SENATE COMMITTEE ON
BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT
Senator Richard Roth, Chair
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Author:	Dodd		
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Consultant:	Elissa Silva		

Subject: Healing arts: pregnancy and childbirth

SUMMARY: Updates independence practice authority for Certified Nurse Midwives (CNM), and revises authority to furnish or order specified controlled substances within a CNM's standard of care without a mutually agreed upon policies or procedures, clarifies a CNM's authority to treat and provide care for common gynecologic conditions, permits a CNM to admit or discharge a patient if a CNM has privileges at a general acute care hospital, as specified, clarifies that a CNM is a practitioner for purposes of certifying disability, and establishes a registration program for alternative birth centers or primary care clinic at the California Department of Public Health (CDPH), to permit those centers to perform CLIA waived tests, as specified.

Existing law:

1) Establishes the Board of Registered Nursing (BRN) to provide for the licensure and regulation of the practice of nursing and authorizes the BRN to issue a certificate to practice nurse-midwifery to a person who meets educational standards established by the BRN or the equivalent of those educational standards. (Business and Professions Code (BPC) §§ 2700 et seq.)

2) States that the certificate to practice nurse-midwifery authorizes the holder 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, as specified.

3) Defines "low-risk pregnancy" for purposes of 2) above to mean a pregnancy in which all of the following conditions are met;

   a) There is a single fetus;

   b) There is a cephalic presentation at onset of labor;

   c) 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.

   d) Labor is spontaneous or induced;

   e) The patient has no preexisting disease or condition, whether arising out of the pregnancy or otherwise, that adversely affects the pregnancy ad that the certified

nurse-midwife is not qualified to independently address. (BPC § 2745.6(b))

4) States that the certificate to practice nurse-midwifery authorizes the holder to practice with a physician and surgeon 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 that do either of the following:

   a) Provide a patient with care that falls outside the scope of authorized services; and,

   b) Provide intrapartum care to a patient who has had a prior cesarean section or surgery that interrupts the myometrium. (BPC § 2746.5(b))

5) States that the practice of midwifery does not include the assisting of childbirth by vacuum or forceps extraction or to perform any external cephalic version. (BPC § 2746.5(f))

6) Permits a CNM to furnish or order drugs or devices, including controlled substances classified in schedule II III IV or V, under the California Uniform Controlled Substances Act when all of the following apply:

   a) The drugs or devices are furnished or ordered incidentally to the provision of any of the following:

      i) The care and services are authorized in the certificate to practice midwifery;

      ii) Care rendered consistent with the CNM's educational preparation or for which clinical competency has been established or maintained, to persons within a specified facility, and,

      iii) Care rendered in an out-of-hospital setting as authorized in the midwifery practice act.

   b) The furnishing or ordering of drugs or devices by a CNM for services that do not fall within the certificate to practice midwifery are in accordance with standardized procedures or protocols, as defined; or a patient-specific protocol approved by a physician and surgeon, as specified. (BPC §2746.51(a))

7) Makes the furnishing or ordering of drugs or devices by a CNM conditional on the issuance of a furnishing number by the BRN, as specified, and requires every CNM issued a BRN furnishing number to register with the United States Drug Enforcement Administration and the Controlled Substance Utilization Review and Enforcement System. (BPC § 2746.51(b)(1))

8) Permits a CNM to perform and repair episiotomies, and to repair first-degree and second-degree lacerations of the perineum and must ensure that all complications are referred to a physician and surgeon and the immediate care of patients who are

in need of care beyond the scope of practice of the CNM, or emergency care for times when a physician and surgeon is not on the premises. (BPC § 2746.52)

9) Requires the collection of specified data, within 90 days, for all maternal or neonatal transfers to the hospital setting during the labor or the immediate postpartum period, for which the intended place of birth was an out-patient hospital setting at the onset of labor, or for any maternal, fetal, or neonatal death that occurred in the out-of-hospital setting during labor or the immediate postpartum period and for which the intended birth care provider is a CNM in the out-of-hospital. (BPC § 2746.55)

10) Provides for the licensure, registration, and regulation of clinical laboratories and various clinical laboratory personnel by CDPH, with specified exceptions. (Business and Professions Code (BPC) § 1200-1327)

11) Defines, for purposes of state regulation of clinical laboratories, the following:

    a) "CLIA" to mean the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a; P.L. 100-578) and the regulations adopted thereunder by the federal Health Care Financing Administration and effective on January 1, 1994, or any later date, when adopted in California pursuant to subdivision (b) of Section 1208. (BPC § 1202.5(a))

    b) "Clinical laboratory" to mean any place used, or any establishment or institution organized or operated, for the performance of clinical laboratory tests or examinations or the practical application of the clinical laboratory sciences. That application may include any means that applies the clinical laboratory sciences. (BPC § 1206(a)(8))

12) Prohibits a person from performing a clinical laboratory test or examination classified as waived under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by specified personnel. (BPC § 1206.5(a))

13) States that no person shall perform clinical laboratory tests or examinations classified as of high complexity under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, where the test is performed by one of the following:

    a) a licensed physician and surgeon holding an M.D. or D.O. degree;

    b) a licensed podiatrist or a licensed dentist, as specified;

    c) a person licensed to engage in clinical laboratory practice or to direct a clinical laboratory, as specified;

    d) a person who supports a public health laboratory in the examination of specimens from suspected cases of infections and environmental diseases, that

may include milk products, waters, and the environment, as specified;

e) a licensed physician assistant, as specified;

f) a perfusionist, as specified;

g) a respiratory care practitioner, as specified;

h) a person performing nuclear medicine technology, as specified;

i) a person if performing blood gas analysis, as specified;

j) any other person within a physician office laboratory if the test is performed under the onsite supervision of the patient's physician and surgeon or a podiatrist who will: 1) ensure that the person is performing test methods as required for accurate and reliable tests; and 2) have personal knowledge of the results of clinical laboratory testing or examination performed by that person before the test results are reported from the laboratory. (BPC § 1206.5(c) and Health and Safety Code (HSC) § 101150)

14) Defines a "practitioner" for purposes of a claimant establishing medical eligibility for filing a claim for disability benefits supported by the certificate of a treating physician or practitioner. (Unemployment Insurance Code § 2708(a)(1) and 2708(e)(2).

Existing Federal Law:

1) Establishes CLIA under federal law, which regulates clinical laboratories that perform tests on human specimens and sets standards for facility administration, personnel qualifications and quality control. These standards apply to all settings, including commercial, hospital or physician office laboratories. (Code of Federal Regulations (CFR) Title 42 § 493)

2) Defines CLIA waived tests as simple laboratory examinations and procedures that are approved by the Food and Drug Administration (FDA) for home use, employ methodologies that are simple and accurate as to render the likelihood of erroneous results negligible or pose no reasonable risk of harm to the patient if the test is performed incorrectly. (CFR Title 42 § 493)

This bill:

1) Authorizes an alternative birth center or primary care clinic to perform tests classified as "waived" under CLIA or a provider-performed microscopy (PPM) that are consistent with services within the scope of the provider's license if the alternative birth center or primary care clinic obtains a registration from the DPH complies with specified provisions, and the following requirements are specified:

   a) If performing tests classified as waived, the alternative birth center or primary care clinic must do both the following:

i) The alternative birth center or primary care clinic obtains a valid CLIA certificate of waiver and complies with all other testing requirements for the performance of waived clinical laboratory tests under applicable federal regulations;

ii) For purposes of CLIA, the person identified as responsible for directing and supervising testing oversight and decision-making to be a CNM, a licensed midwife or a physician and surgeon.

b) If performing a provider-performed microscopy, the alternative birth center or primary care clinic do both of the following:

i) The alternative birth center or primary care clinic obtains a valid CLIA certificate for provider-performed microscopy and complies with specified requirements;

ii) For purposes of CLIA, the person identified as responsible for directing and supervising testing oversight and decision-making must be a CNM or a physician and surgeon, as specified.

2) Defines for the purposes of 1) above:

a) "Alternative birth center" to mean means a clinic that is not part of a hospital and that provides comprehensive perinatal services and delivery care to pregnant women who remain less than 24 hours at the facility, as currently defined in HSC 1204).

b) "Primary care clinic" to mean a primary care clinic as defined in the HSC § 1204, that is established as a clinic or office for one or more CNMs or licensed midwives, as specified.

3) Specifies that in the case of an alternative birth center that applies for registration from the DPH to perform specified waived tests, "laboratory director" means the person identified as the responsible party for directing and supervising testing oversight for the purpose of obtaining a CLIA certificate, as permitted by this bill.

4) Adds common gynecologic conditions to the practice of midwifery by a CNM.

5) Permits a CNM who holds privileges in a general acute care hospital, as defined, to admit and discharge patients upon their own authority, within their scope of practice and in accordance with the bylaws of that facility, as specified.

6) Updates and revises the authority for CNMs to furnish and order controlled substances classified in schedule II, III, IV, and V,

7) Deletes the requirement that a copy of standardized procedure or protocol relating to the furnishing or ordering of controlled substances by a CNM be provided upon request to any licensed pharmacist who is uncertain of the CNM to perform these functions.

8) Clarifies that a CNM may dispense drugs, which are defined in the pharmacy law as not dangerous, as specified.

9) Adds a CNM to the definition of "prescriber" in the pharmacy law, as specified.

10) Adds low-risk pregnancy and childbirth or postpartum conditions consistent with the scope of a CNM's or midwife's professional license to the definition of "practitioner" for purposes of obtaining medical eligibility for disability, as specified.

11) Makes other technical and clarifying changes.

FISCAL EFFECT: Unknown. This bill is keyed fiscal by Legislative Counsel.

COMMENTS:

1. **Purpose.** The California Nurse Midwives Association is the sponsor of this bill. According to the author, "After SB 1237 was passed in 2020, nurse-midwives across the state have noted various barriers to nurse-midwifery care, despite the intention of SB 1237 to solve these issues and allow for nurse-midwifery expansion and sustainability, especially in low-resource areas where the nurse-midwife is one of few providers, in community birth practice settings (such as freestanding birth centers), and where nurse-midwives care for patients with Medi-Cal. The various issues are noted in question #2 above and typically involve delays in patient care and treatment, and the ability of independent nurse-midwifery practices to exist, simply due to unnecessary administrative barriers or supervisory requirements that SB 1237 aimed to solve."

2. **Background.**

   The practice of midwifery. In California, there are two distinct providers of care for those who attend to cases of low-risk pregnancy and childbirth, licensed midwives (LMs) and CNMs. LMs are authorized to attend cases of normal pregnancy and childbirth and to provide prenatal, intrapartum, and postpartum care, including family-planning care, for the mother and immediate care for the newborn. LMs can also directly obtain supplies and devices, obtain and administer drugs and diagnostic tests, order testing and receive reports that are necessary to his or her practice of midwifery and consistent with his or her scope of practice. LMs can practice in a home, birthing clinic or hospital environment. LMs are licensed by the Medical Board of California.

   CNM are advanced practice registered nurses who have specialized education and training to provide primary care, prenatal, intrapartum, and postpartum care, including interconception care and family planning. These individuals are licensed by the BRN, have acquired additional training in the field of obstetrics, and are certified by the American College of Nurse Midwives. In order to obtain a certificate to practice as a CNM, the applicant must provide proof to the BRN that they have either graduated from a BRN approved program in nurse-midwifery or satisfied equivalence standards as set forth in the BRN's regulations (Title 16 California Code of Regulations § 1460).

The nurse-midwifery certificate authorizes the CNM to attend cases of *low-risk* pregnancy and childbirth, as well as immediate care for the newborn along with family planning and interconception care. CNMs are permitted to furnish or order drugs and devices in certain healthcare settings, as permitted in the certificate to practice midwifery in California. If a CNM orders or furnishes a drug or device that would be outside of the standard of care authorized by the certificate to practice midwifery, the CNM may only do so if they have established mutually agreed upon protocols with a physician and surgeon. Additionally, in order to furnish drugs or devices, the CNM must obtain a furnishing number from the BRN, and register with the United States Drug Enforcement Administration and the Controlled Substance Utilization Review and Enforcement System.

In 2020, the Legislative Analyst's Office conducted a study titled *Analysis of California's Physician-Supervision Requirement for Certified Nurse Midwives*[i]. The study was conducted in response to a Legislator request, and analyzed the impact of the prior physician-supervision requirement for CNMs on health care outcomes and access to care for mothers and their infants. Ultimately, the report concluded, "The state's physician-supervision requirement for nurse midwives is intended to improve the safety and quality of women's health care. Following our review of academic literature on the safety and quality of care by nurse midwives, however, we do not find sufficient evidence to justify this occupational restriction for two reasons. First, we do not find evidence that the safety and quality of maternal and infant health care by nurse midwives is inferior to that of physicians. Second, states with physician-supervision or very similar requirements do not have superior maternal and infant health outcomes. Consequently, the supervision requirement for nurse midwives does not appear to positively affect safety and quality."

The report did provide recommendations to ensure the appropriate care and safeguards for recipients of services including: maintaining referral and consultative relationships with physicians and other providers, practice as part of a health system, practice in an accredited facility, maintain medical malpractice, and meet clinical experience standards. As the report noted, the data for outcomes in birth centers was not as robust and drawing conclusions about services provided in those facilities are not as definitive.

SB 1237 and CNM Independent Practice Authorization. Prior to 2020, CNMs were required to practice under the supervision of a physician and surgeon under standardized procedures and protocols. Standardized procedures were developed collaboratively by nurses, physicians, and the administration of the organized health care system. The BRN and the Medical Board of California jointly promulgated guidelines for standardized procedures (CCR, tit. 16, § 1474), based on the competence of the nurses providing the procedures and include record, referral, and setting requirements, among other patient protections. While supervision by a physician was required for CNMs to provide patient care, that supervision did not require the physical presence of a physician and physicians are limited to supervising no more than 4 CNMs at a time. Meaning, a CNM would work miles away from the actual location of the physician, and as long as the standardized procedures are in place, the CNM would deliver babies and provide other authorized practices by a CNM.

SB 1237 (Dodd, Chapter, Statutes of 2019) revised the current practice authorization for CNMs. That bill eliminated the requirement for a CNM to practice midwifery according to standardized procedures or protocols with a physician in an effort to allow CNMs to practice independently of physician supervision.

That bill revised provisions defining the practice of midwifery, authorized a CNM to attend cases of childbirth outside of a define hospital setting; authorizes a CNM to furnish or order drugs or devices in accordance with standardized protocols with a physician; requires a CNM to provide specified disclosures to a patient; and, establishes new reporting and data collection requirements. SB 1237 did not change the scope of work that a CMN could perform, but permitted a CNM to perform their work without physician supervision. For example, prior to SB 1237, a CNM could only provide services under a standardized procedure and protocol established with a licensed physician and surgeon.

Current law, BPC §2746.5 permits a CNM to furnish order or furnish a drug or device that falls within the standard of care, as permitted in the certificate to practice midwifery without mutually agreed upon protocols. However, if the CNM seeks to order or furnish a drug or device that would fall outside of that services authorized in a certificate to practice midwifery, or if it is a controlled substance Schedule, they can only do so under mutually agreed upon protocols of a physician.

It appears that after three years of implementation of independent practice for CNMs, there are aspects of current law that hinder the CNM's ability to fully practice independently as was the aim of SB 1237. This bill attempts to address these challenges by updating and revising a number of provisions related to the CNM's practice authority. One of the more significant updates is the revisions to the CNM's prescribing authority. As a result of SB 1237, CNMs were limited in prescribing certain controlled substances unless they had established mutually agreed upon protocols with a physician and surgeon. This bill revises that requirement and would permit a CNM to furnish or order a drug or device that is schedule II or III, as long as furnishing or prescribing that drug would fall within the standard of care of a CNM's certificate to practice midwifery-if the prescribing would fall outside of those parameters, the CNM would be required to have a mutually agreed upon protocols.

This bill adds CNMs to the definition of "practitioner" under the unemployment insurance code to ensure that CNMs can establish eligibility for disability purposes related to low-risk pregnancy, childbirth and postpartum conditions. This bill would also add the care of "common gynecological conditions" to the list of services that a CNM is able to provide based on a certificate to practice midwifery. If a CNM were to provide care for a gynecological condition that falls outside that normal parameter, they would subject themselves to potential enforcement by the BRN. This bill updates the pharmacy law to include CNMs in the definition of "prescriber", among other provisions.

As part of AB 1237, the bill required established various reporting and data collection requirements related to labor and deliver services occurring in an out-of-hospital setting. Although a report of that data is currently underway, past data on the number of CNMs providing care is relevant. As report, in 2017, CNMs were recorded as attending almost 50,000 births in the state, or somewhat more than 10

percent of the 470,000 births in the state that year. Of that number approximately 781 provided births in birth centers.

Federal and State Regulation for Clinical Laboratory Testing. A facility that performs laboratory tests on human specimens for diagnosis or assessment must be certified under CLIA. CLIA certification requirements 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 CLIA laboratory tests. Waived tests are simple tests with a low risk for an incorrect result. They include tests listed in the CLIA regulations, tests cleared by the FDA for home use, and tests approved for 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, knowledge required, and 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. While CLIA establishes minimum federal standards, it allows states to enact more stringent state law requirements.

While CLIA establishes minimum federal standards, it allows states to enact more stringent state law requirements. At the federal level and in California, anyone may perform a waived test in a licensed laboratory or as part of a nondiagnostic health assessment program under the overall direction of a laboratory director, unless otherwise limited. In applying for a CLIA certificate of waiver, the laboratory director must list the types of analytes to be tested, the tests performed, and the test manufacturer.

Currently, CNMs who work independently at certain facilities including alternative birth centers, where there is not a physician and surgeon owner, and therefore no licensed laboratory director, report that they are unable to provide routine, standard tests unless they contract with a physician and surgeon who is willing to lend their license to the facility simply for oversight purposes. This can be costly for the CNM

As specified in BPC § 2746.51(f), A CNM may directly procure supplies and devices, *obtain and administer diagnostic tests, directly* obtain and administer nonscheduled drugs consistent with the provision of services that fall within the scope of services, as specified, *order laboratory and diagnostic testing*, and receive reports that are necessary to their practice as a certified nurse-midwife within their scope of practice as specified within the certificate to practice midwifery. However, the author and sponsor note difficulties in administering tests.

As noted by the author, “This bill reduces costly barriers to birth center sustainability and practice start-ups, by allowing certified nurse-midwives to perform specific tests within their birth center or independent midwifery practice, consistent with federal CLIA laboratory rules. California still requires physician laboratory directors for birth centers and midwife-led/midwife-owned practices. This is costly for midwifery

practices, unsustainable, and misaligned with federal rules." To remedy the concern that CNMs practicing within these facilities are not able to provide the necessary care and tests for clients, this bill seeks to establish a registration component for alternative birth centers and clinics.

3. **Arguments in Support.** The California Nurse-Midwives Association writes in support, "This bill clarifies and expands upon several other aspects of CNM practice. It advances the integration and sustainability of midwifery care by clarifying that a CNM does not have to "be in the same practice with" a physician to collaborate and consult with that physician. The bill works to enhance continuity of care and improved safety for the patient by allowing hospitals, should they wish to do so, the ability to grant admitting and discharge privileges to CNMs. It also streamlines the current requirement to have both a "standardized procedure" and "mutually agreed upon policies and protocols" into one mandatory document. As mentioned above, it reduces unnecessary appointments and improves person-centered care by making temporary disability certification by CNMs consistent with the CNM scope of practice. This bill also strengthens continuity and access by clarifying the ability of CNMs to dispense drugs that are consistent with their scope of practice and current prescribing capabilities. It also reduces costly barriers that threaten the sustainability of birth centers and midwife-owned clinics by exempting these specific clinics from California rules that require a physician to be the laboratory director. This bill seeks to reduce geographic and economic barriers to reproductive health care by extending the ability of CNMs to manage common gynecologic conditions across the lifespan rather than only within the discrete periods of pregnancy and conception."

   Maternal Mental Health American Association of Birth Centers, American Nurses Association\ California, Best Start Birth Center, NARAL Pro-Choice California, National Health Law Program Purchaser Business Group on Health California Association of Nurse Anesthetists, San Francisco Black & Jewish Unity Coalition, and Training in Early Abortion for Comprehensive Healthcare write in support and notes, "SB 667 addresses the redundancies, and red tape revealed only through the everyday practice of midwives who continue to experience disruptive and unnecessary limitations to practice."

   California Association of Nurse Practitioners writes in support and notes, "In 2020, the Legislature passed SB 1237 (Dodd), which allowed for CNMs to practice independently of physicians for "normal," low-risk pregnancies, as well as collaborate with physicians in caring for patients with more complex needs. SB 667 will further the goal of SB 1237. While SB 1237 was intended to address limitations to CNMs' practice, in working to implement the bill, CNMs have discovered additional disruptive, unnecessary, and redundant limitations that ultimately disrupt and delay patients' care. SB 667 will rectify these issues so that these highly qualified providers may practice to full extent of their training as SB 1237 intended."

4. **Arguments in Opposition.** The American College of Obstetricians and Gynecologists District IX writes in opposition and notes, "SB 667 would authorize nurse midwives to furnish any controlled substance, including narcotics, without mutually agreed upon policies and protocols with a physician. When SB 1237 was negotiated and nurse midwives were granted independence for low-risk

pregnancies, both parties agreed nurse midwives would only furnish these drugs in collaboration with a physician. This resolution was an important element of SB 1237 that allowed ACOG to go neutral; an issue that remains important today. While physicians are working to reduce the utilization of narcotics in obstetric care, SB 667 goes the opposite direction by authorizing nurse-midwives who treat low risk conditions to use high risk, addictive drugs. Given the present scope of nurse-midwives, ACOG does not understand the utility of a blanket authorization and in those rare cases where a scheduled drug may be necessary, the procedure may very well be moving to high risk and per existing law (as establish in SB 1237), mutually agreed upon policies and protocols with a physician are warranted… while we appreciate and understand the nurse midwives desire to perform certain tests without needing a laboratory director, authorizing nurse-midwives to become laboratory directors, solely for that purpose, is problematic. ACOG is willing to discuss other options to address their issues involving certain tests but cannot support allowing nurse-midwives to be laboratory directors."

The California Academy of Family Physicians writes in support, "SB 667 would authorize nurse midwives to furnish any controlled substance, including narcotics, without mutually agreed upon policies and protocols with a physician. While physicians are working to reduce the utilization of narcotics in obstetric care, SB 667 goes in the wrong direction by authorizing nurse-midwives who treat low risk conditions to use high risk, addictive drugs. Given the present scope of nurse-midwives, it is unclear the utility of a blanket authorization and in those rare cases where a scheduled drug may be necessary, the procedure may very well be moved to high risk and per existing law, mutually agreed upon policies and protocols with a physician are warranted."

The California Medical Association writes in opposition and notes, "SB 667 would also authorize nurse midwives to be identified as laboratory directors. CMA understands the reason for this provision is to allow nurse midwives to perform specific CLIA waived tests within their scope without having supervision by a laboratory director. Laboratory directors remain ultimately responsible and must ensure that all the duties are properly performed and applicable CLIA regulations are met, ensuring the laboratory develops and uses a quality system approach to laboratory testing that provides accurate and reliable patient test results. While we appreciate and understand the nurse-midwives desire to perform certain tests without needing a laboratory director, authorizing nurse-midwives to become laboratory directors, solely for that purpose, is problematic. CMA is willing to discuss other options to address their issues involving certain tests but cannot support allowing nurse-midwives to be laboratory directors."

5. **Policy Issues for Consideration and Suggested Amendment.** As currently, drafted, this bill seeks to address the issue that CNMs who may own or practice at a birth center are not able to order and perform certain tests. Under current law, only designated providers may be a licensed clinical laboratory director, and only designated healthcare providers may perform certain waived and moderate complexity tests under the licensed clinical laboratory director. When CNMs were provided independent practice authority in SB 1237, this issue was not contemplated. Because CNMs are not licensed clinical laboratory directors as required under existing law, they are currently unable to conduct, what they

consider routine tests in a birth center if they are unable contract with a physician and surgeon who lends their license as the laboratory director in order for the CNM to provide certain CLIA-waived and specified moderate-complexity tests that are applicable under the CNM's authority under their certificate to practice.

In order to address this issue to providing care, this bill would establish a new registration program under the CDPH, for purposes of obtaining laboratory authority. Specifically, this bill would authorize an alternative birth center or primary care clinic, as defined, to perform testing and examinations classified as waived or a provider-performed microscopy consistent with services within the scope of the CNM's license, if specified requirements were satisfied.

However, the authority to function as a laboratory director is provided to persons, not to facilities as this bill proposes, creating a lack of clarity and implementation issues. The more appropriate way to address this need for independently practicing CNMs to continue to safely serve their patients is to specifically authorize a CNM to become a laboratory director for purposes of conducting CLIA-waived tests or a provider-performed microscopy, consistent with the practice of CNMs, as referenced under the certificate to practice authority. CNMs are currently permitted to perform specified CLIA-waived tests under existing law, but only under the supervision of a physician and surgeon under the licensed clinical laboratory director. *As such, the bill should be amended according to the following:*

Amend BPC Section 1209 as follows:

(a) As used in this chapter, "laboratory director" means any person who is any of the following:

(1) A duly licensed physician and surgeon.

(2) Only for purposes of a clinical laboratory test or examination classified as waived, ***except as otherwise provided in subparagraph (G)***, is any of the following:

(A) A duly licensed clinical laboratory scientist.

(B) A duly licensed limited clinical laboratory scientist.

(C) A duly licensed naturopathic doctor.

(D) A duly licensed optometrist serving as the director of a laboratory that only performs clinical laboratory tests authorized in clause (ii) of subparagraph (E) of paragraph (5) of subdivision (a) of Section 3041.

(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 as delineated under Section 1625.

(F) A pharmacist-in-charge of a pharmacy serving as the director of a laboratory that only performs tests waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C.

Sec. 263a), as authorized by the Pharmacy Law (Chapter 9 (commencing with Section 4000)).

(G) A nurse- midwife holding a certificate as specified by Section 2746.5 serving as the director of a laboratory that only performs clinical laboratory tests, inclusive of provider performed microscopy, authorized within the scope of the certificate to practice midwifery as specified in 2746.5.

(3) Licensed to direct a clinical laboratory under this chapter.

(b) (1) A person defined in paragraph (1) or (3) of subdivision (a) who is identified as the CLIA laboratory director of a laboratory that performs clinical laboratory tests classified as moderate or high complexity shall also meet the laboratory director qualifications under CLIA for the type and complexity of tests being offered by the laboratory.

(2) As used in this subdivision, “CLIA laboratory director” means the person identified as the laboratory director on the CLIA certificate issued to the laboratory by the federal Centers for Medicare and Medicaid Services (CMS).

(c) The laboratory director, if qualified under CLIA, may perform the duties of the technical consultant, technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to persons qualified under CLIA. If the laboratory director reapportions performance of those responsibilities or duties, they shall remain responsible for ensuring that all those duties and responsibilities are properly performed.

(d) (1) The laboratory director is responsible for the overall operation and administration of the clinical laboratory, including 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 this act and CLIA. They shall be responsible for the proper performance of all laboratory work of all subordinates and shall employ 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 this chapter.

(2) Where a point-of-care laboratory testing device is utilized and provides results for more than one analyte, the testing personnel may perform and report the results of all tests ordered for each analyte for which they have been found by the laboratory director to be competent to perform and report.

(e) As part of the overall operation and administration, the laboratory director of a registered laboratory shall document the adequacy of the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the

laboratory test procedures and examinations. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the department that specify the minimum qualifications for personnel, in addition to any CLIA requirements relative to the education or training of personnel.

(f) As part of the overall operation and administration, the laboratory director of a licensed laboratory shall do all of the following:

(1) Ensure that all personnel, prior to testing biological specimens, have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the department that specify the minimum qualifications for, and the type of procedures that may be performed by, personnel in addition to any CLIA requirements relative to the education or training of personnel. Any regulations adopted pursuant to this section that specify the type of procedure that may be performed by testing personnel shall be based on the skills, knowledge, and tasks required to perform the type of procedure in question.

(2) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to ensure that they are competent and maintain their competency to process biological specimens, perform test procedures, and report test results promptly and proficiently, and, whenever necessary, identify needs for remedial training or continuing education to improve skills.

(3) Specify in writing the responsibilities and duties of each individual engaged in the performance of the preanalytic, analytic, and postanalytic phases of clinical laboratory tests or examinations, including which clinical laboratory tests or examinations the individual is authorized to perform, whether supervision is required for the individual to perform specimen processing, test performance, or results reporting, and whether consultant, supervisor, or director review is required prior to the individual reporting patient test results.

(g) The competency and performance of staff of a licensed laboratory shall be evaluated and documented by the laboratory director, or by a person who qualifies as a technical consultant or a technical supervisor under CLIA depending on the type and complexity of tests being offered by the laboratory.

(1) The procedures for evaluating the competency of the staff shall include, but are not limited to, all of the following:

(A) Direct observations of routine patient test performance, including patient preparation, if applicable, and specimen handling, processing, and testing.

(B) Monitoring the recording and reporting of test results.

(C) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

(D) Direct observation of performance of instrument maintenance and function checks.

(E) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.

(F) Assessment of problem solving skills.

(2) Evaluation and documentation of staff competency and performance shall occur at least semiannually during the first year an individual tests biological specimens. Thereafter, evaluations shall be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance shall be reevaluated to include the use of the new test methodology or instrumentation.

(h) The laboratory director of each clinical laboratory of an acute care hospital shall be a physician and surgeon who is a qualified pathologist, except as follows:

(1) If a qualified pathologist is not available, a physician and surgeon or a clinical laboratory bioanalyst qualified as a laboratory director under subdivision (a) may direct the laboratory. However, a qualified pathologist shall be available for consultation at suitable intervals to ensure high-quality service.

(2) If there are two or more clinical laboratories of an acute care hospital, those additional clinical laboratories that are limited to the performance of blood gas analysis, blood electrolyte analysis, or both, may be directed by a physician and surgeon qualified as a laboratory director under subdivision (a), irrespective of whether a pathologist is available.

As used in this subdivision, a qualified pathologist is a physician and surgeon certified or eligible for certification in clinical or anatomical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology.

(i) Subdivision (h) does not apply to any director of a clinical laboratory of an acute care hospital acting in that capacity on or before January 1, 1988.

(j) A laboratory director may serve as the director of up to the maximum number of laboratories stipulated by CLIA, as defined under Section 1202.5

SUPPORT AND OPPOSITION:

Support:

2020 Mom
American Association of Birth Centers
American Nurses Association/California
Best Start Birth Center
California Association for Nurse Practitioners
California Association of Nurse Anesthetists
California Nurse Midwives Association
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

Opposition:

American College of Obstetricians and Gynecologists District IX
California Academy of Family Physicians
California Medical Association

-- END --

[i] https://lao.ca.gov/Publications/Report/4197#Recommendations