SENATE COMMITTEE ON BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT

Senator Steven Glazer, Chair
2019 - 2020 Regular

Bill No:	SB 1237	**Hearing Date:**	May 18, 2020
Author:	Dodd		
Version:	May 13, 2020		
Urgency:	No	**Fiscal:**	Yes
Consultant:	Elissa Silva		

Subject: Nurse-midwives: scope of practice

SUMMARY: Removes the requirement for physician and surgeon supervision for a certified nurse midwife (CNM) to practice midwifery; revises the provisions defining the practice of midwifery; authorizes a CNM to attend cases out of a hospital setting; authorizes a CNM to furnish or order drugs or devices in accordance with standardized protocols; and, requires a CNM to provide specified disclosures to a patient.

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) Authorizes the holder of a nurse-midwifery certificate (CNM) to practice midwifery under the supervision of a licensed physician, to attend cases or normal childbirth, and to provide prenatal, intrapartum, and post-partum care, including family-planning care for the mother and immediate care of the newborn. (BPC § 2746.5(a))

3) Specifies that the practice of "midwifery" is the furthering or undertaking by a CNM, under the supervision of a licensed physician who has current practice or training in obstetrics, to assist a woman in childbirth so long as progress meets criteria accepted as normal and all complications are to be referred to a physician. (BPC § 2746.5(b))

4) States that the practice of midwifery does not include the assisting of childbirth by any artificial, forcible, or mechanical means. (BPC § 2746.5(d))

5) States that physician "supervision" shall not be construed to require the physical presence of the supervising physician. (BPC § 2746.5 (c))

6) Authorizes a CNM to furnish and order drugs or devices incidentally to the provision of family planning services, routine health care or perinatal care, and care rendered consistently with the CNM's educational preparation in specified facilities and clinics, and only in accordance with standardized procedures and protocols, as specified. (BPC § 2746.51 *et seq.*)

7) Authorizes a CNM to perform and repair episiotomies and to repair first-degree and second degree lacerations of the perineum in a licensed acute care hospital and a licensed alternate birth center, if certain requirements are met, including, but not limited to, that episiotomies are performed pursuant to protocols developed and approved by the supervising physician and surgeon. (BPC § 2746.52)

8) Authorizes the BRN to appoint a Nurse-Midwifery Committee of qualified physicians and nurses, including, but not limited to, obstetricians and nurse-midwives, to develop the necessary standards relating to educational requirements, ratios of nurse-midwives to supervising physicians, and associated matters. (BPC § 2746.2)

9) Authorizes a CNM to furnish or order drugs or devices, including Schedule II-V controlled substances, pursuant to physician supervision, standardized procedures and protocols, and other conditions, as specified. (BPC § 2746.51)

10) Prohibits a physician from referring a person for laboratory, diagnostic nuclear medicine, radiation oncology, physical therapy, physical rehabilitation, psychometric testing, home infusion therapy, or diagnostic imaging goods or services if the physician or his or her immediate family has a financial interest with the person or in the entity that receives the referral. (BPC § 650.01)

This bill:

1) Prohibits CNMs from referring a person for laboratory, diagnostic nuclear medicine, radiation oncology, physical therapy, physical rehabilitation, psychometric testing, home infusion therapy, or diagnostic imaging goods or services if the CNM or his or her immediate family has a financial interest with the person or in the entity that receives the referral, and specifies that the BRN is responsible for disciplinary action should a violation occur.

2) Revises the participants on the BRN's committee on nurse midwives and requires the majority of committee members to be nurse midwives, and formally names the committee, the Nurse-Midwifery Advisory Committee.

3) Defines "consultation" to mean a request for the professional advice or opinion of a physician or another member of a health care team regarding a patient's care while maintaining primary management responsibility for the patient's care.

4) Defines "co-management" as the joint management by a CNM and a physician and surgeon of a patient who has become more medically, gynecologically, or obstetrically complicated.

5) Defines "referral" to mean the direction of a patient to a physician or healing arts licensee for management of a particular problem or aspect of the patient's care.

6) Defines "transfer" to mean the transfer of primary management responsibility of a patient's care from a CNM to another healing arts licensee or facility.

7) Deletes the requirement for supervision by a licensed physician as part of a certificate to practice midwifery.

8) Adds specified care guidelines to the practice of midwifery under a certificate to practice.

9) Requires a practicing CNM to emphasize informed consent, preventive care and early detection and referral of complications to physicians.

10) Deletes the current definition of what constitutes practice of nurse-midwifery and redefines the practice to include consultation, co-management, or referral as indicated by the health status of the patient and the resources and medical personnel available in the setting of care subject to the following:

    a) The certificate to practice nurse-midwifery authorizes the holder to work collaboratively with a physician to co-manage care for a patient with more complex health needs;

    b) The scope of comanagement may encompass the physical care of the patent, including birth, by the CNM, according to a mutually agreed upon plan of care with the physician;

    c) If the physician must assume a lead role in the care of the patient due to an increased risk status, the CNM may continue to participate in care, counseling, guidance, teaching and support, according to a mutually agreed upon plan.

    d) After a CNM refers a patient to a physician, the CNM may continue to care for the patient during a reasonable interval between the referral and the initial appointment with the physician;

    e) A patient must be transferred from the primary management responsibility of the CNM to that of a physician for the management of a problem or aspect of the patient's care that is outside the scope of CNM's education, training and experience; and,

    f) A patient that has been transferred from the primary management responsibility of a CNM may return to the care of the CNM after resolution of any problem that required the transfer, as specified,

11) Deletes the definition of "supervision" for purposes of practicing nurse-midwifery.

12) States that a certificate to practice nurse-midwifery authorizes the CNM to attend pregnancy and childbirth in an out-of-hospital setting if all of the following conditions apply:

    a) Neither a pre-existing maternal disease or condition, or disease arising from or during pregnancy creating higher than that of a low-risk pregnancy or birth based on current evidence and accepted practice are present;

    b) There is a singleton fetus;

c) There is cephalic presentation at the onset of labor;

d) The gestational age of the fetus is at least 37 completed weeks of pregnancy and less than 42 completed weeks at the onset of labor; and,

e) Labor is spontaneous or induced in an outpatient setting.

13) Prohibits a CNM from using vacuum or forceps, or performing any external cephalic version.

14) Requires a CNM to maintain clinical practice guidelines that delineate the parameters for consultation, comanagement, referral, and transfer of a patient's care.

15) Requires a CNM to document all consultations, referrals and transfers in the patient record.

16) Requires a CNM to refer all emergencies to a physician immediately.

17) Authorizes a CNM to provide emergency care until the assistance of a physician is obtained.

18) Authorizes a CNM to furnish or order drugs and devices when providing care in an out-of-hospital setting.

19) Deletes the requirement that a CNM's protocol for furnishing drugs or devices contain the extent of the physician supervision.

20) Deletes the requirement that the furnishing and ordering of drugs or devices be done under the supervision of a physician, as specified.

21) Authorizes a CNM to directly procure supplies and devices, obtain and administer diagnostic tests, order laboratory and diagnostic testing, and receive reports that are necessary to their practice as a CNM within their scope of practice.

22) Deletes the current requirements for a CNM to perform episiotomies and repair first and second degree lacerations, and allows CNM to perform and repair episiotomies, and to repair first and second degree lacerations of the perineum without physician supervision.

23) Requires a CNM to provide a disclosure orally and in written form to a prospective patient as part of the patient care plan and obtain informed consent for all of the following when providing care in a setting outside of a hospital:

a) The patient is retaining a CNM and the CNM is not supervised by a physician;

b) The CNM's licensure status, licensure number, and practice setting in which the CNM practices;

c) If the CNM does or does not have liability insurance;

d) There are conditions that are outside the of the scope of practice of a CNM, that will result in a referral for a consultation, or transfer of care to a physician;

e) The specific arrangements for the referral of complications to a physician for consultation;

f) The specific arrangements for the transfer of care during the prenatal period, the intrapartum and postpartum periods, as specified, and access to appropriate emergency medical services for mother and baby if necessary and recommendations for preregistration at a hospital that has obstetric emergency services and is most likely to receive the transfer;

g) If during the course of care, the patient is informed that the patient has or may have a condition indicating the need for a mandatory transfer, the CNM must indicate the transfer;

h) The availability of the text of laws regulating CNM practices and procedures, for reporting complaints to the BRN, which may be found on the BRN's internet website; and,

i) Consultation with a physician does not alone create a physician-patient relationship or any other relationship with the physician. That CNM is independently licensed and practicing midwifery and in that regard is solely responsible for the services the CNM provides.

24) Specifies that the disclosure and consent must be signed by both the patient and the CNM and a copy placed in the patient medical record;

25) Authorizes the Nurse-Midwifery Advisory Committee to recommend the form for the written disclosure and informed consent.

26) Makes findings and declarations related to maternity care in California, including racial disparities.

27) Makes other technical changes.

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

COMMENTS:

1. **Purpose.** This bill is sponsored by California Nurse-Midwives Association and the Black Women for Wellness Action Project. According to the Author, "The United States has some of the highest maternal and infant mortality in the industrialized world, and even though California has made great strides to reduce the rates, we still have rates of maternal and infant mortality and morbidity far higher than other countries that have similar wealth. These rates are even further exacerbated for black women, who are 3 to 4 times more likely to die from childbirth than white women and black babies who are 4 times more likely to die before their first

birthday. Evidence has pointed out that some of the factors that contribute to high rates of infant and maternal mortality are lack of access to timely, culturally sensitive early perinatal care perinatal, neonatal care. In addition, access to care in California is even more of a threat with studies showing that at least 9 counties have no OB/GYN at all and that large counties in Northern and Southern CA are projected to have critical shortages of maternity care providers by 2025."

2. **Background.**

Certified Nurse Midwives. CNMs 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 *normal* childbirth, as well as immediate care for the newborn, but only under the supervision of a licensed physician. A CNM may furnish drugs and devices after completing at least six months of physician supervised experience in the furnishing of drugs and devices and a course in pharmacology. "Furnishing" is the ordering of a drug or device in accordance with standardized procedure or protocol.

Protocols are a part of standardized procedures and are designed to describe the steps of medical care for given patient situations. Protocols are currently developed in consultation with a supervising physician, and CNMs are required to include the extent of that supervisions as part of those standardized procedures related to ordering or furnishing drugs or devices (BPC § 2746.51(A)(2)(B).

There are approximately 700 CNMs practicing in California. In 2017, it was reported that CNMs attended nearly 50,000 births across the state (out of the 470,000 births that occurred that year). Of those births by a CNM, 98% were done in a hospital setting. Although CNMs are also authorized to practice in birth centers and home-based settings, the majority provide client care in a hospital.

As currently drafted, this bill deletes the requirement that in order to practice midwifery, a CNM must be subject to physician supervision, and instead provides the CNM authority practice independently, in various settings, as long as the CNM maintains clinical practice guidelines that outline the appropriate action for consultation, comanagement, referral, and transfer of a patient's care when the patient's condition is beyond the CNM's training and experience.

This bill lays out the specific practice guidelines a CNM must utilize in the event a patient's condition is beyond their training and experience. This bill will allow CNMs to practice without supervision as long as the CNM works collaboratively with a physician in those cases that result in more complex healthcare needs for their patient. CNMs will be required to transfer care of a patient to a physician for the

management of a problem that is outside of the scope of the CNM's training, education, and expertise. This bill would allow a patient's primary care to be transferred back to the CNM in the event the medical problem which required the transfer was resolved. Further, this bill lays out the process by which a CNM would continue to co-manage, with the physician, the care of a patient with more complex needs. This bill requires CNMs to refer all emergencies to a physician immediately, but allow the CNM to provide emergency care until the assistance of a physician and surgeon is obtained. Although a CNM may need to refer a patient to a physician, the provisions of this bill allow for the CNM to maintain a relationship with the patient, as specified.

Related to the furnishing and ordering of drugs or devices, this bill would maintain the majority of the current requirements for establishing protocols and procedures for a CNM to order or furnish drugs, and a CNM would be authorized to procure supplies, devices, order diagnostic tests, and receive reports that are necessary for their practice.

Although CNMs are authorized to practice in home-settings, the majority of CNM practice is in a hospital setting. This bill would authorizes a CNM to attend pregnancy and childbirth in an out-of-hospital setting if specified conditions are met, including that the gestational age of the fetus is within a specified range.

BRN Committee. Per BPC 2746.2, the BRN is authorized, but not required, to appoint a committee of qualified physicians and nurses, including, but not limited to, obstetricians and nurse-midwives, to develop standards related to educational requirements, ratios of nurse-midwives to supervising physicians, and associated matters.

The BRN adopted regulations to require itself to appoint a committee. The committee is currently comprised of at least one CNM and one physician, at least one public member and may include such other members as deemed appropriate. As noted in the regulations, "the purpose of this committee is to advise the [BRN] on all matters pertaining to nurse-midwifery as established by the board, and, if necessary, to assist the board or its designated representatives in the evaluation of applications for nurse-midwifery certification." According to the BRN, the committee meets between 2-3 times annually.

This bill would maintain the existing authority for the BRN to appoint a committee, however, the Committee would formally be named the Nurse-Midwifery Advisory Committee and would not be mandated to focus on supervision or ratios as specified in current statute. While the committee would maintain a representation of physicians, including family physicians, the committee membership would be mandated to be a majority CNMs.

Supervision. Standardized procedures are developed collaboratively by nurses, physicians, and the administration of an organized health care system. The BRN and the Medical Board of California have jointly promulgated guidelines for standardized procedures (CCR, tit. 16, § 1474). They are 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 is required for CNMs to provide patient care, that supervision does not require the physical presence of a physician. Meaning, a CNM can work miles away from the actual location of the physician, and as long as the standardized procedures are in place, the CNM may deliver babies and provide other authorized practices by a CNM.

CNMs are authorized to prescribe under protocols, however, a physician must be available via a telephone at the time of a patient's visit and physicians are limited to supervising no more than 4 CNMs at a time. While this bill would maintain the development of procedures between a CNM and a physician, the prescribing authority is no longer dependent upon a physician' supervision.

Other States. Although CNMs are practicing in all 50 states, their practice authority varies. California is one of only four states that requires physician supervision. The other three are Nebraska, Florida, and North Carolina. In 19 other states, CNMs are required to have some form of a collaboration agreement, and 27 states allow for independent practice.

Licensed Midwives. California has two regulated professionals who provide midwifery services, CNMs and Licensed Midwives (LMs). A LM is an individual who has been issued a license to practice midwifery by the Medical Board of California (MBC) under the LM Act. LMs who have achieved the required educational and clinical experience in midwifery (including completing a three-year postsecondary education program in an accredited midwifery school approved by the MBC) or met the challenge requirements (obtaining credit by examination for previous education and clinical experience –this option is no longer available as of January 1, 2015), must pass the North American Registry of Midwives' comprehensive examination. After successful completion of this examination, prospective applicants are designated as a "certified professional midwife" and are eligible to submit an application for license as an LM.

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. There are about 300 LMs in California.

MBC receives guidance on midwifery issues through a Midwifery Advisory Council (MAC). The MAC is made up of LMs (pursuant to BPC § 2509, at least half of the MAC members are LMs), a physician, and two non-physician public members.

AB 1308 (Bonilla, Chapter 665, Statutes of 2013) removed the statutory requirement for a LM to practice under the supervision of a physician and surgeon and instead specified that a midwife may assist in "normal" pregnancy and birth. MBC has been working for a number of years with stakeholders through the MAC and a specified task force in order to define "normal" in regulations, for purposes of clarifying births an LM can attend, as required under AB 1308. Until MBC adopts regulations, LMs are not able to be a "comprehensive perinatal provider" for

purposes of providing comprehensive perinatal services to Medi-Cal beneficiaries in the Comprehensive Perinatal Services Program (CPSP). (SB 407 (Morrell, Chapter 313, Statutes of 2015) authorized a health care provider to employ or contract with licensed midwives for the purpose of providing comprehensive perinatal services in the CPSP.)

3. **Studies and Access to Care.** On March 11, 2020, the Legislative Analyst's Office released *Analysis of California's Physician-Supervision Requirement for Certified Nurse Midwives*, which analyzed whether the current physician supervision requirement is meeting its intended safety and quality objectives, without significantly increasing cost or decreasing access to health care services. Ultimately, part of the findings of that report noted that California's supervision requirement is "unlikely to improve safety and quality for low-risk pregnancies and births".

   Notably, low-risk pregnancies are the focus of these recommendations, since these are the clients and births that CNMs attend under current law. CNMs do not deliver twins on their own, do not perform cesarean sections, do not use vacuums or forceps or other mechanical means to deliver a baby, and do not deliver babies that are significantly premature or significantly post-term. They are already required to refer patients to a physician when complications arise.

   The LAO report, based on an analysis of various studies, did "not find evidence that the safety and quality of maternal and infant health care by nurse midwives is inferior to that of physicians in cases of low risk pregnancies and births." The report also concludes that "states with physician supervision or collaboration agreement requirements do not have superior maternal and infant health outcomes than states without such requirements." It notes that since the supervision requirements in statute do not clearly define the responsibilities of supervision, "the state's requirement is unlikely to be more effective than other states' similar requirements. Therefore, we find that California's supervision requirement for nurse midwives is unlikely to improve safety and quality for low risk pregnancies and births." The report found "some evidence that access to nurse midwife services specifically, and women's health care services generally, might be limited in California. For example, the recent high growth in earnings for nurse midwives suggests that demand for their services may exceed supply. We also find evidence of geographic disparities across the state in access to care by OB GYNs."

   As noted in the report, it agrees with the Federal Trade Commission's finding that physician supervision requirements likely impede access and raise costs by giving physicians control over nurse midwives' ability to independently deliver services. They cite research on the national level showing that patients in states without occupational restrictions on nurse midwives, such as physician oversight, tend to have greater access to nurse midwife services.

   The report advises that "removing the state's physician supervision requirement could increase access to nurse midwife services, including in the rural and inland areas of the state that today have relatively more limited access to women's health care services. In addition, we find that removing the requirement could improve the cost effectiveness of women's health care services by increasing utilization of a less

costly but capable provider and potentially lowering the medically unnecessary use of certain costly procedures, such as cesareans."

LAO recommends removing the physician supervision requirement for CNMs, as it is "unlikely to be effective in achieving its objective of improving safety and quality." LAO further recommends adding other alternative safeguards to ensure safety and quality like requiring CNMs to:

- Have relationships with physicians and other providers that would allow certified nurse midwives to continue to consult with them and refer their clients to these providers as necessary.
- Practice as a part of a health system (generally defined as a hospital, provider group, or health plan).
- Practice in a licensed or accredited facility.
- Maintain medical malpractice insurance.
- Meet minimal clinical experience standards (such as a minimum number of years of practice) in order to practice without oversight.

The report focused on a number of issues to reach its conclusion. One factor noted in the analysis was the lack of definition of supervision in California state law, making the supervisory practice inconsistent across practitioners and settings. Additionally, the report noted that in states without physician supervision requirements, the population of practicing CNMs was higher. The report further noted that there could be a higher portion of women who seek services of a CNM, but may not be able to access that care as supervision has led to a potential limited number of providers in California. It is important to note that the report analysis highlighted the need for additional research in the area of safety in homebirths and birth centers by CNMs as those settings are not where the majority of the CNMs practice.

On October 19, 2019, the Healthforce Center at the University of California San Francisco released a report, *California's Midwives: How Scope of Practice Laws Impact Care*. That report was part of a series conducted by the center looking at various professions and related scope of practice laws. The study noted that to ensure that women's health care needs are met, national organizations recommend that the midwifery workforce increase and that midwives work within a system of care that fosters collaboration among licensed, independent providers. According to the report, "Recent research has found that states that required physician oversight of midwives between 2012 and 2016 had a lower concentration of midwives as compared with states that allowed autonomous practice; the research also found that counties in states with restrictive practice were less likely to have a midwife than counties in autonomous-practice states." According to research analyzed in the paper, "midwife care results in comparable or improved health outcomes for low- and moderate-risk mothers and infants compared with physician care. Additionally, the literature suggests that midwives help improve access to care

for underserved communities and can help achieve health care expenditure savings. The research also finds that restrictions on midwives' scope of practice may limit their supply and, consequently, the utilization of midwives."

4. **COVID-19 and the Health Care Crisis of 2020.** The World Health Organization has designated 2020, as the "year of the nurse and the midwife" and noted on its internet website that "Nurses and midwives play a vital role in providing health services…They are often, the first and only point of care in their communities. The world needs 9 million more nurses and midwives if it is to achieve universal health coverage by 2030."

   There have been numerous news headlines over the past few weeks that depict a surge in demand for the services of midwives, as concerns of pregnant women rise over hospital and patient safety, stay at home orders and concerns over capacity and supplies as a result of the recent pandemic. As more information and data is compiled related to the care and treatment of pregnant women during the pandemic, there will likely be additional future research necessary that will share how COVID-19 impacted hospital births, who treated these patients, and concerning outcomes from those births will likely be scrutinized in the future, along with the reality that the pandemic likely transformed maternal care.

5. **Current Related Legislation.** AB 890 (Wood) would authorizes a nurse practitioner (NP) to provide specified services, without physician supervision if the NP meets additional education, examination, and training requirements; establishes a new Advanced Practice Registered Nursing (APRN) Board to regulate independent NPs; and establishes regulatory requirements for independent practice. (Status: *This bill is currently pending in the Senate Committee on Rules.)*

6. **Prior Related Legislation.** 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 child birth attendance requirements for naturopathic doctors. *(*Status: *The bill was never heard in this committee).*

   SB 457 (Bates) of 2017 would have established a framework for out-of-hospital childbirths by repealing and revising and recasting provisions of the Licensed Midwifery Practice Act of 1993. Would have authorized physicians and surgeons, licensed midwives (LMs) CNMs to only attend cases of pregnancy and out-of-hospital childbirths according to certain circumstances. Provided that LMs can only attend out-of-hospital childbirths. Granted CNMs the authority to practice without physician and surgeon supervision only for out-of-hospital childbirths. Required reporting to the Office of Statewide Health Planning and Development from hospitals and licensees attending out-of-hospital childbirths. (Status: *The bill was never heard in this committee.*)

   AB 1612 (Burke) would have authorized a CNM to furnish and order drugs and devices related to care rendered in a home under standardized procedures and protocols; authorizes 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 his or her practice and consistent with

nurse-midwifery education preparation; authorizes 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; requires a CNM when performing those procedures, to ensure that all complications are referred to a physician and surgeon immediately. (Status: *This bill was held under submission in the Assembly Committee on Appropriations).*

SB 1306 (Burke) of 2016 removes certain physician supervision requirements for a CNM, increases educational requirements, modifies practice parameters, establishes a Nurse-Midwifery Advisory Committee within the Board of Registered Nursing (BRN), and subjects CNMs to the ban on the corporate practice of medicine, as specified, among other changes. (Status: *This bill failed passage on the Assembly Floor).*

SB 1308 (Bonilla, Chapter 665, Statutes of 2013) authorized a LM to directly obtain supplies and devices, obtain and administer drugs and diagnostic tests, order testing and receive reports that are necessary to his/her practice of midwifery and consistent with his/her scope of practice; expanded the disclosures required to be made by a midwife to a prospective client to include the specific procedures that warrant consultation with a physician and surgeon; and made other correcting and conforming changes.

SB 1950 (Figueroa, Chapter 1085, Statutes of 2002) required the MBC to adopt regulations defining the appropriate standard of care and level of supervision required for the practice of midwifery.

SB 1479 (Figueroa, Chapter 303, Statutes of 2000) expanded the disclosures required to be given by LMs and also required midwives to register birth certificates for home births.

SB 350 (Killea, Chapter 1280, Statutes of 1993) enacted the Licensed Midwifery Practice Act of 1993 to provide for the licensing and regulation of non-nurse and non-physician assistant midwives by the MBC.

7. **Arguments in Support.** Supporters note that California is one of only four states to still require physician supervision of CNMs. Supporters believe that the current physician supervision rule creates many barriers to care and note that, most significantly, this rule tethers CNMs geographically and economically to where obstetricians already practice. Supporters state that this worsens the maldistribution of maternal health care providers in areas where the most vulnerable populations already lack access to care, during a time when we have large disparities in birthing outcomes.

8. **Arguments in Opposition.** The California Medical Association and the American College of Obstetricians and Gynecologists are opposed to this bill, noting that, "SB 1237 would remove the requirement that a [CNM] practice under the supervision of a physician and surgeon and would instead authorize a [CNM] to attend cases of normal pregnancy and childbirth and to provide prenatal, intrapartum, and

postpartum care, including gynecologic and family-planning services, interconception care, and immediate care of the newborn."

The California Association of Licensed Midwives (CALM) states that "While CALM strongly supports the removal of physician supervision of nurse-midwifery care from California statute, we do not believe that the rights of birthing families should be the price exchanged for autonomous practice. Indeed, such language is drawn directly from California's licensed midwife statute, and our members see first-hand on a regular basis the damaging effects on patient care that arbitrary and non-evidence based barriers to access create."

9. **Proposed Author's Amendments**. Pursuant to continued discussions with interested parties, the Author has proposed amendments to make certain clarifying changes in the findings and declarations related to the practice of nurse midwifery, to make various minor and technical clarifications, and to specify that the Nurse-Midwifery Committee is to be comprised of at least 40 percent physician members, but still be authorized to meet if that 40 percent cannot be achieved. *The Committee composition is discussed below.*

10. **Policy Issues for Consideration**.

Outpatient Settings. As currently drafted, this bill would authorize a CNM to provide services, without physician supervision, to a patient in an out-of-hospital setting, as long certain conditions are met, including, that the labor is spontaneous or induced in an outpatient setting. However, what is considered an "outpatient setting" under this bill is unclear. While this language appears to be modeled after provisions in the LM Act, clarifications as to the setting included in this term could be beneficial. *As such, the Author should continue working with interested parties, committee staff, and agencies to ensure that "outpatient setting" reflects the various locations an individual may give birth and may be attended by a CNM.*

Furnishing or ordering of drugs and devices. As currently drafted, this bill would maintain that in order for a CNM to furnish or order drugs or devices, they would need to have collaboratively developed protocols with a physician. If this bill seeks to provide CNMs with independent practice authority, it is unclear why this level of supervision may still be necessary. Could this lead to unintended barriers for access to care? *The Author should continue to refine the requirements that are necessary to ensure patient safety and ensure appropriate furnishing of medications by a CNM.*

Disclosures. This bill was recently amended to require a CNM practicing in an out-of-hospital setting provide a voluminous disclosure document to a patient, in both oral and written form, and obtain informed consent prior to practice.

While disclosures can certainly be beneficial and informative for patients in determining their best care options, some of the proposed prescribed requirements may be more confusing than helpful, including providing patients information about "The arrangements for the referral of complications to a physician and surgeon for consultation, where the CNM shall not be required to identify a specific physician and surgeon." This appears to conflict with the provisions of this bill which require a

CNM's practice guidelines delineate the procedures for comanagement and referral of care.

Additionally, the authority for the Nurse-Midwifery Advisory Committee to recommend a standardized form for the disclosures could be complicated by the specificity of the required disclosure on "The specific arrangements for the transfer of care during the prenatal period, hospital transfer during the intrapartum and postpartum periods, and access to appropriate emergency medical services for mother and baby if necessary, and recommendations for preregistration at a hospital that has obstetric emergency services and is most likely to receive the transfer." It is not clear how this could be easily standardized, given that CNMs' physician recommendations and referrals may vary from CNM to CNM and by condition of a patient.

The new language also requires CNMs to obtain informed consent for all of the various disclosures required. There are various areas of the law providing definitions of informed consent, a requirement that carries legal significance and certainly goes beyond mere disclosure. For example:

- Judicial Council of California Civil Jury Instruction Number 532:

  "Informed Consent—Definition

  A patient's consent to a medical procedure must be "informed." A patient gives an "informed consent" only after the [insert type of medical practitioner] has adequately explained the proposed treatment or procedure.

  [A/An] [insert type of medical practitioner] must explain the likelihood of success and the risks of agreeing to a medical procedure in language that the patient can understand. [A/An] [insert type of medical practitioner] must give the patient as much information as [he/she] needs to make an informed decision, including any risk that a reasonable person would consider important in deciding to have the proposed treatment or procedure, and any other information skilled practitioners would disclose to the patient under the same or similar circumstances. The patient must be told about any risk of death or serious injury or significant potential complications that may occur if the procedure is performed. [A/An] [insert type of medical practitioner] is not required to explain minor risks that are not likely to occur." (1 CACI 532 (2019))

- From the Welfare and Institutions Code:

  "For purposes of this chapter, "written informed consent" means that a person knowingly and intelligently, without duress or coercion, clearly and explicitly manifests consent to the proposed therapy to the treating physician and in writing on the standard consent form prescribed in Section 5326.4." (Welfare and Institutions Code § 5326.5.)

- From the Health and Safety Code:

"As used in this chapter, "informed consent" means the authorization given pursuant to Section 24175 to have a medical experiment performed after each of the following conditions have been satisfied:
(a) The subject or subject's conservator or guardian, or other representative, as specified in Section 24175, is provided with a copy of the experimental subject's bill of rights, prior to consenting to participate in any medical experiment, containing all the information required by Section 24172, and the copy is signed and dated by the subject or the subject's conservator or guardian, or other representative, as specified in Section 24175.
(b) A written consent form is signed and dated by the subject or the subject's conservator or guardian, or other representative, as specified in Section 24175.
(c) The subject or subject's conservator or guardian, or other representative, as specified in Section 24175, is informed both verbally and within the written consent form, in nontechnical terms and in a language in which the subject or the subject's conservator or guardian, or other representative, as specified in Section 24175, is fluent, of the following facts of the proposed medical experiment, which might influence the decision to undergo the experiment, including, but not limited to:
(1) An explanation of the procedures to be followed in the medical experiment and any drug or device to be utilized, including the purposes of the procedures, drugs, or devices. If a placebo is to be administered or dispensed to a portion of the subjects involved in a medical experiment, all subjects of the experiment shall be informed of that fact; however, they need not be informed as to whether they will actually be administered or dispensed a placebo.
(2) A description of any attendant discomfort and risks to the subject reasonably to be expected.
(3) An explanation of any benefits to the subject reasonably to be expected, if applicable.
(4) A disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.
(5) An estimate of the expected recovery time of the subject after the experiment.
(6) An offer to answer any inquiries concerning the experiment or the procedures involved.
(7) An instruction to the subject that he or she is free to withdraw his or her prior consent to the medical experiment and discontinue participation in the medical experiment at any time, without prejudice to the subject.
(8) The name, institutional affiliation, if any, and address of the person or persons actually performing and primarily responsible for the conduct of the experiment.
(9) The name of the sponsor or funding source, if any, or manufacturer if the experiment involves a drug or device, and the organization, if any, under whose general aegis the experiment is being conducted.
(10) The name, address, and phone number of an impartial third party, not associated with the experiment, to whom the subject may address complaints about the experiment.

(11) The material financial stake or interest, if any, that the investigator or research institution has in the outcome of the medical experiment. For purposes of this section, "material" means ten thousand dollars ($10,000) or more in securities or other assets valued at the date of disclosure, or in relevant cumulative salary or other income, regardless of when it is earned or expected to be earned.
(d) The written consent form is signed and dated by any person other than the subject or the conservator or guardian, or other representative of the subject, as specified in Section 24175, who can attest that the requirements for informed consent to the medical experiment have been satisfied.
(e) Consent is voluntary and freely given by the human subject or the conservator or guardian, or other representative, as specified by Section 24175, without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence." (HSC § 24173.)

- The Medical Practice Act is fairly limited as to where informed consent is required, with primarily certain major procedures (breast implants, sterilization, breast cancer treatment, IVF and sperm/ova retrieval) establishing this threshold for a prescriber to obtain. Informed consent is also required prior to treating a patient with DMSO, a clear odorless liquid, a by-product of the paper making process, approved by the FDA to treat interstitial cystitis, a bladder health issue which has been the source of research for a number of years and may provide benefit to patients experiencing other medical conditions.

- Doctors of chiropractic are required to obtain written informed consent prior to initiating clinical care, a requirement established through regulations promulgated by the Board of Chiropractic Examiners, which is comprised of a majority of practitioners.

While prior efforts to provide independent practice authority to CNMs have required patients to be given certain specified information, the informed consent threshold has only previously been considered in one bill which was never heard in a Senate policy committee. Language noting that "the practice of nurse-midwifery care emphasizes informed consent" is consistent but the Author should provide information as to what informed consent means for practitioners and patients, and should continue working with stakeholders to determine the impacts of this requirement, including whether this conforms to current practice.

Committee composition and requirements proposed by the Author. As currently drafted, this bill allows a Nurse Midwifery Advisory Committee to be established and specifies that this body may include, but is not limited to, qualified nurses and qualified physicians and surgeons, including family physicians and others.

As noted in 9) above the Author proposes to require the Nurse Midwifery Advisory Committee membership to be 40 percent of physicians and surgeons. The proposed language would also permit this committee to "continue to make recommendations to the BRN if, the committee is unable, despite good faith efforts, to solicit and appoint committee members."

It would be helpful to understand the added patient value and ability for broad participation that the proposed composition allows for. An advisory body aimed at addressing CNM practice which includes almost a majority of physicians and surgeons, an entirely different profession, regulated by a separate practice act and licensing board, may prove to be a challenge in effectively carrying out its work, given that the existing committee has been hampered by an inability to have full physician membership. Further, while the 40% of threshold designates "physicians", it does not specify that any of those practitioners have specialty board recognition or experience in certain disciplines like family practice or obstetrics which could certainly enhance discussions about safe and proper maternal and fetal care. *The Author should continue working to evaluate the necessary expertise for the Nurse Midwifery Advisory Committee in order to effectively advise BRN on important CNM practice issues.*

SUPPORT AND OPPOSITION:

Support:

Black Women for Wellness (co-sponsor)
California Nurse Midwives Association (co-sponsor)
2020 Mom
Academy of Lactation Policy and Practice INC.
American Association of Birth Centers
American Civil Liberties Union/northern California/southern California/san Diego and Imperial Counties
American College of Nurse-midwives
Association of Women's Health and Neonatal Nursing
Beach Cities Midwifery & Women's Health Care
Best Start Birth Center
Black Wellness & Prosperity Center
Black Women for Wellness
California Association of Nurse Anesthetists (CANA)
California Black Women's Health Project
California Latinas for Reproductive Justice
California Nurse Midwives Association (CNMA)
California Women's Law Center
Center on Reproductive Rights and Justice (CRRJ)
Citizens for Choice
Every Neighborhood Partnership
Feminist Majority Foundation
Grow Midwives
Healthimpact
Healthy Children Project, INC.
If/when/how: Lawyering for Reproductive Justice
Midwives Alliance North America
Momsrising
Naral Pro-choice California
National Council of Jewish Women (NCJW) CA
National Council of Jewish Women Los Angeles

National Health Law Program
New Birth Services
Pacific Business Group on Health
The Praxis Project
Training in Early Abortion for Comprehensive Healthcare
United Nurses Associations of California/union of Health Care Professionals
Urge: Unite for Reproductive & Gender Equity
Western Center on Law & Poverty, INC.

Opposition:

American Congress of Obstetricians & Gynecologists - District Ix
California Association of Licensed Midwives
California Medical Association

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