MEDICAL BOARD OF CALIFORNIA
Licensing Program

MIDWIFERY ADVISORY COUNCIL

MEMBERS OF THE COUNCIL

Carrie Sparrevohn, L.M., Chair
James Byrne, M.D.
Karen Ehrlich, L.M.
Faith Gibson, L.M.
Monique Webster
Barbara Yaroslavsky

December 6, 2012

Medical Board of California
Hearing Room
2005 Evergreen Street
Sacramento, CA 95815
(916) 263-2382

Action may be taken on any item listed on the agenda.

While the Board intends to webcast this meeting, it may not be possible to webcast the entire open meeting due to limitations on resources.

AGENDA

1:00 p.m. – 4:00 p.m.
(or until conclusion of business)

ALL TIMES ARE APPROXIMATE AND SUBJECT TO CHANGE

1. Call to Order/Roll Call

2. Public Comment on Items not on the Agenda
   Note: The Council may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to decide whether to place the matter on the agenda of a future meeting. [Government Code sections 11125, 11125.7(a)]

3. Responsibilities of Council Members Under the Open Meeting Act– Ms. Dobbs

4. Approval of Minutes from the August 30, 2012 Meeting

5. Discussion of Possible Statute Revisions– Ms. Lowe
   A. Legislation to add Certified Nurse Midwives as Licensed Healthcare Providers who can Supervise Students

6. Program Update – Ms. Lowe

   A. Licensing Statistics
   B. Enforcement Statistics Report
   C. Licensed Midwife Annual Report Data Clarification
   D. Student Illegal Practice Letter
   E. Implementation of Continuing Education Audit

7. Update on Task Force for Midwifery Students/Midwife Assistants – Ms. Lowe

8. Update on Midwives Alliance of North America Task Force – Ms. Sparrevohn

9. Proposed Midwifery Advisory Council Meeting Dates for 2013– Ms. Lowe

10. Agenda Items for the First 2013 Midwifery Advisory Council Meeting – Sacramento

11. Adjournment

The mission of the Medical Board of California is to protect healthcare consumers through the proper licensing and regulation of physicians and surgeons and certain allied healthcare professions and through the vigorous, objective enforcement of the Medical Practice Act, and to promote access to quality medical care through the Board's licensing and regulatory functions.

NOTICE: The meeting is accessible to the physically disabled. A person who needs disability-related accommodation or modification in order to participate in the meeting may make a request by contacting Susan Morrish at (916) 263-2393 or sending a written request to that person at the Medical Board of California, 2005 Evergreen Street, Suite 1200, Sacramento, CA 95815. Providing your request at least five (5) business days before the meeting will help ensure availability of the requested accommodation.

Meetings of the Medical Board of California are open to the public except when specifically noticed otherwise in accordance with the Open Meeting Act. The audience will be given appropriate opportunities to comment on any issue presented in open session before the Board, but the Chair may apportion available time among those who wish to speak.

For additional information call (916) 263-2393.

MEDICAL BOARD OF CALIFORNIA
Licensing Operations

Midwifery Advisory Council
Hearing Room
2005 Evergreen Street
Sacramento, CA 95815

August 30, 2012
MINUTES

Agenda Item 1 Call to Order/Roll Call
The Midwifery Advisory Council (MAC) of the Medical Board of California (Board) was called to order by Chair Carrie Sparrevohn at 1:05 p.m. A quorum was present and notice had been sent to interested parties.

Members Present:
Carrie Sparrevohn, L.M., Chair
James Byrne, M.D.
Karen Ehrlich, L.M.
Faith Gibson, L.M.
Monique Webster
Barbara Yaroslavsky

Staff Present:
Diane Dobbs, Department of Consumer Affairs, Legal Counsel
Kurt Heppler, Staff Counsel
Natalie Lowe, Licensing Manager
Susan Morrish, Licensing Analyst
Anthony Salgado, Licensing Manager
Kathryn Taylor, Licensing Manager
Linda Whitney, Executive Director
Curt Worden, Chief of Licensing

Members of the Audience:
Jen Brown
Brooke Casey
Yvonne Choong, CMA
Laurie Gregg, M.D., ACOG
Joselyn Grole, CAM
Deanna Jesus, CAM
Tosi Marceline, LM
Diane Moher, MANA
Debra Newberry Puterbaugh, CAM
Constance Rock, LM, CAM
Shannon Smith-Crowley

Linda Walsh, CNM
(The above list identifies attendees who signed the meeting sign-in sheet.)

Agenda Item 2 Public Comment on Items not on the Agenda
No public comment was provided.

Agenda Item 3 Approval of the Minutes from the March 29, 2012 Meeting
Ms. Sparrevohn made a motion to accept the minutes from the March 29, 2012 meeting; s/Yaroslavsky; motion carried.

Agenda Item 4: Consideration of Revised Regulations; Possible Recommendation to Full Board

A. 1379.23 - Physician Supervision Requirement

Ms. Lowe provided information on the recommendations for two proposed midwifery regulations:

- 1379.23 - Physician Supervision Requirement
- 1379.24 - Practice of Midwifery; Drugs and Devices

The revised proposals were based on recommendations made by members of the public and the midwifery community during the March 29, 2012 "Interested Parties" workshop.

The Physician Supervision Requirement was the first regulation discussed. Ms. Lowe identified Business and Professions Code 2507 (f) which requires the Board to adopt regulations defining the appropriate standard of care and level of supervision required in the practice of midwifery; pointing out that since 2006, three regulatory attempts for a consensus on the supervision requirement have failed.

The proposed section 1379.23 of the California Code of Regulations sets forth a collaborative approach to the issue of physician supervision provided that the licensee establishes a collaborative relationship with a physician who has agreed to provide guidance and instruction within specific circumstances. The proposed regulation also ensures that a business relationship is not created between the physician and licensed midwife solely by consulting with or accepting a referral from the licensed midwife. Ms. Lowe requested that the following language be approved by the MAC and recommended to the Full Board to set for hearing:

1379.23 Physician Supervision Requirement.

(a) The requirement for physician supervision contained in Section 2507 of the Code is deemed to have been met if the licensed midwife has established a collaborative relationship with one or more physicians, who meet the requirements of section 1379.22, for the purpose of providing guidance and instructions regarding the care of women and/or newborns or consulting with the licensed midwife after the care of a patient has been transferred to the physician.

(b) A physician and surgeon shall not be deemed to have established a business relationship or relationship of agency, employment, partnership, or joint venture with a licensed midwife solely by consulting with or accepting a referral from the licensed midwife.

NOTE: Authority cited: Sections 2018 and 2507 (f), Business and Professions Code.

Reference: Section 2507, Business and Professions Code.

Ms. Yaroslavsky asked for a motion to approve the language to present to the Full Board; s/Gibson.

Ms. Sparrevohn asked for committee input on the issue. Ms. Ehrlich had concerns that the proposed language does not provide a definition for physician collaboration when risk factors are an issue. Ms. Ehrlich asked Ms. Dobbs if the absence of a specific definition would leave midwives unable to function independently during cases of normalcy.

Ms. Dobbs answered that, in general, very minute details should be left out of regulations because such details make it difficult to accomplish the main goals.

Dr. Byrne expressed concern that the current language does not define low risk versus high risk and still leaves a requirement for a supervisory relationship. He believes the language is simply changing the relationship from supervisory to collaborative and does not provide for a truly independent practice. Ms. Dobbs disagreed stating that she does not see the proposed regulation language changing the scope of practice for midwives. Ms. Yaroslavsky also had concern that it would be better to leave the assumptions ambiguous, otherwise the regulation would have limitations in what the Council was trying to achieve. Ms. Sparrevohn agreed that the language was specific enough and that it was not going to change how licensed midwives practiced in California.

Dr. Byrne stated that from a risk management standpoint, he has seen plaintiff's attorneys try to draw a relationship where even a midwife's phone call to a doctor can bring both parties into a lawsuit regardless of status. He mentioned in statutes for certified nurse midwives (CNM), the term "supervision" is clear in what it means.

Ms. Sparrevohn stated that, because no one from the insurance industry attended the Interested Parties meeting, input from them was not provided on the proposed regulation language.

Ms. Dobbs asked Council Members to keep in mind that the regulatory language was a suggestion, and she stated interested parties could participate in the regulatory process and make recommendations for any language that is not clear. Ms. Yaroslavsky asked Ms. Dobbs if she was suggesting the Council should move forward with the recommendation and see what takes place during the Public Hearings. Ms. Dobbs responded affirmatively, stating that there would be plenty of opportunity to fine tune the language.

Ms. Sparrevohn asked if there were any additional comments from Council members. Seeing none, she asked for public comment.

Mr. Cuny identified himself as the Director of California Citizens for Health Freedom. He mentioned his organization has followed the issue of physician supervision for about 15 years, and he claims physician supervision has been a problem for the public, midwives, doctors, and the Board. He suggested the Board should sponsor legislation that might resolve the existing problems for all involved parties.

Yvonne Choong with the California Medical Association (CMA) expressed concern that the proposed regulation fails to define and establish what a collaborative relationship is. Ms. Choong believes more definition is needed by identifying what is low risk and what is high risk for physicians and insurance carriers.

Ms. Choong asked for clarification in the following areas: when care has been transferred to the physician; and, what informed consent is provided to the patient that addresses the nature of the relationship between physician and licensed midwife.

Ms. Sparrevhohn invited Dr. Gregg from the American College of Obstetricians and Gynecologists (ACOG) to speak. Dr. Gregg introduced Ms. Smith-Crowley as a lobbyist for ACOG and herself as Chairperson for District 9 in California. Dr. Gregg expressed concern that the word "collaboration" was too vague. She attended the March 29, 2012 Interested Parties meeting and mentioned that former MAC member, Dr. Haskins, provided written comments to the Board on the Physician Supervision regulation. She felt the staff tried to incorporate what was suggested in the proposed regulation, but she believes the language could be better articulated. She suggested working on the language during the current meeting and to send the proposal forward to the Board.

Dr. Gregg identified issues that she would like defined/incorporated into the regulation: informed consent; if physician supervision is removed, she recommends home births are limited to low risk pregnancies as defined by the "World Health Organization"; and, to change "Collaboration" to "midwifery directed physician consultation."

She believes the client needs to know: the training and education of the licensed midwife; the midwife is not a nurse midwife or a physician; there is no physician supervision; a Transfer Plan is in place and it outlines what the transfer plan consists of; whether or not the midwife carries liability insurance; and, additional information on the grievance process.

Dr. Gregg stated that based on home births that work well in other states, it is safer for the consumer if home births are limited to low risk births. She offered the following suggestions pertaining to transporting the mother to the hospital when necessary: the midwife engages the physician when she feels it is needed; physician consultation is done on a face-to-face basis and continues with the California standard of non-vicarious liability; the physicians are not held responsible for situations that occur at the home and outside of their presence; and, the physician assumes responsibility once the client/patient is transferred to the hospital and engages with the physician.

Dr. Gregg believes the wording of the proposed regulation does not reduce the liability concerns for doctors but could potentially make it worse. Ms. Smith-Crowley interjected by specifying that there are two separate issues, ACOG issues and liability issues.

From the standpoint of ACOG and the liability insurance carriers, Ms. Smith-Crowley recommended to stay within the standard of care by having a consultative relationship. She has not found anything that says a physician cannot supervise or consult, collaborate or have back up, and she does not believe removing physician supervision from the regulation is going to be in the best interest of the woman or baby. Based on what the statute currently states, Ms. Smith-

Crowley suggested incorporating Dr. Gregg's recommendations. She recommended putting the regulation in place for now and then work on revising the legislation later.

Ms. Yaroslavsky asked Council Members, "Does having the additional information within the specific language of the regulation resolve the issue?" Ms. Ehrlich stated that it would be redundant because midwives are required to have a Transfer Plan and are required to inform the client whether or not they carry malpractice insurance. She suggested a legislative fix should occur to strengthen the regulation.

Ms. Yaroslavsky countered by stating if the information was already in law or statute, it would not be redundant to have everything identified in one regulation. Ms. Sparrevohn suggested the language should require midwives to provide clients with informed consent documentation and a reference to the Standard of Care for California Licensed Midwives.

Dr. Gregg agreed that the additional language would better define the collaborative relationship between physician and licensed midwife. She suggested taking wording from national documentation, and she referenced a collaborative statement that is currently in place with certified nurse midwives who have standardized training. Due to the differences in how licensed midwives are trained, doctors are somewhat cautious about involving themselves. Physician protocol is to consult or seek assistance with a higher specialist when medical issues outside his/her scope. Physicians may touch base immediately with a specialist by phone but then would send the patient to have a face-to-face consult to get a better impression of what is going on. She recommended a midwife directed consultative process where the physician and the client/patient see each other face-to-face and then, if necessary, when the patient is transferred.

Dr. Byrne felt integrating the language from with the World Health Organization criteria would be very helpful. Regarding current regulations, he said there are midwives who want to practice clinically in a safe manner but are having a hard time finding physician supervisors. Physicians often are not willing to be supervisors because they do not want to be involved with clinical problems that could have been avoided with earlier contact or be drawn into litigation issues.

Dr. Byrne suggested that the regulatory changes should not be a one sided relationship where midwives are in agreement and the regulations would not change the paradigm for the doctors. Dr. Gregg agreed with this statement.

Ms. Ehrlich asked Dr. Gregg if midwifery-directed consultation would involve every client under the care of a midwife. Dr. Gregg responded no. Dr. Gregg indicated that the requirements vary from state to state. Dr. Gregg believes that if a woman chooses home birth, the hope would be that it is done with adequate education and informed consent and that the physicians are available should the midwife need them.

Ms. Ehrlich reiterated that "informed consent" was currently included in the laws and regulations, pointing out that the language identifying "moderate risk" was removed. Ms. Ehrlich stated that pregnancies are not just low risk and high risk; she argued that women in the moderate risk category have a right to determine their own care in the setting of their choice. Dr. Gregg mentioned that home births for multiples, breeches, and vaginal births after cesarean are legal in California, although ACOG continues to disagree with that.

Ms. Ehrlich stated that full informed consent is the centerpiece for midwifery. Ms. Sparrevohn added that the Standards of Care for Licensed Midwives were passed well after midwives knew they did not have physician supervision and that supervision will be defined in many different ways.

Ms. Gibson stated that at one time a document had been produced by the Board that defined all circumstances that fell under the supervision requirement. She asked Dr. Gregg to provide a definition for physician supervision and to define language used within states that do not require physician supervision.

Dr. Gregg stated that the word "supervision" was less than ideal because she thought what was being discussed was not truly supervision and did not describe the situation. She stated that a minority of states have a mandate where a client choosing home birth must consult with a doctor. She offered to provide language utilized in other states, but did not currently have the information. She added that the practice of midwifery has evolved in the last 20 years and other entities may have been involved when physician supervision was placed in the law. Dr. Byrne said that it is a challenge to compare all states because some states do not allow licensed midwifery.

Ms. Webster expressed interest in removing barriers to care and addressing liability issues. She asked if there had been feedback from the insurance companies. Ms. Sparrevohn responded that they had been invited to the Interested Parties Workshop but did not attend.

Ms. Sparrevohn invited Ms. Holtzer to speak on this topic. Ms. Holtzer introduced herself as a midwife and stated that she liked the language in the current draft, even though it wasn't perfect. In her opinion, it reflected what was actually happening with midwives who have collaborative relationships with physicians. She stated that there were physicians across California who do collaborate with midwives but are not able to supervise. She was in agreement with the suggestions Dr. Gregg recommended, but did not see how defining the word "collaborate" would work. She asked how many midwives have collaboration, based on the Office of Statewide Planning and Development, (OSHPD) statistics. Ms. Ehrlich provided the following data:

- Clients served while the licensed midwife had supervision in 2011: 6.5%
- Clients who received collaborative care: 58.2%

Ms. Holtzer pointed out the statistics reflect more than half of the midwives received collaborative care, and she stated that defining collaboration would backfire on the midwives. Ms. Holtzer was interested in knowing what the physicians collaborating with midwives thought about the regulation and asked if ACOG knew whether the physicians wanted a more defined relationship, or if they were content in collaborating with the midwives.

Dr. Byrne stated that a lot of the work he performs is directed at improving health care systems and dual care for individual women. He pointed out that the self-reported "collaboration" at 60% is great, but he questioned whether the persons identified as the "collaborators" knew they were the collaborator.

Ms. Grote identified herself as a licensed midwife in Santa Cruz County and stated that most midwives in California collaborate with a doctor who is on call, "in house" at the time of need. She claims many midwives have informal relationships with doctors they can call for non-

emergent consultation.

Ms. Grote questioned what would happen if a midwife could not find a doctor in her community to collaborate with. She questioned, "What would happen if a doctor did not want to provide consultation for the 20 midwives in his/her city?" Ms. Sparrevohn mentioned implementing the regulation would provide a more fluid process. If it didn't, the next step would be to amend the law.

Ms. Grote asked if the regulation would provide further definition in identifying the consulting doctor and what the consultation was about via the charting process. Ms. Sparrevohn explained that the regulation did not specify how a midwife should document the information but she said the consultation process may be negotiated differently between the midwife and each physician.

Ms. Grote asked if there was any value in having a regulatory stipulation for the midwife if she was unable to find a collaborating doctor. Ms. Sparrevohn acknowledged that there are places where there are no collaborating physicians, but she said it is unclear whether having a collaborative relationship would make the situation easier or harder until it was tried.

Ms. Marceline identified herself as a midwife and commented that in her practice they see approximately 60-65 women per year and their collaborative efforts are through Kaiser. Ms. Marceline includes in their OSHPD statistics related to physician supervision, clients who transfer (to her practice) because the physician chooses not to be involved if the client is planning a home birth.

Dr. Gregg stated that there are physicians who collaborate with midwives "underground" and do so at their own peril. She further stated she would be willing to collaborate with midwives if the regulation was better defined. She felt that more physicians would "step up to the plate" if they would not be put at risk and the "collaborative relationship" between physician and licensed midwife was better defined.

Ms. Ehrlich asked for Dr. Gregg's assistance in revising the drafted physician supervision language. Dr. Gregg defined collaboration as "midwife directed physician consultation." Dr. Gregg's opinion is physicians are covered under liability carriers if they have face-to-face interaction with a patient. If physicians perform an exam and provides an opinion, they are covered. Physicians do not have liability coverage when they provide advice to a midwife over the phone. If anything happened during a pregnancy, the assumption is, the client would bring suit against the physician because that is generally the person who has liability coverage.

Ms. Sparrevohn mentioned that in the physician's office where she works, a high risk client would be referred to a perinatologist for consultation. She further added that by defining the collaborative relationship as a "midwife directed doctor consultation," the physicians may be more on board. Dr. Gregg mentioned that they often see documentation in the chart referencing whether a relationship is ongoing or if it is a one-time consultation. Ms. Ehrlich stated that she would like language in the regulation to make clear that there would be no physician liability until transfer of care.

Mr. Heppler advised that when the Board and all of its Committees practice these types of

exercises for licensing or for disciplinary functions, it does so with consumer protection being paramount. In Mr. Heppler's opinion, when the Board disciplines a licensee or denies a license, it does so with the purpose to protect the public. He further stated the Board does not deal in civil litigation, as it is not the Board's duty to award monetary damages. It is not within the arena of the Board to determine or discuss civil litigation and the avoidance of civil litigation. Mr. Heppler asked the MAC to be clear in that trying to shield or promote exposure to legal liability is not the Board's role. The Board deals in administrative discipline and in public protection.

Ms. Sparrevohn asked Dr. Gregg if no change was made to the proposed physician supervision language, could the midwife and the physician define what collaboration is? She stated ACOG and the liability insurance carriers could identify what would or would not be covered. Dr. Gregg said she believed physicians would be more willing to collaborate if there were standardized procedures instead of the midwife defining the relationship. It comes down to engaging the physicians in this process.

Ms. Smith-Crowley provided information concerning physician costs associated with having to defend himself/herself in a court case. Oftentimes insurance carriers try to prove that it is a collaborative relationship so they do not have to defend the suit. She recommended adding language identifying limited responsibility to the physician would be helpful.

Ms. Sparrevohn asked for legal counsel's opinion as to whether the draft language could be changed from collaborative to midwife-directed consultation. In response, Ms. Dobbs stated that a motion was on the floor and if Ms. Sparrevohn was considering changing the regulatory language, a request should be made to send the draft back to staff and to have them continue to work on the language.

A question was asked whether the revisions could be made at the time the regulation went to a Hearing.

Mr. Heppler provided a brief overview of the regulatory process. He indicated the MAC would need to bring the recommended language to the Board for approval. The Board would then deliberate on the matter and determine whether it accepts the MAC's recommendation and if so would set the matter for a Hearing.

If the matter was set for a Hearing, there would be a 45 day comment period for the Board to accept written comments. At the Regulatory Hearing, the Board would again accept both oral and written comments. If the Board decided to proceed, all comments would be addressed by the Board. It could take an additional 45 or 50 days if further steps were required due to revisions being made.

Ms. Rock identified herself with the California Association of Midwives (CAM). She suggested midwives who are currently collaborating with physicians be surveyed to find out which of the two drafts of language was preferable from the doctor's viewpoint. Ms. Sparrevohn asked CAM if they could do this and Ms. Rock agreed.

Ms. Sparrevohn asked if there were any more comments from the Council. Mr. Heppler asked if the Council was asking for a motion. He outlined three available options: to forge ahead with the regulation as is, understanding that it may be revised; send it back for revisions; or, amend it now.

Mr. Heppler confirmed that the draft could be amended at the current time. She stated that the pitfall in amending the draft language without additional input from the medical community is that there could be additional change recommendations down the road. Ms. Sparrevohn recommended submitting the original draft proposal to the full Board in October and did not see value in changing the wording of the regulation at the time.

Ms. Yaroslavsky stated that she had made the motion and would prefer to have additional input from other people. In order to move the process forward, she was not willing to pull the motion. She recommended that in the essence of time, it would be better to work out the verbiage at the time rather than waiting. She asked legal staff if there would be any opportunity prior to October to tighten up the draft language since it appeared there wasn't complete agreement from members and ACOG.

In order to consider new language, Ms. Yaroslavsky pulled the original motion to accept the revised language and made a new motion to consider new language; Ms. Gibson who had seconded the motion agreed.

Ms. Ehrlich recommended to move forward with Dr. Gregg's suggestions as they had enough specific information.

Dr. Gregg summarized ACOG's recommendations: midwives should direct the consultation when necessary, and consultation should be face-to-face between physician and patient. In each case, consultation would not be mandated, but performed when the midwife deems it necessary.

Ms. Erhlich preferred the verbiage "medical indication" rather than "necessary" as she claims the word necessary sounds like "high risk." Mr. Heppler questioned whether it would be up to the discretion of the midwife to decide what the medical indications or conditions were to initiate the physician consultation. Council members responded yes.

Additional discussion ensued to edit and enhance the regulatory language.

Dr. Byrne clarified that if it is a consultation, the patient-physician relationship is established with face-to-face contact. By utilizing that language, in a supervisory role or in a hospital-health care system, sending a patient or wanting to send patients (even if they don't show) puts the responsibility on the physician to track them down.

Dr. Gregg recommended from the physician's perspective that section (b) should be restated. She used Utah as an example; there is no liability until there is a face-to-face consult. She was under the impression that the Council was trying to distinguish between face-to-face consultation and midwife/physician consultation, whereas the midwife continues to be the primary care provider until full transfer of care. She said they are relying on the physicians to document this information in their charts.

Ms. Sparrevohn recommended leaving section (b) as is, since the face-to-face takes place prior to the possibility of the patient being transferred. She read section (a) again, "The requirement for physician supervision contained in 2507 of the code is deemed to have been met if the licensed midwife establishes a midwife directed physician/patient consultation for medical indication."

Ms. Ehrlich interjected that the physician must meet the requirements of section 1399.72.

Ms. Sparrevohn requested public comment.

Mr. Zacherman stated that his understanding of the first part of the originally proposed regulatory language implies that the midwife would send all midwifery clients to a physician. Ms. Sparrevohn clarified that legal staff does not read the regulation in that way and they do not want to direct midwives to have a collaborative relationship with a physician for every client.

Ms. Grote questioned if there was liability protection for the doctor who provides advice over the phone to a midwife with a moderate risk client. Ms. Sparrevohn clarified that the physician is not responsible until care has been transferred from the midwife. Based on comments made by Dr. Gregg and Ms. Smith-Crowley, Ms. Sparrevohn suggested that there probably should not be a phone relationship if the physician intends to be protected. In medical settings, clarification is generally provided in writing.

Ms. Sparrevohn requested a 10 minute recess while staff typed up the edited language. The following draft regulation to Section 1379.23 in Article 3.5 in Chapter 4 of Division 13, Title 16 of the California Code of Regulations was presented. ***Council Members voted to approve the language and present to the Board at the October meeting.***

1379.23 Physician Supervision Requirement.

(a) The requirement for physician supervision contained in Section 2507 of the Code is deemed to have been met if the licensed midwife establishes a midwife-directed physician- patient consultation for medical indication. The physician must meet the requirements of Section 1379.22.

(b) A physician and surgeon shall not be deemed to have established a business relationship or relationship of agency, employment, partnership, or joint venture with a licensed midwife solely by consulting with or accepting a referral from the licensed midwife.

NOTE: Authority cited: Section 2018 and 2507(f), Business and Professions Code. Reference: Section 2507, Business and Professions Code.

B. 1379.24 - Practice of Midwifery

Council Members were asked to refer to page 14 of their packets concerning the Practice of Midwifery, proposed regulation 1379.24 of the California Code of Regulations. Ms. Lowe stated that current regulations outline the requirement for midwifery education programs. The education program must prepare the midwife for the management of a normal pregnancy, labor, and delivery. Midwives often face difficulty in securing supplies, such as oxygen, anesthetics, and oxytocics in order to practice safely and effectively.

Ms. Lowe provided a brief history concerning the regulation stating that at the December 2011 MAC meeting, legal counsel presented language for the proposed regulation. The MAC members approved the proposed language with minor edits. At the March 29, 2012 Interested Parties Workshop, recommendations were made to remove language pertaining to diaphragms and cervical caps and requested adding, "family planning care" instead. Ms. Lowe requested the

following language be approved by the MAC and recommended to the Full Board to set for Hearing:

1379.24. Practice of Midwifery

A licensed midwife shall have the authority, limited to the practice of midwifery as defined in section 2507 of the Code, to obtain and administer drugs, immunizing agents, diagnostic tests and devices, and to order laboratory tests. This authority includes, but is not limited to, obtaining and administering intravenous fluids, analgesics, postpartum oxytocics, RhoGAM, local anesthesia, oxygen, local infiltration, vitamin K, eye prophylaxis, and family-planning care.

NOTE: Authority cited: Section 2018, Business and Professions Code.
Reference: Section 2507, Business and Professions Code, and Title 16 California Code of Regulations 1379.30.

Ms. Ehrlich made a motion to recommend to the Board that the revised language be set for Hearing; s/Gibson.

Ms. Sparrevohn asked for input from the Council.

Ms. Ehrlich suggested that instead of stating postpartum oxytocics, it would be better stated as "post antihemmoragics" and to eliminate either local anesthesia and local infiltration as they mean the same thing.

Ms. Sparrevohn recommended eliminating local anesthesia from the regulation. Ms. Gibson clarified that local anesthesia is used to do infiltration.

Dr. Byrne questioned the phrase, "family planning care" stating that with so many options considered invasive, he was concerned the current language was overly broad as it could imply IUD insertions, sub dermal implants, and tubal obstruction. Ms. Sparrevohn referred to the Midwives Standard of Care that allows a midwife to add skills to her practice if she has appropriate physician backup. She indicated the midwife is able to perform an IUD insertion with a physician available, while working in a clinical setting and feels that having a physician as backup should be adequate to allow a midwife to do this. Dr. Byrne agreed, but questioned whether that should be extended to sub-dermal implants and other invasive procedures since such procedures have evolved over the last ten years.

Ms. Yaroslavsky asked if there should be more definition by outlining the scope of the appropriate level of training and the appropriate level of back up.

Ms. Dobbs recommended adding "subject to appropriate training and skill level."

Ms. Sparrevohn suggested referencing the Midwifery Standard of Care Sections (1)(J) in the family planning care.

Ms. Dobbs voiced concern over the current verbiage which seemed to suggest midwives are allowed to write prescriptions, even though it does not specifically say prescription. Ms. Ehrlich stated that midwives were authorized to obtain and administer only the specific drugs, devices and diagnostics outlined in the regulation and that midwives usually obtain supplies through supply houses or occasionally from a pharmacy, hospital, or physician. She said midwives were authorized to utilize the items identified in regulation. Ms. Dobbs suggested replacing the word "obtain" with "utilize."

Ms. Sparrevohn identified the big issue is how midwives obtain supplies. Ms. Yaroslavsky questioned whether the issue of not being able to obtain supplies caused the regulation to be written in the first place. Ms. Gibson acknowledged that it was. Ms. Yaroslavsky clarified that midwives can receive the supplies needed to do their job. She agreed that the word "obtain" should be changed.

Mr. Heppler reminded attendees the purpose of the regulation was to reconcile the educational requirements, regulatory practice requirements, and some of the statutes involving midwifery training. He conveyed issues in the pharmacy law that did not identify licensed midwives having the authority to issue prescriptions. The regulation states, "If a prescription is something that is either signed or issued by a physician, a dentist, an optometrist, a podiatrist, a veterinarian, a naturopathic doctor, a PA, nurse practitioner or a certified nurse midwife." Mr. Heppler stated that there were practical limitations per section 4040 of the Business and Professions Code, and based on the pharmacy code, midwives may not be able to acquire supplies through these means. He recommended moving ahead with the midwifery regulation. The issue comes down to whether the pharmacist could fill it or elect not to fill it. Ms. Ehrlich confirmed that midwives do have the ability to get supplies through supply houses because other states have formularies to assist practitioners.

Ms. Sparrevohn listed supplies that are prescription driven and are a problem to obtain: RhoGAM, litacaine, vitamin K, profolaxics, and oxytocics. She asked if all of these supply houses were in compliance with the law or not. She recommended looking into fixing this problem for midwives. Ms. Ehrlich acknowledged that ultimately statutory changes needed to be made; however, she recommended moving ahead with the proposed language at this time.

Ms. Yaroslavsky asked if utilizing the word "furnish" would be a better definition since the supplies are not furnished by a pharmacy. She also recommended removing the word "drug" since the term is associated with pharmacology. Ms. Sparrevohn suggested the revised language should state, "to obtain and administer," and recommended the following changes: remove the word "drug"; change oxytocics to "anti-hemorrhagics"; remove local infiltration; and, end the paragraph with "family planning care in accordance with (1)(J) of the Standard of Care for Licensed Midwives".

Ms. Sparrevohn asked for public comment on the regulation. No comments were provided.

As the maker of the motion and the second of the motion Ms. Ehrlich and Ms. Gibson accepted the revised language. ***Council Members voted to approve the language and present it to the Board at the October meeting.***

1379.24. Practice of Midwifery

A licensed midwife shall have the authority, limited to the practice of midwifery as defined in section 2507 of the Code, to obtain and administer immunizing agents, diagnostic tests and devices, and to order laboratory tests. This authority includes, but is not limited to, obtaining and administering intravenous fluids, analgesics, postpartum anti-hemorrhagics, RhoGAM, local anesthesia, oxygen, vitamin K, eye prophylaxis, and family-planning care in accordance with section (1)(J) of the Standard of Care for Licensed Midwives.

NOTE: Authority cited: Section 2018, Business and Professions Code.
Reference: Section 2507, Business and Professions Code, and Title 16 California Code of Regulations1379.30.

Agenda Item 5: Midwifery Program Update

A. Licensing Statistics

Ms. Morrish provided an update on the fourth quarter statistics for fiscal year 2011/2012 indicating that there were nine licenses issued, 37 licenses renewed, and zero applications pending.

B. 2011 Licensed Midwife Annual Report

Ms. Morrish provided an update on the 2011 Licensed Midwife Annual Report stating that as of June 30, 2012 there were 267 midwives with current/renewed status and 30 with delinquent status. Those in delinquent status did not include canceled, surrendered or revoked licenses. Of the 283 midwives that were expected to report, 241 submitted statistics to the Office of Statewide Health Planning and Development (OSHPD). There were 42 midwives who did not file a report. The Board sent out deficiency letters to remind midwives that the Licensed Midwife Annual Report (LMAR) was past due.

Ms. Morrish indicated that the Board hosted the North American Registry of Midwifes (NARM) exam on August 15, 2012 in which nine individuals sat for the exam. Ms. Morrish informed the Council that the next exam was scheduled for February 15, 2013.

C. Enforcement Statistics Report

Ms. Morrish provided an update on the enforcement statistics stating that there were a total of 26 complaints received for Fiscal Year 2011/2012. Twenty complaints were related to licensed midwives and six concerned unlicensed midwives. The Complaint Unit closed 17 complaints.

Ms. Sparrevohn inquired as to how many closed complaints involved licensed versus unlicensed midwives. She also asked how many licensed versus unlicensed midwives were referred for criminal action. Ms. Morrish did not have the specific breakdown at the time but indicated that this information could be provided in the future.

Ms. Sparrevohn recommended that in the future it would be useful for the statistics to reflect licensed versus unlicensed midwives. Ms. Yaroslavsky reiterated the importance of keeping separate statistics for licensed and unlicensed midwives.

Agenda Item 6: Update on Task Force for Midwifery Students/Midwife Assistants

Ms. Lowe provided an update on the Taskforce for Midwifery Students and Midwife Assistants. During the March 29, 2012 MAC meeting a recommendation was made to create a Task Force to determine regulations for midwife students and assistants. The meeting was scheduled for September 13, 2012 at the Board and notification was posted on the Board's website. The goal of the meeting was to discuss the apprenticeship model.

Ms. Sparrevohn asked for comment from Council Members.

Ms. Yaroslavsky recommended it would be beneficial to review the apprenticeship models used by other states to get a broader picture of the situation. Ms. Lowe stated that reference material would be provided for the Task Force meeting. Ms. Lowe confirmed Ms. Gibson was identified as a task force member.

Ms. Sparrevohn asked for public comments; none were provided.

Agenda Item 7: Consideration of Nizhoni Institute Advanced Placement and Transfer or Credit Proposal.

Mr. Worden stated that staff were not prepared to provide an update to Council Members on the Advanced Placement Proposal provided by the Nizhoni Institute at the time because the proposal was still under staff review.

Ms. Sparrevohn asked for public comments; none were provided.

Agenda Item 8: Discussion and Possible Recommendation to the Full Board on MAC Term Limits

Ms. Sparrevohn requested the Council consider adopting the following term limits: two, three year terms per Council Member.

She mentioned the term limits for Chair and Vice Chair were unclear and opened the topic up for discussion.

Ms. Yaroslavsky asked if members could serve again after their consecutive terms were up if a period of time had lapsed between appointments.

Ms. Ehrlich raised concern that with term limits there is a loss of institutional memory and knowledge on how things have come about and how decisions have been made in the past. Ms. Sparrevohn pointed out the terms do not expire at the same time and institutional memory can come from the public who attend the meetings. Her concern is that without term limits, it will be hard for new people to get the opportunity to serve and provide fresh ideas on the Council. Ms. Gibson mentioned that her term is up in March 2013, rather than June 30, 2014, as was stated in the meeting materials.

Ms. Yaroslavsky voiced her opinion that term limits are not beneficial in a democracy, and she believes the issue is not so much about term limits but rather engaging the broader community to participate beyond the day-to-day level with a governing body. She questioned why the two year terms were previously eliminated. Ms. Sparrevohn stated that the terms were adjusted to create

staggered expiration dates. Ms. Yaroslavsky noted that participants who have been involved from the beginning, like Dr. Gregg, continue to be involved. She stated that it was a good opportunity for ex-official members to participate and stay involved as audience members. She also stated that there are opportunities to chair Task Force meetings, etc., to get a variety of opinions at the table to institute change.

Mr. Heppler stated that the Council has no statutory limit on the number of members and the Council could request the Board to add additional members since there are no number restrictions. If the Council members decided that they needed new input besides conducting task force and interested parties meetings, they could expand or contract members as they see fit.

Ms. Yaroslavsky stated that an increase in the size of the Council was a good idea and ex-official members should be involved or appointed to subcommittees. She recommended having volunteers in place to help support staff to research and culminate national and international information and she suggested the MAC Chairperson meet with Board staff and legal counsel to set that up. Ms. Sparrevohn stated that she is looking for participation from the public and other midwives so as not to lose the history of the Council.

Ms. Sparrevohn indicated that the MAC did not want to enact term limits for the members.

Ms. Sparrevohn asked how long the term limits have been for the Chairperson. Members stated that the time frames have varied but recommended term limits should be two years. Ms. Yaroslavsky recommended the Chairperson give thought to this issue and discuss with staff before providing a recommendation to the MAC.

Ms. Sparrevohn made a motion to set two year term limits for officers; s/Ehrlich.

Ms. Yaroslavsky asked Ms. Sparrevohn to outline her perspective. Ms. Sparrevohn clarified by stating the issue of term limits has been discussed and she would set the term in office at two years without term limits. Mr. Heppler asked Ms. Sparrevohn if she was making no limit to the terms served as a MAC member, clarifying that she was making a term limit for an officer. Ms. Sparrevohn stated she was attempting to identify the length of term since it had not been previously identified.

Council Members voted to approve two year term limits for officers.

Agenda Item 9: Agenda Items for the December 6, 2012 Midwifery Advisory Council Meeting

Ms. Gibson voiced concern with data discrepancies on the OSHPD Licensed Midwife Annual Report. Ms. Sparrevohn asked Mr. Worden to look into the issue. Mr. Worden stated that staff would meet with OSHPD once the change recommendations were identified. He further clarified that the Board's Information Systems staff were working to incorporate a new computer system at the Board and currently do not have the time to work on changing the LMAR. Staff are also involved in preparing the Annual and Sunset Review Reports, but should be able to focus on addressing these issues in the next month or two.

Some MAC members voiced concern that they had hoped the recommended changes would be in

the works. Mr. Worden mentioned, due to deadlines, staff have had to prioritize workload.

Ms. Sparrevohn asked if there were additional items to place on the agenda for the next meeting.

Dr. Byrne asked for an overview of the goals and objectives related to the data reporting processes.

The following agenda items were identified by Ms. Sparrevohn for the December 6, 2012 MAC meeting:

- Midwifery Program Statistics
- Student Assistants Task Force Update
- MANA Task Force Update
- OSHPD LMAR Update
- An Overview of the Goals and Objectives related to Data Reporting

Agenda Item 10 Adjournment
Ms. Sparrevohn made a motion to adjourn the meeting. Motion carried, adjourned at 3:49 p.m.

MIDWIFERY PROGRAM LICENSING STATISTICS

Licensed Midwives	FY 12/13	Q1	Q2	Q3	Q4
Applications Received	8	8			
Applications Pending	5	5			
Licenses Issued	5	5			
Licenses Renewed	31	31			
Licenses Cancelled					

Licensed Midwives	FY 11/12	Q1	Q2	Q3	Q4
Applications Received	31	9	5	8	9
Applications Pending	0	6	3	3	0
Licenses Issued	31	4	8	10	9
Licenses Renewed	123	24	31	31	37
Licenses Cancelled	1	0	0	1	0

Licensed Midwives	FY 10/11	Q1	Q2	Q3	Q4
Applications Received	41	12	11	6	12
Applications Pending	2	4	1	2	2
Licenses Issued	40	9	13	5	13
Licenses Renewed	98	30	17	20	31
Licenses Cancelled	3	0	2	0	1

Licensed Midwives	FY 09/10	Q1	Q2	Q3	Q4
Applications Received	16	2	0	10	4
Applications Pending	N/A	N/A	1	0	2
Licenses Issued	19	2	2	10	5
Licenses Renewed	74	18	4	29	23
Licenses Cancelled	3	0	0	2	1

MBC Licensing Statistics	
Renewed / Current Status	272
Delinquent Status	29

MIDWIFERY PROGRAM ENFORCEMENT STATISTICS	FY 09/10	FY 10/11	FY 11/12	FY 12/13 1st Quarter
COMPLAINTS				
Total number of complaints received	**7**	**10**	**26**	**4**
Licensed midwives	6	8	20	3
Unlicensed midwives	1	2	6	1
Total number of closed complaints	5	8	17	3
Licensed midwives	5	6	11	3
Unlicensed midwives	0	2	6	0
INVESTIGATIONS				
Total number of open investigations	**5**	**2**	**3**	**2**
Licensed midwives	3	2	3	1
Unlicensed midwives	2	0	0	1
Total number of closed investigations	**3**	**0**	**1**	**2**
Licensed midwives	2	0	1	1
Unlicensed midwives	1	0	0	1
Total number of cases referred to the Attorney General (AG)	**1**	**1**	**2**	**1**
Licensed midwives	1	1	2	1
Unlicensed midwives	0	0	0	0
Total number of cases referred for criminal action	**1**	**1**	**1**	**1**
Licensed Midwives	0	0	0	1
Unlicensed Midwives	1	1	1	0
Number of probation violation reports referred to the AG	0	0	0	0

STATE AND CONSUMER SERVICES AGENCY- *Department of Consumer Affairs* EDMUND G. BROWN JR., *Governor*

MEDICAL BOARD OF CALIFORNIA

Licensing Program

November 27, 2012

Dear Licensed Midwife,

It has come to the attention of the Medical Board of California that some midwifery students who are not yet licensed midwives in the State of California are soliciting for clients and employing licensed midwives to assist them in out of hospital births. **The purpose of this letter is to inform you that this is an improper activity and is considered practicing without a license.**

Pursuant to Business and Professions Code section 2511(a), "No person, other than one who has been licensed to practice midwifery by the board, shall hold himself or herself out as a licensed midwife, or use any other term indicating or implying that he or she is a licensed midwife."

Business and Professions Code 2519 states that the Board may suspend or revoke the license of a midwife for unprofessional conduct which includes, (i) "Aiding or assisting, or agreeing to aid or assist any person or persons, whether a licensed physician or not, in the performance of or arranging for a violation of any of the provisions of Article 12 (commencing with section 2221).

A licensed midwife who is involved in aiding and abetting a student in the practice stated above may be subject to Board action including but not limited to suspension or revocation of his or her license. Likewise, any student found to be in violation of this provision risks possible denial of licensure as well as criminal action.

Should you require further clarification, please contact Natalie Lowe, Licensing Program Manager, at: (916) 263-2399 or Natalie.lowe@mbc.ca.gov.

Sincerely,

Curtis J. Worden
Chief of Licensing
Medical Board of California

2005 Evergreen Street, Suite 1200, Sacramento, CA 95815-3831 (916) 263-2382 (800) 633-2322 FAX: (916) 263-2944 www.mbc.ca.gov

Exploration of the Use of the Midwives Alliance of North America Statistics Project for California Licensed Midwife Data Reporting

This report, written by Bruce Ackerman and Jen Brown of the MANA Division of Research (DOR) and Carrie Sparrevohn, Chair of the Midwifery Advisory Council (MAC), continues a discussion of the need for more accurate, transparent, and accountable data collection between California licensed midwives and the Medical Board of California (MBC) via the Office of Statewide Health Planning and Development (OSHPD) and ultimately the State of California via an annual report delivered to the legislature by the MBC. The MAC has been exploring alternatives to the current data collection system, mandated by B&P section 2516, (Appendix E), for some time and has become aware of the Midwives Alliance of North America Statistics Project (hereafter cited as MANA Stats). The MANA Stats project will be described in detail below but constitutes a recommended approach, using nationally accepted best practices, to improving the collection of data related to out of hospital births attended by California licensed midwives (LMs) and the reporting of that data, annually, to the Medical Board of California.

Background

Current California LM reporting process as dictated by Business and Professions code Section 2516

California's licensed midwives are currently required to report annually, to OSHPD, aspects of their practice and client load related to out of hospital births that are prescribed by B&P section 2516 (a). (See Appendix E for current language). The form currently used for this process was developed by the MAC in conjunction with OSHPD and has been in use since the 2008 reporting year. (For a copy of the current form see Appendix F)

There have been several issues/concerns associated with the current process. First, data is submitted for each of the midwife's clients *after* the end of the reporting year, in a *retrospective* manner. This begs the question of both transparency and possible accuracy as there is no way to confirm complete data. When using data to create statistics (as this data is intended to be used) data collected in a *prospective* manner is deemed, by the scientific community, to be superior. Currently the state does not have this ability, although the MANA Stats Project does. Secondly, the current data collection tool is difficult for midwives to use correctly which has led to the reporting of inaccurate data. There is no mechanism (or funding) to evaluate suspected errors or even identify inconsistencies that may be reporting errors. As a result, the aggregate reports forwarded to the Medical Board and made public are allowed to stand without correction as submitted and therefore may be an inaccurate or mis-representation of actual data.

A national standard of data collection exists in the MANA Stats Project. In order for California statistics to be compared with like data, on a national level, California must collect LM data in a similar manner to what is now being collected nationally. The unique method, currently used in California, was developed before the MANA Stats Project was the viable option it now is. Currently, the Legislature, OSHPD, the MBC, or any other entity or researcher would be unable to compare and contrast the practices of California LMs with other similar practitioners nationwide, making it more difficult to address issues of best practices on a regulatory or legislative level to ensure the safety of California's birthing families.

Introduction to the Midwives Alliance of North America Statistics Project (MANA Stats)

MANA Statistics Project (MANA Stats) is a research registry of birth information operated by the Midwives Alliance of North America since 2004. At present approximately 123 California midwives voluntarily participate in MANA Stats. Nationwide, midwives or midwifery practices from 43 states actively participate. There have also been a number of scientific, peer reviewed, papers published using the data from the MANA stats project over the last five or so years. (Johnson K, Daviss BA. Outcomes of planned home birth with certified professional midwives: large prospective study in North America. BMJ 2005;330;1416; http://www.bmj.com/content/330/7505/1416)
Midwives voluntarily enrolled in MANA Stats enter each individual client into a database as the client enters care, continuing to submit data as it becomes available over the course of the client's care, completing it when care is complete. All data is entered on-line, through a sophisticated web-based data collection tool. This type of data collection is generally termed *prospective data collection,* and is a much more respected form of data collection in the scientific community than *retrospective data collection* which is what California is currently using. With prospective data collection the client is entered into the database at the beginning of care, when the outcome is unknown. There is no ability to then leave that client out of the data set regardless of the birth outcome. If California began participating in a nationally recognized process of data collection, such as the MANA stats, we would ensure California data was collected in the most respected, professional and responsible, scientific way.

The MANA data collection form itself has received a great deal of improvement and validation. The form currently in use is version 4.0, and has been re-designed twice by an interdisciplinary team experienced in the field of maternal-child health research, acquainted with the way midwives practice, and experienced in information systems design and maintenance. Each data form revision has built upon measurement of the prior versions' performance, producing a well-refined, sophisticated yet simple design.

Software aids the midwife in completing the form appropriately without any information either left out or incomplete, thus avoiding many of the inaccuracies seen with the current California reporting instrument. As the midwives submit these completed forms to MANA stats, some will be sent to the Data Review Team, which would review and contact, if necessary, the reporting midwife. This ensures not only accuracy but transparency. (This review process is described in greater detail in Appendix B)

Each contributing midwife is able to view her own personal statistics for a given year via her Annual Summary Report (ASR) on the secure website. The ASR details her caseload for that year and the outcomes of clients in her care for labor and birth. The ASR is designed to report standard statistics used in maternal-child health. (See the Appendices for an overview of the MANA Stats data collection tool, the process for using it and a sample ASR)

MANA Statistics in other States

Oregon, as described below, requires licensed midwives to contribute to the MANA Stats Project. Vermont has similar legislation in effect. Washington is currently in the process of drafting a similar requirement, and Arizona, Colorado, New Hampshire, Texas and New Mexico are considering such rules.

Oregon reporting process:

An example of how this is being used in other states

Oregon licensed midwives (as stated above) are required by statute to participate in the MANA Stats Project, ensuring accurate data for their annual reports. The Oregon Health Licensing Agency (OHLA) looked to the MANA stats project, proactively, as the means to accomplish this for their licensees. The reporting midwife now prints a copy of her ASR, which is sent with her license renewal application, to the OHLA. This process is in its first year and all parties are working through the start-up kinks, but it shows promise for several reasons:

- Due to the well-developed processes by which the MANA Stats Project ensures accurate and consistent data collection, the reports submitted are as complete as possible and categorize outcomes in ways accepted within the research community, making them comparable with existing benchmarking.
- As Oregon midwives all participate in MANA Stats, a research cohort is created which could allow further study of licensed midwifery practice in the state, and which contributes to the national MANA Stats database.
- The Oregon process requires no state-specific software, but leverages the existing MANA Stats web system maintained by the Midwives Alliance.

What would be required for California Licensed Midwives to utilize the MANA Stats reporting tool to collect state data?

The intent of this report is to explore the implications of changing from the current reporting methodology in California to leveraging the strengths of the MANA Stats Project. First and foremost, the existing statute would need to be amended to require California LMs to participate in and meet the requirements of the MANA Stats Project as their sole reporting requirement. LMs would be required to submit a copy of the Annual Summary Report (ASR) from their MANA Stats account to OSHPD each year. OSHPD would then submit the aggregate data to the MBC, just as they currently do.

The present California statute is quite detailed as to the specific data that must be reported by CA LMs. Such detail has constrained the MAC, OSHPD and the Medical Board, resulting in the present difficult reporting instrument. For the new process to ensure best practices are enabled regarding an ability to gather information that is both relevant and a tool to better refine the practice of midwifery in California, as envisioned here, the statute would have to describe the data in broad terms, or not at all, leaving it up to the MAC and the MBC to, through regulations, bring it in-line with what is currently on the MANA Stats data collection tool. This would allow for incremental changes without returning to the legislature. (See the Appendix D for a complete list of changes to captured data). By changing the statute so that the existing MANA Stats Annual Summary Report would satisfy its requirement and subsequently leaving it to the MBC to keep current with what MANA Stats is collecting, California could adopt the approach of requiring MANA Stats of licensed midwives without requiring custom software design, custom form design, or the maintenance of custom software.

If this approach were taken, the reporting deadline for CA LMs would need to align with the MANA Stats timeline to allow completion of midwives' individual birth forms and completion of MANA's review process. If midwives were to continue to report their outcomes on a calendar year basis (January through December), the deadline for midwives to send their ASR to OSHPD would need to be no earlier than July 15. Alternatively, the existing March reporting deadline could be retained, but with the reporting period being from November through October of the previous year, or some other variation

that would allow adequate time for the complete submission of data by midwives, review by MANA and aggregation by OSHPD. Either of the afore mentioned approaches would be equally workable, but a report of births through December that would be completed by March is not feasible since the MANA stats project is set up to work on a national level and its timeline for data submission and data review is already set for all participating midwives across the country. Adherence to the March deadline for a calendar year report would not allow enough time for completion of the process on MANA's end.

The present California reporting process can be compared with the MANA Stats process as follows.

Present Reporting Process	**Process using MANA Stats**
Midwife provides care for clients	Midwife enters clients in database at onset of care and provides on-going care for those clients
Throughout the year, some but not all midwives voluntarily participate in the MANA Stats project (pre-logging each client and completing the data form on each)	Throughout the year, all California LMs would participate in the MANA Stats project (pre-logging each client and completing the data form on each)
After the reporting year, midwife reviews her charts, tallies the numbers, and completes the on-line reporting form	After the reporting year, when all entries have been reviewed by the MANA Stats project team, the midwife sends her ASR to OSHPD by a method to be determined (mail or electronic)
Deadline for midwives' reporting to OSHPD is March 30 of the following year	Deadline for midwives' sending their complete ASR should be no earlier than July 15 of the following year if reporting for Jan-Dec, OR deadline could remain March 30 for reporting of data on a different timeline, as described above.
OSHPD tallies the reporting forms, and produces an aggregate report for the Medical Board	OSHPD tallies the reporting forms, and produces an aggregate report for the Medical Board
Research data for California Licensed Midwives is not available	Research data for California Licensed Midwives is available through the MANA Division of Research, as a complete cohort.

Details and Caveats

Need for support of new MANA Stats contributors

As Oregon has discovered, if it were decided to require all California LMs to participate in the MANA Stats Project, it is imperative that they be notified of the change early and more than once so that full compliance is reached. Participation in the MANA Stats project requires that the midwife make log entries for all her births as she takes on the clients, completing the data forms in a timely manner. Midwives who are not familiar with the process might assume that they can wait until their California reporting is due to "catch up" with this, but they will not be able to do so. This is a further safeguard to ensure accuracy as well as transparency. The Support team at the MANA Stats Project would be the point group for the data collection, not OSHPD. The MANA stats support team, working through the MAC with the MBC and/or with the California Association of Midwives (CAM) would do outreach and continue, on an on-going basis, to educate LMs on the process, thus ensuring a more total capture of the required data.

When these changes are adopted there would be an expected influx of new enrollees into the MANA Stats Project. It would be essential for the success of this process for there to be funding made available to allow the MANA support team to increase its level of attention to California enrollees, especially in the first year, as they would all benefit from personal contact to assure the data was collected efficiently and accurately. The fiscal portion of this proposal would need to be worked out and decided upon as the process moves forward through the legislature.

Non-Consented births

The MANA Stats process requires that each of the midwife's clients sign a Consent Form (See Appendix H), agreeing to allow their data to be included in the research registry. This is a standard requirement of all research data collection: the subject needs to consent to having their data used in this way. It is rare for a client to decline consent, but it does happen occasionally (less than 1% nationwide). The Oregon Health Licensing Agency created a form for midwives to use for those clients who declined consent during a reporting year. This form could be a basis for creating a similar form for California.

(to see a copy of this consent form: https://www.manastats.org/docs/ConsentForm_Color.pdf AND to look at the Oregon form for non-consenting clients: http://www.oregon.gov/OHLA/DEM/docs/form/DEM_MANA_Declined_Reporting_Form_OHLA.pdf)

Limiting the report to California births

It should be mentioned that some California licensed midwives attend births outside California. It would need to be decided if the current system, of California LMs only reporting on births attended within California, would be continued. If it was decided to limit the ASR for California midwives, to births that occurred in California, this could be done, but would require an addition to the MANA Stats software. That software change would require advance notice, and funding would be needed to pay for programming time. If it were decided to collect data on all of the births attended by a California LM then no change to software would be required.

Allowing for an exception for midwives who do not attend out-of-hospital births

For California LMs who attend no out-of-hospital births within the state in a reporting year, the current system of allowing those LMs to report just that, rather than participate in the MANA stats project, should be continued.

In Conclusion

California should utilize the midwives' Annual Summary Report (ASR) from the MANA Statistics Project for reporting practice data by licensed midwives through OSHPD to the Medical Board. Doing so would leverage an existing and mature process that would result in the most accurate aggregate data being reported to the Medical Board. The use of this process by California, would allow California's data on out of hospital births attended by licensed midwives to be incorporated, in total, in a national data base. The underlying data (that not included in the summary but used to create it) would reside in the MANA Stats research registry, where it could be the basis of research to further understand and improve midwifery practice and outcomes in California. Several other states, as referenced herein, are currently passing or have passed legislation requiring Licensed Midwives to participate in the MANA stats project for data collection in their respective states. This makes it apparent that the use of the same process for all states is the most sustainable path forward.

Appendix A: MANA Stats data collection process

This is a very brief "tour" of the MANA Statistics Project web system, to show how the midwife enters her birth data. For more detail or to ask questions, please contact the MANA Division of research, or take a look at the demonstration site, at http://demo.manastats.org where you can make a sample log entry and explore the data form completely.

The midwife begins by making a log entry for each of her clients as they enter her care. By pre-registering her planned births, it is assured that a data form is completed for every one of them.

Your Workspace
Client Log
Data Forms
Statistics
Preferences
Contact Us
Sign Out

MANA Statistics Project

Midwives Alliance

Client Log and Data Forms

The Client Log lists all the prospective births logged to date by you or the other midwives in your practice. Clients for which data forms have not yet been submitted are shown below. You can sort the log by birth code, initial visit date, age, EDD, or consent status: just click on the heading by which you want to sort.

To update log information for a client--if you've sent off a consent form or if the EDD is revised--click on the "Update" link to the left of the appropriate entry.

Add a new client to the log

Items in your log: 9

Log Entry	Birth Code	Initial Visit Date	Age	Due Date▲	Client Consent	Consent Form	Data Form
Update	AN-02	6/17/11	34	9/3/11	Yes	received	Add to data form
Update	AN-08	4/11/11	30	9/7/11	Yes	received	Add to data form
Update	AN-05	7/7/11	26	9/18/11	Yes	received	Add to data form
Update	AN-49	2/4/11	21	9/18/11	Yes	received	Start data form
Update	AN-22	5/9/11	36	9/19/11	Yes	received	Add to data form
Update	AN-48	4/8/11		9/23/11	Yes	received	Start data form
Update	AN-43	7/17/11	27	9/29/11	Yes	received	Start data form
Update	AN-51	4/4/11	40	10/2/11	Yes	received	Keep checking
Update	AN-47	8/1/11	32	2/1/12	Yes	received	Add to data form

Web site and data forms ©2004-2011 Midwives Alliance

Signed in as: Anne Midwife

A Consent Form is collected, on paper, from each client, which assures that the client agrees to allow her data to be included in the MANA Stats registry, informing her of the purpose of the registry and of its operation including safeguards taken to protect and de-identify her data. In order for research to be done on human subjects' data, Institutional Review Boards will require that this informed consent process was followed. The great majority of women agree, but occasionally a client will decline consent, and her data form will not be able to be entered by the midwife; in these cases that client's log entry is recorded as non-consenting and the midwife is not able to complete the on-line data form. The Annual Summary Report would include a warning if there were any log entries during the reporting year for which client consent was not obtained.

The midwife completes the MANA Stats data form for those clients who gave consent. This is the third generation of data form since the inception of the web-based data collection system in 2004, and it is considerably refined, streamlined and simplified based on study of the performance of prior versions. The present "Minimal Form" does an excellent job of collecting consistent data to allow the key Maternal/Child Health outcomes to be accurately derived from it, while minimizing the burden on practicing midwives so they can keep current with the data collection process.

Shown below is a portion of the data form within the Labor & Birth page.

Start | Demographic | History | Pregnancy | Labor & Birth | Postpartum | Newborn | Finish

Birth Summary

Was a pharmacological induction of labor attempted?: ○ - ○ Yes ● No

Was induction by herbs/castor oil, homeopathy, nipple stimulation, AROM, or membrane-stripping attempted?
○ - ● Yes ○ No

Mode of birth: ○ - ● spontaneous vaginal ○ forceps ○ vacuum ○ cesarean

State or province where the birth occurred: CA

Place of birth:

○ -
● home
○ birth center
○ hospital
○ higher-level hospital after transport from planned hospital
○ en route
○ other

Number of babies: 1

Estimated blood loss (until point at which uterine tone was established): 0.5 cups or 118 cc (milliliters)

Was the baby born before 37 completed weeks? ○ - ○ Yes ● No ○ Unknown

Stages of Labor *(You can use 12- or 24-hour time; you must fill out all boxes of the time and date.)*

Time and date active labor began:	12 : 24	AM	1 / 5 / 2012	*(MM/DD/YYYY)*
Time and date continuous pushing began:	4 : 17	AM	1 / 5 / 2012	*(MM/DD/YYYY)*
Time and date of birth:	4 : 42	AM	1 / 5 / 2012	*(MM/DD/YYYY)*
Time and date third stage ended:	5 : 18	AM	1 / 5 / 2012	*(MM/DD/YYYY)*
Rupture of membranes:	4 : 13	PM	1 / 4 / 2012	*(MM/DD/YYYY)*

After completing the data form, the software checks the form for completeness and consistency, and might display flags on questions that were not answered, or for which the answer given could be erroneous or inconsistent. The midwife may correct the form to clear these flags, or if she cannot she may enter an explanation into the flag itself. Thus the software always allows the form to be submitted (even if it lists a 66-pound baby!) but the data is far more complete and accurate for analysis due to this checking process.

Sex: ○ - ○ female ● male ○ ambiguous

Birth weight: 66 lb 4 oz or 30050 g

Please double-check this value. If it is mistyped, please correct it. If not, please confirm that it is correct here:

Appendix B: MANA Stats Review Process

After the midwife submits her data forms, some of them will be queued for review by the Data Review Team. The review process accomplishes three goals: it produces data that is transparent and accurate, ready for analysis by researchers; it educates the midwives (who might receive a call from the reviewer to resolve questions about her use of the form); and it allows the DOR to continually monitor where the data form might be improved. Data reviewers follow a detailed protocol, assisted by sophisticated software, to focus their review on exactly the issue(s) that caused the form to be sent to review. All changes made to a data form, throughout its history even before the midwife submits it, are recorded by the software for audit purposes.

Forms are sent to review for many reasons which fall into four basic categories- notes, unanswered questions, possible errors or logical inconsistencies, and deaths.

- ***Notes:*** On the form there are two large text boxes where a midwife may write notes. The temporary box is used for the midwife's notes to herself or to the MANA stats team, and are deleted after review. The other note box stays with the form and allows the midwife to provide additional narrative information to researchers. Forms with notes in these boxes are reviewed because midwives may write a note asking the reviewer to add another midwife to the form, change a birth code, or some other administrative chore. The other purpose of reviewing these forms is to de-identify any information (i.e. remove names) in the notes that will be seen by researchers.
- ***Unanswered questions:*** Forms on which the midwife has left a question unanswered and entered an explanation into the error flag are sent to review. The vast majority of these explanations are some version of "unknown" where the midwife does not have the information, generally after cases of transfer of care. In these cases the reviewer approves the explanations and submits the form as is.
- ***Possible errors or logical inconsistencies:*** Besides explanations for unanswered questions there are also many scenarios which are flagged to prevent errors from typos. For example if the date of birth is more than 28 days before or after the due date, the form is flagged. If it is correct the midwife simply enters something like "correct, preterm" in the explanation and the reviewer would approve the form as is. Forms where the midwife enters a low birth weight, under 2500 grams, are also flagged and reviewed in this manner. The software also follows a sophisticated set of validation protocols to flag a midwife when she has entered data into a form that is inconsistent and therefore a possible error. If the midwife does not correct the form to clear the flag, she must enter an explanation which is then reviewed. Examples of this kind of review are forms where the midwife marks that the planned place of birth at the start of labor was home but the birth took place in the hospital but there is no transport shown in the form, or where there is both a transfer of care in pregnancy and a transport in labor. The reviewer would follow the specific review protocol and most likely contact the midwife to verify the scenario and get the error corrected. For example if a midwife has entered a transfer of care in pregnancy for a breech and also a transport in labor for a breech, the reviewer must contact her to determine when the transfer actually took place. The reviewer would then correct the form according to the midwife's instructions.
- ***Deaths:*** All forms with a death reported will be reviewed using a FIMR-type (Fetal and Infant Mortality Review) interview with the midwife to ensure accurate classification of the death

according to accepted research standards. Death reviewers are experienced reviewers who have undergone additional training. The goals of death review are to ensure accurate classification of each death, provide additional information regarding cause of death, and to allow the midwife to provide a narrative explanation of the situation. Deaths are classified as miscarriages (pregnancy loss before 20 weeks), intrauterine fetal demise (pregnancy loss after 20 weeks but before birth), neonatal death (after birth until 28 days) and infant deaths (after 28 days). An example of a misclassified death would be one where the midwife reports that the baby died during labor but the APGAR was listed as 3 at 5 minutes which indicates the baby was alive at birth. During the death interview the reviewer would determine exactly when the baby died and change the form to reflect the correct type of death. In the above case the correct classification would be a neonatal death. Maternal deaths are also reviewed in this manner and are classified as before, during or after the birth and whether or not they were pregnancy-related.

Appendix C: Sample Annual Summary Report (ASR)

The following two pages show the complete Annual Summary Report as viewed by a typical midwife through her account on the MANA Stats web system.

This report covers all entries to care and all births that took place in the report year. It covers all clients who enter care in the report year and subsequently miscarry or transfer out of care (even if the miscarriage or transfer occurred in the following year).

Clients who enter care in this report year but are still pregnant on 12/31 will not have their birth outcomes represented in this year's report.

The first two statistics in the Caseload section are based on data forms either in progress or submitted. All other statistics are based on completed and submitted data forms only. Fetal losses and deaths are reported as "not yet reviewed" if the Midwives Alliance Data Review Team has not yet completed review of those data forms; they are reported as "confirmed" if the review has been completed.

MANA Stats Annual Summary Report (2010)	
MIDWIFE CASELOAD	
Clients who entered care with midwife in report year	24
Clients who entered care in report year and transferred out in pregnancy (in report year or after)	2
Clients who entered care in report year and died AP (in report year or after)	0 confirmed, pregnancy-related 0 confirmed, not pregnancy-related 0 confirmed, unknown whether pregnancy-related 0 not yet reviewed
Clients who entered care in report year and were in midwife's care for labor/birth in report year	12
Clients who entered care in previous year and were in midwife's care for labor/birth in report year	3
Total number of clients who were in midwife's care for labor/birth in report year	15
Total number of labors/births attended in report year as Midwife 2 or Midwife 3	9
OUTCOMES OF LABOR/BIRTHS AS PRIMARY MIDWIFE	
Clients who went into labor intending to give birth at home/birth center	15
Home/birth-center births as planned	13
Intrapartum transports	2 (0 urgent)
Postpartum maternal transports	0 (0 urgent)
Neonatal transports	1 (0 urgent)
Babies admitted to hospital in first 6 weeks of life (including neonatal transports)	1
NICU admissions in first 6 weeks of life	1

Antepartum fetal demises	0 confirmed, due to congenital anomalies 0 confirmed, not due to congenital anomalies 0 not yet reviewed
Intrapartum fetal demises	0 confirmed, due to congenital anomalies 0 confirmed, not due to congenital anomalies 0 not yet reviewed
Fetal demises at unknown point	0 confirmed, due to congenital anomalies 0 confirmed, not due to congenital anomalies
Neonatal deaths (first 28 days of life)	0 confirmed, due to congenital anomalies 0 confirmed, not due to congenital anomalies 0 not yet reviewed
Infant deaths, post-neonatal, in first 6 weeks of life (between 29 and 42 days of life)	0 confirmed, due to congenital anomalies 0 confirmed, not due to congenital anomalies 0 not yet reviewed
Maternal deaths in labor or first 6 weeks postpartum	0 confirmed, pregnancy-related 0 confirmed, not pregnancy-related 0 confirmed, unknown whether pregnancy-related 0 not yet reviewed
Cesarean sections	1
Vacuum or forceps deliveries	0
3rd or 4th degree lacerations	0
Estimated blood loss of 500 ml or more	1
Meconium (thick/particulate)	0
Babies with 5-minute Apgar under 7	0
VBACs attempted in home/birth center (whether outcome was vaginal or surgical birth)	1
VBACs completed in home/birth center (successful VBACs)	1
VBACs attempted in home/birth center and completed in hospital (successful VBACs)	0
Vaginal breech births completed in home/birth center/hospital	0
Frank	0
Complete	0
Footling	0
Other/unknown	0
Multiple births	0
Births after 42 weeks	0
Births with active labor over 24 hours	0
Births with 2nd stage over 4 hours	1
Births with 3rd stage over 1 hour	1
Breastfeeding as of last postpartum visit	12

Appendix D: List of items currently required by B&P Section 2516 which will not be captured on the ASR

- Births with collaborative care or under physician supervision.
- Outcomes are not listed by county, though the larger data base does include mother's county and zip code of residence and also the state where the birth occurred.
- Breeches are not listed by where the birth is completed. (ASR lists vaginal breeches, but does not specify location as home, birth center or hospital)
- Transfers by antepartum, intrapartum, postpartum and neonatal are captured though not the reason's for such transfers or their outcomes. This information resides in the full data base.
- All multiple births are listed together, twins are not separated out
- Reasons for deaths are not captured on the summary, however the ASR separates out fetal deaths as due to anomalies or not and maternal deaths as pregnancy-related or not and reasons for deaths are maintained in the larger data base.
- Either California could change the deadline for LM reporting from March 30 to July 15, or alternatively the report could be due in March but be for a reporting period other than the calendar year, e.g. for October through September.

Appendix E: B&P Section 2516

2516. (a) Each licensed midwife who assists, or supervises a student midwife in assisting, in childbirth that occurs in an out-of-hospital setting shall annually report to the Office of Statewide Health Planning and Development. The report shall be submitted no later than March 30, with the first report due in March 2008, for the prior calendar year, in a form specified by the board and shall contain all of the following:

(1) The midwife's name and license number.

(2) The calendar year being reported.

(3) The following information with regard to cases in California in which the midwife, or the student midwife supervised by the midwife, assisted during the previous year when the intended place of birth at the onset of care was an out-of-hospital setting:

(A) The total number of clients served as primary caregiver at the onset of care.

(B) The total number of clients served with collaborative care available through, or given by, a licensed physician and surgeon.

(C) The total number of clients served under the supervision of a licensed physician and surgeon.

(D) The number by county of live births attended as primary caregiver.

(E) The number, by county, of cases of fetal demise, infant deaths, and maternal deaths attended as primary caregiver at the discovery of the demise or death.

(F) The number of women whose primary care was transferred to another health care practitioner during the antepartum period, and the reason for each transfer

(G) The number, reason, and outcome for each elective hospital transfer during the intrapartum or postpartum period.

(H) The number, reason, and outcome for each urgent or emergency transport of an expectant mother in the antepartum period.

(I) The number, reason, and outcome for each urgent or emergency transport of an infant or mother during the intrapartum or immediate postpartum period.

(J) The number of planned out-of-hospital births at the onset of labor and the number of births completed in an out-of-hospital setting.

(K) The number of planned out-of-hospital births completed in an out-of-hospital setting that were any of the following:

(i) Twin births.

(ii) Multiple births other than twin births.

(iii) Breech births.

(iv) Vaginal births after the performance of a cesarean section.

(L) A brief description of any complications resulting in the morbidity or mortality of a mother or an infant.

(M) Any other information prescribed by the board in regulations.

(b) The Office of Statewide Health Planning and Development shall maintain the confidentiality of the information submitted pursuant to this section, and shall not permit any law enforcement or regulatory agency to inspect or have copies made of the contents of any reports submitted pursuant to subdivision (a) for any purpose, including, but not limited to, investigations for licensing, certification, or regulatory purposes.

(c) The office shall report to the board, by April 30, those licensees who have met the requirements of subdivision (a) for that year.

(d) The board shall send a written notice of noncompliance to each licensee who fails to meet the reporting requirement of subdivision (a). Failure to comply with subdivision (a) will result in the midwife being unable to renew his or her license without first submitting the requisite data to the Office of Statewide Health Planning and Development for the year for which that data was missing or incomplete. The board shall not take any other action against the licensee for failure to comply with subdivision (a).
(e) The board, in consultation with the office and the Midwifery Advisory Council, shall devise a coding system related to data elements that require coding in order to assist in both effective reporting and the aggregation of data pursuant to subdivision (f). The office shall utilize this coding system in its processing of information collected for purposed of subdivision (f).
(f) The office shall report the aggregate information collected pursuant to this section to the board by July 30 of each year. The board shall include this information in its annual report to the Legislature.
(g) Notwithstanding any other provision of law, a violation of this section shall not be a crime.

Appendix F: Current Licensed Midwife Reporting Form

https://lmar.oshpd.ca.gov/

MEDICAL BOARD OF CALIFORNIA
Licensing Program

PROPOSED MIDWIFERY ADVISORY COUNCIL MEETING DATES FOR 2013

Location
2005 Evergreen Street
Sacramento, CA 95815
Lake Tahoe Conference Room
1:00 p.m. - 4:00 p.m.

March 21, 2013	**or**	**March 28, 2013**
August 8, 2013	**or**	**August 15, 2013**
December 5, 2013	**or**	**December 12, 2013**