standardized procedures are required. (BPC §§ 2746.51, 4170)

5) Defines "CLIA" as the federal Clinical Laboratory Improvement Amendments of 1988 and the relevant regulations adopted by the federal Health Care Financing Administration that are also adopted by the California Department of Public Health (CDPH). (BPC § 1202.5(a))

6) Regulates clinical laboratories and the performance of clinical laboratory tests through the licensing of clinical laboratories and laboratory directors, scientists, and other laboratory personnel under the CDPH and CLIA. (BPC §§ 1200-1327)

7) Requires every clinical laboratory to have a laboratory director who is responsible for the overall operation and administration of the clinical laboratory, including (1) administering the technical and scientific operation of a clinical laboratory, the selection and supervision of procedures, the reporting of results, and active participation in its operations to the extent necessary to ensure compliance with state clinical laboratory laws and CLIA, (2) the proper performance of all laboratory work of all subordinates, and (3) employing a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests, and report test results in accordance with the personnel qualifications, duties, and responsibilities described in CLIA and state clinical laboratory laws. (BPC § 1209(d)(1))

8) Defines "laboratory director," for purposes of a clinical laboratory test or examination classified as waived, as any of the following:

a) A duly licensed clinical laboratory scientist. (BPC § 1209(a)(2)(A))

b) A duly licensed limited clinical laboratory scientist. (BPC § 1209(a)(2)(B))

c) A duly licensed naturopathic doctor. (BPC § 1209(a)(2)(C))

d) A duly licensed optometrist serving as the director of a laboratory that only performs specified clinical laboratory tests. (BPC § 1209(a)(2)(D))

e) A duly licensed dentist serving as the director of a laboratory that performs only clinical laboratory tests authorized within the scope of practice of dentistry. (BPC § 1209(a)(2)(E))

f) A pharmacist-in-charge of a pharmacy serving as the director of a laboratory that only performs waived tests. (BPC § 1209(a)(2)(F))

9) Authorizes a licensed nurse to perform clinical laboratory tests classified as waived or of moderate complexity. (BPC § 1206.5)

10) Authorizes a CNM, nurse practitioner, or physician assistant to perform clinical laboratory examinations classified as provider-performed microscopy procedures (PPMP) under CLIA to be personally performed using a brightfield or phase/contrast microscope under physician supervision or protocols using the microscope during the patient's visit on a specimen obtained from their own patient or from the patient of a clinic, group medical practice, or other health care provider of which the CNM, licensed nurse practitioner, or licensed physician assistant is an employee. (BPC § 1206.5(d)(3))

11) Defines "prescriber," for purposes of the pharmacy law, to mean a person, who holds a physician's and surgeon's certificate, a license to practice optometry, a license to practice naturopathic medicine, a license to practice dentistry, a license to practice veterinary medicine, a certificate to practice podiatry, or a certificate to practice as a nurse practitioner without standardized procedures, and who is duly registered by the Medical Board of California, the Osteopathic Medical Board of California, the California State Board of Optometry, the Bureau of Naturopathic Medicine, the Dental Board of California, the Veterinary Medical Board, the Podiatric Medical Board of California, or the Board of Registered Nursing. (BPC § 4170(c))

12) Defines "practitioner," for purposes of establishing medical eligibility for unemployment insurance, to include a midwife or CNM in cases of normal pregnancy or childbirth. (Unemployment Insurance Code § 2708(e)(2)(A))

THIS BILL:

1) Expands the definition of "laboratory director" to include CNMs for purposes of a clinical laboratory test or examination classified as waived or PPMP under CLIA.

2) Expends the scope of practice for CNMs to include common gynecologic conditions.

3) Clarifies that CNMs practicing under mutually agreed-upon policies and protocols with a physician and surgeon are not required to practice with a physician and surgeon.

4) Authorizes CNMs to furnish or order Schedule II or III controlled substances under mutually agreed-upon policies and protocols with a physician and surgeon rather than patient-specific protocols approved by a physician and surgeon or standardized procedures.

5) Authorizes CNMs to dispense drugs under mutually agreed-upon policies and protocols with a physician and surgeon rather than standardized procedures.

6) Includes CNMs in the definition of "prescriber" under the Pharmacy Law.

7) Expands the definition of "practitioner" for purposes of whether a CNM or licensed midwife may establish medical eligibility for disability benefits from "normal pregnancy or

childbirth" to "pregnancy, childbirth, or postpartum conditions consistent with the scope of their professional licensure."

FISCAL EFFECT: According to the Senate Appropriations Committee, pursuant to Senate Rule 28.8, no significant state costs anticipated.

COMMENTS:

Purpose. This bill is co-sponsored by the *California Nurse-Midwifes Association* and *Black Women for Wellness Action Project*. According to the author, this bill "builds upon the recent efforts by the legislature to expand access to women's health care across the state by removing barriers and ensuring [CNMs] can practice to the full extent of their scope and training. [This] bill removes and streamlines redundant requirements and creates consistency for CNMs regardless of practice setting. There is a direct link between race, access, and maternity outcomes in minority communities. Improving access to nurse-midwifery care has been named by leading organizations, such as the March of Dimes and the World Health Organization, as one of the most innovative strategies in addressing racial disparities in communities of color. In the face of these persistent disparities in maternity care and ongoing provider shortages, [this bill] improves access to care for birthing people by ensuring CNMs can truly practice with full independence within their low-risk scope no matter the care setting and preserves the ability to collaborate with physicians to provide care to patients with more complex needs."

Background. CNMs are licensed registered nurses (RNs) with additional training in the field of obstetrics and certification by the American Midwifery Certification Board or an equivalent program. As a result of their additional training, they are considered advanced practice RNs.

As a result of that training, CNMs are also specifically authorized to perform midwifery services and attend cases of low-risk pregnancies and childbirth. CNMs provide midwifery and nursing services in many settings, including the home, birth centers, clinics, and hospitals.

Midwifery. Midwifery is a healthcare profession dealing with maternal care, similar to obstetrics. According to the World Health Organization, midwifery includes the care of a person during pregnancy, labor, and the postpartum/postnatal period, including care of the newborn. Midwifery providers aim to prevent health problems in pregnancy, detect abnormal conditions, seek medical assistance when necessary, and provide emergency services when medical help is unavailable.

On its own, midwifery care is not technically the practice of medicine. While pregnancy may create additional physical and emotional stress, it is not an illness or ailment requiring medical treatment under normal circumstances. Instead, CNMs monitor for abnormal conditions and provide preventive care. A pregnancy without abnormal conditions is called a "low-risk" pregnancy, and CNMs are authorized to independently provide all services and care incidental to a low-risk pregnancy.

CNMs are also authorized to provide services in cases of "high-risk" pregnancies but must do so under mutually agreed-upon policies and procedures with a physician. According to the National Institutes of Health (NIH), "high-risk pregnancy refers to anything that puts the mother or fetus at increased risk for poor health during pregnancy or childbirth. A pregnancy is considered high risk if the mother has chronic health conditions such as high blood pressure or diabetes, or if she

weighs too much or too little. Any pregnancy where complications are more likely than normal is considered a high-risk pregnancy." The mutually agreed-upon policies and protocols ensure that medical care can be provided if abnormal conditions or emergencies arise.

This bill would clarify that a CNM does not have to be in the same practice as a physician to establish mutually agreed-upon policies and protocols. This bill would also clarify that hospitals are allowed to grant admitting and discharge privileges to CNMs.

Furnishing or Ordering Drugs and Devices. Existing law authorizes CNMs to provide drugs and devices to patients as part of their midwifery care, but requires them to establish written standardized procedures with a physician or health system for certain drugs, even if they have mutually agreed-upon policies and procedures developed with and signed by a physician. This bill would delete the requirement for separate standardized procedures and allow for the furnishing of those drugs under mutually agreed-upon policies and protocols. It would also add CNMs to the definition of "prescriber" for purposes of the Pharmacy Law.

CLIA. Existing law generally limits the use of laboratory testing because the tests are used in the diagnostic process. The purpose of CLIA and the California requirements is to minimize the risk of incorrect or unreliable results, patient harm during testing, and improper diagnoses, among other things.

At both the federal and state level, a facility that performs laboratory tests on human specimens for diagnostic or assessment purposes must be certified under CLIA. While CLIA establishes the minimum standards under federal law, it allows states to establish more stringent requirements.

The requirements for CLIA certification vary depending on the complexity of the laboratory tests performed. Clinical laboratories or other testing sites need to know whether each test system used is waived, moderate, or high complexity. In general, the more complicated the test, the more stringent the requirements, including increased training and licensing of laboratory personnel. At a minimum, all laboratories must have a licensed clinical laboratory director.

The FDA determines the complexity of laboratory tests under CLIA. Waived tests are simple tests with a low risk of incorrect results. They include tests listed in the CLIA regulations, tests cleared by the FDA for home use, and tests approved for a waiver by the FDA using the CLIA criteria. Tests not classified as waived are assigned a moderate or high complexity category based on seven criteria given in the CLIA regulations, including ease of use, the knowledge required, and the types of materials tested. For commercially available FDA-cleared or approved tests, the test complexity is determined by the FDA during the pre-market approval process.

CNMs are currently authorized to perform provider-performed microscopy procedures (PPMP) under standardized procedures, as well as waived and moderate complexity tests under the overall operation and administration of the laboratory director, who is typically a physician or clinical laboratory scientist.

This bill would authorize CNMs to act as the laboratory director for purposes of independent midwifery care for waived and PPMP only. According to the sponsors, the waived tests performed by CNMs at birth centers include:

- Pregnancy tests.
- Hemoglobin by fingerstick.
- Urinalysis dipstick for ketones, nitrites, leukocytes, and nitrites.
- Glucose by finger stick.
- Fecal occult blood.
- Ovulation tests.

PPMP includes four simple tests:

1) The Fern Tes, which involves looking at vaginal secretions under the microscope to diagnose that the water bag has broken.
2) Looking at a "wet mount" (slide) of vaginal secretions under the microscope to diagnose a common vaginitis called bacterial vaginosis.
3) Looking at a wet mount of vaginal secretions to diagnose a yeast infection.
4) Looking at a wet mount of vaginal secretions to diagnose a sexually transmitted infection called trichomoniasis.

Medical Eligibility for Disability. Existing law authorizes CNMs to establish medical eligibility for disability in cases of "normal" pregnancy or childbirth. This bill would update the law to reflect the scope of practice of CNMs.

Prior Related Legislation. SB 1237 (Dodd), Chapter 88, Statutes of 2020, authorized CNMs to attend to low-risk pregnancies and perform related incidental functions without physician supervision; replaces the supervision requirement for higher-risk pregnancies with mutually agreed-upon policies and protocols; required the Board of Registered Nursing to establish a Nurse-Midwifery Advisory Committee; established a disclosure and informed consent requirement; and established reporting and data collection requirements.

AB 2682 (Burke) of 2018 would have authorized a CNM to attend cases of normal pregnancy and childbirth without the supervision of a physician and surgeon, required BRN to establish a nurse-midwifery practice committee, and made conforming changes to childbirth attendance requirements for naturopathic doctors. AB 2682 died pending a hearing in the Senate Business, Professions and Economic Development Committee.

SB 457 (Bates) of 2017 would have revised the requirements for physicians and surgeons, LMs, and CNMs who attend cases of pregnancy and out-of-hospital childbirth, including specifying risk factors, referral requirements, and settings. SB 457 died pending hearing in the Senate Business, Professions and Economic Development Committee.

AB 1612 (Burke) of 2017 would have: authorized a CNM to furnish and order drugs and devices related to care rendered in a home under standardized procedures and protocols; authorized a CNM to directly procure supplies and devices, to obtain and administer drugs and diagnostic tests, to order laboratory and diagnostic testing, and to receive reports that are necessary to their practice and consistent with nurse-midwifery education preparation; authorized a CNM to

perform and repair episiotomies and to repair first-degree and second degree lacerations of the perineum, in a licensed acute care center, as specified, in a home setting and in a birth center accredited by a national accrediting body approved by the BRN; required a CNM when performing those procedures, to ensure that all complications are referred to a physician and surgeon immediately. AB 1612 died pending a hearing in the Assembly Appropriations Committee.

AB 1306 (Burke) of 2016 would have removed specified physician and surgeon supervision requirements for CNMs, increased educational requirements, modified practice parameters, established a Nurse-Midwifery Advisory Committee within the Board of Registered Nursing BRN, and subjected CNMs to the ban on the corporate practice of medicine, as specified, among other changes. AB 1306 failed on concurrence on the Assembly floor.

ARGUMENTS IN SUPPORT:

The *California Nurse-Midwives Association (CNMA)* and *Black women for Wellness Action Project* (co-sponsors) write in support, "This bill builds upon recent expansions to maternity care by Certified Nurse Midwives (CNMs) who can now practice fully independently for "normal," low-risk pregnancies and can also collaborate with physicians to provide care to patients with more complex medical needs. One piece of the solution is to allow these highly qualified providers to practice to the full extent of their scope as the original law establishing independent practice intended. The bill addresses redundancies and red tape revealed only through the everyday practice by midwives who experienced disruptive and unnecessary limitations to practice that SB 1237 (Dodd, Chaptered, 2020) intended to address…. For example, low-risk pregnant patients often need temporary disability certification for common pregnancy conditions that require them to take time off work, such as the RN in an Emergency Department whose back pain at 34 weeks keeps her from lifting patients, or a kindergarten teacher who has significant nausea and vomiting in the initial weeks of pregnancy. While these are typical conditions of pregnancy, the CNM cannot currently certify temporary disability for them. This unnecessary requirement disrupts and delays patient care, especially in health provider shortage areas, and burdens physicians with these approvals that otherwise fall within the scope and training of CNMs."

ARGUMENTS IN OPPOSITION:

None on file

REGISTERED SUPPORT:

California Nurse Midwives Association (co-sponsor)
Black Women for Wellness Action Project (co-sponsor)
2020 Mom
American Association of Birth Centers
American Association of University Women California
American Nurses Association/California
Best Start Birth Center
California Association for Nurse Practitioners

California Association of Nurse Anesthetists
Citizens for Choice
Maternal and Child Health Access
NARAL Pro-choice California
National Health Law Program
Purchaser Business Group on Health
San Francisco Black, Jewish and Unity Group
Training in Early Abortion for Comprehensive Health Care
Women's Foundation California
Women's Health Specialists
REGISTERED OPPOSITION:

None on file

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