

SENATE THIRD READING

SB 667 (Dodd)

As Amended May 24, 2023

Majority vote

SUMMARY

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

Major Provisions

- 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."

COMMENTS

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 United States Food and Drug Administration (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:

- 1) Pregnancy tests.
- 2) Hemoglobin by fingerstick.
- 3) Urinalysis dipstick for ketones, nitrites, leukocytes, and nitrites.
- 4) Glucose by finger stick.
- 5) Fecal occult blood.
- 6) 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.

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."

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

FISCAL COMMENTS

According to the Assembly Appropriations Committee:

- 1) Minor and absorbable costs to the California Department of Public Health.
- 2) No costs to the Board of Registered Nursing (BRN) and Medical Board of California.

VOTES

SENATE FLOOR: 40-0-0

YES: Allen, Alvarado-Gil, Archuleta, Ashby, Atkins, Becker, Blakespear, Bradford, Caballero, Cortese, Dahle, Dodd, Durazo, Eggman, Glazer, Gonzalez, Grove, Hurtado, Jones, Laird, Limón, McGuire, Menjivar, Min, Newman, Nguyen, Niello, Ochoa Bogh, Padilla, Portantino, Roth, Rubio, Seyarto, Skinner, Smallwood-Cuevas, Stern, Umberg, Wahab, Wiener, Wilk

ASM BUSINESS AND PROFESSIONS: 18-0-1

YES: Berman, Flora, Alanis, Alvarez, Bains, Bonta, Chen, Dixon, Gipson, Grayson, Irwin, Jackson, Lee, Lowenthal, McCarty, McKinnor, Stephanie Nguyen, Joe Patterson

ABS, ABST OR NV: Ting

ASM APPROPRIATIONS: 15-0-1

YES: Holden, Megan Dahle, Bonta, Wendy Carrillo, Dixon, Mike Fong, Hart, Lowenthal, Mathis, Papan, Pellerin, Sanchez, Soria, Weber, Wilson

ABS, ABST OR NV: Bryan

UPDATED

VERSION: May 24, 2023

CONSULTANT: Vincent Chee / B. & P. / (916) 319-3301

FN: 0001221