Medical Spa Services Work Group

Alaska Division of Corporations, Business and Professional Licensing

DRAFT MEETING MINUTES

Wednesday, October 2, 2024, at 12:00 PM AKDT

https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/MedicalSpaServicesWorkGroup

Members Present: Wendy Palin, Board of Barbers & Hairdressers; April Erickson, APRN, Board of Nursing; Brian Larson, DC, Board of Chiropractic Examiners; Kenley Michaud, DDS, Board of Dental Examiners; Eric Nimmo, MD, State Medical Board; James Henderson, RPH (for Ashley Schaber), Board of Pharmacy

Staff Present: Sara Chambers, Boards and Regulations Adivsor, Facilitator; Sylvan Robb, Glenn Saviers, Michael Bowles, Patty Wolf, Natalie Norberg, Reid Bowman, Shane Bannarbie, Rachel Billiet

Approximately nine members of the public were in attendance.

Call to Order

Ms. Chambers, facilitator, called the meeting to order at noon. Members declared they had no conflicts of interest. Ms. Chambers reiterated the purpose of the work group, as outlined on the web page:

- Identify "lifestyle enhancement" services that have a medical nexus and are currently performed or likely to be performed outside of a medical clinic or without appropriate supervision.
- Identify existing statutes and regulations that govern current requirements for training, licensure, and supervision of these procedures.
- Clarify how licensing boards could—jointly or in part—explain existing statutes and regulations that would help the public and licensees understand how these procedures should be safely administered according to the current laws of the state.
- Suggest changes in statute that would allow defensible and transparent pathways forward for appropriately trained and supervised individuals to provide these services without imposing undue economic or regulatory barriers.
- Carry forward work group updates and work products to the member boards for their subsequent review and action.

She stated that the focus of this meeting was for members to learn more about the various levels of esthetics procedures and modalities, as well as to review the Master Medical Spa Services Matrix sections on esthetics and IV hydration. She noted that two hours was not a lot of time, so the group may not get to everything today.

The floor was opened to public comment; there were no members of the public who wished to speak.

Esthetics Education

Susanne Schmaling, President and CEO of the Esthetics Council, reviewed esthetics procedures and modalities, including definitions, considerations, and FDA and MoCRA requirements. The information she provided was based on her experience as an advanced esthetician, client, and advocate working with several state boards and legislators on this topic. It was intended as a starting point for learning, as well as to establish a reliable framework of training and education for the work group and other stakeholders to potentially consider.

Ms. Schmaling explained that her recommendation in the orange column regarding basic licensure pertained to the national standard of 600-1000 hours, at which level these modalities are usually included in a basic curriculum, widely and thoroughly tested, and generally considered safe. She explained that the FDA classifications are useful; however, decisionmaking about device usage and treatment is in the hands of the states. She pointed out that although estheticians may hold a "basic" license, many with go out of their way to get additional training, especially on how to use specific devices. Manufacturer training should always be a requirement for use by an esthetician.

In the green column on the document, she clarified the impact on the epidermis, which is important to differentiate between use by estheticians currently licensed by the Board of Barbers and Hairdressers and procedures that may require supervision by a physician, physician assistant, or Advanced Practice Registered Nurse.

Highlights of specific devices, procedures, and modalities:

- Chemical peels: Some are safe for basic use and others require advanced training; she will provide the work group with further information on this breakdown. Old-style calculations are no longer useful because modern buffering agents make products safer. These basic peels do not require sedation; they are not penetrating to the the dermis but may cause superficial and temporary redness and irritation. Manufacturer training should be required for safety and is likely required by the provider's insurance coverage.
- Ultrasound is "sonic massage" and should not be confused with the type of ultrasound used in a doctor's office.
- HiFU (High Intensity Focused Ultrasound) is a deeper-penetrating type of ultrasound used primarily for facials at lower levels and body at higher levels. States usually regulate use of this treatment at a master/advanced level or under supervision.
- Cryotherapy for estheticians does not include lipolysis or surgery. It is just the application of cold for appearance of tightening or reduced redness and should not be confused with lipolysis that uses cold.
- Hydrotherapy may be considered advanced because training that exceeds 600 hours is typically needed.
- Body contouring treatments for cellulite are superficial, using compression, caffeine, massage. They do not break cellulite bands or otherwise reduce cellulite or have long-term effects.
- Dermaplaning uses a scalpel to remove dry skin and hair; it does not incise skin but may require additional training.
- Microneedling requires training and has many variations. Some states look at needle depth to regulate use. Typically 1.5mm does not go beyond the epidermis; deeper penetraion may require medical supervision. The work group may want to look at how to regulate procedures such as platelet-rich plasma (PRP) and Morpheus8 microneedling/radiofrequency adipose remodeling.

As relevant, the work group, licensing boards, and the Alaska State Legislature should consider intended use, depth of penetration, and the training and education obtained by the user. Ms Schmaling recommended adding a column to the review document that includes safety risk information. In this rapidly-changing industry, a lot of the training and safety information is only available by the vendor. New devices are coming out all the time and are pending with the FDA; devices in use may not yet be regulated, and there may be very little testing available for safety evaluation.

Ms. Schmaling encouraged stakeholders to keep statutory language broad and details expressed in regulation, especially given the rapid changes in technology. Alaska and other states are currently "behind the times" because legislatures can't keep up with the evolution of technology and training standards.

Ms. Schmaling reviewed her suggested regulatory definition of "appliances." Ms. Chambers reminded the work group that the Board of Barbers and Hairdressers is currently working to adopt a definition, which is within their statutory purview. She encouraged members of other licensing boards to engage in the regulatory comment process if they have input.

Ms. Palin asked for recommendations of where individuals could receive advanced training. Ms. Schmaling cited several sources (NCEA, CIDESCO) but clarified that obtaining training doesn't change state law allowing individuals to perform a service: The state license must include the procedure in its scope of practice. Ms. Chambers mentioned that manufacturers may offer a "license" to use their product (much like an owner of a McDonald's restaurant owns a francise license); however, this is not the same as a license issued by the appropriate state board. Ms. Schmaling recommended that any increase in mandatory training hours include a grandfathering provision that allows existing licensees to prove they have received adequate education and training.

Review updated matrix

Ms. Chambers walked through the purpose of the Medical Spa Services Matrix and introduced the scenario envisioned within the "IV hydration" topic. She asked Mr. Henderson, a registered pharmacist, to explain compounding of prescription medications at a high level to ensure members understood the basic elements and how they may be related to use in IV hydration clinics. Mr. Henderson explained sterile compounding is regulated by the Board of Pharmacy to ensure safety and sanitation. USP <797> governs sterile compounding within the United States. Conditions for sterile compounding are outlined in the guidance, including standards for "immediate use" (mixing and using within four hours) and use of a clean room if prepared outside of immediate use.

Dr. Nimmo asked if administration by IV changes a substance's status as a prescription drug. For example, does an over-the-counter vitamin become a prescription drug if administered intravenously? Mr. Henderson said a substance has to be sterile to begin with or be made sterile to be legally used for infusion. This is called "high risk" compounding and is regulated separately. Dr. Michaud agreed it would become prescription if administered by IV. Dr. Larson clarified the Board of Chiropractic Examiners is working on statutory changes to allow chiropractors to use prescription drugs in their practice.

Ms. Chambers asked for additional discussion about who can evaluate, diagnose, or treat a patient in an IV hydration clinic. Dr. Nimmo said medical training is required to evaluate a patient and diagnose whether IV infusion is a proper treatment—for example, excess fluid can lead to heart failure in some patients. Dr. Michaud's understanding is that assistants may be able to place but not start an IV without a direct order from prescribing provider, depending on the governing statutes for the supervising licensee. Ms. Erickson agreed. Evaluation and diagnosis of each individual patient is required by the prescriber—there is no situation where a standing order can be used on all patients. A benign substance to most might be harmful to others. Medications labeled for prescription require an authorized prescriber.

Ms. Erickson said people are sometimes unclear on the limitations on adding IV substances. Dr. Michaud said that the guidance is not based on number of medications but how they interact with each other. The work group requested more information from the Board of Pharmacy on compounding. For example, what is compunding vs. reconstituting? Mr. Bowles stated that the definition is in AS 08.80.480. Henderson said the current statutes and regulations may need some work; Dr. Michaud agreed. Mr. Bowles stated the board is currently working on a regulation to clarify the statute.

Next Steps
With the alloted time coming to a close, Ms. Chambers directed the group to narrow down goals for the next meeting on October 31 (10am-12pm). They agreed to:

- Continue review and research of advanced esthetics and IV hydration procedures and issues presented
- Review FDA definition of compounding

She said she would work with Ms. Schmaling to provide the additional esthetics details she had discussed. Ms. Chambers also said she would sent out a "scaffolding" for esthetics regulation for the group to begin identifying their observations of current parameters of practice and recommendations for future statutory and regulatory changes.

The meeting was adjourned at 1:55 p.m.