Medical Spa Services Work Group

Alaska Division of Corporations, Business and Professional Licensing

Agenda for Wednesday, October 31, 2024, at 10:00 AM AKDT

All times approximate and subject to change

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

Microsoft Teams: **Join the meeting now**
Meeting ID: 265 631 387 30
Passcode: dwBzUo

10:00 a.m. **CALL TO ORDER**

- Roll call
- Declarations of conflicts of interest
- Clarify the purpose of the Work Group:
  - 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.

10:10 a.m. **PUBLIC COMMENT**

Each speaker will be limited to three minutes. To offer written comments, please email sara.chambers@alaska.gov for distribution to the group five business days prior to the meeting.

10:30 a.m. **ADVANCED ESTHETICS**

- Review esthetics procedures from the last meeting
- Work on the continuum for current and future recommended scopes of practice
  - Considerations under current law pertaining to esthetics:
    - What procedures and modalities can a licensed esthetician perform without additional training or education?
    - What procedures and modalities require direct supervision by a medical professional, and how is that defined?
    - What prodecures and modalities may only be performed by a medical professional, and how is that defined?

- What special training, if any, is required of any person performing these services?

11:00 a.m. **IV HYDRATION**

- Review updated matrix and issues list regarding IV hydration
- Review FDA definition of compounding and how it relates to onsite crafting of intravenously delivered medicines
    - Considerations under current law pertaining to IV hydration:
        - What are the standards for evaluating, diagnosing, and treating a person with IV fluids, including additives?
        - Who may perform these activities?
        - Who may "craft" an IV hydration product on site (i.e. compounding)?
        - What type and level of supervision is required?
        - What special training, if any, is required?
        - What are the facility safety and sanitation requirements for IV hydration clinics, including mobile locations?

11:45 a.m. **PLANNING FUTURE MEETINGS**

- Assign next steps and schedule future meetings
- Continue review and research of procedures and issues presented
    - Definition and regulation of medical spas
    - Cosmetic injectables (Botox, Juvederm, etc.)
    - Prescriptions such as semaglutide and sildenafil
    - Nonsurgical lipolysis (cryo, injection, radiofrequency, laser, etc.)
- Identify opportunities for boards to review recommendations, adopt regulations, or seek statutory changes to solve the problems presented

11:50 a.m. **FINAL THOUGHTS**

12:00 a.m. **ADJOURN**

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.

October 21, 2024

To the members of the Medical Spa Services Work Group,

My name is Lindsay Trieweiler and I am a Certified Laser Technician (CLT) who completed my training at the National Laser Institute in 2013. I have kept my license active under the Arizona Radiation Regulatory Agency since moving to Alaska in 2019, despite the lack of a formal pathway to transfer my credentials to this state. I am passionate about the field of laser hair removal and am committed to ensuring that non-medical professionals like myself have the opportunity to pursue fulfilling careers as CLTs in Alaska.

I am reaching out to advocate for non-medical professionals to be eligible for certification and employment as Certified Laser Technicians in Alaska. I believe that well-trained individuals can perform laser hair removal safely and effectively without the need for a nursing degree or other medical qualifications. This position is rooted in my own experience, as the training I received was both comprehensive and specialized, equipping me with the knowledge to operate lasers safely and manage patient contraindications, while providing a quality service to the client.

The goal is to create reasonable pathways for certification that allow non-medical professionals to join this growing industry while upholding the highest standards of safety. By doing so, Alaska can expand job opportunities, support the local economy, and meet the increasing demand for laser hair removal services.

In support of this advocacy, I have provided a highly detailed document that outlines key information related to laser hair removal certification, the role of CLTs, and the broader industry regulations. Sections 1 through 13 of this document cover everything from the safety of laser hair removal to the need for more accessible certification programs. I hope this information will provide useful context as you consider updates to Alaska's regulations for the medical spa industry.

Thank you for your time and attention to this important matter. I appreciate your efforts to ensure that Alaska's medical spa regulations reflect the needs of both practitioners and the public. Please feel free to reach out if you have any questions or would like further insights.

Sincerely,

Lindsay Trieweiler

Lindsay Trieweiler

Certified Laser Technician

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8. Laser Hair Removal vs. Tattoo Removal

- Differences between laser hair removal and tattoo removal technologies.
- Overview of the energy sources and techniques used in each.
- Risks and benefits of both procedures.

9. Dangers of Laser Hair Removal

- Possible side effects (e.g., burns, pigmentation changes, scarring).
- Importance of proper technique and equipment calibration.
- The role of certification in ensuring safety and minimizing risks.

10. Contraindications

- Situations where laser hair removal is not recommended (e.g., certain skin conditions, active infections, recent sun exposure).
- Precautions and screening for candidates prior to treatment.

11. Role of Medical Providers

- What medical providers do in relation to laser treatments.
- Oversight of CLTs by medical professionals in some states.
- Medical providers handle more complex cases and manage complications.

12. Ablative vs. Non-Ablative Lasers

- Explanation of how ablative lasers work by heating the underlying tissue, damaging the hair follicle, and stopping future growth.
- Ablative lasers as the gold standard for hair removal and FDA-approved.
- CLTs can safely and effectively use ablative lasers without the need for on-site medical directors or requiring a nursing or medical background.
- States like Arizona, Texas, and Florida allow CLTs to operate ablative lasers under indirect supervision.

13. Laser Services Beyond Hair Removal

- Overview of additional services CLTs can provide: photo facials, tattoo removal, body contouring, skin resurfacing, etc.
- Different types of lasers used for these services (IPL, Q-Switched, Fractional CO2, Diode).
- State regulations allowing CLTs to perform without on-site medical supervision.
- The importance of maintaining comprehensive certifications that cover a variety of laser services, allowing CLTs to grow their practice and expertise.
- Advocacy for CLTs to perform these services without needing a nursing degree or medical director, provided they are certified through accredited programs.

14. Conclusion

15. References

1. What is Laser Hair Removal?

Laser hair removal is a cosmetic procedure that uses concentrated beams of light (laser) to remove unwanted hair. The process involves directing laser light at the hair follicles, where the pigment (melanin) in the hair absorbs the light, converting it into heat. This heat damages the follicle, inhibiting or delaying future hair growth. While it may not guarantee permanent hair removal, it significantly reduces hair regrowth, making it a popular long-term solution for managing unwanted hair.

How Laser Hair Removal Works:

1. **Light Absorption:** The laser emits light at a specific wavelength, targeting the melanin in the hair. Darker hair absorbs more light, making the procedure most effective for individuals with dark hair and light skin. Certain lasers do allow removal for persons with dark hair and dark skin.
2. **Heat Generation:** The light energy is converted into heat, which selectively heats the hair shaft and hair follicle, causing damage to the follicle while minimizing harm to surrounding skin.
3. **Hair Growth Cycle:** Hair grows in three phases—anagen (active growth phase), catagen (transition phase), and telogen (resting phase). Laser hair removal is most effective during the anagen phase when the hair is actively growing. Since not all hair is in this phase simultaneously, multiple sessions are required to target hair in the active growth stage.

Benefits of Laser Hair Removal

- **Long-term Hair Reduction:** While not completely permanent, laser hair removal drastically reduces hair regrowth, with some individuals experiencing permanent hair loss after multiple treatments.
- **Precision:** Lasers can selectively target dark, coarse hairs while leaving the surrounding skin undamaged.
- **Speed:** Each pulse of the laser takes a fraction of a second and can treat many hairs simultaneously. Small areas, like the upper lip, can be treated in less than a minute, while larger areas, such as the back or legs, may take up to an hour.
- **Fewer Ingrown Hairs:** Laser hair removal helps reduce ingrown hairs, a common issue with shaving, waxing, and plucking.

Common Treatment Areas:

Laser hair removal can be performed on almost any part of the body, including:

- Face (upper lip, chin, and sideburns)
- Legs
- Arms
- Underarms

- Bikini line
- Back
- Chest

Note: The procedure is most effective on individuals with light skin and dark hair because the contrast allows the laser to target the pigment in the hair without affecting the skin. Technological advancements have allowed treatment for a wider variety of skin tones and hair types, but individuals with light hair (blonde, red, grey) may still find laser hair removal less effective, as there is less pigment in the hair to absorb the laser energy.

Procedure and Sensation:

The procedure itself involves several steps:

1. **Preparation:** Before the procedure, the target area is cleaned, and any remaining hair is shaved to ensure the laser can focus on the hair follicle beneath the skin.
2. **Laser Application:** The technician adjusts the laser settings according to the individual's skin type, hair color, and treatment area. Protective eyewear is used, and a cooling device or gel may be applied to protect the skin and increase comfort.
3. **Sensation During Treatment:** Most people describe the sensation during laser hair removal as feeling like a rubber band snapping against the skin. Some devices use cooling mechanisms to minimize discomfort. The sensation varies depending on the sensitivity of the area being treated and the individual's pain tolerance.

Post-Procedure Care:

- **Redness and Swelling:** Immediately after the treatment, the skin may appear red or swollen, similar to a mild sunburn. This typically subsides within a few hours.
- **Avoid Sun Exposure:** Treated areas should be protected from direct sunlight to avoid hyperpigmentation or irritation. Sunscreen should be applied diligently to treated areas.
- **Multiple Sessions Required:** Since hair grows in cycles, 6–8 sessions spaced 4–6 weeks apart are typically needed to achieve the best results. Maintenance treatments may be required over time, depending on hair regrowth.

Limitations:

While laser hair removal is highly effective, it has some limitations:

- **Hair Color:** The procedure works best on individuals with dark hair and light skin. The contrast allows the laser to better target the pigment in the hair follicle. Advances in laser technology have improved outcomes for people with darker skin, but the treatment is still less effective for those with light or grey hair due to the low levels of melanin.

- **Skin Types:** Different lasers are used depending on skin types (e.g., Alexandrite lasers for lighter skin types and Nd lasers for darker skin tones). A proper consultation is essential to ensure safety and efficacy for individuals with darker skin tones.
- **Multiple Sessions:** Complete hair reduction typically requires several treatments, as not all hair follicles are in the active growth stage during each session.

Citations:

American Academy of Dermatology Association. “Laser Hair Removal: What to Expect.” AAD, Accessed October 2024.

Mayo Clinic. "Laser Hair Removal: Risks, Results, and What to Expect." Mayo Clinic, Accessed October 2024.

2. CLT vs. Esthetician

Laser hair removal services can be provided by a variety of professionals, including Certified Laser Technicians (CLTs) and estheticians. While both roles involve performing cosmetic treatments to improve skin appearance, the key differences between them lie in their training, scope of practice, and the types of procedures they are licensed to perform.

Certified Laser Technician (CLT):

A **Certified Laser Technician (CLT)** specializes in performing laser-based cosmetic treatments, including but not limited to laser hair removal. Their primary focus is on procedures that use lasers or light-based devices to target specific skin and hair issues. Depending on the state and the regulations in place, CLTs may work independently or under the supervision of a medical professional, such as a dermatologist or plastic surgeon. In some states, CLTs may also require additional oversight by licensed medical providers, while in others, they can operate more autonomously.

Training and Certification:

- **Laser-Specific Training:** CLTs undergo specialized training that focuses solely on the use of lasers for cosmetic purposes, including laser hair removal, tattoo removal, skin resurfacing, and treatment of vascular conditions (e.g., spider veins).
- **Clinical Hours:** Most CLT programs require hands-on clinical experience with laser devices, ensuring technicians are comfortable using the technology and understanding the safety protocols.
- **Certification:** CLTs must receive certification from a reputable and accredited laser training program. This certification demonstrates competency in laser safety, techniques, and protocols.

Scope of Practice:

- CLTs are trained to use a variety of light and laser devices to treat hair, skin, and some cosmetic imperfections. Their expertise is focused specifically on laser technologies, including advanced devices like IPL (Intense Pulsed Light) and Nd lasers.
- They are capable of performing laser hair removal, tattoo removal, skin resurfacing, and photofacials, depending on their training and the regulations in their state.
- In some states, CLTs work under the supervision of a licensed medical professional, but their role is distinct from medical professionals in that they do not diagnose or treat medical conditions.

Key Responsibilities:

- Operate laser devices in a safe and effective manner.
- Assess the patient's skin type, hair color, and medical history to determine if they are suitable candidates for laser hair removal.
- Adjust laser settings for individual clients to ensure effective treatment and avoid skin damage.

- Ensure proper skin care before and after the procedure to reduce risks and enhance results.

Esthetician:

An **esthetician** is a licensed skincare professional who provides a wide range of cosmetic treatments focused on improving the appearance and health of the skin. While estheticians can specialize in laser hair removal, their primary focus is typically on non-laser treatments such as facials, exfoliation, and chemical peels.

Training and Certification:

- **General Skincare Training:** Estheticians undergo training in broader skincare treatments, including facials, chemical peels, microdermabrasion, and basic hair removal methods like waxing or sugaring. This training covers skin anatomy, skin conditions, and cosmetic treatments but typically includes little or no laser-specific education.
- **State Licensing Requirements:** Estheticians are licensed by state cosmetology or esthetic boards after completing a required number of training hours at an accredited esthetician school. Each state has its own licensing requirements, with the number of training hours ranging from 300 to 1,500 hours, depending on state regulations.
- **Additional Laser Training:** In some states, estheticians can perform laser hair removal, but they need to complete additional laser certification beyond their basic esthetician training. In other states, estheticians are not allowed to operate lasers at all without further medical or CLT credentials.

Scope of Practice:

- Estheticians primarily focus on cosmetic skin treatments such as facials, exfoliation, moisturizing treatments, and various forms of hair removal that don't require laser technology (e.g., waxing, threading).
- While some estheticians may pursue additional training to perform laser hair removal, it is not typically included in their core education.
- In states that allow it, estheticians who have received additional certification may perform laser hair removal, but their focus remains on overall skin health and non-invasive skincare treatments.

Key Responsibilities:

- Perform non-laser skincare treatments like facials, chemical peels, and waxing.
- Provide consultations to clients to assess skin conditions and recommend appropriate treatments.
- Advise clients on post-treatment skincare and how to maintain the health of their skin.
- In states where laser hair removal is permitted for estheticians, they may offer this service after completing specialized training.

Key Differences Between CLTs and Estheticians:

Aspect	Certified Laser Technician (CLT)	Esthetician
Primary Focus	Laser-based cosmetic procedures (laser hair removal, tattoo removal, skin treatments)	General skincare treatments (facials, peels, waxing)
Training	Specialized training in laser technologies and safety	General skincare training, laser training optional/extra
Certification	Requires certification from accredited laser training programs	Requires state esthetician license, optional laser certification
Scope of Practice	Operates various laser devices for hair and skin treatments	Performs non-laser skincare treatments; laser hair removal only with additional certification
Supervision Requirements	May require supervision by a medical professional, depending on state regulations	Often works independently in salons, but may require medical oversight for laser procedures
Allowed Procedures	Laser hair removal, tattoo removal, skin resurfacing	Facials, chemical peels, waxing, limited laser treatments (with certification)

Overlap and Complementary Skills:

- In some cases, CLTs and estheticians may collaborate in clinics or med spas. Estheticians may handle skincare consultations, recommending clients to CLTs for laser-based treatments, while focusing on non-laser procedures themselves.
- Estheticians who gain additional laser training can expand their services to include laser hair removal, giving them more versatility in their practice.

Regulatory Differences by State:

- Some states regulate laser hair removal strictly and require CLTs to work under medical supervision (e.g., dermatologists or physicians). Other states allow licensed estheticians to perform laser hair removal after additional training, creating variability in the practice across the U.S.

This distinction between CLTs and estheticians highlights how each profession has its own strengths and limitations but it should be noted that it is not a requirement for a CLT to be an esthetician to perform laser hair removal and both professions are required to get additional training specific to laser hair removal.

Citations:

American Med Spa Association. “Laser Hair Removal Regulation by State.” AmSpa, Accessed October 2024.

National Laser Institute. "What is a Certified Laser Technician?" National Laser Institute, Accessed October 2024.

3. State Requirements (Lower 48)

In the United States, the requirements to perform laser hair removal vary significantly by state. While some states have strict regulations, including requirements for medical supervision or licensure, the vast majority of states **do not** require practitioners to be registered nurses (RNs) or have a nursing degree to become a Certified Laser Technician (CLT). In most cases, CLTs can operate under specific certifications without needing medical qualifications, so long as they have undergone appropriate laser training. Here's a detailed breakdown to support this assertion:

States That Do Not Require a Nursing Degree for CLTs:

- **Arizona:** In Arizona, a CLT can perform laser hair removal under the supervision of a licensed medical director but does not need to be a nurse. CLTs must complete an accredited laser training program and meet state-specific requirements set by the Arizona Radiation Regulatory Agency.
- **Texas**: Texas allows estheticians, cosmetologists, and CLTs to perform laser hair removal with appropriate certification. No nursing degree is required.
- **Nevada:** Nevada states that licensed estheticians and cosmetologists can perform laser hair removal without being registered nurses. They need to complete specialized laser training.
- **Colorado:** In Colorado, a professional (such as a doctor or nurse) must supervise the use of lasers, but the technician does not need to be a nurse. Certified Laser Technicians can work under supervision with the appropriate training.
- **Florida:** In Florida, laser hair removal performed by a CLT under the direct supervision of a licensed medical professional, but the technician does not need to hold a nursing degree. Estheticians and cosmetologists can also provide laser services if properly trained.
- **New York:** New York requires that laser hair procedures be performed under the supervision of a physician, but again, it does not mandate that the laser operator be a nurse.

Other States with No Specific Nursing Requirement:

In many states, there are **no specific requirements** for CLTs to hold a nursing degree. The focus is on completing accredited laser training and obtaining a certificate from a reputable institution. For example:

- **Illinois**
- **Georgia**
- **Michigan**
- **Ohio**
- **Pennsylvania**
- **North Carolina**

States Requiring Medical Supervision (But Not Nursing Credentials):

In a number of states, regulations stipulate that laser hair removal be performed under medical supervision (such as under a physician or other licensed medical professional), but the technician handling the laser does not need to be a nurse. Examples of these states include:

- **Massachusetts:** CLTs must work under the supervision of a licensed physician, but the operators themselves do not need to be nurses.
- **Virginia:** Like Massachusetts, Virginia requires physician oversight not mandate that CLTs hold nursing qualifications.

States That Require a Nursing Degree:
While the vast majority of states do not require a nursing degree to perform laser hair removal, a few do have stricter regulations. These states are exceptions rather than the norm:

- **New Jersey:** New Jersey requires that laser hair removal procedures be performed by licensed medical professionals, including registered nurses or physician assistants, under the supervision of a physician.
- **Oregon:** In Oregon, licensed nurses or other medical professionals must perform laser.
- **California**: California only allows nurses to perform laser hair removal after they have completed appropriate training.

Conclusion:

The data strongly support the point that most states do not require a nursing to perform laser hair removal. Instead, the majority of states focus on ensuring that laser operators, such as CLTs, have completed appropriate training and operate under some form of medical oversight or within state-specific regulations. These requirements are generally designed to ensure safety without limiting the field to medical professionals, which would restrict access to the profession and limit job opportunities for non-medical practitioners. By allowing trained, non-nursing professionals to perform laser hair removal, states ensure the expansion of the cosmetic industry, making it accessible for more people while maintaining high safety standards. This is an essential point when advocating for maintaining clear and accessible certification paths for CLTs without imposing unnecessary nursing requirements.

Citations:

American Med Spa Association. "Laser Hair Removal Regulation by State." AmSpa, Accessed October 2024.

Texas Department of Licensing and Regulation. "Laser Hair Removal Program." TDLR, Accessed October 2024.

California Board of Barbering and Cosmetology. "Laser Services in California." BBC, Accessed October 2024.

Nevada State Board of Cosmetology. "Esthetician Licensing and Laser Hair Removal." NSBC, Accessed October 2024.

Colorado Office of Barber and Cosmetology Licensure. "State Laser Hair Removal Regulations." CO, Accessed October 2024.

Florida Department of Health. "Laser Hair Removal Guidelines." FL DOH, Accessed October 2024.

New York State Department of Health. "Laser Hair Removal." NY DOH, Accessed October 2024.

Massachusetts Office of Consumer Affairs and Business Regulation. "Laser Hair Removal Regulation." MA, Accessed October 2024.

Virginia Department of Professional and Occupational Regulation. "Laser Hair Removal Requirements." VDPOR, Accessed October 2024.

New Jersey State Board of Medical Examiners. "Laser Regulations." NJ, Accessed October 2024.

Oregon Health Licensing Office. "Laser Hair Removal Licensure." Oregon HLO, Accessed October 2024.

4. Certification

Certification is a crucial step for anyone looking to become a Certified Laser Technician (CLT). Reputable laser training programs ensure that technicians are well-versed in the technology, safety protocols, and techniques required to perform procedures like laser hair removal effectively. Among the many institutions offering laser certification, the National Laser Institute (NLI) is widely considered the gold standard for training. This section covers the certification process, including the training hours, duration, and cost of becoming a CLT.

National Laser Institute (NLI) Certification:

The National Laser Institute is one of the leading training institutions for laser and medical aesthetics, and it provides comprehensive education for individuals seeking certification as a CLT. Their program is recognized across the United States for its high standards in laser safety, hands-on training, and in-depth theoretical knowledge.

Training Hours:

NLI's laser certification program includes a combination of didactic (classroom) instruction and clinical hands-on training. The training consists of **40 hours of didactic training**, during which students learn about the physics of lasers, skin anatomy, laser safety, and the specifics of various laser treatments, including hair removal, tattoo removal, and skin rejuvenation.

Hands-On Clinical Training:

The program also includes **24 hours of clinical hands-on training**, where students get to operate laser devices on real clients under the supervision of experienced instructors. This training ensures that technicians are confident and competent in the safe operation of laser technology.

Total Duration:

The full certification program typically takes **7 to 14 days** to complete, depending on the specific course schedule and whether the program is taken in-person or as a combination of online and in-person learning. This condensed schedule allows participants to enter the workforce quickly without sacrificing the depth of education.

Program Cost:

The cost of the National Laser Institute's comprehensive laser certification program can range from **$10,000 to $15,000** depending on whether additional medical aesthetics training (such as for injectables or skin care) is included in the package. For those focusing solely on laser certification, the base cost is typically around **$10,000**.

Importance of a Reputable Trainer:

Choosing a reputable institution like NLI is critical because it ensures the technician receives quality training that adheres to industry standards. Accredited programs provide students with the necessary knowledge of laser safety and usage, which is essential in avoiding accidents or mishaps that could harm clients. Completing training from an accredited program not only opens doors for employment but also instills confidence in potential clients and employers.

National Standard:

The need for a national standard in laser certification is important to ensure consistency across states. While individual states may have varying regulations regarding laser hair removal, a certification from a recognized institution like NLI serves as a benchmark for quality and safety across the country. This helps bridge gaps between differing state laws and ensures that all certified technicians meet a high level of proficiency in laser technology.

Citations:

National Laser Institute. "Laser Hair Removal Certification: Course Overview." NLI, Accessed October 2024.

American Med Spa Association. "Laser Hair Removal Training and Certification." AmSpa, Accessed October 2024.

5. Who Oversees CLTs & Scope of Practice

Certified Laser Technicians (CLTs) are typically overseen by medical professionals in many states, but contrary to some misconceptions, it is **not necessary** for a medical provider to be physically present in the building while a CLT is operating. In most states, CLTs can operate lasers for procedures like laser hair removal under what is known as **"indirect supervision"** or **"delegated authority"** from a medical provider. This means that as long as the medical provider has established protocols and remains available for consultation, they do not need to be physically on-site while the CLT performs the procedure.

Indirect Supervision of CLTs:

In states that allow CLTs to operate under indirect supervision, the medical provider, such as a dermatologist or a physician, delegates the task of performing laser treatments to a trained CLT. The medical provider is responsible for overseeing the overall safety and quality of care, but the CLT can work independently within the clinic or med spa without requiring the medical provider to be present. CLTs can own their own businesses and hire a medical director, they do not have to work under a medical director's office.

The **indirect supervision** model allows CLTs to perform laser hair removal and other non-invasive treatments without requiring the physician or nurse to oversee every treatment in person. This arrangement is common in the cosmetic industry, particularly in med spas and dermatology offices, where licensed professionals delegate routine procedures to trained technicians.

States That Allow CLTs to Operate Without On-Site Medical Supervision:

- **Arizona:** In Arizona, CLTs can perform laser treatments under the supervision of a medical director, but the director does not need to be present at the location. The medical provider must ensure that proper protocols are in place, and the CLT must be certified and competent to perform the treatments independently.
- **Texas:** Texas regulations allow CLTs to work under indirect supervision of a licensed medical professional. The physician is required to establish treatment protocols and provide oversight, but they do not need to be on-site while the laser treatments are performed.
- **Nevada:** In Nevada, as long as the supervising physician has delegated authority to the CLT and the technician has the proper training and certification, the medical provider does not need to be physically present in the facility during laser treatments.
- **Florida:** In Florida, CLTs can operate laser equipment under the indirect supervision of a physician. The physician must be available for consultation but does not need to be in the room or building during the procedure.
- **California:** While California requires laser hair removal to be performed under physician supervision, the supervising physician does not need to be physically on-site. Instead,

they delegate the procedures to CLTs, provided the technicians follow established protocols and have the necessary certification.

Responsibility of Medical Providers:

In all these states, the supervising medical provider is responsible for establishing treatment protocols, ensuring the CLT is properly trained and certified, and being available for any questions or complications that may arise during treatment. They do not need to supervise the day-to-day operations of the CLT directly but must be involved in overseeing the clinic or med spa's safety standards.

Benefits of Indirect Supervision:

- **Increased Accessibility to Treatments:** Allowing CLTs to work without constant on-site supervision increases access to cosmetic laser treatments for clients, especially in high-demand settings such as med spas and dermatology clinics.
- **Reduced Overhead for Clinics:** Clinics and med spas can operate more efficiently when CLTs perform procedures without requiring a medical provider to be present. This helps lower operating costs and enables medical providers to focus on more complex tasks.
- **Expanding the Role of CLTs:** The indirect supervision model expands the scope of practice for CLTs, allowing them to take on more responsibility in delivering cosmetic treatments.

Importance of Proper Certification and Protocols:

While states that allow indirect supervision empower CLTs to perform laser hair removal without the medical provider being on-site, it's critical that the CLT receives **proper training** and adheres to **established safety protocols**. Certification from reputable institutions like the National Laser Institute ensures that CLTs are competent and confident in performing laser treatments safely and effectively.

Citations:

National Laser Institute. "State Regulations for Laser Technicians." NLI, Accessed October 2024.

Texas Department of Licensing and Regulation. "Laser Hair Removal Program." TDLR, Accessed October 2024.

Arizona Radiation Regulatory Agency. "Certified Laser Technicians Supervision Guidelines." ARRA, Accessed October 2024.

Nevada State Board of Cosmetology. "Supervision Requirements for Laser Technicians." NSBC, Accessed October 2024.

Florida Department of Health. "Laser Hair Removal Supervision Guidelines." FL DOH, Accessed October 2024.

California Board of Barbering and Cosmetology. "Laser Hair Removal Regulations in California." BBC, Accessed October 2024.

6. Barriers to Entry in Alaska's Laser Hair Removal Industry

Alaska is often noted for its **limited workforce** and is considered by many to be "behind the times" when it comes to implementing the latest trends in the beauty and wellness industries, including laser hair removal. Despite this, there is a growing demand for laser hair removal in the state, as more individuals seek out convenient and long-lasting solutions for unwanted hair. The challenge is finding a balance between creating enough regulation to ensure safety and quality while not establishing overly restrictive barriers that hinder the growth of the industry.

Alaska's Workforce Challenges:

- **Limited Workforce:** Alaska faces unique challenges in maintaining a robust workforce in the beauty and wellness industry. The state's vast geography, smaller population, and remote locations make it difficult to attract and retain skilled professionals.
- **Behind the Times:** Alaska has often been perceived as being slow to adopt modern cosmetic practices. While the demand for procedures like laser hair removal is increasing, the regulatory framework and workforce have not always kept pace with that demand.
- **Growing Need for Laser Hair Removal:** Despite workforce limitations, there is a clear demand for laser hair removal services. Clients in Alaska want access to the same high-quality services that are easily available in other parts of the country.

Creating Reasonable Barriers:

While **safety is paramount**, Alaska must avoid establishing unnecessary barriers that prevent trained professionals from entering the laser hair removal market. Currently, the state has restrictions that, in many cases, limit non-medical professionals from operating laser equipment. This has led to an undersupply of available practitioners, leaving clients underserved.

To address this, Alaska should consider implementing **reasonable barriers** that emphasize proper training without requiring a medical license or nursing degree to perform laser hair removal.

Why Creating Barriers Is Harmful:

- **Restricting Market Entry:** When barriers to entry are too high—such as requiring only medical professionals (e.g., nurses or physicians) to perform laser hair removal—many potential CLTs are kept out of the industry. This stifles job growth and limits the number of available technicians, further straining an already limited workforce.
- **Delaying Industry Growth:** Overly strict regulations prevent Alaska's laser hair removal market from growing in response to demand. If only a select few are allowed to operate laser hair removal devices, it limits accessibility and raises prices, ultimately slowing the state's ability to meet the evolving needs of its population.
- **Economic Realities in Alaska**: While laser hair removal can be a lucrative service, Alaska's relatively small population does not create a demand that would support full-

time positions for many practitioners. For nurses who already have full-time jobs in more essential healthcare roles, transitioning into laser hair removal—particularly in such a niche market—may not be financially viable. As a result, even if nurses are trained to perform the procedure, they are unlikely to leave secure full-time jobs to provide part-time cosmetic services. This creates a shortage of available practitioners, making the service inaccessible to many Alaskans. A full career transition can also leave medical establishments shorter on nurses than they already are.

The Case for Reasonable Barriers:

While there should be safeguards in place to prevent unqualified individuals from practicing laser hair removal, requiring non-medical professionals to complete a renowned training program like the one offered by the National Laser Institute (NLI) is a reasonable barrier. The NLI program requires extensive training in laser safety, techniques, and hands-on experience, ensuring that graduates are fully capable of operating laser equipment safely and effectively. By focusing on proper certification rather than medical licensure, Alaska could open up the market to qualified CLTs, without sacrificing safety or quality.

NLI as a Standard for Certification:

The National Laser Institute's Certified Laser Technician program is the gold standard for laser hair removal training. With **40 hours of didactic education** and **24 hours of clinical hands-on training**, the program ensures that graduates are highly trained in the use of laser technologies, including hair removal, skin resurfacing, and tattoo removal.

By adopting training requirements that align with NLI's rigorous standards, Alaska can:

- Ensure that all laser hair removal technicians meet national safety and quality benchmarks.
- Increase the pool of qualified professionals entering the workforce.
- Allow non-medical professionals to work in the industry, thus expanding access to services.

Balancing the Needs of Safety and Accessibility:

While it is essential to prevent untrained individuals from entering the marketplace, Alaska can still allow non-medical professionals to operate within the industry by setting standards for certification and competency rather than medical licensure. This will:

- **Enhance industry growth:** More certified CLTs would enter the market, creating jobs and expanding service availability.
- **Support consumer demand:** Alaskans seeking laser hair removal services would no longer need to rely on a limited number of providers.
- **Maintain safety standards:** By ensuring that technicians are certified through reputable programs, the state can maintain high safety standards without unnecessary medical barriers.

Citations:

National Laser Institute. "Laser Hair Removal Certification: Course Overview." NLI, Accessed October 2024.

Alaska Department of Labor and Workforce Development. "State Workforce Data and Trends." Alaska DOL, Accessed October 2024.

American Med Spa Association. "State Regulations for Laser Hair Removal." AmSpa, Accessed October 2024.

7. Becoming a CLT in Alaska: Commitment and Challenges

For individuals in Alaska who wish to pursue a career as a Certified Laser Technician (CLT), there are significant hurdles, primarily because **Alaska does not currently offer any certified laser hair removal programs** within the state. This lack of local educational opportunities creates additional barriers for anyone interested in entering the laser hair removal field, requiring them to travel out of state to obtain the necessary certification.

No Local Training Programs:

Unlike many other states that offer laser hair removal training at cosmetology schools, medical spas, or specialized laser training centers, Alaska does not have any programs that offer accredited laser certification. This forces aspiring CLTs to look outside the state for their education. This gap in local resources adds another layer of difficulty for those interested in entering the industry.

Out-of-State Travel Requirements:

Becoming a CLT in Alaska involves a serious commitment—not only in time but also in financial resources. Individuals must travel to another state to complete their certification, which requires paying for:

- **Airfare** to and from the training location.
- **Accommodation and meals** during the duration of the program.
- **Program tuition**, which typically costs around $10,000 for reputable certification programs like the National Laser Institute.

These additional expenses can significantly increase the overall cost of obtaining certification, and the travel itself demands a commitment of time away from family, work, and other responsibilities. Only those who are fully committed to making this career shift are likely to invest in these additional resources.

Not a Quick Weekend Course:

It's important to emphasize that becoming a CLT is not a process that can be done over a weekend or with minimal effort. Unlike some industries where a brief course might qualify someone to open a business, laser hair removal certification requires intensive training and hands-on experience. A regular person wouldn't be able to complete a short course and immediately start offering services.

The path to certification is rigorous and demands a significant investment of time and money, meaning only those who are determined, motivated, and willing to spend the necessary resources will be able to pursue this career. This commitment serves as a natural filter, ensuring that only those truly serious about the profession can enter the industry.

Program Cost and Duration:

As noted, reputable training programs, such as the National Laser Institute (NLI), typically require a financial investment of $10,000 to $15,000 for certification. The program generally takes 7 to 14 days to complete, adding further time away from home. In addition to program costs, the expenses for travel, hotel, and meals can add several thousand dollars more to the final bill.

Serious Career Commitment:

The requirement to leave the state and invest additional money makes pursuing laser hair removal certification a decision that only those truly dedicated to making a serious career move will undertake. This is not a simple or quick process; it requires careful planning, a financial commitment, and a strong desire to enter the field of laser hair removal. For individuals who do make this commitment, the rewards can be substantial in terms of job satisfaction and career opportunities, but the initial hurdles are high.

By offering reasonable certification paths within Alaska, such as through remote learning options combined with local clinics for hands-on training, the state could help reduce these barriers and allow more people to enter the workforce, helping to meet the growing demand for laser hair removal services.

Citations:

National Laser Institute. "Laser Hair Removal Certification: Course Overview." NLI, Accessed October 2024.

Alaska Department of Labor and Workforce Development. "State Workforce Data and Trends." Alaska DOL, Accessed October 2024.

8. Laser Hair Removal vs. Tattooing

Both laser hair removal and tattooing involve skin-focused procedures, but they differ significantly in terms of invasiveness, safety concerns, and how they affect the skin. While both are cosmetic services, laser hair removal is much less invasive than tattooing, making it a safer and less complex procedure. This section will explore the differences between these two services and the relative safety of each, focusing on the fact that laser hair removal does not puncture the skin and is generally safer, yet it is subject to stricter oversight compared to tattooing.

Laser Hair Removal: A Less Invasive Procedure

Laser hair removal is a non-invasive cosmetic procedure that targets hair follicles beneath the skin's surface. The laser energy penetrates into the **subcutaneous layer of the skin**, where it is absorbed by the pigment (melanin) in the hair follicles. This process heats the follicle, damaging it to prevent or reduce future hair growth. Importantly, the laser **does not puncture or break the skin**, making the procedure much less invasive than other skin treatments, including tattooing.

- **No Skin Piercing or Bleeding:** Since the laser focuses on the hair follicles below the skin, the surface remains intact. There is no bleeding, scarring, or puncturing of the skin, which greatly reduces the risk of infection or other complications.
- **Minimal Recovery Time:** Clients who undergo laser hair removal typically experience mild side effects like redness or slight swelling, which resolve within hours to a day. The skin remains unbroken, so there's no need for extensive recovery time or special aftercare, unlike more invasive procedures.

Tattooing: A More Invasive Process

Tattooing, in contrast, involves **piercing the skin** repeatedly with needles that deposit ink into the **dermal layer** of the skin. This process creates a permanent design in the skin by introducing foreign pigments that the body does not absorb.

- **Skin Puncturing and Bleeding:** Tattooing inherently involves puncturing the skin thousands of times per minute, which causes **bleeding**, swelling, and scabbing during and after the procedure. This breaks the skin's natural barrier and can increase the risk of infection if proper aftercare is not followed.
- **Introducing Foreign Substances:** During tattooing, foreign pigments (inks) are injected into the skin. These pigments are often composed of various chemicals that the body must process, and complications like allergic reactions, infections, and scarring are possible. The fact that tattooing involves introducing foreign materials into the body increases the complexity and risk compared to laser hair removal, which involves no such substances.

Regulatory Disparity:

Despite tattooing being more invasive and having a higher risk of complications, the regulatory requirements for tattooing are often less stringent than those for laser hair removal. In many states, individuals can become licensed tattoo artists with basic training and minimal oversight, whereas laser hair removal often requires extensive certification and, in some cases, medical supervision.

- **Tattooing: Invasive with Fewer Regulations:** Tattoo artists are not usually required to operate under medical supervision, and many states have lenient regulations when it comes to licensing. This is despite the fact that tattooing involves breaking the skin, introducing foreign substances, and carrying a higher risk of infection and complications.
- **Laser Hair Removal: Less Invasive but More Heavily Regulated:** In contrast, laser hair removal, which does not involve skin puncturing or the introduction of foreign substances, is more stringently regulated. In some states, Certified Laser Technicians (CLTs) must operate under the indirect supervision of a medical professional, even though the procedure is far less invasive than tattooing.

Key Differences in Invasiveness:

- **Laser Hair Removal:**
  - Targets hair follicles in the subcutaneous layer of the skin.
  - **Does not pierce or break the skin**.
  - No bleeding or scarring.
  - Minimal side effects such as temporary redness or swelling.
- **Tattooing:**
  - Punctures the skin repeatedly with needles to introduce ink into the dermal layer.
  - Causes **bleeding, scabbing, and swelling**.
  - Involves foreign substances (ink) that the body must process, increasing the risk of allergic reactions or infections.
  - Requires more detailed aftercare to avoid complications like infection or scarring.

Conclusion:

While both laser hair removal and tattooing are cosmetic procedures, laser hair removal is **significantly less invasive**. It does not involve puncturing the skin or introducing foreign substances, which means it carries a much lower risk of complications. Despite this, laser hair removal is often subject to more stringent regulations and oversight than tattooing, which has greater potential risks due to its invasive nature. This regulatory disparity highlights the need for more consistent standards that reflect the true risks associated with each procedure.

Citations:

National Laser Institute. "Laser Hair Removal Certification: Course Overview." NLI, Accessed October 2024.

Mayo Clinic. "Tattooing: Risks, Recovery, and Results." Mayo Clinic, Accessed October 2024.

American Academy of Dermatology. "Laser Hair Removal: What to Expect." AAD, Accessed October 2024.

9. Dangers of Laser Hair Removal

While laser hair removal is often perceived as a highly technical procedure, the reality is that laser hair removal is not inherently dangerous when performed by trained and certified professionals. The risks associated with the procedure are minimal and can be easily mitigated with proper safety protocols, such as the use of laser safety goggles and pre-treatment consultations to review any potential contraindications. The most significant danger is improper handling of the laser equipment, particularly regarding eye safety, but even these risks are rare and easily preventable with standard precautions.

Laser Safety:

The primary safety concern with laser hair removal revolves around the laser device itself, not the procedure on the skin. Laser equipment, if mishandled, could pose a danger to the eyes, which is why laser safety goggles are a standard requirement for both the technician and the patient during treatment.

- **Eye Protection:** In most states, both the technician and the patient are required to wear **laser safety goggles** during the procedure to prevent accidental exposure to the laser beam, which could cause permanent damage to the eyes. This is the most critical safety measure in laser hair removal. However, the risk of accidental eye injury is very low when these precautions are followed, and certified laser technicians are trained specifically in laser safety.
- **Proper Equipment Handling:** Certified Laser Technicians (CLTs) undergo extensive training in handling laser devices. The most dangerous scenario occurs when the laser is **improperly managed** or aimed at areas it shouldn't be—particularly the eyes. When safety protocols are followed, such as calibrating the laser properly and ensuring that goggles are worn, the risks of injury are negligible.

Reviewing Contraindications:

To ensure safe and effective treatment, many states require that patients provide a list of medications or medical conditions prior to laser hair removal. This allows the technician to screen for any contraindications that might make laser treatment inappropriate. Certain medications, such as those that make the skin more sensitive to light (e.g., photosensitizing medications like retinoids or antibiotics), may increase the risk of skin irritation or burns.

- **Pre-Treatment Consultation:** During this consultation, the technician reviews the patient's medical history, medications, and any skin conditions that could increase the risk of adverse reactions. For example, those with certain skin conditions (such as active infections or conditions like psoriasis) may need to avoid laser treatments or postpone the procedure until the condition resolves.
- **Minimal Risks:** When these precautions are followed, laser hair removal is generally very safe. Unlike more invasive cosmetic procedures, laser hair removal **does not break the**

skin and does not introduce foreign substances, which significantly reduces the risk of infection or complications.

Injury and Malpractice Records:

The safety of laser hair removal is also reflected in the **lack of reported injuries** and the **absence of widespread malpractice claims** associated with the procedure. Despite millions of treatments being performed annually, cases of significant injury from laser hair removal are extremely rare. This is largely due to the non-invasive nature of the treatment and the stringent training and certification standards required of laser technicians.

- **Low Incident Rate:** Injuries, when they do occur, are typically minor and resolve on their own, such as mild redness or irritation. Burns, pigmentation changes, or blistering are exceedingly rare, especially when performed by a certified technician following proper protocols. There are few, if any, cases of serious injuries reported in reputable medical or legal databases regarding laser hair removal.
- **Lack of Malpractice Claims:** Unlike other cosmetic procedures, laser hair removal has no significant record of malpractice cases. Because the procedure is minimally invasive and doesn't involve breaking the skin or introducing foreign substances, the likelihood of a client experiencing a severe injury that would lead to a malpractice suit is very low. This stands in stark contrast to more invasive procedures, such as surgical cosmetic treatments, which have a much higher rate of complications and legal actions.

Conclusion:

Laser hair removal is not a dangerous practice when performed by trained and certified technicians. The most significant risk—eye injury—can be easily avoided with the use of mandatory safety goggles, which are required in most states. Additionally, pre-treatment consultations to review a patient's medical history and medications help ensure that contraindications are identified and addressed. The low number of reported injuries and the lack of malpractice claims further demonstrate the safety of this procedure. Overall, laser hair removal is one of the safest and most effective cosmetic treatments available, provided that proper precautions are taken.

Citations:

National Laser Institute. "Laser Hair Removal Certification: Safety and Risks." NLI, Accessed October 2024.

American Academy of Dermatology. "Laser Hair Removal: Risks and Benefits." AAD, Accessed October 2024.

Mayo Clinic. "Laser Hair Removal Safety Guidelines." Mayo Clinic, Accessed October 2024.

10. Contraindications

Certified Laser Technicians (CLTs) are thoroughly trained to understand and recognize contraindications—factors that might make laser hair removal unsafe or ineffective for certain clients. Contrary to the belief that a medical professional is necessary to determine these contraindications, CLTs are fully capable of making these assessments based on their training and established protocols. They follow a standard process of reviewing paperwork completed by the client before the procedure, allowing them to identify any issues that might interfere with treatment.

Training on Contraindications:

CLTs receive specific training on how to identify contraindications during their certification programs, such as the one offered by the National Laser Institute. This training includes detailed information on medications, skin conditions, and other factors that may impact the safety or effectiveness of laser hair removal.

- **Comprehensive Education:** CLTs learn about the interactions between the laser and various skin types, medical conditions, and medications that can affect the outcome of the procedure. This includes understanding how medications like retinoids or antibiotics (which can increase skin sensitivity) may pose a risk, or how conditions like photosensitivity or active skin infections might require postponing treatment.
- **Non-Medical Professionals Can Handle Contraindications:** Importantly, CLTs **do not need to be medical professionals** to identify and manage contraindications. Their training provides them with the necessary skills to recognize when a treatment should not proceed. CLTs are taught to understand the potential risks and to act accordingly, whether that means delaying a session or advising the client to consult a healthcare provider.

Paperwork and Pre-Treatment Review:
Before a laser hair removal session, clients are required to fill out detailed paperwork that includes their medical history, current medications, and any relevant skin or health concerns. This paperwork is reviewed by the CLT to determine if there are any contraindications that would prevent safe treatment.

- **Pre-Session Consultation:** Based on this review, the CLT can either proceed with the treatment or recommend modifications. For example, if a client is taking medications that cause photosensitivity, the CLT may decide to reschedule the session or adjust the laser settings to minimize any potential skin damage.
- **Self-Sufficient Review:** The process of reviewing paperwork and making these determinations can be done independently by the CLT. There is no need for a doctor or nurse to step in, as CLTs are trained to assess this information and make appropriate decisions regarding treatment.

Safe and Effective Process:

By completing this pre-treatment review and understanding contraindications, CLTs are able to provide safe and effective laser hair removal treatments without requiring constant oversight from medical professionals. This further supports the argument that CLTs, when properly trained, are fully capable of managing the laser hair removal process from start to finish.

Examples of Common Contraindications:

- **Photosensitizing Medications:** Certain drugs can make the skin more sensitive to light, increasing the risk of burns or irritation. CLTs are trained to recognize these medications and adjust the treatment or reschedule the session if necessary.
- **Active Skin Conditions:** Conditions such as eczema, psoriasis, or dermatitis in the treatment area may require delaying or modifying the procedure to avoid aggravating the condition.
- **Recent Tanning or Sunburn:** Laser hair removal is less effective and riskier on recently tanned or sunburned skin, so CLTs are trained to identify these situations and adjust the treatment schedule accordingly.

Conclusion:

Certified Laser Technicians are well-equipped to identify and manage contraindications, thanks to their extensive training. They do not need to be medical professionals to make informed decisions regarding the safety of laser hair removal treatments. The pre-treatment paperwork provides all the necessary information, allowing CLTs to review it and proceed independently, ensuring that the process is safe for every client.

Citations:

National Laser Institute. "Laser Hair Removal Certification: Contraindications and Safety." NLI, Accessed October 2024.

American Academy of Dermatology. "Laser Hair Removal: What to Expect and Contraindications." AAD, Accessed October 2024.

Mayo Clinic. "Medications and Skin Conditions That Impact Laser Hair Removal." Mayo Clinic, Accessed October 2024.

11. Role of Medical Providers

In many states, Certified Laser Technicians (CLTs) are required to operate under the indirect supervision of a medical director, who provides oversight and answers questions related to client safety and contraindications. However, the role of the medical director in this context is often limited to administrative and advisory responsibilities rather than direct involvement in the laser hair removal procedures. Most medical directors are not trained or certified to operate lasers and do not need to be present in the facility while treatments are performed.

Use of Medical Directors in Other States:

In states that regulate laser hair removal, a medical director is often required to provide indirect oversight for CLTs. This model allows CLTs to operate independently while ensuring that there is a qualified medical professional available to handle any complex questions, particularly those related to contraindications.

- **States With Medical Director Requirements:**
    - **Texas:** In Texas, CLTs can operate under the supervision of a medical director, who oversees the practice and ensures that safety protocols are followed. However, the medical director is not required to be physically present during the procedure. They provide oversight to ensure that the laser hair removal facility adheres to state regulations, and they can be consulted as needed if complications arise.
    - **California:** California requires that laser hair removal be performed under the supervision of a licensed physician, but the physician does not need to be on-site. CLTs work under their medical director's authority, with the physician serving as an advisor who can be contacted in case of questions or contraindications.
    - **Florida:** In Florida, medical directors oversee laser hair removal technicians but are not required to be physically in the building during treatments. They provide the necessary supervision on an administrative level and ensure compliance with state laws, but day-to-day laser operations are handled by the CLT.

The Medical Director's Role:

The role of the medical director in these settings is primarily one of oversight. They serve as a resource for the CLT to consult in cases of uncertainty or when questions arise about specific client health concerns, such as contraindications. However, it is important to note that most medical directors are not laser certified and may have no experience operating a laser themselves.

- **Answering Questions About Contraindications:** Medical directors can be consulted when a CLT encounters a potential contraindication during the pre-treatment screening process. These contraindications could include the client's use of **photosensitizing**

medications (like antibiotics or retinoids), the presence of **active skin infections**, or certain medical conditions like autoimmune disorders or skin cancers. While the CLT is trained to recognize these issues, they may consult the medical director for additional guidance or confirmation.

- **Administrative and Legal Oversight:** The medical director's role is largely administrative, ensuring that the laser practice operates in compliance with state regulations. They are responsible for ensuring that proper safety protocols are in place, and that the CLTs are certified and trained to operate the laser equipment safely.

Medical Directors Do Not Need to Be Laser Certified:

Interestingly, in most states, the medical director **does not need to be trained or certified** in the operation of lasers. Their oversight role is focused on ensuring the safety and legal operation of the facility, not on the technical aspects of laser procedures. This creates a situation where the medical director provides a legal and safety umbrella for the CLT but does not intervene in the actual treatment process unless a medical complication arises.

- **Not Required to Be Present or Laser Trained:** The medical director does not need to be present in the facility when laser hair removal treatments are being performed. Their oversight is provided remotely, allowing CLTs to operate independently as long as they have access to the medical director for consultation when necessary. In most cases, the medical director has little to no involvement in the day-to-day operations of the clinic beyond fulfilling regulatory requirements.

Why This Model Works:

This model of supervision works well because CLTs are trained to handle most of the responsibilities associated with laser hair removal, including identifying contraindications and following safety protocols. The medical director is available to **answer more complex medical questions** when necessary but is not involved in the technical aspects of the procedure. This system allows the CLT to operate independently while still maintaining a **safety net** in the form of indirect medical oversight.

- **Minimal Involvement in Laser Operations:** Since medical directors are typically not laser certified and have no direct experience with laser procedures, their role is limited to offering guidance on broader medical issues rather than providing specific laser-related expertise. This reflects the reality that laser hair removal is a **cosmetic procedure** that can be safely performed by trained technicians without direct medical intervention.

Examples of Common Contraindications Addressed by Medical Directors:

- **Photosensitizing Medications:** If a client reports using medications that increase sensitivity to light, the CLT may consult the medical director to confirm whether the treatment should be rescheduled or adjusted.
- **Medical Conditions:** Conditions such as autoimmune diseases or skin cancers may require additional medical input before proceeding with laser treatments, allowing the medical director to offer guidance on whether the treatment is appropriate.

Conclusion:

The use of medical directors to oversee Certified Laser Technicians in states like Texas, California, and Florida ensures that laser hair removal practices operate safely and in compliance with regulations. However, the role of the medical director is primarily administrative and advisory, and they do not need to be on-site or certified to operate lasers. CLTs are trained to manage the technical aspects of laser hair removal, while the medical director provides oversight and is available to address contraindications or broader health concerns as needed. This model allows for safe and effective operation while giving CLTs the autonomy to perform treatments independently.

Citations:

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12. Ablative vs. Non-Ablative Lasers

In the world of cosmetic laser treatments, there are two primary categories of lasers: ablative and non-ablative. Ablative lasers work by heating the underlying tissue in the skin, which damages the hair follicle and stops future hair growth. Non-ablative lasers, on the other hand, penetrate the skin without damaging the surface. In the context of laser hair removal, ablative lasers are considered the gold standard due to their efficiency and effectiveness. I believe that Certified Laser Technicians (CLTs) should be allowed to use ablative lasers without the need for a medical director to be on-site, nor should they be required to be nurses or other medical professionals to operate these lasers.

Ablative Lasers: The Gold Standard for Hair Removal

Ablative lasers work by heating the underlying tissue in the skin, targeting the hair follicles with precision. This heat damages the follicle, effectively stopping future hair growth. Ablative lasers are known for their high efficacy and have been FDA-approved for use in laser hair removal procedures.

- **Efficiency and Effectiveness:** Ablative lasers provide longer-lasting results than non-ablative lasers. By reaching the subcutaneous layer and heating the underlying tissue, ablative lasers are able to target hair follicles more directly and effectively. This makes them a superior choice for clients seeking significant and permanent hair reduction.
- **FDA-Approved Technology:** Ablative lasers have been thoroughly evaluated and approved by the FDA for use in hair removal procedures. Their safety and efficacy have been well-documented, providing reassurance that these devices can be operated safely when handled by certified professionals, like CLTs, who are trained in laser operation and safety protocols.

CLTs and Ablative Lasers: No Medical Director or Nursing Degree Required

Certified Laser Technicians (CLTs) are specifically trained to handle both ablative and non-ablative laser technologies. The rigorous training programs provided by reputable institutions cover the technical and safety aspects of using these powerful devices.

- **No Medical Expertise Required:** Contrary to some regulations in other fields, operating an ablative laser for hair removal does not require medical expertise. CLTs receive comprehensive training that covers all safety concerns, including recognizing contraindications and using the laser equipment properly. There is no need for a nurse or medical professional to oversee the procedure or operate the laser. This training makes CLTs fully competent in handling ablative lasers without requiring the involvement of a medical director or having one present in the office.
- **No On-Site Medical Director:** In states like Texas, California, and Arizona, ablative lasers are used under the supervision of a medical director, but the director is not required to be on-site. Instead, the medical director provides oversight, reviews treatment protocols, and is available for consultation if needed, but the day-to-day operations are conducted by the CLT independently.

State Regulations Supporting CLTs' Use of Ablative Lasers

Many states across the U.S. already recognize that ablative laser hair removal can be safely and effectively performed by trained CLTs without requiring the presence of a medical director or any further medical qualifications.

- **Arizona:** In Arizona, CLTs are allowed to use ablative lasers under the supervision of a medical director who does not need to be present in the facility. CLTs are expected to follow safety protocols and are fully trained to operate the lasers autonomously.
- **Florida:** In Florida, CLTs can operate ablative lasers under indirect supervision. Medical directors are not required to be on-site, allowing the CLTs to work independently once they have completed the necessary certification programs.
- **Nevada:** Nevada follows a similar approach, allowing CLTs to use ablative lasers as long as they are trained and certified. The state does not require CLTs to have medical qualifications, only that they adhere to established safety guidelines and are overseen by a medical director who does not need to be physically present.

Why Ablative Lasers Should Remain Accessible to CLTs

The continued ability of CLTs to use ablative lasers without needing to be medical professionals or having an on-site medical director is crucial for the growth and accessibility of laser hair removal services in Alaska and beyond. Requiring medical degrees or the constant presence of a medical director would limit access to these services, increase costs, and create unnecessary barriers for both professionals and clients.

- **Safety Through Proper Training:** CLTs are already trained to a high standard to ensure the safe use of ablative lasers. By allowing them to continue operating these lasers independently, states can ensure that the industry remains both accessible and safe without imposing unnecessary barriers to entry.
- **Maintaining High Standards While Encouraging Growth:** Allowing trained, certified professionals to use ablative lasers without additional medical supervision supports job growth, opens up career opportunities for non-medical professionals, and helps meet the growing demand for laser hair removal services.

Citations:

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13. Laser Services Beyond Hair Removal

Certified Laser Technicians (CLTs) are trained to perform a wide range of cosmetic laser services beyond just hair removal. These additional services, including **photo facials, laser tattoo removal, body contouring**, and skin resurfacing, open up significant opportunities for CLTs to grow their practice and brand. It is important that CLTs have access to certifications in these advanced treatments without the need for a nursing degree or on-site medical supervision, but still under the requirement of obtaining certifications from reputable and accredited programs.

Laser Services CLTs Can Provide Beyond Hair Removal

- **Photo Facials (Intense Pulsed Light - IPL):** IPL treatments, often referred to as photo facials, are used to treat pigmentation, sun damage, and vascular lesions by delivering pulses of light into the skin to target discoloration. This procedure requires knowledge of how different skin types react to light, and CLTs are trained in this area to perform the treatment safely and effectively.
- **Laser Tattoo Removal:** Laser tattoo removal is one of the most common services CLTs offer beyond hair removal. Using **Q-switched lasers**, CLTs can break down ink particles in tattoos without damaging the surrounding skin. This service requires technical expertise in handling different wavelengths depending on the ink colors used in the tattoo, and CLTs receive specialized training to handle this procedure safely.
- **Body Contouring (Laser Lipolysis):** CLTs also perform **laser body contouring** procedures such as laser lipolysis, which uses **non-invasive lasers** to break down fat cells in targeted areas of the body. These treatments require precision and knowledge of body anatomy, both of which are covered in certification programs for CLTs.
- **Skin Resurfacing:** Ablative and non-ablative lasers are used in skin resurfacing procedures to treat wrinkles, scars, and other skin imperfections by stimulating collagen production. CLTs who specialize in skin resurfacing use lasers like **fractional CO2** or **Erbium lasers**, depending on the depth and intensity of the treatment required.

Types of Lasers Used in These Procedures

- **IPL (Intense Pulsed Light):** Commonly used in photo facials for pigmentation and sun damage correction.
- **Q-Switched Lasers:** Specifically used for tattoo removal, these lasers break down ink particles in the skin without affecting the surrounding tissue.
- **Fractional CO2 Lasers:** Used for deeper skin resurfacing, these lasers remove layers of skin to promote collagen production and new skin growth.
- **Erbium Lasers:** Often used in less aggressive skin resurfacing treatments, these lasers focus on treating fine lines and wrinkles with minimal downtime.
- **Diode Lasers:** Commonly used in body contouring, diode lasers heat fat cells to break them down without invasive surgery.

State Regulations Allowing CLTs to Operate Independently

Many states allow CLTs to perform various laser services independently or with indirect supervision, meaning that a medical director does not need to be physically present for treatments, nor does the CLT need to hold a nursing degree. This allows CLTs to perform a variety of laser services safely while keeping the barriers to entry reasonable.

- **Arizona:** Arizona allows CLTs to perform laser hair removal and other laser services like tattoo removal and skin resurfacing under **indirect supervision**. The medical director must oversee the facility but does not need to be on-site during treatments.
- **Texas:** In Texas, CLTs can perform laser hair removal, IPL treatments, and other laser services without requiring a medical professional to be present. Medical directors are required to oversee the practice remotely, providing supervision as needed, but they are not required to be on-site.
- **Florida:** In Florida, CLTs can offer a variety of services, including body contouring and tattoo removal, under **remote medical supervision**. Similar to Arizona and Texas, the supervising physician must be available but does not need to be physically present.
- **Nevada:** CLTs in Nevada can independently perform laser hair removal and advanced procedures such as skin resurfacing and tattoo removal under **indirect supervision**. A medical director oversees the practice but is not required to be on-site, allowing CLTs to operate autonomously as long as they adhere to safety protocols.

Certification and Licensing Considerations

It is crucial that CLTs have access to **comprehensive certification programs** that cover all laser services, not just hair removal. Each service requires specific training due to the varying types of lasers used and the technical skills needed to operate them. However, it is not necessary for CLT licensure to be fragmented into individual certifications for each service. Instead, CLTs can achieve comprehensive certification that covers multiple services, allowing them to grow their expertise and practice.

- **Maintaining Comprehensive Certification:** A **comprehensive certification** that includes hair removal, tattoo removal, photo facials, body contouring, and skin resurfacing allows CLTs to offer a broad range of services. This helps them grow their practice and avoid limitations caused by fragmented licensing.
- **Importance of Accredited Programs:** The need for **accredited programs** cannot be overstated. These programs ensure that CLTs are fully equipped to handle a variety of laser procedures, maintaining high standards of safety and efficacy. This ensures that clients receive the best care, and the industry remains professional and regulated.

Why It's Important to Allow CLTs to Grow Without Medical Barriers

By enabling CLTs to be certified in a variety of laser services, the industry encourages growth and allows these professionals to build their brands. Requiring a nursing degree or on-site supervision by a medical director would place unnecessary barriers to entry and limit the ability of CLTs to expand their offerings.

- **No Medical Degree Required:** The technical nature of these laser procedures does not require a medical background. Certified Laser Technicians receive specialized, focused

training that equips them to handle these treatments safely. By allowing CLTs to perform these services without needing a nursing degree, the industry can flourish without restricting job opportunities.

- **No On-Site Medical Director Needed:** States like **Arizona, Texas, and California** allow CLTs to operate under indirect medical supervision, ensuring safety without requiring a medical director to be on-site. This model works well for procedures like tattoo removal and skin resurfacing, where the CLT is trained to handle the lasers independently, and the medical director can be consulted remotely if needed.
- **Opportunities for Growth:** Allowing CLTs to expand their services and certifications supports the growth of their businesses and the industry as a whole. It also ensures that clients have access to a broad range of cosmetic laser treatments, making these services more accessible to a wider population.

Conclusion

Certified Laser Technicians should be allowed to perform a variety of laser services beyond hair removal, including photo facials, tattoo removal, and body contouring, without the requirement of being a nurse or needing an on-site medical director. Comprehensive certification programs from accredited institutions ensure that CLTs are fully trained in these procedures, allowing them to expand their expertise and grow their practice without unnecessary barriers. This approach benefits both the professionals in the field and the clients seeking safe, effective cosmetic treatments.

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14. Conclusion: The Vital Role of Certified Laser Technicians (CLTs) in the Industry

Certified Laser Technicians (CLTs) are critical to the continued growth and accessibility of the laser services industry. These professionals are trained to provide a wide range of laser treatments, including laser hair removal, tattoo removal, body contouring, and skin resurfacing, without needing to be medical professionals such as nurses or doctors. Through rigorous training programs, CLTs acquire the knowledge and technical skills necessary to perform these services safely and effectively, ensuring a high standard of care for their clients.

It is important to emphasize that the risk associated with laser hair removal and other cosmetic laser services is minimal when proper protocols are followed. CLTs are trained to recognize contraindications, handle laser equipment safely, and mitigate any potential risks. Safety protocols, such as the use of protective eyewear and pre-treatment consultations to review medical history, are integral parts of the certification process. These measures ensure that CLTs can deliver treatments that are both effective and safe, without the need for direct oversight by a medical professional.

In light of this, it is crucial that the state of Alaska recognizes CLTs as a distinct professional entity, separate from estheticians or other cosmetology licenses. Establishing a specific CLT licensure would allow individuals to be certified in one or multiple areas of laser expertise, such as laser hair removal, tattoo removal, or body contouring. This would provide a clear, regulated pathway for non-medical professionals to enter the field, while maintaining the highest standards of training and safety through accredited programs.

By acknowledging CLTs as their own category of professionals, Alaska can encourage growth within the cosmetic laser industry, opening up job opportunities and providing consumers with greater access to these in-demand services. At the same time, this approach ensures that the industry remains regulated and that only those who have undergone the necessary training and certification can perform laser services. Offering licensure in multiple areas allows CLTs to expand their practice and meet the varied needs of clients, from hair removal to more advanced skin treatments, fostering both professional growth and industry innovation.

In conclusion, Certified Laser Technicians play an indispensable role in the cosmetic laser industry, providing safe, effective, and specialized services. With minimal risk involved and comprehensive training requirements in place, there is no need to require medical degrees or on-site supervision for CLTs. Instead, Alaska should create clear pathways for licensure, supporting the growth of the industry while ensuring that clients receive the highest level of care from certified professionals. Establishing CLTs as a recognized and licensed profession will benefit both the workforce and the public, driving forward a thriving and safe laser services industry in the state.

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From: Adam Looney
To: Chambers, Sara C (CED)
Subject: Medical Spa Services Work Group Public Comment
Date: Wednesday, October 2, 2024 7:57:57 AM

Hello Sara,
Thank you for taking time to organize this meeting, please see my public comment below (I think this can be done in 3 minutes):

I am writing to express concerns as a registered nurse in the community regarding the safety and efficacy of compounded injections and medications administered in medical spa settings. With the increasing use of compounded products, I urge the group to consider the following critical issues:

1. Safety and Efficacy: How is safety and efficacy of these compounded medications being verified before being administered to patients in these settings? Often compounded medications can be sourced from a reputable lab but process and quality control is essential to patient safety; it is unclear how consistent checks are being maintained by unlicensed personnel without clear guidelines.

2. Lack of Patient Disclaimers: There appears to be no or very little disclaimer to patients that compounded medications are not FDA-regulated. Many patients may not be aware that the products they are receiving cannot be guaranteed to contain the specific medication or ingredient they believe they are being treated with. This lack of transparency raises concerns about informed consent and patient safety.

As of March 31, 2024, the FDA Adverse Event Reporting System (FAERS) includes 442 cases of adverse events associated with compounded drugs claiming to contain semaglutide. Alarmingly, 319 of these cases were classified as serious, with 99 resulting in hospitalization and seven involving death. These numbers highlight the urgent need for regulatory oversight and patient education regarding compounded products.

I ask the work group to address these concerns by requiring clearer patient disclaimers and more stringent verification processes for compounded medications to ensure patient safety in medical spa services.

Adam Looney, BSN RN

10/24/2024

Rhianna Boone RDH, BS and Skya Maxon RDH, BS

Homer, AK 99603

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907-299-1240, 907-205-7014

We urge you to consider not only broadening the scope of practice for dental hygiene by allowing us to administer Botox and dermal fillers, but also allowing us to use cosmetic lasers in a med spa and clinical setting.

Laser Safety and Training

Both fields require comprehensive training for safe and effective use. The protocols in dental laser treatments and cosmetic laser procedures are similar regarding patient safety, understanding tissue interaction, and preventing damage to surrounding areas.

Bridging Strategy: By offering cross-disciplinary training programs for practitioners, professionals in dentistry and aesthetics could become proficient in using lasers for dual purposes, leveraging their existing skills to expand into new treatment areas.

Aesthetic Dentistry and Facial Aesthetics

The growing field of aesthetic dentistry already incorporates cosmetic laser techniques to enhance the overall facial appearance. Diode lasers are increasingly being used in gum contouring to complement smile designs, which tie into facial cosmetic outcomes.

Combined Approach: A natural way to bridge this gap would be to combine dental treatments (teeth whitening, gum reshaping) with facial aesthetics, using diode lasers for both intraoral and perioral (around the mouth) applications.

Conclusion

The gap between diode dental lasers and cosmetic lasers can be bridged by advancing diode laser technology, offering multidisciplinary training, and developing dual-purpose laser systems. As the aesthetics industry evolves, diode lasers have the potential to integrate seamlessly into cosmetic treatments, expanding their role beyond dentistry into more comprehensive aesthetic procedures.

Thanks for your consideration.

Rhianna Boone RDH, BS

Skya Maxon RDH, BS

10/24/2024

Rhianna Boone RDH, BS and Skya Maxon RDH, BS

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Board of Dental Examiners:

I hope this letter finds you well. I am writing to express my support for expanding the scope of practice for dental hygienists in Alaska to include the administration of Botox and dermal fillers. I believe that allowing dental hygienists to provide these services would not only benefit patients but also advance the profession of dental hygiene in meaningful ways. Below, I outline the key reasons why this change should be seriously considered.

1. Dental Hygienists' Expertise in Facial Anatomy

Dental hygienists undergo extensive training in facial anatomy, physiology, and pathology, making them highly qualified to administer treatments that involve the facial muscles and structures. The expertise required to perform dental cleanings, periodontal treatments, and other oral health procedures already demands a deep understanding of the face and oral cavity. Injecting Botox and dermal fillers—procedures that primarily involve facial muscles and skin—naturally aligns with the knowledge and skill set dental hygienists already possess.

Furthermore, dental professionals are more familiar with working near sensitive areas such as the lips, cheeks, and jaw than a registered nurses. They possess the fine motor skills required for precise injections, ensuring patient safety and efficacy in delivering Botox and filler treatments. There is a similarity between the education of a Bachelor of Science in nursing and a Bachelor of Science in dental hygiene. In the state of Alaska registered dental hygienists are required to take a separate written and clinical exam before administering local anesthesia.

2. Improving Patient Access to Care

Allowing dental hygienists to offer Botox and dermal fillers would significantly improve access to these services, particularly in rural and underserved areas of Alaska where access to cosmetic treatments is limited. Patients seeking these treatments often face long travel distances to reach specialized providers, which can create barriers to care.

Dental hygienists, who are already practicing in many communities, would be well-positioned to fill this gap, offering an additional service that meets growing patient demand. Expanding their scope of practice would enable patients to receive treatments in a familiar and trusted environment, reducing the burden of travel and providing more comprehensive care close to home.

3. Enhancing Aesthetic and Therapeutic Options

Botox and dermal fillers are not only used for cosmetic purposes but also for therapeutic treatments. For example, Botox can be effective in treating temporomandibular joint (TMJ) disorders, bruxism (teeth grinding), and facial pain—conditions that dental hygienists are already managing in collaboration with dentists. By allowing dental hygienists to administer these injections, we can enhance patient care by providing more integrated therapeutic options within the dental setting.

This holistic approach would benefit patients who may already be visiting their dental hygienist for routine care or treatment of dental issues. The ability to offer Botox as part of a comprehensive treatment plan for TMJ or other facial conditions would streamline care, improving both patient outcomes and satisfaction.

4. Keeping Alaska Competitive

In several other states, dental professionals, including dentists and, in some cases, dental hygienists—are already permitted to administer Botox and dermal fillers. By allowing Alaska's dental hygienists to offer these services, we would ensure that the state remains competitive in the field of dental care and aesthetics. This move would also contribute to the growth of the dental hygiene profession, allowing practitioners to expand their skill sets and meet the evolving needs of patients.

Allowing dental hygienists to administer Botox and dermal fillers would not only align Alaska with forward-thinking states but also promote innovation in the dental field, opening new avenues for professional development.

As of 2023, the regulations for dental hygienists administering Botox and dermal fillers vary significantly across states in the U.S. While dental hygienists in some states are permitted to perform these procedures, others have restrictions or do not allow it at all. Below is an overview of how this is typically regulated in different states:

States Where Dental Hygienists Can Inject Botox and Dermal Fillers (with specific conditions):

1. Arizona: Dental hygienists are allowed to perform Botox and dermal filler injections, but only under the supervision of a licensed dentist and for dental purposes (such as managing temporomandibular joint disorders, bruxism, or for therapeutic dental-related treatments).

2. Colorado: Hygienists may administer Botox and dermal fillers under a dentist's supervision if the injections are related to dental therapeutic purposes (for instance, treatment of facial pain or temporomandibular joint disorders).

3. Idaho: Dental hygienists may inject Botox or fillers if they have received proper training and it is administered under the direct supervision of a dentist, primarily for dental or therapeutic reasons.

4. Nevada: Licensed dental hygienists can administer Botox and dermal fillers, but it must be under the supervision of a dentist and within the scope of dental practice. They must complete proper certification courses before being allowed to perform the procedures.

5. Michigan

6. Massachusetts

7. Kansas

8. Oklahoma

9. Texas- Not under supervision of a licensed dentist, but under the supervision of a licensed Physician of Nurse Practitioner.

5. Ensuring Patient Safety through Regulation

By establishing clear guidelines and requiring proper certification and training for dental hygienists who wish to administer Botox and dermal fillers, the Board of Dental Examiners can ensure that patient safety remains a top priority. Dental hygienists are already subject to stringent regulations and ethical standards, and the introduction of additional training and certification for these procedures would maintain the high level of care patients expect from their dental professionals.

In conclusion, expanding the scope of practice for dental hygienists to include the administration of Botox and dermal fillers is a logical and progressive step. It leverages the existing expertise of dental hygienists, improves access to care, enhances both cosmetic and therapeutic treatment options, and keeps Alaska’s dental community competitive. I urge the Board to consider this proposal and take the necessary steps to make it a reality.

10/24/2024

Thank you for your time and consideration.

Sincerely,

Rhianna Boone RDH, BS

Skya Maxon RDH, BS

Esthetics Procedures Continuum DRAFT – October 2024

This document reflects recommendations by the Esthetics Council and does not reflect any deliberation or decisionmaking by an Alaska professional licensing work group or board. This document is a working draft and does not define current Alaska requirements.

This chart may be used in whole or in part to assist the Alaska Medical Spa Services Work Group and related Alaska professional licensing boards understand the procedures in question, as well as assist in clarifying current and future scope of practice of:

- **Currently licensed estheticians** under the Board of Barbers and Hairdressers
- Future **advanced esthetician** licensees (requires statute change)
- Persons performing these procedures under **medical supervision:** In the context of this document, "medical supervision" means on-site supervision by a physician, physician assistant, or APRN operating within the supervisor's scope of practice and all statutes and regulations pertaining to the supervisor's license. May be currently allowable or require statute or regulation change to clarify necessary training and education.

Numbering refers to additional information available in the Esthetics Procedures List, available on the Medical Spa Services Work Group website: https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/MedicalSpaServicesWorkGroup.aspx

Can currently be performed under the existing 350-hour Alaska esthetician license	Recommend statute to require continuing education under existing 350-hour license	Recommend statute to require additional training as part of a 600-hour basic esthetician license	Recommend statute to require additional training as part of a 900+ hour advanced esthetician license (no medical supervision)	Currently requires medical supervision of any delegated duties	Statute should require medical supervision of unlicensed, trained personnel
1. Ultrasonic devices Epidermis Impact: Superficial **2. Oxygen Concentrator devices** Epidermis Impact: Superficial **3. Electrotherapy devices (galvanic current, High Frequency)** Epidermis Impact: Superficial **4. Mechanical brush devices** Epidermis Impact: Superficial **5. Vacuum spray devices** Epidermis Impact: Superficial **6. Steamers** Epidermis Impact: Superficial **7. LED (light emitting diode) devices.** Epidermis Impact: Superficial/Light **8. Microcurrent devices** Epidermis Impact: Superficial **9. Microdermabrasion devices, including hydradermabrasion devices.** Epidermis Impact: Superficial **10. Skin analysis equipment** Epidermis Impact: None **11. Thalassotherapy (application of sea water)** Epidermis Impact: Superficial **12. Thermotherapy (application of heat), manually applied or with the use of devices.** Epidermis Impact: Superficial **14. Superficial and light chemical exfoliation; alpha hydroxy acids, beta hydroxy acids, modified Jessner solutions, trichloroacetic acid less than 20% and vitamin based acids.** Epidermis Impact: Superficial at lower concentrations	**13 & 14. Superficial and light chemical exfoliation; alpha hydroxy acids, beta hydroxy acids, modified Jessner solutions, trichloroacetic acid less than 20% and vitamin based acids.** Epidermis Impact: Superficial at lower concentrations	**1. Ultrasonic devices** Epidermis Impact: Superficial **2. Oxygen Concentrator devices** Epidermis Impact: Superficial **3. Electrotherapy devices (galvanic current, High Frequency)** Epidermis Impact: Superficial **4. Mechanical brush devices** Epidermis Impact: Superficial **5. Vacuum spray devices** Epidermis Impact: Superficial **6. Steamers** Epidermis Impact: Superficial **7. LED (light emitting diode) devices.** Epidermis Impact: Superficial/Light **8. Microcurrent devices** Epidermis Impact: Superficial **9. Microdermabrasion devices, including hydradermabrasion devices.** Epidermis Impact: Superficial **10. Skin analysis equipment** Epidermis Impact: None **11. Thalassotherapy (application of sea water)** Epidermis Impact: Superficial **12. Thermotherapy (application of heat), manually applied or with the use of devices.** Epidermis Impact: Superficial **13 & 14. Superficial and light chemical exfoliation; alpha hydroxy acids, beta hydroxy acids, modified Jessner solutions, trichloroacetic acid less than 20% and vitamin based acids.** Epidermis Impact: Superficial at lower concentrations	**13 & 14. Medium chemical exfoliation** including higher-level concentrations, Jessner solutions and TCA Epidermis Impact: Medium **15. Low-level Ultrasound devices (Sonophoresis)** Epidermis Impact: Superficial **16. HIFU (High Intensity Focused Ultrasound)** Epidermis Impact: Superficial: Medium Dermis Impact: Deep **17. Low-level Radio Frequency devices** Epidermis Impact: Superficial **18. Radio Frequency devices (Class 2)** Epidermis Impact: Medium Dermis Impact: Deep **19. Cryotherapy (application of cold, not lipolysis), manually applied or with the use of devices.** Epidermis Impact: Superficial **20. Hydrotherapy (Vichy shower or Scotch hose)** Epidermis Impact: Superficial **21. Cellulite appearance and contouring treatments with mechanical devices** Epidermis Impact: SMAS or deeper depending on device **22. Dermaplaning devices** Epidermis Impact: Superficial **23. Mechanical stimulation (facial massage)** Epidermis Impact: Superficial/Medium **24. Collagen induction device (microneedling) including microchanneling or nanostamp, not OTC devices**	**14. Deep chemical exfoliation** Epidermis Impact: Deep **18. Radio Frequency devices (Class 3) Epidermis Impact: Medium** Dermis Impact: Deep **19. Lipolysis** Epidermis Impact: Deep **24. Collagen induction device (microneedling) above 1.0mm** Dermis Impact: 1.5mm-2.5mm	**13 & 14. Deep chemical exfoliation** Epidermis Impact: Deep **18. Class 3 laser and radiofrequency devices other than hair removal** Epidermis Impact: Medium Dermis Impact: Deep **19. Lipolysis** Dermis Impact: Deep **24. Collagen induction device (microneedling) above 1.0mm** Dermis Impact: 1.5mm-2.5mm **(NEW) Cosmetic injectables:** Prescription drugs intended to treat wrinkles, lines, and other cosmetic complaints, such as botulinum toxin (Botox) and other neuro-modulators, hyaluronic acid gel (Juvederm), calcium hydroxylapatite (Radiesse), polylactic acid (Sculptra)

19. Cryotherapy (application of cold, not lipolysis), manually applied or with the use of devices. Epidermis Impact: Superficial **20. Hydrotherapy** Epidermis Impact: Superficial **21. Cellulite appearance and contouring treatments (creams, wraps, etc.)** Epidermis Impact: Superficial **22. Dermaplaning devices** Epidermis Impact: Superficial **23. Mechanical stimulation (facial massage)** Epidermis Impact: Superficial/Medium		**19. Cryotherapy (application of cold, not lipolysis), manually applied or with the use of devices.** Epidermis Impact: Superficial **20. Hydrotherapy (not Vichy shower or Scotch hose)** Epidermis Impact: Superficial **21. Cellulite appearance and contouring treatments (creams, wraps, etc.)** Epidermis Impact: Superficial **22. Dermaplaning devices** Epidermis Impact: Superficial **23. Mechanical stimulation (facial massage)** Epidermis Impact: Superficial/Medium	Epidermis Impact at or below 1mm: Superficial **(NEW) Semi-permanent hair removal** by nonablative IPL or ablative laser		

Esthetics Procedures List – October 2024

This document reflects recommendations by the Esthetics Council and does not reflect any deliberation or decisionmaking by an Alaska professional licensing work group or board. This document is a working draft and does not define current Alaska requirements.

This chart may be used in whole or in part to assist the Alaska Medical Spa Services Work Group and related Alaska professional licensing boards understand the procedures in question, as well as assist in clarifying current and future scope of practice of:

- **Currently licensed estheticians** under the Board of Barbers and Hairdressers
- Future **advanced esthetician** licensees (requires statute change)
- Persons performing these procedures under **medical supervision:** In the context of this document, "medical supervision" means on-site supervision by a physician, physician assistant, or APRN operating within the supervisor's scope of practice and all statutes and regulations pertaining to the supervisor's license. May be currently allowable or require statute or regulation change to clarify necessary training and education.

Green: List of procedures and modalities used in esthetics practices
Purple: Examples of brand names, web site links, and other terms and descriptions to help identify and define what is meant by the procedure. This list is not exhaustive.
Orange: Description of FDA classification and federal regulatory oversight.
Blue: Esthetics Council recommendation whether to allow these procedures under an existing Alaska esthetician license (350 hours of training and independent practice) or whether additional training and education (i.e. statute or regulation change) or medical supervision is needed.

* NOTE: The Esthetics Council recommends the current esthetician license requirements be increased to 600 hours to ensure training on a wide range of basic modalities for which they are licensed.

Procedure	**Examples of Common Brand Names, links to web sites** ***This is a very limited list that can be expanded. Most modalities are tied to a product line as well.***	**Description of Procedure**	**FDA Designation** (Class 1 or 2: Should not fall within Class III, 3A, 3B, or IV Radiation Emitting Devices designation)	**FDA Regulation** Device required to be registered under 201(h) of the FD&C Act? Product regulated as a cosmetic by FDA?	**Safe to allow under existing esthetician license?** • 350 hours training • Curriculum in 12 AAC 09.163 • NIC esthetician test	**If not generally safe under existing esthetician requirements, what is minimum recommended amount and type of training? Should this require supervision by a medical director?**

1. Ultrasonic devices Epidermis Impact-Superficial	www.universalcompanies.com www.biotherapeutic.com	Ultrasonic spatula emits high-frequency sound waves, typically at a rate of 20,000 to 30,000 vibrations per second (Hz). Intended outcome: cleansing and exfoliation.	Class I	Yes	Yes	N/A
2. Oxygen Concentrator devices Epidermis Impact-Superficial		Deliver atmospheric concentrated oxygen to the skin to boost circulation, promote healing, and enhance the glow. Intended outcome: Brighter, revitalized skin with improved oxygenation.	Class I Does not include hyperbaric chamber or "longevity" treatments		Yes	N/A
3. Electrotherapy devices (galvanic current, High Frequency) Epidermis Impact-Superficial	www.universalcompanies.com www.silhouettone.com www.equipro.com www.massagewarehouse.com	Low-voltage direct current or alternating current (High Frequency) to enhance product penetration, stimulate skin, disinfect, and improve tone. Intended outcome: Improved skin hydration, enhanced product absorption.	Class 1	Yes	Yes	N/A
4. Mechanical brush devices Epidermis Impact-Superficial	www.universalcompanies.com www.massagewarehouse.com www.zemits.com	Rotary or oscillating brushes for deep cleansing and exfoliation. Intended outcome: Deeply cleansed skin, reduced clogged pores.	Class I-generally unregistered		Yes	N/A
5. Vacuum spray devices	www.universalcompanies.com www.massagewarehouse.com www.zemits.com	Uses suction to clean pores and remove impurities, often	Class I-generally unregistered		Yes	N/A

Epidermis Impact-Superficial		combined with a spray mist to hydrate. Intended outcome: Cleansed, refreshed skin.				
6. Steamers Epidermis Impact-Superficial	Varies www.universalcompanies.com www.massagewarehouse.com www.zemits.com	Generates steam to open pores and hydrate the skin. Intended outcome: Loosening of debris in pores, enhanced product absorption.	Class 1-generally unregistered		Yes	N/A
7. LED (light emitting diode) devices. Epidermis Impact-Superficial/Light	www.lightstim.com www.omnilux.com www.celluma.com	Emits specific wavelengths of light to target acne, reduce inflammation, and stimulate collagen. Intended outcome: Acne reduction, anti-aging, and skin rejuvenation.	Class 2	Yes	Yes	N/A
8. Microcurrent devices Epidermis Impact-Superficial	www.biotherapeutic.com www.neurotris.com www.silhouettone.com	Low-level electrical currents stimulate facial skin, improve circulation and firmness. No direct muscle stimulation (visible contractions) Intended outcome: Lifted, more toned facial appearance.	Class 1 or Class 2 based on intended use-direct muscle stimulation Class 2.	Yes	Yes	N/A
9. Microdermabrasion devices, including hydradermabrasion devices. Epidermis Impact-Superficial	www.diamondglow.com www.hydrafacial.com www.silhouettone.com www.equipro.com	Mechanically exfoliates the skin using crystals or diamond tips, often with suction. Intended outcome: Smoother skin texture, improved clarity, and reduced fine lines.	Class 1	Yes	Yes	N/A

10. Skin analysis equipment Epidermis Impact-None	Wood's lamp Magnifying Lamp	Uses UV light to examine skin conditions like pigmentation, hydration, and bacteria. Mag Lamp uses different levels of magnification with a light source. Intended outcome: Accurate skin assessment for customized treatments.	Class 1		Yes	N/A
11. Thalassotherapy Epidermis Impact-Superficial	www.thalgo.com www.elemis.com www.massagewarehouse.com www.universalcompanies.com	Uses seawater and marine products for detoxification and rejuvenation in body treatments or facials. Intended outcome: Hydration, skin nourishment, and relaxation.	No Classification MOCRA registration		Yes	N/A
12. Thermotherapy (application of heat), manually applied or with the use of devices. Epidermis Impact-Superficial		Heat application to improve blood circulation and relax muscles. Intended outcome: Improved skin tone, relaxation, enhanced healing.	Class 1	Yes	Yes	N/A
13. Vitamin-based acids Epidermis Impact-Superficial at lower concentrations	Same as above	Vitamins like vitamin C and retinoic acid are applied for antioxidant benefits and skin rejuvenation. Intended outcome: Brightened skin tone, reduced wrinkles, and sun damage.	MOCRA Registration Required		Yes for light/superficial peels but should require manufacturer training	N/A
14. Superficial and light chemical exfoliation including	Varies-common vendors. www.circadia.com www.dermastart.com www.linderhealth.com	Chemical agents applied to exfoliate the outer skin layers.	MOCRA registration		Yes for light/superficial peels but	Recommend performance of

but not limited to; alpha hydroxy acids, beta hydroxy acids, modified Jessner solutions, and trichloroacetic acid less than 20% Epidermis Impact-Superficial at lower concentrations	https://www.dannemking.com www.osmosis.com www.skinscript.com www.haleandhush.com www.pcaskin.com	Chemical peels available to estheticians are light & superficial light depth. Intended outcome: Smoother, more radiant skin, treatment of acne or hyperpigmentation	required for products		should require manufacturer training	Modified Jessners and TCA only by an Advanced/Master Esthetician (900-1200hr)
15. Low-Level Ultrasound devices (Sonophoresis) Epidermis Impact-Superficial	www.environ.com www.zemits.com www.massagewarehouse.com	Uses low-intensity ultrasonic waves typically below 3 MHz, which target more superficial layers of the skin ("sonic massage"). Intended outcome: Skin texture improvement, product penetration, and superficial treatments like cellulite appearance reduction.	Class I or II based on intended use	Yes	No	Recommend performance only by an Advanced/Master Esthetician (900-1200hr)
16. HIFU (High Intensity Focused Ultrasound) Epidermis Impact-Superficial-Medium Dermis Impact Deep		Utilizes high-intensity ultrasound waves, delivering focused energy to precise depths. Intended outcome: skin tightening, non-surgical facelifts. 1.5 mm: This shallow depth targets 3.0 mm: This depth targets the deeper dermal layer. 4.5 mm: This depth reaches the SMAS layer (Superficial Muscular Aponeurotic System)	Class II	Yes	No	Recommend performance only by an Advanced/Master Esthetician (900-1200hr)

17. Low-Level Radio Frequency devices Epidermis Impact-Superficial	www.nuface.com www.zemits.com	Operates at lower power and frequency compared to traditional RF devices. The energy delivered is less intense, so it targets the upper skin layers. Intended outcome: Used for superficial skin treatments like mild skin tightening, improving circulation, and stimulating collagen production without deep tissue penetration.	Class II (includes OTC)	Yes	No	Recommend performance only by an Advanced/Master Esthetician (900-1200hr)
18. Radio Frequency devices Epidermis Impact-Medium Dermis Impact-Deep	www.candelamedical.com www.morpheous8.com	Operates at higher power and frequency, delivering more energy to the skin. RF devices typically heat tissues more deeply, stimulating collagen in the deeper dermis and subcutaneous layers. Intended Outcome: Designed for deeper skin tightening, lifting, and more intensive collagen remodeling.	Class 2 or Class 3 based on intended use	Yes	No	Recommend performance at Class 2 only by an Advanced/Master Esthetician (900-1200hr) Performance at Class 3 only by a trained physician, physician assistant, or APRN.
19. Cryotherapy (application of cold), manually applied or with the use of devices. Epidermis Impact-Superficial	Same as above www.artemis.com www.zemits.com www.universalcompanies.com www.thalgo.com Superficial body treatments included.	Does not employ nitrogen spray; is not cryolipolysis or cryosurgery. Cold application to reduce redness, improve circulation, and tighten skin.	Class 1 MOCRA registration for products	Yes	Yes, but only manual application or cold tools	Recommend performance using a device only by an Advanced/Master Esthetician (900-1200hr)

Not Lipolysis (Coolsculpting)		Intended outcome: Reduced redness, firmer skin.				
20. Hydrotherapy Epidermis Impact-Superficial	www.thalgo.com www.massagewarehouse.com	Water-based treatments for relaxation, detoxification, and skin hydration including Vichy shower, Scotch hose & hydrotub. Intended outcome: Relaxation, improved circulation, and hydrated skin.	Class 1 (hydrotherapy tubs, showers) No classification for products.	Yes	Yes, not including Vichy shower or scotch hose.	Recommend performance of Vichy shower and Scotch hose only by an Advanced/Master Esthetician (900-1200hr)
21. Cellulite appearance and contouring treatments Epidermis Impact-Superficial Dermis Impact-SMAS or Deeper depending on device	Same as above www.artemis.com www.zemits.com Body treatments including wraps.	Non-invasive treatments targeting cellulite with mechanical stimulation, manual body treatments or energy-based devices. Intended outcome: Smoother skin texture, reduced appearance of cellulite.	Class 1 or Class 2 depending on modality used. MOCRA registration for body treatment products.	Yes	Yes, only superficial	Recommend performance affecting below the epidermis only by an Advanced/Master Esthetician (900-1200hr)
22. Dermaplaning devices Epidermis Impact-Superficial	www.dermaplane.pro	Manual or mechanical exfoliation that removes the top layer of dead skin and fine hair. Intended outcome: Smooth skin texture and enhanced product absorption.	Class 1	Yes	No	Recommend performance only by an Advanced/Master Esthetician (900-1200hr)
23. Mechanical body stimulation (massage) Epidermis Impact-Superficial/Medium	G8, Endermologie www.universalcompanies.com www.massagewarehouse.com	Devices that use rolling, kneading, or suction to stimulate circulation and reduce cellulite. Intended outcome: Smoother skin	Class 1	Yes	No	Recommend performance only by an Advanced/Master Esthetician (900-1200hr)

		appearance, reduced cellulite.				
24. Collagen induction device (microneedling) *Includes microchanneling or nanostamp not OTC devices Epidermis Impact at or below 1mm-Superficial Dermis Impact-1.5mm-2.5mm	www.dermapen.com https://360aestheticdevices.com www.candelamedical.com	Uses tiny needles to create micro-injuries, stimulating collagen production. Ranges .25-2.0 mm. Intended outcome: Improved skin texture, reduced wrinkles, acne scars.	Class 2	Yes	No	Recommend performance of up to .1mm only by an Advanced/Master Esthetician (900-1200hr) Deeper penetration should require medical supervision

Resources:

https://wwwcommercealaskagov/web/Portals/5/pub/MED_Guide_Dermatologicalpdf
https://wwwcommercealaskagov/web/Portals/5/pub/MED_Guide_Lasers_Laser_Surgerypdf
https://wwwcommercealaskagov/web/Portals/5/pub/MED_Guide_Delegating_to_Unlicensed_Assistantspdf
https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/BoardofNursing/AdvisoryOpinions.aspx

https://wwwcommercealaskagov/web/Portals/5/pub/MedicalStatutespdf
https://wwwcommercealaskagov/web/Portals/5/pub/NursingStatutespdf
https://wwwcommercealaskagov/web/Portals/5/pub/BAH_Stats_Regspdf

Draft language suggested for Board of Barbers and Hairdressers regulation definition of "appliances" available for use as a licensed esthetician without medical supervision with only 350 hours of training as described above:

The use of esthetic devices, or combinations of devices that stimulate natural physiological processes intended to improve skin appearance and health, devices should meet the following criteria: Do not directly ablate or destroy live tissue, or involve incision into skin beyond the epidermis. Devices must operate within manufacturer guidelines, and FDA registration if required by 21 U.S. Code § 321 of the Federal Food, Drug, and Cosmetic (FD&C) Act. These devices should not fall within Class III, 3A, 3B, or IV Radiation Emitting Devices designation.

FDA Classification

FDA Device Classification Database: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

Devices used in cosmetic and therapeutic treatments must undergo appropriate FDA review based on their **classification** under the FD&C Act. Devices are classified into three categories based on their risk level:

- **Class I Devices** (Low-Risk): These devices are considered to have the lowest risk to users. Examples include simple cosmetic tools like mechanical exfoliation brushes or handheld LED devices. **Class I devices are generally exempt from premarket notification (510(k))**, although manufacturers are still required to register their facility and list their devices with the FDA.
- **Class II Devices** (Moderate-Risk): Devices that pose moderate risk and require special controls to ensure safety and effectiveness. Examples include; radiofrequency (RF) devices for skin rejuvenation, ultrasonic disinfectant devices, certain paraffin dips, microneedling, and LED devices. **Class II devices must undergo the 510(k) premarket clearance process**, where manufacturers must demonstrate that the device is substantially equivalent to a legally marketed device.
- **Class III Devices** (High-Risk): These devices present the highest risk to patients and typically require **premarket approval (PMA)** from the FDA. Devices in this category are often those intended for critical functions, such as lasers for surgical use or invasive treatments. High-Intensity Focused Ultrasound (HIFU) for deep skin tightening may fall under this classification.

Labeling

- The FDA distinguishes between **Over the Counter (OTC)** and **Prescriptive (Prescription)** devices based on their intended use, safety, and the necessity of professional supervision. This designation pertains to **LABELING** requirements only. T**he FDA does not designate who is qualified to use such devices, this is a STATE regulatory issue.**

Key Points about **Cosmetic Devices**:

- **Cosmetic Claims**: Devices used for purely cosmetic purposes can **make cosmetic claims**, but they cannot make **medical claims** (such as treating wrinkles, acne, or skin diseases) without being regulated as medical devices. Examples of cosmetic claims would be "improves skin appearance" or "hydrates the skin" without implying treatment of any medical condition.
- **No "Cosmetic Device" Category**: The FDA does not have a special category for "cosmetic devices." If a device interacts with the skin and claims to change its structure, function, or treat a condition (such as wrinkles or acne), it is classified as a **medical device**, even if the primary purpose seems cosmetic.
- **Pre-Amendment Devices**: example: Galvanic Current Devices & Tesla High Frequency (Electrotherapy Category)
    - Devices that were legally marketed in the U.S. before **May 28, 1976**, are known as **pre-amendment devices**.
    - These devices were **grandfathered** under the Medical Device Amendments of 1976, meaning that they could continue to be marketed without going through the new premarket approval process that was introduced after the amendments.
    - Pre-amendment devices still need to comply with certain FDA requirements, including **registration** with the FDA and compliance with applicable regulations such as **labeling** and **Good Manufacturing Practices (GMPs)**.

MOCRA (Modernization of Cosmetics Regulation Act)

MoCRA Registration info: https://www.fda.gov/cosmetics/registration-listing-cosmetic-product-facilities-and-products

While **MOCRA** directly pertains to **cosmetic products** (like creams, lotions, and makeup), it does not apply to **devices**. However, it is essential for device manufacturers who also create cosmetic products to understand the new requirements under MOCRA:

- **Mandatory Facility Registration**: Cosmetic product manufacturers must now register their facilities with the FDA. Device manufacturers should ensure that any cosmetic products used with their devices (e.g., serums for micro-needling or topical treatments for ultrasonic devices) comply with this requirement.
- **Adverse Event Reporting**: MOCRA requires reporting of serious adverse events related to cosmetic products, which extends to cosmetic treatments used in conjunction with FDA-registered devices.
- **Good Manufacturing Practices (GMPs)**: While devices are already subject to GMPs, MOCRA introduces specific GMP requirements for cosmetic products, which may influence manufacturers of dual-use products. GMP cosmetic manufacturing guidelines are scheduled for 2025.
- **Product Registration**: Brands and manufacturers that sell directly to the public must register their products with the FDA, this includes labeling requirements that include “professional use” designation on products. Fragrance allergens are included, and guidance is further scheduled in the FDA rulemaking process through 2025.

Interdisciplinary Matrix of Medical Spa Services Under Alaska Law

DRAFT— Medical Spa Services Work Group Member Input – October 2024

This document is a draft based on individual work group member input. It has NOT been reviewed by the Department of Law or reviewed or endorsed by any board. It should not be read as a definitive description of allowable practices under any license type or situation.

Purple notes indicate comments made by a representative of a different board.

	Medical Board Physician Osteopath Podiatrist Physician Assistant	**Board of Nursing** APRN RN LPN CNA	**Board of Dental Examiners** Dentist Dental Hygienist	**Board of Pharmacy** Pharmacist Pharmacy Technician	**Board of Chiropractic Examiners** Chiropractor	**Board of Barbers & Hairdressers** Esthetician Hairdresser Tattooist Permanent Cosmetic Colorist
IV Hydration: Voluntary intravenous administration of liquids containing one or more prescription or nonprescription substances intended to improve hydration and/or nutrition outside of an acute clinical setting						
1. Can I evaluate a patient?	All licensees may	APRN may per AS 08.68.850(1) and (9)	Dentist may, only if within the practice of dentistry under AS 08.36.360.	No	Yes	No
2. Can I diagnose a patient?	All licensees may	APRN may per AS 08.68.850(1) and (9)	Dentist may, only if within the practice of dentistry under AS 08.36.360.	No	Yes	No
3. Can I order a prescription?	All licensees may	APRN may per AS 08.68.850(1) and (9)	Dentist may, only if within the practice of dentistry under AS 08.36.360.	Could order under a collaborative agreement	No	No
4. Can I compound substances for IV administration? Defined in AS 08.80.480; also look at FDA definition of Human Drug Compounding Food Drug Cosmetic Act 503(b)	Yes; immediate use requirements under USP <797> must be met. Example ORs and Ambulatory Surgery Centers.	Yes; immediate use requirements under USP <797> must be met. Example ORs and Ambulatory Surgery Centers.	Yes, if within the practice of dentistry under AS 08.36.360	Yes	No but working on statute/reg changes	No

5. Can I administer an IV?	All licensees may	APRN may per AS 08.68.850(1) and (9) RN's & LPN's may if have the training and they follow provider orders.	Dentist may, only if within the practice of dentistry under AS 08.36.360.	No	Yes AS 08.20.100 AS 08.20.900(1) AS 01.10.040	No
6. Can I monitor a patient during and after administration?	All licensees may	Monitoring vital signs and bodily functions may be delegated under 12 AAC 44.955	Dentist may, only if within the practice of dentistry under AS 08.36.360.	No	Yes	No, unless delegated as unlicensed personnel by a primary care provider authorized to delegate.
7. Can I supervise personnel who administer? If so, who and what?	Licensees must supervise personnel if they delegate duties to an "agent" who is unlicensed or not able to independently perform the duties under the scope of their own license.	APRN can	The Dental board moved away from "supervising advanced practice nurses about 8-9 years ago and moved to collaborative agreements. Duties within the scope of an LPN may be delegated to practical nurse per AS 08.68.265	No	Uncertain	No
8. Can I delegate to personnel? If so, who and what?	Licensees may not delegate the initiation, administration, and monitoring of intravenous therapy. 12 AAC 40.920 (f)(6) except to registered and	A nurse may not delegate patient evaluation, diagnosis, prescription, and IV administration to a non-nurse per 12 AAC 44.970(1) and (6)	Dentists may delegate to practical nurses under AS 08.68.265. Dentists may delegate dental related tasks, however a dentist	No	Only within scope of practice. Not typically.	No

	practical nurses under AS 08.68.265.		may not delegate to a dental assistant a dental operation or service that requires the professional skill of a licensed dentist AS 08.36.346.			
9. Am I liable if something goes wrong?	Yes. All Licensees may be liable if something goes wrong.	See 12 AAC 44.770.	Yes	Yes, if practicing outside of the scope of practice	Yes	Possibly, but should also be covered under primary care provider's malpractice insurance
	Medical Board Physician Osteopath Podiatrist Physician Assistant	**Board of Nursing** APRN RN LPN CNA	**Board of Dental Examiners** Dentist Dental Hygienist	**Board of Pharmacy** Pharmacist Pharmacy Technician	**Board of Chiropractic Examiners** Chiropractor	**Board of Barbers & Hairdressers** Esthetician Hairdresser Tattooist Permanent Cosmetic Colorist
Advanced Esthetics: Medical devices and procedures intended to treat skin texture, pigmentation, and other cosmetic complaints, such as microneedling, microchanneling, nanoneedling, skin stamping, and dermaroller services, or similar services that puncture the skin; ablative treatments; radiofrequency devices; chemical peels below the dermal layer; autotransplantation of biological materials, etc.)						
10. Can I evaluate a patient?	Yes	APRN may per AS 08.68.850(1) and (9)	No	No	Yes	No
11. Can I diagnose a patient?	Yes	APRN may per AS 08.68.850(1) and (9)	No	No	Yes	No
12. Can I order a prescription?	Yes	APRN may per AS 08.68.850(1) and (9)	No	No	No	No
13. Can I administer laser treatments?	Yes, this falls under general definition of the practice of medicine under AS 08.64.380 (6) (no specialized training	12 AAC 44.430- APRN Scope of Practice IF they have the specialized training	No	No	Yes--not typically done w/ respect to esthetics AS 08.20.100 AS 08.20.900(1) AS 08.20.900(12)	Not within scope of license and cannot be delegated by physicians or APRNs. (MED position)

	requirements are specified in regulation or statute)					
14. Can I administer chemical treatments or lasers that penetrate below the dermal layer?	Yes, this falls under general definition of the practice of medicine (no specialized training requirements are specified in regulation or statute)	12 AAC 44.430- APRN Scope of Practice IF they have the specialized training	No	No		Not within scope of license and cannot be delegated by physicians or APRNs. (MED position)
15. Can I administer treatments using an invasive device such as a needle or radiofrequency device?	Yes, this falls under general definition of the practice of medicine (no specialized training requirements are specified in regulation or statute)	12 AAC 44.430- APRN Scope of Practice IF they have the specialized training	No	No		Not within scope of license and cannot be delegated by physicians or APRNs. (MED position)
16. Can I monitor a patient during and after administration?	Yes	Monitoring vital signs and bodily functions may be delegated under 12 AAC 44.955	No	No		Monitoring vital signs and bodily functions may be delegated under 12 AAC 44.955
17. Can I supervise personnel? If so, who and what?	Licensees must supervise personnel if they delegate duties to an "agent" who is unlicensed or not able to independently	APRN can supervise RN, LPN, CNA See advisory opinion	No	No		No

	perform the duties under the scope of their own license. Licensees may delegate routine medical duties within the scope of their practice in accordance with 12 AAC.40.920					
18. Can I delegate to personnel? If so, who and what?	A physician may not delegate activities that are the practice of medicine and may delegate only within the scope of the Alaska license of the person to whom delegation is given. A physician may delegate routine, nonmedical duties to unlicensed personnel. (MED position statement) 12 AAC 40.920 specifies what may or may not be delegated. A licensee may delegate "routine	A nurse may not delegate patient evaluation, diagnosis, prescription, and IV administration to a non-nurse per 12 AAC 44.970(1) and (6)	No	No		No

	medical duties" to an "agent" of the licensee under certain conditions outlined under 12 AAC 40.920 (e), which includes duties that 1) occur frequently in the daily care of a patient or group of patients; 2) do not require the person to exercise professional medical knowledge or judgement; 3) do not require complex medical skills; 4) have a standard procedure and predictable results, and 5) present minimal potential risk to the patient					
19. Am I liable if something goes wrong?	Yes	Yes. See 12 AAC 44.770.	N/A	N/A		Possibly, but should also be covered under primary care provider's malpractice insurance

	Medical Board Physician Osteopath Podiatrist Physician Assistant	**Board of Nursing** APRN RN LPN CNA	**Board of Dental Examiners** Dentist Dental Hygienist	**Board of Pharmacy** Pharmacist Pharmacy Technician	**Board of Chiropractic Examiners** Chiropractor	**Board of Barbers & Hairdressers** Esthetician Hairdresser Tattooist Permanent Cosmetic Colorist
Cosmetic injectables: Prescription drugs intended to treat wrinkles, lines, and other cosmetic complaints, such as botulinum toxin (Botox) and other neuro-modulators, hyaluronic acid gel (Juvederm), calcium hydroxylapatite (Radiesse), polylactic acid (Sculptra)						
20. Can I evaluate a patient?	Yes	APRN may per AS 08.68.850(1) and (9)	Botox Only: Dentist may, only if within the practice of dentistry under AS 08.36.360. Hygienists cannot. This is not limited to botox only, general provisions indication this would be limited to oral cavity, maxilla, mandible, or adjacent tissues.	No	Yes	No
21. Can I diagnose a patient?	Yes	APRN may per AS 08.68.850(1) and (9)	Botox Only: Dentist may, only if within the practice of dentistry under AS 08.36.360. Hygienists cannot. This is not limited to botox only, general provisions indication this would be limited to oral cavity, maxilla, mandible, or adjacent tissues.	No	Yes	No
22. Can I order a prescription?	Yes	APRN may per AS 08.68.850(1) and (9)	Botox Only: Dentist may, only if within the practice of	Yes, under collaborative practice	No	No

			dentistry under AS 08.36.360. Hygienists cannot. This is not limited to botox only, general provisions indication this would be limited to oral cavity, maxilla, mandible, or adjacent tissues.	agreement. 12 AAC 52.240.		
23. Can I administer injections?	Yes	Yes, if trained. APRN, RN, LPN (RN & LPN-need an order)	Botox Only: Dentist may, only if within the practice of dentistry under AS 08.36.360. Dentist can delegate monitoring after the fact to a dental hygienist under Sec. 08.32.110 This is not limited to botox only, general provisions indication this would be limited to oral cavity, maxilla, mandible, or adjacent tissues.	Yes, under collaborative practice agreement. 12 AAC 52.240.	Non-Prescription Substances, w/ appropriate training AS 08.20.100(b)(1) AS 08.20.900(1) 12 AAC 16.990(b)(1)	No
24. Can I monitor a patient during and after administration?	Yes	Monitoring vital signs and bodily functions may be delegated under 12 AAC 44.955	Botox Only: Dentist may, only if within the practice of dentistry under AS 08.36.360 This is not limited to botox only, general provisions indication this would be limited to oral cavity, maxilla,	No	Must be for procedure within scope--no prescriptive authority	Monitoring vital signs and bodily functions may be delegated under 12 AAC 44.955

			mandible, or adjacent tissues.			
25. Can I supervise personnel? If so, who and what?	Licensees must supervise personnel if they delegate duties to an "agent" who is unlicensed or not able to independently perform the duties under the scope of their own license.	APRN can supervise RN and LPN. See advisory opinion	Botox Only: Dentist may, only if within the practice of dentistry under AS 08.36.360 This is not limited to botox only, general provisions indication this would be limited to oral cavity, maxilla, mandible, or adjacent tissues.	No	No--Must be within scope of practice	No
26. Can I delegate to personnel? If so, who and what?	Prescriptive authority is not a duty that can be delegated. See #18 above, for list of routine duties that may be delegated und under 12 AAC 40.920 (e) A licensee may delegate to an "agent" of the licensee, the administration of an injectable medication if it is a single intramuscular, intradermal, or subcutaneous	This task does not appear in the regulations to be delegated. Only listed in the advisory opinion on botox that APRN/MD/PA may delegate to appropriately trained RN/LPN under certain circumstanced and delegating supervisor must be on site. This should probably be placed in regulation with initial visit having supervisor present and subsequent visits for the same procedures being able to be carried out with supervisor being able to be	Botox Only: Dentist may, only if within the practice of dentistry under AS 08.36.360 No other clarification about who can be delegated to was provided by staff. Delegations in regulation is limited to RDH and Dental assistant. Dentists may delegate dental related tasks, however a dentist may not delegate to a dental	No	No	No

	injection, not otherwise prohibited under 12 AAC 40.967 (33); in accordance with 12 AAC 40.920 (f) (14) (A)(B)(C)	contacted via phone/electronically for low risk procedures.	assistant a dental operation or service that requires the professional skill of a licensed dentist 08.36.346			
27. Am I liable if something goes wrong?	Yes. All licensees may be liable if something goes wrong.	See 12 AAC 44.770.	Yes	Yes, if working under collaborative practice agreement.	Yes--must remain within scope of practice	Possibly, but should also be covered under primary care provider's malpractice insurance
	Medical Board Physician Osteopath Podiatrist Physician Assistant	**Board of Nursing** APRN RN LPN CNA	**Board of Dental Examiners** Dentist Dental Hygienist	**Board of Pharmacy** Pharmacist Pharmacy Technician	**Board of Chiropractic Examiners** Chiropractor	**Board of Barbers & Hairdressers** Esthetician Hairdresser Tattooist Permanent Cosmetic Colorist
Nonsurgical fat reduction: Techniques to remove fat by revision, destruction, incision or other structural alteration of human tissue such as cryolipolysis (CoolSculpting), injection lipolysis (Kybella), radiofrequency lipolysis (Vanquish) and laser lipolysis (SculpSure)						
28. Can I evaluate a patient?	Yes	Uncertain Not in regulation, but should be in scope of adult/lifespan APRN with appropriate training	N/A for dentists or hygienists.	No	Yes May not perform procedures as covered in AS 08.20.900(3),(6) OR 12AAC16.990(b)(2)	No
29. Can I diagnose a patient?	Yes	Uncertain Not in regulation, but should be in scope of adult/lifespan APRN with appropriate training	N/A for dentists or hygienists.	No	Yes May not perform procedures as covered in AS 08.20.900(3),(6) OR	No

					12AAC16.990(b)(2)	
30. Can I order a prescription?	Yes	Uncertain Not in regulation, but should be in scope of adult/lifespan APRN with appropriate training	N/A for dentists or hygienists.	No	No	No
31. Can I administer injections?	Yes	Uncertain Not in regulation, but should be in scope of adult/lifespan APRN with appropriate training	N/A for dentists or hygienists.	No	No	No
32. Can I dispense prescription medications?	Yes	Uncertain Not in regulation, but should be in scope of adult/lifespan APRN with appropriate training	N/A for dentists or hygienists.	Yes	No	No
33. Can I monitor a patient during and after administration?	Yes	Uncertain Not in regulation, but should be in scope of adult/lifespan APRN with appropriate training	N/A for dentists or hygienists.	No		Monitoring vital signs and bodily functions may be delegated under 12 AAC 44.955
34. Can I supervise personnel? If so, who and what?	See #17	Uncertain Not in regulation, but should be in scope of adult/lifespan APRN with appropriate training RN able to perform supervised procedures based on competency and proper training.	N/A for dentists or hygienists.	No		No
35. Can I delegate to personnel? If so, who and what?	See #18	Uncertain Not in regulation, but should be in scope of	N/A for dentists or hygienists.	No		No

		adult/lifespan APRN with appropriate training APRN delegate to properly trained RN				
36. Am I liable if something goes wrong?	Yes. All licensees may be liable if something goes wrong.	See 12 AAC 44.770.	N/A for dentists or hygienists.	Yes, only regarding dispensing.		Possibly, but should also be covered under primary care provider's malpractice insurance
	Medical Board Physician Osteopath Podiatrist Physician Assistant	**Board of Nursing** APRN RN LPN CNA	**Board of Dental Examiners** Dentist Dental Hygienist	**Board of Pharmacy** Pharmacist Pharmacy Technician	**Board of Chiropractic Examiners** Chiropractor	**Board of Barbers & Hairdressers** Esthetician Hairdresser Tattooist Permanent Cosmetic Colorist
Lifestyle Drugs: Prescription drugs like semaglutides (Ozempic) or sildenafil (Viagra), including in a telemedicine setting						
37. Can I evaluate a patient?	Yes	APRN may per AS 08.68.850(1) and (9)	Dentist may, only if within the practice of dentistry under AS 08.36.360. It is unlikely that these drugs have a use within the practice of dentistry.	No	Yes AS 08.20.100(b)(1) AS 08.20.900(3),(6) 12AAC16.990(b)(1)	No
38. Can I diagnose a patient?	Yes	APRN may per AS 08.68.850(1) and (9)	Dentist may, only if within the practice of dentistry under AS 08.36.360. It is unlikely that these drugs have a use within the practice of dentistry.	No	Yes	No
39. Can I order a prescription?	Yes	APRN may per AS 08.68.850(1) and (9)	Dentist may, only if within the practice of dentistry under AS 08.36.360. It is	Yes, under collaborative practice	See above statutes	No

			unlikely that these drugs have a use within the practice of dentistry.	agreement. 12 AAC 52.240.		
40. Can I administer injections?	Yes	APRN may per AS 08.68.850(1) and (9)	Dentist may, only if within the practice of dentistry under AS 08.36.360. It is unlikely that these drugs have a use within the practice of dentistry.	Yes, under collaborative practice agreement. 12 AAC 52.240.		No
41. Can I dispense prescription medications?	Yes	No	Dentist may, only if within the practice of dentistry under AS 08.36.360. It is unlikely that these drugs have a use within the practice of dentistry.	Yes	No	No
42. Can I monitor a patient during and after administration?	Yes	Yes	Dentist may, only if within the practice of dentistry under AS 08.36.360. It is unlikely that these drugs have a use within the practice of dentistry.	No	Only within scope	Monitoring vital signs and bodily functions may be delegated under 12 AAC 44.955
43. Can I supervise personnel? If so, who and what?	No	APRN can supervise RN and LPN.	No	No		No
44. Can I delegate to personnel? If so, who and what?	No	APRN can delegate to CMA 12 AAC 44.950 if in a private or public ambulatory setting	No	No		No
45. Am I liable if something goes wrong?	Yes. All Licensees may be liable if something goes wrong.	Ordering provider and administrator of medication should be	Yes	Yes, only regarding dispensing.		Possibly, but should also be covered under primary care

		responsible. See 12 AAC 44.770.				provider's malpractice insurance
	Medical Board Physician Osteopath Podiatrist Physician Assistant	**Board of Nursing** APRN RN LPN CNA	**Board of Dental Examiners** Dentist Dental Hygienist	**Board of Pharmacy** Pharmacist Pharmacy Technician	**Board of Chiropractic Examiners** Chiropractor	**Board of Barbers & Hairdressers** Esthetician Hairdresser Tattooist Permanent Cosmetic Colorist
Hyperbaric Therapy: Breathing pure oxygen in a pressurized environment						
46. Can I evaluate a patient?	Yes	APRN with appropriate education and training	Hyperbaric treatment is an acceptable treatment for osteonecrosis. I complication, usually associated with bone fracture in a patient who has taken IV Bisphosonates. So yes, a dentist may evaluate a patient for hyperbaric oxygen treatment as long as it is in accordance with AS 08.36.360	No	Yes	No
47. Can I diagnose a patient?	Yes	APRN with appropriate education and training	As long as it is in accordance with AS 08.36.360	No	Yes	No
48. Can I order hyperbaric therapy?	Yes	APRN with appropriate education and training	As long as it is in accordance with AS 08.36.360	No	Yes	No
49. Can I administer hyperbaric therapy?	Yes	APRN with appropriate education and training	As long as it is in accordance with AS 08.36.360	No	Yes	No

			I don't believe a dentist would maintain a hyperbaric chamber in their dental office in the office chance there is a rare complication associated with oral bone fracture.			
50. Can I monitor a patient during and after administration?	Yes	APRN with appropriate education and training RN with training could monitor under supervision	As long as it is in accordance with AS 08.36.360	No	Yes	Monitoring vital signs and bodily functions may be delegated under 12 AAC 44.955
51. Can I supervise personnel? If so, who and what?	Yes. Licensees may supervise / delegate licensed and unlicensed personnel to perform routine medical duties within the scope of their practice in accordance with 12 AAC 40.920.	APRN can supervise	N/A for dentists or hygienists.	No	Only within scope of practice	No
52. Can I delegate to personnel? If so, who and what?	A licensee may delegate "routine medical duties to an "agent" of the licensee in accordance with 12 AAC 40.920. See #18, above.	Yes 12 AAC 44.950	Dentist may, only if within the practice of dentistry under AS 08.36.360 Delegations in regulation is limited to RDH and Dental assistant.	No	Only appropriately trained and within scope	No

			Dentists may delegate dental related tasks, however a dentist may not delegate to a dental assistant a dental operation or service that requires the professional skill of a licensed dentist 08.36.346			
53. Am I liable if something goes wrong?	Yes. All licensees may be liable if something goes wrong.	Yes	N/A for dentists or hygienists.	N/A	Yes	Possibly, but should also be covered under primary care provider's malpractice insurance
	Medical Board Physician Osteopath Podiatrist Physician Assistant	**Board of Nursing** APRN RN LPN CNA	**Board of Dental Examiners** Dentist Dental Hygienist	**Board of Pharmacy** Pharmacist Pharmacy Technician	**Board of Chiropractic Examiners** Chiropractor	**Board of Barbers & Hairdressers** Esthetician Hairdresser Tattooist Permanent Cosmetic Colorist
Locations: Clinics, retail locations, and mobile locations						
54. Can I own a clinic that offers medical procedures like any listed above?	Yes	APRN can if within their population foci or if employs appropriately trained people	Under Sec. 08.36.365 A dentist licensed in this state may practice under the name of "dental center" or other descriptive term that does not deceive the public about the nature of the services provided; and	Yes	Yes--A chiropractic clinic may only be owned by a chiropractic physician and perform services with the scope of chiropractic practice; A specialty clinic may be owned by anyone, but the	Medical clinics are not regulated by the board of Barbers and Hairdressers. Medical service may be offered at a shop licensed under AS 08.13.120; however, the shop license is

			under Sec. 08.36.367 For the purpose of owning or operating a dental practice, office, or clinic, an entity described in (a) of this section shall (1) name a licensed dentist as its dental director, who shall be subject to the provisions of AS 08.36.315 and 08.36.317 in the capacity of dental director; the dental director, or an actively licensed dentist designated by the director, shall have responsibility for the entity's practice of dentistry. As a passive investor, yes but not as a practicing licensed dental practitioner as that would be deceiving to the public. See 08.36.365		services provided must be within the scope of practice of whomever is performing or supervising the specific service.	irrelevant: Requires licensed primary care provider to be present and all relevant laws under health care professions to be followed.
55. Can I supervise at a clinic that offers medical procedures like any listed above?	Yes	Supervision is according to nursing statutes and regulations	Dentist may, only if within the practice of dentistry under AS 08.36.360.	No	Within scope	No

56. Must the clinic be stationery/have a fixed address?	No statutes/ regulation address this under the Medical Board.	Not addressed in regulation	Not specified in dental statutes or regulations. The majority of board members agree that mobile practices are legal. However one memer states that he believes it is required that any change in location must be submitted to the board within 30 days. He will follow up further and report to the board at the next meeting. I am unable to find any language or precedent precluding this. In the past the dental board has given licenses to boat slip location knowing the intention was to provide dentistry to Alaska islands from the location of a mobile boat.	Uncertain	No	Not according to BAH regulation:
57. Must the clinic itself hold an Alaska license? If so, by who and what?	No statutes/ regulation address this under the Medical Board.	Maybe a business license currently- no facility regulations	Not specified in dental statutes or regulations. Practices themselves are not regulated. Although this is	Depends on therapy provided.	No	12 AAC 09.110 (Shop owner license) and 12 AAC 09.111 (Mobile shops)

			commonly done in other states.			
58. Must a medical professional be onsite while these procedures are offered?	Yes. If medical services are being offered, the patient must be assessed to determine the patient's medical condition before services are administered.	Yes	A dentist must be present for services that require either direct or indirect supervision; services that require general supervision may be performed by hygienists without a dentist present.	Uncertain	If required/performed under specific license/ scope of practice	Medical clinics are not regulated by the board of Barbers and Hairdressers. Medical service may be offered at a shop licensed under AS 08.13.120; however, the shop license is irrelevant: Requires licensed primary care provider to be present and all relevant laws under health care professions to be followed.
59. Must a medical professional be onsite while these procedures are administered?	Yes. However, the level of professional that must be onsite when the procedures are delivered depends on the procedure and license type of that individual.	Yes	A dentist must be present for services that require either direct or indirect supervision; services that require general supervision may be performed by hygienists without a dentist present.	Uncertain	As required by license/scope under which procedure is performed	Yes
60. Am I liable if something goes wrong?	Yes	See 12 AAC 44.770.	Yes.	Yes, as an owner or if practicing outside of the	Yes--according to license/scope	Yes, as business owner

				scope of practice		

Links and Resources:

USP <797> Sterile Compounding: https://www.usp.org/compounding/general-chapter-797

MoCRA Registration info: https://www.fda.gov/cosmetics/registration-listing-cosmetic-product-facilities-and-products
FDA Device Classification Database: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

State Medical Board Opinions:
https://wwwcommercealaskagov/web/Portals/5/pub/MED_Guide_Dermatologicalpdf
https://wwwcommercealaskagov/web/Portals/5/pub/MED_Guide_Lasers_Laser_Surgerypdf
https://wwwcommercealaskagov/web/Portals/5/pub/MED_Guide_Delegating_to_Unlicensed_Assistantspdf

Board of Nursing Opinions:
https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/BoardofNursing/AdvisoryOpinions.aspx

Alaska Professional Licensing Board Statutes and Regulations
https://wwwcommercealaskagov/web/Portals/5/pub/MedicalStatutespdf
https://wwwcommercealaskagov/web/Portals/5/pub/NursingStatutespdf
https://wwwcommercealaskagov/web/Portals/5/pub/BAH_Stats_Regspdf
https://www.commerce.alaska.gov/web/Portals/5/pub/PharmacyStatutes.pdf
https://www.commerce.alaska.gov/web/Portals/5/pub/DentalStatutes.pdf
https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/BoardofChiropracticExaminers.aspx

Additional Narrative:

Erickson (Nursing): I believe our current regulations project will allow APRNs to supervise unlicensed personnel including medical assistants and estheticians, current regulations only allow for supervision of nursing related fields, but we know there's overlap.

The way I see many of these new procedures is that with the appropriate population foci, and proper education and training all of these are in the scope of the appropriate APRN. It's impossible to list all the new products and procedures that will come in the future so making regulation with that in mind is important.

<795> FAQs

Updated: November 1, 2023

General

1. Where can I find FAQs and other information on USP Compounding Standards?

For FAQs on USP Compounding Standards, please see below:

- General Chapter <795> *Pharmaceutical Compounding—Nonsterile Preparations*
- General Chapter <797> *Pharmaceutical Compounding—Sterile Preparations*
- General Chapter <800> *Hazardous Drugs—Handling in Healthcare Settings*
- General Chapter <825> *Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging*
- Compounded Preparation Monographs (CPMs)

2. Where can I find information about how to interpret and apply General Chapters?

The *General Notices and Requirements* describe the basic assumptions, definitions, and default conditions for the interpretation and application of *USP–NF* content. For example, Section *2.30. Legal Recognition* describes the legal recognition of USP and NF. Section *3.10.30 Applicability of Standards to the Practice of Compounding* describes when USP compounding practice standards are or are not applicable.

3. Can USP provide some clarity as to when a preparation needs to be prepared as sterile (CSP) as opposed to as nonsterile (CNSP)?

<795> and <797> both describe compounded preparations that are required to be sterile or can be prepared as nonsterile. In general, preparations designed to be delivered to any body space that does not normally freely "communicate" or have contact with the environment outside of the body, such as the bladder cavity or peritoneal cavity, are typically required to be sterile. Additionally, ophthalmic products and compounded aqueous inhalation solutions and suspensions are required to be sterile. Otic preparations are not required to be sterile unless being administered to a patient with a perforated eardrum. Irrigations for the mouth, rectal cavity, and sinus cavity are not required to be sterile, nor are nasal sprays.

Introduction and Scope

4. What is the definition of nonsterile compounding?

For purposes of General Chapter <795>, nonsterile compounding is defined as combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance to create a nonsterile preparation.

5. To whom do the standards in General Chapter <795> apply?

The chapter applies to all persons who prepare compounded nonsterile preparations (CNSPs) and all places where CNSPs are prepared for human and animal patients. This includes but is not limited to pharmacists, technicians, nurses, physicians, dentists, naturopaths, and chiropractors, in all places including but not limited to pharmacies, hospitals and other healthcare institutions, patient treatment sites, and physicians' practice sites. Personnel engaged in the compounding of CNSPs must additionally comply with laws and regulations of the applicable regulatory jurisdiction. Compounding of nonsterile hazardous drugs (HDs) must additionally comply with General Chapter <800> *Hazardous Drugs—Handling in Healthcare Settings*.

6. How do I know what are requirements versus recommendations in the chapter?

Generally, requirements in a General Chapter are conveyed by use of the term "must". Recommendations are conveyed by use of the terms "should" and "may".

7. What does "official date" mean?

The USP "official date" indicates the date by which affected users are expected to meet the requirements of a particular standard. Ensuring compliance with the requirements of these standards is the responsibility of the applicable regulatory jurisdiction. USP has no role in enforcement.

All text in the United States Pharmacopeia (USP) or National Formulary (NF) that has reached its official date is "official text." Although all text of the *USP–NF* that has reached its official date is "official text," not all official text states requirements with which compendial users must comply. Some official text is intended to assist or guide compendial users or to serve informational purposes.

8. When do the revisions to General Chapter <795> become official?

The revision of <795> published on November 1, 2022, became "official" on November 1, 2023. The "official date" indicates the date by which affected users are expected to meet the requirements of a particular standard. However, ensuring compliance with the requirements of these standards is the responsibility of the applicable regulatory jurisdiction. Regulatory bodies such as state boards of pharmacy may have a different official date. USP has no role in enforcement.

9. Does the chapter apply for breaking or cutting a tablet into smaller portions?

No, breaking or cutting a tablet into smaller portions is not required to meet the standards in this chapter.

10. Does the chapter apply for reconstitution of conventionally manufactured nonsterile products (e.g., compounding kits)?

Reconstitution of a conventionally manufactured nonsterile product in accordance with the directions contained in the manufacturer approved labeling is not required to meet the standards in this chapter. Reconstitution that is not performed according to manufacturer approved labeling is considered nonsterile compounding and is subject to the requirements in the chapter. Compounding kits are within the scope of the chapter unless they are FDA-approved and reconstitution is performed in accordance with the directions contained in the manufacturer approved labeling.

11. Am I required to use purified water for reconstitution of a conventionally manufactured product?

Reconstitution of a conventionally manufactured nonsterile product in accordance with the directions contained in the manufacturer approved labeling is out of the scope of the chapter. As such, the chapter does not specify the quality of water to be used for reconstitution. Compounders can reach out to other resources, such as the regulatory bodies in their jurisdiction or the manufacturer of the products, for additional information.

12. Is administration out of the scope of the chapter?

The intent of the chapter is to establish minimum standards for practitioners when preparing compounded nonsterile preparations in order to minimize harm, including death, to human and animal patients. The scope of the chapter is intended to be limited to compounding and the standards are designed to help ensure a CNSP maintains its integrity up until the time when administration begins. Administration is out of scope of the chapter, and for purposes of <795>, is defined as the preparation of a single dose for a single patient when administration will begin within 4 hours.

13. Does the chapter address compounded radiopharmaceutical dosage forms?

No. Compounding of radiopharmaceuticals is not required to meet the standards of this chapter as they are subject to the requirements in General Chapter <825> *Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging*.

14. Are the temperatures in the chapter expressed in degrees Fahrenheit or Celsius?

Unless otherwise specified, all temperatures in the *USP–NF* are expressed in degrees centigrade (Celsius) (see also *General Notices 8.180 Temperatures*).

15. Are products manufactured by 503B facilities or conventionally manufactured products considered active pharmaceutical ingredients (APIs)?

No. The term "API" refers to any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals or affecting the structure and function of the body. Also referred to as *Bulk drug substance*. A conventionally manufactured drug product is not an API but is typically manufactured from an API(s).

16. Why were the categories of compounding (simple, moderate, and complex) in the previous chapter eliminated in the new revision?

These categories of compounding were originally adapted from <1075> *Good Compounding Practices* in 2011. They often led to confusion among users on how to apply the criteria and the chapter did not provide standards on how to use these categories in applying the compounding standards.

17. Who can be the designated person(s)?

The designated person is one or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel for the preparation of compounded nonsterile preparations (CNSPs). Facilities must determine whether they have one or more designated person, select the designated person, and determine how to allocate responsibility if there is more than one designated person.

18. Does the chapter apply for repackaging of a conventionally manufactured product?

No, repackaging of conventionally manufactured drug products is not required to meet the standards in this chapter (see <1178> *Good Repackaging Practices* for recommendations).

19. Please clarify the phrase, "variability from the intended strength of correct ingredients (e.g., ±10% of the labeled strength)".

There may be variability from the labeled strength of a CNSP. The acceptable range is listed in the applicable monograph for official articles. The acceptable range is ±10% of the labeled strength for nonofficial articles (i.e., 90-110%).

20. <795> defines altering a drug or bulk drug substance as nonsterile compounding. It is unclear whether flavoring a manufactured liquid would fall under this category or whether the preparation of premeasured kits, such as FIRST Magic Mouthwash and FIRST Omeprazole, would be required to meet the standards of this chapter.

Flavoring a manufactured product outside of any directions in approved labeling is compounding and must be conducted under compounding standards in accordance with the exemptions for compounding in the Federal Food, Drug, and Cosmetic Act, otherwise the drug product would be deemed adulterated under the Act. Compounding standards apply to the assembly of premeasured kits that are not FDA-approved.

21. Is flavoring still considered compounding even though it is less than 5% of the total volume of the drug to which the flavoring agent is added?

Yes. Flavors are organic chemicals with reactive functional groups. The effect of adding these substances, even in very small quantities or concentrations, to conventionally manufactured products is unpredictable due to the potential for a variety of chemical reactions.

Flavoring a manufactured product is compounding and must be conducted under compounding standards in accordance with the exemptions for compounding in the Federal Food, Drug, and Cosmetic Act, otherwise the drug product would be deemed adulterated under the Act.

22. When repackaging capsules into unit dose containers using a robotic system, is the BUD limited to 180 days?

Repackaging nonsterile conventionally manufactured drug products is outside the scope of <795> so the BUD limits in *Table 4* do not apply. See <1178> *Good Repackaging Practices* for recommendations.

Personal Hygiene and Garbing

23. What garb is required for nonsterile compounding?

Gloves must be worn for all compounding activities. Other garb (e.g., shoe covers, head or hair covers, facial hair covers, face masks, and gowns) should be worn as required by the facility's standard operating procedures (SOPs). Garb is recommended for the protection of personnel and to minimize the risk of CNSP contamination. The garb must be appropriate for the type of compounding performed. The garbing requirements and frequency of changing the garb must be determined by the facility and documented in the facility's SOPs.

24. Are gloves required to be wiped or changed before beginning to compound a CNSP with different components?

The chapter recommends wiping or replacing gloves before beginning to compound a CNSP with different components to minimize the risk of cross-contaminating other CNSPs and contaminating other objects. General Chapter <795> does not describe the use of specific wipes or agents to use for wiping gloves. Facilities must determine whether gloves should be changed or replaced and the appropriate wipe/agent to use if they are wiped.

25. Can gowns be reused for multiple days if not soiled?

If gowns are worn, they may be re-used if not soiled. If gowns are visibly soiled or have tears or punctures, they must be changed immediately. Facilities must determine the frequency for changing gowns.

Buildings and Facilities

26. Is a compounding space required to be in an enclosed room (i.e., with walls and doors)?

No. While a room may be used as the compounding space, the chapter does not require a separate room. The chapter requires a space that is specifically designated for nonsterile compounding. A visible perimeter should establish the boundaries of the nonsterile compounding area.

27. What is considered an appropriate temperature range to store CNSPs or components?

The storage area must be maintained at a temperature that is appropriate for the CNSPs and components. The storage conditions for the CNSP would be dependent on the assigned beyond-use date (BUD) and CNSP-specific properties (see <795>, *10.2 Parameters to Consider in Establishing a BUD*). The storage conditions for components may be provided by the manufacturer or vendor on the labeling and/or specified in the USP monograph for that component (see also <659>).

28. Since reconstitution and repackaging are not considered compounding and are out of scope of the chapter, can they still be performed in the designated compounding space?

Yes, other activities may be performed in the compounding space when compounding is not occurring. The chapter requires that a compounding space be designated for nonsterile compounding, however, the space is not required to be dedicated for sole use in compounding. Other activities may occur in the compounding space, but they must not be occurring in the space at the same time as compounding.

Cleaning and Sanitizing

29. Can non-compounding personnel clean and sanitize the compounding space?

Facilities must determine the appropriate personnel for cleaning and sanitizing the compounding space. The chapter does not specify who may perform the cleaning and sanitization procedures. However, the chapter does specify that knowledge and competency must be demonstrated initially and at least every 12 months for those that are cleaning and sanitizing.

30. Is daily cleaning only required when nonsterile compounding has occurred?

Cleaning and sanitizing of the surfaces in the nonsterile compounding area(s) must occur on a regular basis at the minimum frequencies specified in *Table 1* or, if compounding is not performed daily, it must be performed before initiating compounding.

31. What is the difference between cleaning and sanitizing?

Cleaning is the process of removing substances (e.g., organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products. Sanitizing is the process of reducing, on inanimate surfaces, the number of all forms of microbial life including fungi, viruses, and bacteria.

32. Why does sterile compounding per <797> require cleaning daily, whereas for nonsterile compounding, cleaning is required at the beginning and end of a shift?

Cleaning and sanitizing of the surfaces in the nonsterile compounding area(s) must occur on a regular basis at the minimum frequencies specified in *Table 1* or, if compounding is not performed daily, it must be performed before initiating compounding.

Cleaning is required at the beginning and end of each shift in <795> due to the particle-generating nature of nonsterile compounding. Sterile compounding is less particle-generating than nonsterile, and compounders sanitize after preparing each batch of CSPs. There is greater risk of cross-contamination from particle-generation for nonsterile compounding.

33. If the dedicated compounding area is in the middle of a room (i.e., dedicated cart, island), does this mean we have to clean walls and storage shelving?

The designated person can define in an SOP what specifically constitutes the 'compounding area' that is specifically designated for nonsterile compounding. Defining the compounding area will determine what surfaces require cleaning and sanitizing per *Table 1*.

Equipment and Components

34. Are containment ventilated enclosures (CVEs) required for nonsterile compounding?

No. The chapter requires facilities to assess particle-generating activities (e.g., weighing, measuring, or other manipulation of components) to determine whether a closed-system processing device is needed. The chapter does not require a closed-system processing device but does require facilities to perform a process evaluation to determine whether a device is needed. A closed-system processing device reduces the potential exposure to personnel and contamination to the facility from airborne particles that weighing, measuring, or otherwise manipulating components could generate. A CVE is one example of a closed-system processing device; other examples include BSCs and single-use containment glove bags.

35. Section *6.2 Components* of <795> only lists API, other bulk components, or water. Can manufactured products be used as a component as well?

Yes, conventionally manufactured products should be used when available and appropriate for the intended CNSP.

36. Why are APIs required to be obtained from an FDA-registered facility and components other than APIs only recommended to be obtained from an FDA- registered facility?

The Federal Food, Drug, and Cosmetic Act requires compounded preparations to be prepared from bulk drug substances that are obtained from FDA-registered facilities. The Expert Committee recognizes that there may be some components other than APIs that cannot be obtained from an FDA-registered facility, thus, it is a recommendation that these components be obtained from an FDA-registered facility but is not a requirement.

37. *Table 2* mentions "other devices and equipment"—does this include tools like a mortar and pestle? How should these be cleaned, and do they need to be sanitized?

Yes, these tools are considered equipment. Select sanitizing agents appropriate for the equipment (e.g., 70% IPA). The chapter also states, *Purified Water* (see *Water for Pharmaceutical Purposes* <1231>, *3.1.1 Purified Water*), distilled water, or reverse osmosis water should be used for rinsing equipment and utensils.

Table 2. Minimum Frequency for Cleaning and Sanitizing in Nonsterile Compounding Area(s)—Equipment

Site	Minimum Frequency
CVE	• At the beginning and end of each shift on days when compounding occurs, after spills, and when surface contamination (e.g., from splashes) is known or suspected • Clean and sanitize the horizontal work surface of the CVE between compounding CNSPs with different components
BSC	• At the beginning and end of each shift on days when compounding occurs, after spills, and when surface contamination (e.g., from splashes) is known or suspected • Clean and sanitize the horizontal work surface of the BSC between compounding CNSPs with different components • Clean and sanitize under the work surface at least monthly
Other devices and equipment used in compounding operations	• Before first use and thereafter in accordance with the manufacturer's recommendations • If no recommendation is available, between compounding CNSPs with different components

38. What does it mean when Purified Water is printed in italics?

It means the *Purified Water* is an official article and must meet the applicable monograph (e.g., Purified Water, USP).

39. When is the use of distilled water acceptable?

Purified Water, distilled water, or reverse osmosis water should be used for rinsing equipment and utensils. Note that *Purified Water* or better quality, e.g., *Sterile Water for Irrigation*, must be used for compounding CNSPs when formulations indicate the inclusion of water.

40. Can I use distilled water to compound CNSPs?

If the water meets the requirements of the *Purified Water* USP monograph, then it can be used to compound CNSPs.

41. If *Sterile Water for Irrigation* is used as a component in a CNSP, what is the BUD of the *Sterile Water for Irrigation* once opened?

Purified Water or better quality, e.g., *Sterile Water for Irrigation*, must be used for compounding CNSPs when formulations indicate the inclusion of water. Since sterility is not required, *Sterile Water for Irrigation* may be used until its labeled expiration date if it is stored in its original container per the manufacturer's recommendations.

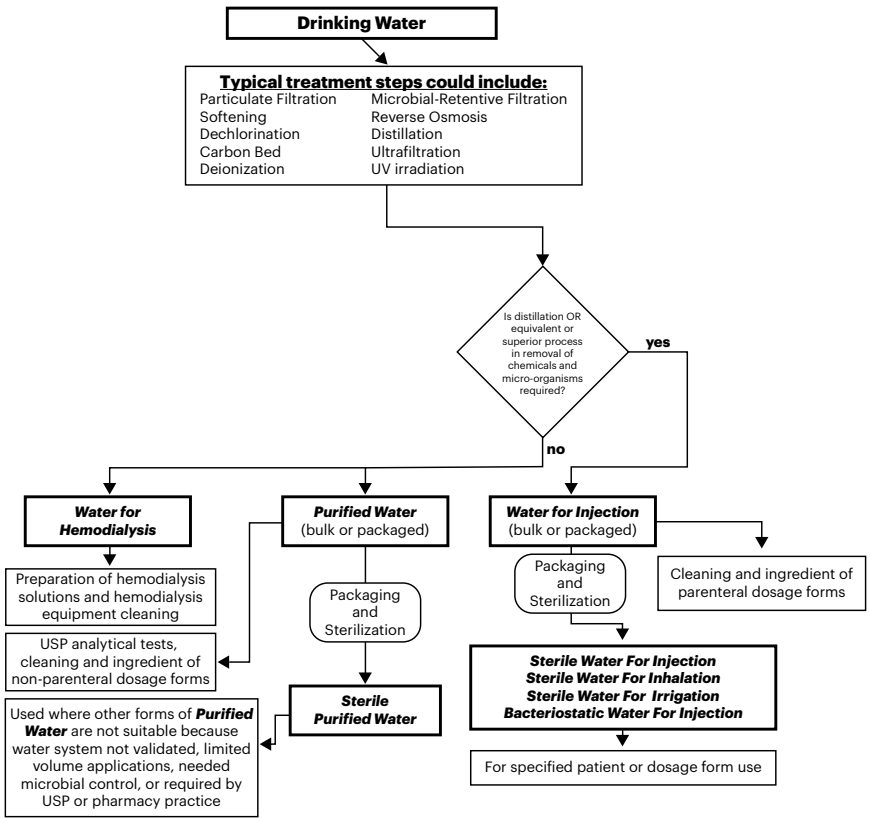
42. Our Board of Pharmacy inspector is questioning our use of *Sterile Water for Irrigation* in place of *Purified Water* in CNSPs. Does USP reference this in other general chapters?

Purified Water or better quality, e.g., *Sterile Water for Irrigation*, must be used for compounding nonsterile drug preparations when preparations indicate the inclusion of water. Per <1231> *Water for Pharmaceutical Purposes, 3.2.4, Sterile Water for Irrigation* may be used in other applications that do not have particulate matter specifications, including where *Purified Water* is indicated but where access to a validated water system is not practical.

43. FDA prescribing information for a specific brand of *Sterile Water for Irrigation* says, "Sterile Water for Irrigation is not potable water and is not intended for oral administration." If *Sterile Water for Irrigation* is labeled as non-potable, may it be used as a component in a CNSP intended for oral administration?

Sterile Water for Irrigation, USP, is prepared from *Water for Injection* that is sterilized and suitably packaged. It contains no antimicrobial agent or other added substance. *Water for Injection* is water purified by distillation or a purification process that is equivalent or superior to distillation in the removal of chemicals and microorganisms. It is prepared from water complying with the U.S. Environmental Protection Agency National Primary Drinking Water Regulations or with the drinking water regulations of the European Union or of Japan or with the World Health Organization's Guidelines for Drinking Water Quality. Per <1231> *Water for Pharmaceutical Purposes, Sterile Water for Irrigation,* USP, 'may be used in other applications that do not have particulate matter specifications, where bulk *Water for Injection* or *Purified Water* is indicated but where access to a validated water system is not practical, or where somewhat larger quantities are needed than are provided as *Sterile Water for Injection*.' However, if *Sterile Water for Irrigation* is labeled as non-potable, it must not be used in oral preparations.

Per <1231>



44. Is there any guidance on reverse osmosis (RO) systems, such as testing and maintenance requirements?

Water from RO systems that is used as a component in CNSPs must meet the monograph requirements for *Purified Water* including <643> *Total Organic Carbon* and <645> *Water Conductivity*. RO systems must be maintained per manufacturer's recommendations.

45. Regarding the statement, "Once removed from the original container, any component not used in compounding (e.g., excess after weighing) should be discarded and not returned to the original container to minimize the risk of contaminating the original container", given the risk of contamination that this could present, why isn't the "should" a "must"?

There may be instances (e.g., drug shortages, controlled drugs) when discarding excess component is not possible. Personnel who perform weighing procedures must be trained and demonstrate knowledge and competency on handling components to minimize the risk of contamination, and avoid using excessive materials.

46. What organizations certify BSCs or CVEs?

The Compounding Expert Committee removed all references to specific professional organizations and facilities must determine the appropriate certification guide to use for certifying their equipment. Some examples of organizations that provide certification guidance include the Controlled Environment Testing Association (CETA), NSF International, and American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE).

47. Are these terms interchangeable: API, drug substance, drug product, active ingredient?

For the purposes of *USP* Chapters <795> and <797>, a bulk drug substance and an active pharmaceutical ingredient are the same. They are defined in the glossary of *USP* <795> and <797> as: Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals or affecting the structure and function of the body.

A conventionally manufactured drug product is not an API but is typically manufactured from an API(s). There is no statutory or USP definition for active ingredient, but the term is used generically in USP when referring to the active ingredient in either a conventionally manufactured drug product or API (e.g., when labeling a CSP or a CNSP).

For the purposes of the USP Compounding Chapters, a drug product is the same as a conventionally manufactured product and defined as: A pharmaceutical dosage form, usually the subject of an application approved by the applicable national regulatory agency, that is manufactured under current good manufacturing practice conditions. Drug products and conventionally manufactured products are not CSPs or CNSPs.

Master Formulation and Compounding Records

48. Does a new master formulation record (MFR) need to be made for each different quantity of a CNSP compounded (e.g., same ointment of 120 grams and 60 grams)?

No, the quantity compounded is reflected in the compounding record (CR).

49. How specific must the description of the container closure be in the MFR?

A thorough description of the container closure would be considered best practice, which ideally would also include the material of composition that is in contact with the compounded preparation. The size of the container closure may vary depending on quantity of prescription dispensed. For example, "White opaque HDPE airless pump." There should be enough detail so the selection of that container closure could be made by someone else.

Labeling

50. Are all CNSPs required to be labeled, regardless of whether they are dispensed?

Yes. CNSPs must be labeled with the information specified in *9. Labeling* regardless of whether or not they are dispensed. Labeling provides the information of the package contents.

Establishing Beyond-Use Dates

51. What is water activity (a_w)?

Put simply, water activity is the measure of free water that is available to participate in chemical reactions such as hydrolysis or may provide an environment that can support microbiological growth. See <922> and <1112> for more detailed information.

52. Are compounders expected to measure the a_w of CNSPs to determine the BUD?

No, the chapter does not require compounders to measure a_w for CNSPs. a_w is intended to be used as a guide for assigning BUDs. General Chapter <795> provides examples of dosage forms that have an $a_w < 0.6$ and those that have an $a_w \geq 0.6$. Additionally, General Chapter <1112> *Application of Water Activity Determination to Nonsterile Pharmaceutical Products* provides a list of products and corresponding a_w in *Table 2*.

53. Why is the BUD for nonaqueous oral liquid dosage forms with an a_w < 0.6 (e.g., oral suspensions or solutions) limited to 90 days?

Although many nonaqueous preparations, including anhydrous oil preparations, may be stable for a long period of time, this is not consistently demonstrated for all nonaqueous formulations. For example, a stability-indicating assay of doxycycline compounded in oil exhibited degradation before 90 days. Additionally, there are other ingredients that may oxidize or otherwise react with the fatty acids in the oil. The chapter provides a conservative approach due to examples where preparations in oil are not stable for 180 days. Further, the chapter allows the BUD of CNSPs to be extended up to 180 days if there is a stability study using a stability-indicating assay (see <795>, *10.5 Extending BUDs for CNSPs*).

54. If a stability study shows that a CNSP is stable for longer than 180 days, can that BUD be assigned?

No. General Chapter <795> specifies that the BUD for CNSPs may be extended up to a maximum of 180 days if there is a stability study (published or unpublished) using a stability-indicating analytical method for the API(s), CNSP formulation, and material of composition of the container closure that will be used. If the CNSP is aqueous, the chapter additionally requires testing for antimicrobial effectiveness for extending BUDs beyond those contained in *Table 4* (see *10.5 Extending BUDs for CNSPs*).

However, if there is a *USP–NF* compounded preparation monograph for the CNSP, and the preparation is labeled to indicate that it meets the monograph specifications, the BUD must not exceed the BUD specified in the monograph. As stated in *General Notices 3.10*, monograph requirements supersede the requirements of General Chapters.

55. If I extend the BUD beyond those described in *Table 4. BUD Limit by Type of Preparation in the Absence of a USP-NF Compounded Preparation Monograph or CNSP-Specific Stability Information*, why does the aqueous CNSP have to be tested for antimicrobial effectiveness?

The chapter allows an extension of the BUD if there is stability data supported by a stability-indicating study. Although the CNSP may be stable, the CNSP may be susceptible to microbial proliferation especially from prolonged and repeated use. Testing for antimicrobial effectiveness when assigning an extended BUD helps to ensure the efficacy of the preservative system is maintained for the duration of the assigned BUD. If the BUD of the CNSP is extended beyond the BUDs in *Table 4*, an aqueous CNSP must be tested for antimicrobial effectiveness, and only needs to be performed once for a particular CNSP. If a range of concentrations are used in the same CNSP formulation and stored under the same conditions, the antimicrobial effectiveness test can be conducted for the highest and lowest concentrations. The results can be extrapolated for the concentrations within the range studied (e.g., bracketed study design).

56. Is there a difference between testing stability with a strength (potency) over time or a stability-indicating method?

Yes, a strength (potency) over time test determines the amount of active ingredient in a preparation, however, it may not be able to separate the active ingredient from its degradation products and impurities for quantitation depending on the analytical methods used for the test. A stability-indicating method will be able to quantitate the active ingredient and its degradation products or related impurities in the preparation by separating the active ingredient from its degradation products and impurities, and to show a change in the concentration of the active ingredient with increasing storage time. A stability-indicating method is used to determine stability of a drug and used to establish the beyond-use date. (See article, "Strength and Stability Testing for Compounded Preparations.")

57. What is the difference between a BUD and an expiration date?

Beyond-use dates (BUDs) and expiration dates are not the same. Expiration dates are assigned by manufacturers based on analytical and performance testing of the sterility, chemical and physical stability, and packaging integrity of the conventionally manufactured product, API, or added substance. Expiration dates are specific to a particular formulation in its container and at stated exposure conditions of illumination and temperature. Section *14.1 Terminology* in *USP* <797> and Section *10.1 Terminology* in *USP* <795> define an expiration date as: The time during which a product can be expected to meet the requirements of the *USP–NF* monograph, if one exists, or maintain expected quality provided it is kept under the specified storage conditions. Beyond-use dates are assigned by compounders and apply to CSPs and CNSPs. The *Terminology* sections in *USP* <797> *and* <795> define a BUD as: Either the date, or hour and date, after which a compounded preparation must not be used. The BUD is determined from the date and time that preparation of the compounded preparation is initiated.

58. What is the BUD of a stock solution with no API?

Section *10.4* states, "For CNSPs prepared from one or more compounded components, the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CNSP exceeds the BUD assigned to compounded components (e.g., pH-altering solutions). If the assigned BUD of the final CSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CSP must not be negatively impacted."

Examples of acceptable instances may include use of a pH-altering solution that has a 24 h BUD or preparing a methylcellulose or similar suspension (14 day BUD) for use during the same shift in CNSPs that are preserved (35 day BUD).

59. How may a BUD beyond *USP* <795> limits be assigned to a stock solution with no API?

Information may be found in the Formulation and Stability Reference Document for Pharmaceutical Compounding posted here. In general, the following tests must be considered:

- Appearance (e.g., appearance, color, clarity, and particulates)
- Antimicrobial effectiveness testing (*USP* <51>) for aqueous preparations
- pH
- Microbiological tests for water-containing formulations ($a_w \geq 0.6$)
- <61> *Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests*
- <62> *Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms*

60. How do I choose an appropriate preservative for my CNSP?

Preservative selection is dependent on the level of potential microbiological growth over the intended period of the BUD (amount of preservative in preparation must be sufficient to protect the preparation through the end of the BUD), the pH of the preparation being preserved (the preservative must have effectiveness at the pH of the preparation), specific microbiological organisms with which the preparation could be exposed (preservative system must be effective against the microbiological organism(s) that have a potential to propagate in the preparation), and chemical compatibility with the API and other excipients.

61. Given the water activity examples in *Table 3*, and the fact that these do not cover all formulation possibilities, how does a pharmacist determine total water activity of multi-ingredient compounds, and how should a pharmacist determine when water activity testing is needed?

Pharmacists can always reference <922> and <1112> for more information regarding a_w and its determination. The chapter does not require a compounded preparation to be tested for water activity, but a_w is the determining factor in categorizing a preparation as aqueous or nonaqueous. The table was meant to provide actual examples of formulations tested for water activity to assist the pharmacist in determining if a preparation would likely be squarely in the aqueous or nonaqueous category. It is also important to note that waters of hydration do not affect water activity. When in doubt, the best course of action to know water activity would be to test it. This is a one-time test for the specific preparation.

62. How is the BUD of a CNSP affected by pH-modifiers or other stock solutions that are used as components?

For CNSPs prepared from one or more compounded components, the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CNSP exceeds the BUD assigned to compounded components (e.g., pH-altering solutions). If the assigned BUD of the final CNSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CSP must not be negatively impacted.

63. Must the stability studies used to extend BUDs to 180 days be published?

No. Any stability study that meets the requirements of a stability-indicating assay method can be used, whether published or unpublished, to extend beyond-use dates up to 180 days for a CNSP. To learn the requirements for a stability-indicating assay method, visit the Formulation and Stability Reference Document for Pharmaceutical Compounding posted here.

64. When must <51> testing be performed?

<51> testing should be performed to verify a formulation for a multiple-dose preparation is capable of meeting the antimicrobial effectiveness testing requirements. Changes in package size, container closure system, or preparation components may necessitate repeating the <51> testing. Testing is not necessary for every batch.

65. Must antimicrobial effectiveness testing results be provided by an FDA-registered facility?

The designated person(s) may rely on antimicrobial effectiveness testing results provided by an FDA-registered facility or published in peer-reviewed literature as long as the CNSP formulation (including any preservative) and container closure materials of composition are the same as those tested (unless a bracketing study is performed). Outside of the United States, facilities must comply with the laws and regulations of the applicable regulatory jurisdiction.

66. Can unpublished antimicrobial effectiveness testing results be used?

Yes. Compounders are not required to perform their own *USP* <51> *Antimicrobial Effectiveness Testing* on each compound prepared. They may perform or contract the study themselves, or they may use published or unpublished peer-reviewed literature results or *USP* <51> results performed in an FDA-registered facility provided that the CNSP or CSP preparation (including any preservative) and container closure system are exactly the same as those that produced the preparation that produced the test results. Antimicrobial effectiveness testing may also be performed in what is known as a bracketing study by testing a low concentration and a high concentration of the active ingredient in the formulation to establish preservative effectiveness across various strengths of the same formulation. The concentration of all other ingredients (including preservatives) must be the same throughout the bracketing study.

<797> FAQs

Updated: December 11, 2023

General

1. Where can I find FAQs and other information on USP Compounding Standards?

For FAQs on USP Compounding Standards, please see below:

- General Chapter <795> Pharmaceutical Compounding—Nonsterile Preparations
- General Chapter <797> Pharmaceutical Compounding—Sterile Preparations
- General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings
- General Chapter <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging
- Compounded Preparation Monographs (CPMs)

2. Where can I find information about how to interpret and apply General Chapters?

The *General Notices and Requirements* describe the basic assumptions, definitions, and default conditions for the interpretation and application of *USP–NF* content. For example, Section 2.30. *Legal Recognition* describes the legal recognition of USP and NF. Section *3.10.30 Applicability of Standards to the Practice of Compounding* describes when USP compounding practice standards are or are not applicable.

Introduction and Scope

3. What is the definition of sterile compounding?

For purposes of General Chapter <797>, sterile compounding is defined as combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance to create a sterile medication. However, administration and preparation per the manufacturer's approved labeling are out of the scope of the chapter as described in *1.2 Administration* and *1.4 Preparation Per Approved Labeling,* respectively.

4. To whom do the standards in General Chapter <797> apply?

This chapter applies to all persons who prepare compounded sterile preparations (CSPs) and all places where CSPs are prepared for human and animal patients. This includes, but is not limited to, pharmacists, technicians, nurses, physicians, veterinarians, dentists, naturopaths, and chiropractors in all places including, but not limited to, hospitals and other healthcare institutions, medical and surgical patient treatment sites, infusion facilities, pharmacies, and physicians' or veterinarian practice sites. Any person entering a sterile compounding area, whether preparing a CSP or not, must meet the requirements in *3. Personal Hygiene and Garbing*.

Please note, compounding of sterile hazardous drugs (HDs) must additionally comply with General Chapter <800> *Hazardous Drugs—Handling in Healthcare Settings*.

5. What is considered a compounding facility? Are there requirements that have to be met in order to be considered a compounding facility?

The requirements of the chapter apply to all places where CSPs are prepared for human and animal patients. Additionally, there may be local or federal requirements that must be met.

6. How do I know what are requirements versus recommendations in the chapter?

Generally, requirements in a General Chapter are conveyed by use of the term "must". Recommendations are conveyed by use of the terms "should" and "may".

7. What does "official date" mean?

The USP "official date" indicates the date by which affected users are expected to meet the requirements of a particular standard. Ensuring compliance with the requirements of these standards is the responsibility of the applicable regulatory jurisdiction. USP has no role in enforcement. All text in the United States Pharmacopeia (USP) or National Formulary (NF) that has reached its official date is "official text." Although all text of the *USP–NF* that has reached its official date is "official text," not all official text states requirements with which compendial users must comply. Some official text is intended to assist or guide compendial users or to serve informational purposes.

8. When do the revisions to General Chapter <797> become official?

The revision of <797> published on November 1, 2022, became "official" on November 1, 2023. The "official date" indicates the date by which affected users are expected to meet the requirements of a particular standard. However, ensuring compliance with the requirements of these standards is the responsibility of the applicable regulatory jurisdiction. Regulatory bodies such as state boards of pharmacy may have a different official date. USP has no role in enforcement.

a) Why is there a version of <797> in the *USP-NF* that shows up as "To be Official on 01-May-2024"?

The revision of <797> published on November 1, 2022, became official on November 1, 2023. Section *14.4.3 Stability Requirements for Category 3 CSPs* in <797> includes a reference to *USP* <789>. The USP General Chapters – Dosage Forms Expert Committee revised the title of <789> from <789> *Particulate Matter in Ophthalmic Solutions* to <789> *Subvisible Particulate Matter in Intraocular Solutions*, with this change scheduled to become official on May 1, 2024. Due to this title revision, the reference to <789> in <797> *14.4.3* will be revised to reflect the new title when the <789> revision becomes official. This is the only change in the <797> version that shows as "To be Official on 01-May-2024" in the *USP-NF* and the *Compounding Compendium*. An alert has been added to the <797> version to be official on May 1, 2024, for clarification. To view the version of <797> that became official on November 1, 2023, please visit: https://online.uspnf.com/uspnf/document/1_GUID-A4CAAA8B-6F02-4AB8-8628-09E102CBD703_7_en-US.

9. Are the temperatures in the chapter expressed in degrees Fahrenheit or Celsius?

Unless otherwise specified, all temperatures in the *USP–NF* are expressed in degrees centigrade (Celsius) (see also *General Notices 8.180 Temperatures*).

10. Who can be the designated person(s)?

The designated person is one or more individuals assigned by the facility to be responsible and accountable for the performance and operation of the facility and personnel for the preparation of compounded sterile preparations (CSPs). Facilities must determine whether they have one or more designated person(s), select the designated person(s), and determine how to allocate responsibility if there is more than one designated person. The designated person(s) can delegate activities to an assigned trainer provided that is described in the organization's policies.

11. Why were the categories of low-risk, medium-risk, and high-risk CSPs renamed?

In the 2015 proposed revision of *USP* <797>, it was first introduced to change the compounded sterile preparation (CSP) categories from a three-termed format of low-risk, medium-risk, and high-risk to a two-termed format of Category 1 and Category 2. This change was to avoid inaccurately conferring a level of risk to a particular CSP without consideration for all factors that influence the quality of that CSP. Renaming the CSP categories as Category 1 and Category 2, distinguished primarily by the conditions under which they are made and the time within which they are used, is intended to be a neutral designation. The 2021 proposed revision of *USP* <797> added Category 3 which allows compounders who are willing to add additional quality assurance requirements, the ability to assign BUDs longer than Category 2 BUDs.

12. What are Category 3 CSPs?

Category 3 describes CSPs made in a compounding facility that meets additional quality assurance requirements. Category 3 CSPs may be assigned longer BUDs than those set for Category 2 CSPs but not exceeding the limits in *Table 14,* if compounded in accordance with all applicable requirements for Category 3 CSPs in <797>. Category 3 CSPs undergo sterility testing, supplemented by endotoxin testing when applicable, and have more requirements than Category 2 CSPs for personnel qualification, use of sterile garb, use of sporicidal disinfectants, frequencies for environmental monitoring, and determining stability.

13. Does docking and activation of a proprietary bag and vial system for immediate administration in accordance with the manufacturer's labeling instructions have to occur under ISO 5 conditions?

No. Docking and activation of proprietary bag and vial systems in accordance with the manufacturer's labeling for *immediate* administration to an individual patient is not considered compounding and may be performed outside of an ISO Class 5 environment.

14. When does the chapter apply for docking a proprietary bag and vial system?

Docking of the proprietary bag and vial systems for *future activation* and administration is considered compounding and must be performed in an ISO Class 5 environment in accordance with <797>, with the exception of *14. Establishing Beyond-Use Dates*. BUDs for proprietary bag and vial systems must not be longer than those specified in the manufacturer's labeling.

15. Am I required to keep proprietary bags and vials which have been docked for future activation in a classified cleanroom?

The chapter does not address storage of the docked proprietary bag and vial system, nor does the chapter require it to be stored in a cleanroom suite. The chapter states that docking of the proprietary bag and vial systems for future activation and administration is considered compounding and must be performed in accordance with this chapter, with the exception of *14. Establishing Beyond-Use Dates*. Users should refer to the manufacturer's labeling for storage recommendations.

16. Does the chapter apply for repackaging of a conventionally manufactured sterile product?

Yes, repackaging of a sterile product or preparation from its original container into another container must be performed in accordance with the requirements in this chapter.

17. Is administration out of the scope of the chapter?

Yes. The intent of the chapter is to establish minimum standards for practitioners when compounding sterile products in order to minimize harm, including death, to human and animal patients. The scope of the chapter is intended to ensure a CSP maintains its integrity up until the time when administration begins. Standard precautions such as the Centers for Disease Control and Prevention's (CDC's) safe injection practices apply to administration (see *1.2 Administration*).

18. Does a conventionally manufactured sterile product prepared for administration to a single patient in accordance with manufacturer's approved labeling outside of ISO Class 5 conditions have to be administered within 4 hours of reconstitution or mixing if it meets all the conditions in *1.4 Preparation Per Approved Labeling*?

No. When all of the conditions in *1.4 Preparation Per Approved Labeling* are met, the storage information in the manufacturer's approved labeling may be followed.

19. What is the appropriate BUD to assign when preparing a conventionally manufactured sterile product for administration?

Preparation of a single dose of a conventionally manufactured sterile product in accordance with the approved labeling that includes information about the diluent to be used, the resultant strength, storage time, and container closure system is not considered compounding and these preparations are not subject to the BUD limits in the chapter. The BUD provided in the approved labeling may be assigned to these preparations when the labeling contains the required information mentioned above. (See *1.4 Preparation per Approved Labeling*).

20. Is withdrawing a dose from a container of a conventionally manufactured sterile product or spiking an IV bag, without any further manipulation, for immediate administration to a patient considered compounding?

No, withdrawing a dose from a container or spiking an IV bag of a conventionally manufactured sterile product without any further manipulation is considered administration rather than compounding and is out of the scope of <797>. If the dose is further mixed with another product, it would be considered compounding and subject to the requirements of <797>.

21. Is spiking IV fluids (taking IV spikes and putting them into a bag; putting a set into an IV bag) considered compounding?

No, a facility's policies and procedures regarding spiking IV fluids is outside the scope of the chapter.

22. When compounding immediate-use CSPs, may more than three individual containers of a sterile products be used?

The immediate-use CSPs provision states that the preparation must not involve more than 3 different sterile products. Two or more of the same sterile components (product) may be used as long as there are not more than three different sterile components (products). For example, two vials of the same component (drug product) are reconstituted using two vials of *Sterile Water for Injection* (component products) and added to a single component product intravenous diluent bag such as NS or D5W. As another example, when the CSP requires combining 4 vials of the same component (drug product) into a single component product intravenous bag of diluent, only 2 different sterile components (products) are used to prepare the CSP. Both examples may be considered immediate-use as long as the criteria listed in *1.3 Immediate-Use* CSPs are met.

23. Are COVID-19 vaccines limited by the 4-hour immediate-use BUD or can the BUD from the manufacturer be used?

As long as the approved labeling or supplemental materials provided by the product's manufacturer includes information for the diluent, the resultant strength, the container closure system, and storage time, then this would be considered *1.4 Preparation Per Approved Labeling* and is not considered compounding.

24. Can a single-dose container be used to prepare doses for more than one patient when compounding an immediate-use CSP?

No. One of the conditions of the immediate-use CSP provision specifies that any unused starting components from a single-dose container must be discarded after preparation for the individual patient is complete. Single-dose containers must not be used for more than 1 patient when used for preparing immediate-use CSPs.

25. Why does the immediate-use CSP provision allow for administration to begin within 4 hours following the start of the preparation?

The immediate-use CSP provision was revised to allow up to 4 hours for beginning administration to balance the need for ensuring CSP quality with timely access to medication in a variety of healthcare settings. The allowance of up to 4 hours was based on the 4-to-6-hour lag phase of microbial growth, during which potential bacterial cells are adjusting to their environment and change very little, and they do not immediately start reproducing.[1] In the event bacterial cells were inadvertently introduced into a CSP during compounding, replication is unlikely and therefore there is a window of time in which a CSP can be held prior to administration.

[1] References:

- Daquigan N et al. Early recovery of *Salmonella* from food using a 6-hour non-selective pre-enrichment and reformulation of tetrathionate broth. *Front Microbiol*. 2016;7:2103.
- Jarvis, Basil. *Statistical Aspects of the Microbiological Examination of Foods, Third Edition*. Academic Press, 2016.
- Ryan, Kenneth et al. *Sherris Medical Microbiology, Sixth Edition*. McGraw-Hill Education, 2014.
- Wang J et al. A novel approach to predict the growth of *Staphylococcus aureus* on rice cake. *Front Microbiol*. 2017;8:1140.

26. Is it considered compounding if the steps used to prepare a single dose of a conventionally manufactured product are different from the directions contained in the manufacturer's approved labeling?

Yes. Any compounding (e.g., mixing, reconstituting) that is not performed according to the manufacturer's approved labeling is considered sterile compounding and is subject to the requirements in the chapter.

27. What information is needed to meet the requirements of Section *1.4 Preparation Per Approved Labeling?*

The approved labeling or supplemental materials provided by the product's manufacturer, including information for the diluent, the resultant strength, the container closure system, and storage time.

28. Does the chapter address compounded radiopharmaceutical dosage forms?

No. Compounding of radiopharmaceuticals is not required to meet the standards of this chapter as they are subject to the requirements in General Chapter <825> *Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging*.

29. Do pharmaceutical manufacturers have to comply with <797>?

No. Manufacturers must comply with FDA's current good manufacturing practices (CGMP) and/or laws and regulations of the applicable regulatory jurisdiction.

30. What is the difference between compounding and what is described in *1.4 Preparation Per Approved Labeling?*

Compounding does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling or supplemental materials provided by the product's manufacturer if the product is prepared as a single dose for an individual patient and the approved labeling includes information for the diluent, the resultant strength, the container closure system, and storage time.

31. Where may Category 1 CSPs be prepared?

Category 1 CSPs must be prepared in a primary engineering control (PEC) that may be placed in an unclassified segregated compounding area (SCA) or a cleanroom suite.

32. What qualifications must a designated person have?

This must be determined by the facility's SOPs. Some states and accreditation organizations have more specific guidance.

33. Is the use of technology other than what is listed in the chapter allowed?

The introduction and scope section outlines the use of technologies, techniques, materials, and procedures not specifically covered by the chapter, as it would be impossible for this chapter to address all of the current technology on the market and potential for new technology coming to market in upcoming years after release of the finalized chapter. It is important that the technology that is being used as indicated in the manufacturer's approval documentation or if it is being used for a different intended purpose that it is validated for that purpose. This ensures that any use of technology does not bypass any safety requirements within the chapter itself and meets or exceeds those requirements. *USP* chapters <1223> and <1225> can assist compounders in this validation process.

34. What is USP's position on drug vial optimization (DVO)?

USP <797> does not address drug vial optimization (DVO). The organization would need to determine if the process used is noninferior to the requirements of the chapter.

35. Will there be any future USP guidance on the use of technology in compounding?

The Compounding Expert Committee will consider the development of future resources or a standard related to the use of technology in compounding. The introduction and scope section of <797> outlines the use of technologies, techniques, materials, and procedures not specifically covered by the chapter, as it would be impossible for this chapter to address all of the current technology on the market and potential for new technology coming to market in upcoming years after release of the finalized chapter. It is important that the technology that is being used as indicated in the manufacturers approval documentation or if it is being used for a different intended purpose that it is validated for that purpose. This ensures that any use of technology does not bypass any safety requirements within the chapter itself and meets or exceeds those requirements. *USP* chapters <1223> and <1225> can assist compounders in this validation process.

36. If a device (e.g., a repeater pump) has undergone validation by the FDA, is the compounder required to verify the volumetric accuracy each day of use?

Yes. Before using automated compounding devices or other similar equipment, compounding personnel must conduct an accuracy assessment before the first use and again each day the equipment is used to compound CSPs.

37. Are albumin, IVIG, etc., included as part of "blood-derived and other biological materials" in Section *1.1.2*?

No. These commercial products have been processed by the manufacturer to be sterile. Blood or biological materials derived directly from a patient are not sterile.

38. Do facilities have to change their standard operating procedures (SOPs) and practices for immediate-use from 1 h to 4 h?

No, facilities may choose to maintain the 1-hour limit for administration of immediate-use CSPs, however increasing the time to 4 hours would be considered acceptable.

39. Can immediate-use CSPs be made in a batch for more than one patient?

Compounders can prepare multiple doses of immediate-use CSPs intended for use in one or more patients in a single batch as long as the conditions in Section *1.3* are met.

40. What does "directly administered" mean in *1.3 Immediate-Use CSPs*?

"Directly administered" refers to the dose being prepared and then immediately administered by the person who prepared it, or administration is witnessed by the person who prepared it. In a situation where a CSP may be prepared for direct and immediate administration there is risk involved if a CSP is unlabeled and the person who compounded it is not administering or present for the administration.

41. What are the training and competency assessment requirements for personnel who only prepare immediate-use CSPs?

Training and competency assessment requirements are determined by the specific tasks performed and the facility's SOPs, and must include aseptic processes to minimize the potential for contact with nonsterile surface surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs.

42. How often does the training and competency of personnel who perform immediate-use products need to be performed?

Section *1.3 Immediate-Use CSPs* requires that personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs. No specific frequency is identified for training and competency of personnel who perform compounding of immediate-use CSPs.

43. Is the use of dispensing pins allowed per <797>?

The chapter does not address the use of specific disposable supply items other than to say supplies in direct contact with the CSP must be sterile and depyrogenated. It is the responsibility of the facility to determine the appropriateness of specific items, including dispensing pins.

Personnel Training and Evaluation

44. Section *2.1 Demonstrating Knowledge and Competency of Core Skills* states that personnel must complete training and be able to demonstrate knowledge of principles initially and at least every 12 months. Does this mean that each person needs written or electronic testing on each of the listed topics in addition to competency testing?

The written training program must describe the required training and the process for evaluating the performance of personnel, but personnel must both demonstrate knowledge of principles and competency of skill for performing sterile manipulations and achieving and maintaining appropriate environmental conditions as applicable to their assigned job functions.

45. Must cleaning staff or personnel who restock the cleanroom undergo the same training as compounders?

Personnel who only perform restocking or cleaning and disinfecting duties outside of the primary engineering control (PEC) must be initially trained and demonstrate competency in maintaining the quality of the environment in which they are performing their assigned task. At a minimum, these personnel must meet the requirements for personal hygiene and garbing that are described in *3. Personal Hygiene and Garbing*. Facility SOPs must outline what initial and ongoing training is required.

46. Must vendors and certifiers be trained before entering the cleanroom?

Section *1.1.3* specifies that any person entering a sterile compounding area, whether preparing a CSP or not, must meet the requirements in *3. Personal Hygiene and Garbing*. Facility SOPs must outline specific requirements.

47. Do supervising pharmacists that do not compound have to undergo training and evaluation?

Yes. The following must be included:

1. **Core skills:** <797> requires that personnel who do not compound, but supervise compounding personnel, have to be trained and demonstrate competency initially and at least every 12 months as outlined in Section *2.1 Demonstrating Knowledge and Competency of Core Skills*.
2. **Garbing Competency:** Initially and at least every 12 months.
3. **Aseptic Manipulation Competency:** Personnel who have direct oversight of compounding must complete an aseptic manipulation competency evaluation at least every 12 months. The evaluation should correspond to the type of activities of the personnel they oversee but does not require the same quantities.

48. If a compounder floats between pharmacies under the same healthcare system, do media fills have to be repeated at each location?

This must be determined by the designated person(s) and specified in the facility's SOPs. Sites might differ in facilities and engineering controls, so media fills must capture the most difficult and challenging conditions and simulate the conditions and procedures encountered by the compounder and meet the requirements of Section *2.3*.

The designated person(s) must develop a written training program that describes the required training, the frequency of training, and the process for evaluating the performance of individuals who compound, have direct oversight of compounding personnel, perform in-process checks, final verification, and dispensing of CSPs.

49. Compounding independently is mentioned multiple times. Does that mean someone can compound for patients before passing testing as long as they are observed? Is this left entirely to SOPs?

Before beginning any compounding (independently or with supervision), personnel must successfully complete the initial garbing competency. Additionally, all personnel entering a compounding area must abide by *3. Personal Hygiene and Garbing*. The process of developing competency requires practice. Each compounding facility must develop a written training program that outlines what is permitted.

50. How many gloved fingertip and thumb sampling tests and media-fill tests must be done initially and subsequently?

In the revised chapter gloved fingertip and thumb samplings are taken during both the aseptic manipulation competency (i.e., immediately after media-fills) and the garbing competency evaluation (i.e., after garbing and gloving). The complete garbing competency evaluation, including gloved fingertip and thumb sampling, must be successfully completed no fewer than 3 separate times initially, and only 1 time on subsequent evaluations. All aseptic manipulation competency evaluations, including media-fill and gloved fingertip and thumb sampling after media-fill, must be successfully completed 1 time for the initial and 1 time for all subsequent evaluations.

51. What is the purpose of the increased frequency of the garbing competency?

Personal hygiene and garbing are essential to maintain microbial control of the environment. Most microorganisms detected in cleanrooms are transferred from individuals. Preparation of compounded sterile preparations by personnel who lack proper training and competency may result in increased contamination risk and potentially poor outcomes for patients. Preventing contamination by ensuring personnel are trained and competent is more impactful than detecting contamination through sampling methods.

52. Is documentation of gloved fingertip and thumb sampling and media-fill testing only required when results exceed action levels?

No. All results of the evaluations must be documented and maintained to provide a record and long-term assessment of personnel competency. Documentation must at a minimum include the name of the person evaluated, evaluation date/time, media and components used including the manufacturer, expiration date and lot number, starting temperature for each interval of incubation, dates of incubation, the results, and the identification of the observer and the person who reads and documents the results.

53. If compounding personnel fail media-fill testing or gloved fingertip and thumb sampling, are they required to stop compounding until corrective action and reevaluation have been completed?

General Chapter <797> chapter does not require compounding personnel to cease compounding, however, the facility must evaluate the cause of failure and determine appropriate corrective actions. The results of the evaluation and corrective action must be documented, and the documentation must be maintained to provide a record and long-term assessment of personnel competency. General Chapter <797> describes gloved fingertip and thumb sampling and media-fill testing in Sections *2.2 Demonstrating Competency in Garbing and Hand Hygiene* and *2.3 Competency Testing in Aseptic Manipulation,* and required documentation in *20. Documentation*.

54. Why are incubation conditions different for media-fill testing, gloved fingertip and thumb sampling, and environmental air and surface sampling?

Environmental air and surface samples and gloved fingertip and thumb samples are incubated at a high temperature 30°–35° for no less than 48 h and then a low temperature 20°–25° for no less than 5 additional days. Incubation at a lower temperature first may compromise recovery of Gram-positive cocci which are often associated with humans. The incubation conditions are consistent with General Chapter <1116> *Microbiological Control and Monitoring of Aseptic Processing Environments*. Media-fill test samples are incubated for a longer period, 7 days each at two temperatures, 20°–25° and 30°–35° to detect a broad spectrum of microorganisms. The order of the incubation temperatures must be described in the facility's SOPs.

55. Why must a higher incubation temperature be used first for gloved fingertip and thumb sampling, and environmental air and surface sampling?

Incubating gloved fingertip and thumb samples, and environmental air and surface samples at a higher incubation temperature first helps recover bacteria first. Incubation at a lower temperature first may compromise recovery of Gram-positive cocci which are often associated with humans.

56. If the controlled room temperature is 20-25°, can the samples be incubated without an incubator?

No. Samples must be incubated in an incubator.

57. Do the three initial gloved fingertip tests need to be done on the same day?

Not necessarily. The organization can determine the interval for the three initial gloved fingertip tests. In any case, these need to be three separate instances of hand hygiene, garbing, and the gloved fingertip test. Garbing once and completing three sets of gloved fingertip tests does not meet the requirement for the initial testing. The 3 successful completions must be in succession—failure of any of the 3 initial garbing competency evaluations requires repeat testing until personnel successfully complete 3 evaluations in a row.

58. Are personnel who only prepare immediate-use CSPs required to perform media-fill testing?

No, but the facility's SOPs must determine how their competency will be evaluated. When specific conditions in <797> are met, compounding of CSPs for direct and immediate administration is not subject to the requirements for Category 1, Category 2, or Category 3 CSPs. Personnel must be trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs. The competency should include appropriate preparation (e.g., hand washing, cleaning the area that will be used) and technique that is evaluated and approved by a qualified individual.

59. Can gloved fingertip testing be done more frequently than what is in the chapter?

The chapter provides minimum compounding standards. Compounders can implement more frequent sampling if they deem it appropriate for their facility.

60. The media used for the media-fill test doesn't filter easily and personnel may need to use additional filters for the media-fill test than used for the actual batch. Is this acceptable?

Yes. Additional filters may be used as necessary for the media-fill test. Using a pre-filter may help maximize the volume of the sterilizing filter. A filter integrity test (e.g., bubble point test) must be performed on all sterilizing filters used during media-fill testing.

61. Does the ongoing garbing competency include gloved fingertip and thumb sampling (GFT) after the visual observation of garbing?

Yes. Performing GFT after the visual observation of garbing ensures personnel can don sterile gloves without contaminating them.

62. Are the staff that are currently competent according to the <797> 2008 chapter required to repeat the initial GFT (three times) with the new incubation temperatures on November 1, 2023?

No. The initial requirement applies to personnel who are beginning to compound, not those who are currently competent according to the <797> 2008 chapter.

63. Describe how to appropriately handle and store samples for media-fill testing, including the right temperature.

All samples must be incubated for 7 days each at two temperatures, 20°–25° and 30°–35°, to detect a broad spectrum of microorganisms. The order of the incubation temperatures must be described in the facility's SOPs. If sending samples to the laboratory for incubation, samples must be sent as soon as possible (e.g., within 24 h) for the most accurate results. Samples must be protected from damage as well as temperature and humidity extremes during transit. Refer to <1117> *Microbiological Best Laboratory Practices* for additional information.

64. Does the media-fill need to include multiple dosage forms that are compounded?

No. When performing a media-fill test, simulate the most difficult and challenging aseptic compounding procedures encountered by the person replacing all the components used in the CSPs with soybean–casein digest media. Only one dosage form needs to be represented, but it must meet the requirements of Section *2.3* that require the elements that affect the sterility of the CSP be captured, including the complexity of manipulations that may be associated with dosage forms.

65. How many personnel are allowed in the buffer room or SCA during media-fill testing?

Media-fill testing must simulate the most difficult and challenging aseptic compounding procedures encountered by the person, and it must capture all elements that could potentially affect the sterility of the CSP. The chapter does not specify the exact number of personnel in the buffer room or SCA, but it must simulate the conditions encountered by the compounder.

Personal Hygiene and Garbing

66. What is the order and location of garbing?

General Chapter <797> does not specify the order and location of garbing. The order and location of donning and doffing each article of required garb would depend on the type of garb used (e.g., sterile gowns) and the placement of the sink (e.g., if the sink is located inside or outside of the anteroom). The garbing order, location, and donning/doffing each article of required garb must be determined by the facility and documented in the facility's SOP. For example, if a sink is located outside of the anteroom, a facility's garbing policies and procedures may indicate that certain garb would be donned outside of the anteroom to more easily transition into hand hygiene procedures. Garb must be donned and doffed in an order that reduces the risk of contamination. Please note, sterile gloves must be donned in a classified room or SCA. Skin must not be exposed inside the ISO Class 5 PEC (e.g., gloves must not be donned or doffed inside the ISO Class 5 PEC exposing bare hands).

67. Can donning and doffing activities by different personnel occur in the same room at the same time?

The chapter recommends (but does not require) that donning and doffing not occur in the anteroom or the segregated compounding area (SCA) at the same time. Personnel must be aware of activity in the room to ensure that the integrity of garb is not compromised. For example, if one person is performing hand hygiene while another is donning a gown, personnel must consider the risk of contaminating the gown (e.g., from potential splashing).

68. What are examples of methods to cover jewelry that cannot be removed?

Examples of jewelry that cannot be removed are dermal piercings (also known as a microdermal piercing), which is a piercing that is held in place with a dermal anchor that is installed underneath the skin. Facilities must determine the appropriate method for covering dermal piercings to minimize the risk of contaminating the CSP and the environment. For example, depending on the location of the piercing, an adhesive bandage or head cover may be used to cover the jewelry.

69. Are wedding rings permitted to be worn under sterile gloves?

The chapter requires removing all hand jewelry that could interfere with the effectiveness of garbing or otherwise increase the risk of contamination of the CSP. Wedding rings may potentially compromise the integrity of the glove (e.g., tearing) and prevent adequate hand hygiene.

70. Are eyelash extensions allowed in the cleanroom?

No. Cosmetics are not permitted.

71. What accommodations can the designated person allow with regards to garbing in the cleanroom?

The designated person(s) may permit accommodations to personnel preparation as long as the quality of the CSP and environment will not be affected. Accommodations must be documented.

72. Must the accommodation to personnel preparation be documented each time or just once?

The accommodation must be documented per the facility's SOPs and *20. Documentation*.

73. Are 3 pairs of gloves required for using a compounding aseptic isolator (CAI) or compounding aseptic containment isolator (CACI)?

No, if using a CAI or CACI, the chapter recommends disposable gloves to be worn inside gloves attached to the restricted-access barrier system (RABS) sleeves. However, the chapter requires sterile gloves to be worn over the gloves attached to the RABS sleeves. The use of disposable gloves inside of gloves attached to the RABS sleeve is intended to maintain the cleanliness of the gloves attached to the RABS sleeve which may collect sweat or other touch contaminants. Sterile gloves outside of the gauntlet gloves help minimize the risk of contamination to the environment and the CSP.

74. If I am compounding Category 1 CSPs in an SCA, do I have to wear the same garb as when compounding Category 2 CSPs in a cleanroom suite?

Yes. Minimum garbing requirements are not stratified based on facility design. The chapter lists the minimum garbing requirements to protect the CSP and the environment. Sterile gloves are required for preparing CSPs inside an ISO Class 5 PEC.

75. Can gowns be re-used?

Yes. If compounding Category 1 and Category 2 CSPs, gowns used for nonhazardous compounding may be reused within the same shift by the same person if the gown is maintained in a classified area or adjacent to, or within, the SCA in a manner that prevents contamination. Garb must be replaced immediately if it becomes visibly soiled or if its integrity is compromised. Additionally, gowns and other garb must be stored in a manner that minimizes contamination (e.g., away from sinks to avoid splashing).

76. Regarding Section *3.1*, gum-chewing and mints are considered food. Why can't compounders have anything in their mouths or put anything in their mouths while in the cleanroom suite?

It is too easy to want to blow bubbles or move gum and candy around in the mouth that could spew additional wet into the mask and contaminate it. The candy or gum can also fall out of the mouth, out of the mask and onto a hood counter or floor and contaminate the area.

77. Why is the use of brushes not allowed for hand hygiene?

The practice of using a brush to scrub hands in hand-antisepsis can damage skin of personnel and result in an increase of bacteria shed from the hands. The CDC recommended discontinuing the use of the brushes and the brush side of scrub/sponge brushes in 2002. See the CDC Guideline for Hand Hygiene in Health-Care Settings, Morbidity and Mortality Weekly Report, October 25, 2002, 51(RR16); 1-44.

78. Where should I garb when preparing Category 1 CSPs in an SCA?

Sections *3.2* and *3.3* outline the requirements for hand hygiene and garbing for Category 1. The order of hand washing and garbing depends on the placement of the sink, is determined by the facility, and is documented in the facility's SOPs.

An example garbing procedure in a facility that has a sink in the SCA is as follows:

1. The compounder enters the SCA and dons head, face, and shoe covers in an order determined by the facility and documented in the facility's SOPs.
2. The compounder washes their hands then dons a gown.
3. The compounder applies alcohol-based hand rub to all surfaces of hands and fingers and allows hands to dry thoroughly then dons sterile gloves.

79. When sterile garb is required, does the equipment, such as goggles or PAPRs, need to be sterile as well?

No. Sterile garb is limited to powder-free gloves when compounding Category 1, 2, and 3 CSPs, and low-lint garb when compounding Category 3 CSPs. Facilities must have an SOP describing the disinfection procedures for reusable equipment.

80. For which categories must the facility's SOPs describe disinfection procedures for reusing goggles, respirators, and other reusable equipment?

For Category 1, 2, and 3 CSPs, the facility's SOPs must describe disinfection procedures for reusing goggles, respirators, and other reusable equipment.

81. When must laundering be performed with a validated cycle?

For facilities that compound Category 3 CSPs, laundered sterile garb must not be reused without being laundered and resterilized with a validated cycle. The facility's SOPs must describe this process.

82. When should I apply sterile 70% IPA to gloves?

Application of sterile 70% IPA to gloves must occur immediately before compounding (e.g., before entering the ISO Class 5 PEC) and regularly throughout the compounding process.

83. Do conditions such as dandruff, eczema, or psoriasis exclude someone from compounding CSPs?

These are all conditions that could cause someone to be at higher risk for contaminating a CSP or the environment so they must be reported to the designated person(s). The designated person(s) is responsible for evaluating the situation and making a decision on whether the affected person must be excluded from working in compounding areas until the condition is resolved.

Facilities and Engineering Controls

84. Why must the HEPA filter be located in the ceiling of the buffer and anterooms?

Placement of HEPA filters in the ceiling eliminates the potential for post-filtration contamination of the air stream. Air distribution systems with duct-mounted HEPA filters are susceptible to introduction of unfiltered air into the airstream after the air is filtered. HEPA filter placement in the ventilation duct is difficult to leak test and susceptible to contamination, especially in the event of water leakage or other breaches. Ceiling mounted filters help facilitate testing and servicing.

85. Why are CAIs and CACIs required to be placed in an ISO Class 7 buffer room with an ISO Class 8 anteroom for preparing Category 2 CSPs?

The PEC must be located in a controlled environment for preparing Category 2 CSPs to minimize the risk of contamination. Movement of materials in and out of the RABS (e.g., CAI or CACI) in unclassified air carries a higher risk of contamination. Placement of the RABS in a classified area mitigates the risk of inadvertent contamination of CSPs with the longer BUDs that are permitted for Category 2 CSPs.

86. Does the integrated vertical laminar flow zone (IVLFZ) require 100% HEPA filter coverage in the ceiling? Can returns be under the worktable?

In the IVLFZ, unidirectional airflow is created by placing HEPA filters over the entire surface of the worktables and by effective placement of air returns. Strategic location of air returns in addition to full coverage of HEPA filters above the work surface is required. Specific location of the air returns is not specified. Both static and dynamic smoke studies verifying a continuous flow of HEPA-filtered air void of turbulence, dead air zones, and refluxing from the HEPA filters to and across the entire work area and to the air returns must be documented (e.g., with video). [Note—Dynamic airflow smoke pattern tests have shown that it is difficult to achieve this type of design and also achieve and maintain unidirectional airflow under dynamic operating conditions.]

87. Can a containment ventilated enclosure (CVE) be used for presterilization procedures (e.g., weighing, mixing nonsterile components)?

Presterilization procedures must be performed in a single-use containment glove bag, CVI, BSC, or CACI to minimize the risk of airborne contamination.

88. When pass-through chambers are used, do the doors have to be interlocking?

The chapter recommends that pass-through doors be interlocking. However, if a pass-through is used, both doors must never be opened at the same time.

89. How often are visual smoke studies performed (e.g., in rooms where air returns are not located low on the wall)?

Air returns in the cleanroom suite must be low on the wall unless a visual smoke study demonstrates an absence of stagnant airflow. This smoke study along with environmental monitoring must be repeated whenever a change is made to the placement of equipment within the room or any other alteration is performed within the cleanroom suite that affects the quality of the air (e.g., HVAC alterations, change of HEPA filter units). A visual smoke study uses a visible source of smoke, which is neutrally buoyant, to verify an absence of stagnant airflow where particulates can accumulate in ISO Class 7 and ISO Class 8 rooms that do not have unidirectional airflow.

90. What is the difference between a pharmaceutical isolator and a RABS (i.e., a CAI or CACI)?

Unlike RABS, pharmaceutical isolators are different in that they contain 4 major elements: controlled workspace, transfer device, access device, and a decontamination system. A pharmaceutical isolator is equipped with a generator that distributes a sporicidal disinfectant throughout the chamber. If the isolator is used to prepare Category 2 CSPs, it must be placed in an ISO Class 8 or better positive-pressure room. In contrast, if a CAI or CACI is used to prepare Category 2 CSPs, the CAI or CACI must be placed in a cleanroom suite with an ISO Class 7 or better positive-pressure buffer room with an ISO Class 8 or better positive-pressure anteroom.

91. Can analog pressure gauges be used for monitoring pressure differentials?

Yes, analog pressure gauges may be used to monitor pressure. The quantitative results from the pressure monitoring device must be reviewed and documented at least daily on the days when compounding is occurring. Some analog pressure gauges do not warn or alert personnel to events where there is a loss of pressure whereas there are other pressure monitoring systems that may have audible or visible alarms.

92. Why are sinks allowed to be placed outside of the anteroom? Does the sink placement in <797> contradict the sink placement requirements in <800>?

In facilities with cleanroom suites, the sink used for hand hygiene may be placed either inside or outside of the anteroom. If the sink is located outside of the anteroom, it must be located in a clean space to minimize the risk of bringing in contaminants into the anteroom. Sinks are permitted outside of the anteroom to offer more flexibility to the cleanroom design and help minimize the risk of contamination from water sources to the classified areas. In facilities preparing hazardous drugs (HDs) in a cleanroom suite, General Chapter <800> requires the sink to be placed in the anteroom at least 1 meter away from the entrance of the HD buffer room to avoid contamination migration into the negative-pressure HD buffer room. There are no conflicts for the sink placement in <797> and <800>. Facilities compounding sterile HDs must meet the requirements in both <797> and <800>.

93. Is an SCA required to be in an enclosed room (i.e., walls and doors)?

No. An SCA is defined as a designated, unclassified space, area, or room with a defined perimeter that contains a PEC and is suitable for preparation of only Category 1 CSPs.

94. Why do I need a line of demarcation in the anteroom?

The line of demarcation serves to create visible separation between the clean and dirty sides of the anteroom. Distinguishing the "dirty" side of the anteroom from the "clean" side ensures all personnel abide by the garbing and material transfer procedures defined by the sterile compounding organization's SOPs. The line of demarcation signifies the locations where specific contamination control principles are implemented to aid in decreasing the number of particles introduced into the buffer room. The facility may choose where the line of demarcation is located. Please note, the anteroom is entered through the dirty side, and the clean side is the area closest to the buffer room (see Section *4.2 Facility Design and Environmental Controls*). Facilities may also utilize a design with two physically separate anterooms, one clean and one dirty.

95. Can presterilization procedures (e.g., weighing) be performed in an unclassified environment?

Yes. Presterilization procedures can be performed in unclassified environments for Category 1 CSPs. For Category 2 and Category 3 CSPs, presterilization procedures must be completed in an ISO Class 8 or better environment (e.g., anteroom or buffer room) wherein the compounder uses a containment device (e.g., single-use containment glove bags, containment ventilated enclosure (CVE), BSC, or CACI) to minimize the risk of airborne contamination.

96. In an SCA, can the sink be in the same area or room?

The sink needs to be accessible to the compounding area. It can be inside the area defined as the SCA but cannot be closer than 1 meter to the PEC. That distance is intended to ensure that splashes do not reach the PEC.

97. How can the garbing location be in a classified area with a sink outside the anteroom?

The order of garbing must be determined by the facility and documented in the facility's SOPs. If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb. Hands must also be sanitized with alcohol-based hand rub before donning sterile gloves.

An example garbing procedure in a facility that has a sink outside the anteroom is as follows:

1. The compounder washes their hands in the sink located outside of the anteroom.
2. The compounder enters the anteroom and applies alcohol-based hand rub to all surfaces of hands and fingers and allows hands to dry thoroughly.
3. The compounder dons garb in an order determined by the facility and documented in the facility's SOPs.
4. Before donning sterile gloves, hands are re-sanitized with alcohol-based hand rub and allowed to dry thoroughly.

98. What types of biological safety cabinets (BSCs) are appropriate for compounding?

A BSC is a ventilated cabinet that is typically used for compounding hazardous sterile and nonsterile preparations but may be used to compound nonhazardous sterile and nonsterile preparations as well. BSCs are divided into three general classes (Class I, Class II, and Class III). Class II and Class III BSCs provide an ISO Class 5 environment so are suitable for sterile compounding. Class II BSCs are further divided into types (Type A1, Type A2, Type B1, Type B2, and Type C1). Class I BSCs are suitable for nonsterile compounding only. A BSC used for hazardous drugs must exhaust to the outdoors.

Nonsterile Non-HD	Nonsterile HD	Sterile Non-HD	Sterile HD
Class I, II, or III	Class I, II, III Must exhaust to outdoors	Class II, III	Class II, III Must exhaust to outdoors

99. What are the requirements for temperature and humidity for an SCA?

There are no specific requirements for temperature or humidity in an SCA, but it is reasonable to use the requirements for a cleanroom suite as guidance. However, if drugs or supplies are stored in the SCA, there may be other USP, FDA, or manufacturer/supplier requirements. See *USP* <659> for additional information on storage requirements for drugs.

100. May personnel reach across the perimeter of the SCA to access supplies without actually stepping over the perimeter?

The chapter requires that when personnel exit the compounding area, garb, except for gowns, cannot be reused. At minimum, this would require changing the affected garb (e.g., gloves).

101. May an anteroom be shared between a Category 2 and Category 3 buffer room?

Yes.

102. May an anteroom be shared between an HD and non-HD buffer room?

Yes.

Certification and Recertification

103. Is certification of the compounding area required to be performed using the current Controlled Environment Testing Association (CETA) *Certification Guide for Sterile Compounding Facilities?*

Before a compounding area is used to compound either Category 1, Category 2, or Category 3 CSPs, it must be independently certified using the requirements in this chapter and when applicable, manufacturer specifications. Facilities must determine the appropriate certification guide to use for certifying their compounding area.

104. What is ASHRAE?

The American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) is a professional organization that provides certification (including healthcare facility design) and professional development for engineers in this field.

105. What is CETA?

The Controlled Environment Testing Association is a professional organization for controlled environment certification personnel that provides certification (including Registered Certification Professional – Sterile Compounding Facilities), education, and resources for certification personnel.

106. A facility may have several cleanrooms under the same corporate structure (e.g., within a healthcare system) but state law requirements may require separate licenses for each compounding area. Are personnel that float between the different cleanrooms required to complete training and competency at each location if they are working in the same type of primary and secondary engineering controls?

This is in the purview of the state board of pharmacy and outside the scope of <797>. The chapter requires that each compounding facility develop a written training program that describes the required training, the frequency of training, and the process for evaluating performance. This program must equip personnel with the appropriate knowledge and train them in the required skills necessary to perform their assigned tasks. The facility's SOPs should specify the training required for such tasks, and training and evaluation of personnel must be documented.

107. Regarding 'dynamic operating conditions', what does "the largest number of personnel and highest complexity" mean as it relates to certification of ISO-classified areas?

This refers to testing in a particular ISO-classified area (e.g., ISO Class 5 PEC, ISO Class 7 buffer room). The highest number of personnel that would be expected to work in a PEC and/or SEC should be present and performing the highest complexity of compounding expected including use of compounding equipment and performance of particle-generating activities (e.g., pre-sterilization activities such as weighing and mixing powders). Testing under dynamic operating conditions is required for particle testing of ISO-classified areas, air changes per hour (ACPH) of ISO-classified rooms, and some types of smoke studies.

Microbiological Air and Surface Monitoring

108. Why has the frequency of surface sampling changed?

Surface sampling was previously required "periodically", which was interpreted differently by users (e.g., monthly, quarterly, or biannually). The change requiring minimum frequencies based on the category of CSP the facility compounds is intended to provide an additional measure of control and monitoring in between viable air monitoring and certification requirements. Regular surface sampling provides additional data for trending and allows for monitoring of contamination risks.

109. How many microbiological air and surface samples are required based on the size of classified areas?

Microbiological air and surface testing must be conducted in all classified areas to confirm that the required environment quality is maintained. The microbiological air and surface sampling must be facility-specific and must be described in the facility's SOPs. The chapter does not specify a minimum number of air or surface samples based on the size of the room, however, the International Organization for Standards (ISO) 14644-1:2015(E) Table A.1 – 'Sampling locations related to cleanroom area' states the area of a cleanroom (m^2) and the minimum number of sampling locations to be tested (N_L) that are necessary for certification. Facilities must determine the appropriate number of locations and select the locations of sampling based on their relationship to the activities performed in the area.

110. What is the appropriate method for cleaning the hood after surface sampling?

After sampling, the sampled area must be thoroughly cleaned and disinfected using a cleaning agent followed by a disinfecting agent or by using a one-step disinfectant cleaner. Additionally, in a PEC, sterile 70% IPA must be applied after cleaning and disinfecting.

111. Do microorganisms need to be identified to the genus level regardless of action level?

No. An attempt must be made to identify any microorganisms recovered to the genus level if the levels measured during sampling exceed the action levels in the chapter.

112. What is the rationale for only requiring an attempt to identify any microorganisms recovered to the genus level if the levels measured during sampling exceed the action levels in the chapter?

In some instances, microorganisms cannot be identified to the genus level because the microorganism is no longer viable, or if a mold, it may not be producing the reproductive structures necessary for identification. In these instances, the genus may not be identified, but the chapter does require that an attempt be made to identify the microorganism to the genus level.

113. Is changing HEPA filters considered "servicing facilities or equipment" for the purposes of requiring microbiological air and surface monitoring?

Yes, changing HEPA filters in the ceiling would require microbiological air and surface sampling because there is potential for unclassified air to enter the cleanroom. Changing HEPA filters in the ISO Class 5 PEC would also require microbiological air and surface sampling to ensure the PEC is operating as expected. Changing prefilters for the ISO-classified rooms and PECs usually would not require additional sampling because the downstream HEPA filter remains intact.

114. If two media samples are collected at a single location, how are the colony-forming units (CFU) counted?

If a facility were to choose to utilize two different media devices for sampling, they would sample each location according to their sampling map using both devices (e.g., TSA and MEA). If each device at one location demonstrates growth, the CFU are counted separately. For example, if a TSA plate grows 5 CFU and the MEA plate at the same location grows 3 CFU, the CFU would be recorded separately as 5 CFU and 3 CFU for the respective plates. The count would NOT be recorded as 8 CFU.

115. Is a self-enclosed robotic device different than a "closed RABS" as used in <1211>? When should surface sampling occur in a self-enclosed robotic device?

This verbiage "self-enclosed robotic device" was specifically used in <797> as there are robotic enclosures on the market that do not meet the definition of a closed-RABS, whereas some would meet this definition. For self-enclosed robotic devices that meet the definition of closed-RABS, it would be detrimental to the air quality inside the device to surface sample at the completion of each batch. Therefore, the requirement for these specific devices is to be conducted at least once daily at the end of compounding operations. This is generally when the device is opened for cleaning and disinfecting.

116. May settle plates be used in place of an impaction air sampler for viable air sampling?

No. An impaction air sampler must be used to collect 1 cubic meter or 1000 L of air from each classified area.

117. When should samples be submitted by certifiers to the laboratory after collection?

If the certifier is sending samples to the laboratory for incubation and identification, samples must be sent as soon as possible (e.g., within 24 h) for the most accurate results. Samples must be protected from damage as well as temperature and humidity extremes during transit. Refer to <1117> *Microbiological Best Laboratory Practices* for additional information.

118. Describe the process and action levels associated with testing of pass-through chambers.

For entities compounding Category 1 and Category 2 CSPs, each pass-through chamber must have surface sampling performed monthly (see <1116> *Microbiological Control and Monitoring of Aseptic Processing Environments*). For entities compounding Category 3 CSPs, each pass-through chamber must have surface sampling completed prior to assigning a BUD longer than the limits established in *Table 13*, and at least weekly (see <1116>) on a regularly scheduled basis regardless of the frequency of compounding of Category 3 CSPs.

Neither General Chapter <797> nor <1116> states which ISO classification to correlate with. The facility's SOPs should describe how growth bacteria will be defined. For example, if a pass-through chamber goes between an ISO 7 and an ISO 8 area, the surface sampling growth criteria could be based on either the ISO 7 or ISO 8 limits.

Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA

119. What is the difference between cleaning and disinfecting?

Cleaning is the process of removing substances (e.g., organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products. Disinfecting is the process of destroying fungi, viruses, and bacteria on inanimate surfaces and objects.

Sporicidal disinfectants are also indicated in the chapter. A sporicidal disinfectant destroys bacterial and fungal spores and is expected to kill all vegetative microorganisms.

120. What is a one-step disinfectant cleaner?

A one-step disinfectant cleaner is a product with an EPA-registered (or equivalent) claim that it can clean and disinfect a nonporous surface in the presence of light to moderate organic soiling without a separate cleaning step.

It is important to note that sterile isopropyl alcohol (IPA) is not a one-step disinfectant cleaner. Sterile IPA is a sanitizing agent which, when used on inanimate surfaces and objects, reduces the number of all forms of microbial life including fungi, viruses, and bacteria.

121. Where can I find examples or sources of EPA-registered one-step disinfectant cleaners?

USP cannot endorse particular products. Users may research one-step disinfectant cleaners or contact cleaning/disinfecting agent manufacturers to get more information on available products.

122. Does *Table 10. Minimum Frequency for Cleaning and Disinfecting Surfaces and Applying Sporicidal Disinfectants in Classified Areas and in the SCA* apply to all surfaces in the SCA?

The minimum frequencies in *Table 10* apply to all surfaces within the perimeter of the SCA except the ceiling. Ceilings of the SCA are required to be cleaned, disinfected, and applied with sporicidal disinfectant only when visibly soiled and when surface contamination is known or suspected.

123. Does the equipment inside a PEC need to be cleaned?

Yes, the chapter requires equipment inside of the PEC to be cleaned, disinfected, and a sporicidal disinfectant applied (see *Table 10*).

124. Are cleaning supplies required to be sterile?

Cleaning and disinfecting supplies used in the PEC must be sterile with the exception of tool handles and holders, which must be cleaned and disinfected prior to use in a PEC. The chapter states that all cleaning supplies (e.g., wipers, sponges, and mop heads) with the exception of tool handles and holders must be low lint.

Further, the chapter recommends that wipers, sponges, and mop heads be disposable.

125. Are cleaning agents required to be sterile?

Cleaning, disinfecting, and sporicidal disinfectants used within the PEC must be sterile. In classified areas outside of the PEC, sterile cleaning and disinfecting agents should be used.

126. Where can I find information about the minimum contact time for the cleaning, disinfecting, and sporicidal disinfectants used?

Refer to the manufacturer's directions or published data for the minimum contact time for the agent used. The minimum contact time may differ depending on the agent used and on the intended purpose. For example, an agent may have a 1-minute contact time to be bactericidal and a 3-minute contact time to be sporicidal.

127. Does the chapter require a separate cleaning and disinfecting step in addition to applying a sporicidal disinfectant?

The chapter requires cleaning and disinfecting of the compounding areas. These steps can be combined if an EPA-registered one-step disinfectant is used. One-step disinfectants have been formulated to be effective in the presence of light to moderate soiling without a separate cleaning step. Sporicidal disinfectants must be used at least monthly. Some EPA-registered disinfectant cleaners may also have sporicidal properties. If the sporicidal disinfectant is an EPA-registered (or equivalent) one-step disinfectant sporicidal cleaner, separate cleaning and disinfecting steps are not required.

128. Is an EPA-registered disinfectant required if the compounding process is over 30 minutes? <797> states "During the compounding process sterile 70% IPA must be applied to the horizontal work surface, including any removable work trays, of the PEC at least every 30 min if the compounding process takes 30 min or less. If the compounding process takes more than 30 min, compounding must not be disrupted, and the work surface of the PEC must be *disinfected* immediately after compounding."

No. As with compounding that takes 30 minutes or less, sterile 70% IPA must be used when the compounding process is over 30 minutes, and must be applied immediately after compounding.

129. Is a biological safety cabinet the only PEC that has a removable work surface tray?

No. CAIs, CACIs, and some laminar airflow workbenches (LAFWs) have removable work trays.

130. Do cleaners and disinfectants have to be EPA-registered?

In the U.S., yes. Disinfectants are registered with the EPA in the USA, and depending on the international location, registered with entities with an equivalent jurisdiction in that nation.

131. Can containers of sterile supplies (such as bottles of sterile alcohol and containers of sterile saturated wipers) be used for more than one compounding session?

Yes, as long as they remain in the intended area once opened. This needs to be defined by the organization's policies, based on information provided by the manufacturer/supplier. Sterile solutions and supplies are used to avoid introducing spores or other contamination into the cleanroom. For example, a packet of saturated sterile alcohol wipers opened in the ISO 5 PEC can remain in the PEC until depleted, unless the packet is contaminated. A bottle of sterile alcohol can remain open and used in the ISO 7 cleanroom until depleted, unless contaminated.

132. Once opened, how long may a cleaning and disinfecting agent or package of sterile wipers be used?

Once opened, sterile cleaning and disinfecting agents and supplies (e.g., closed containers of sterile wipers) and sterile 70% IPA may be reused for a time period specified as by the manufacturer and/or described in the facility written SOPs.

133. Are personnel that only clean and disinfect ISO 7 and ISO 8 areas, but not ISO 5 areas, required to wear sterile gloves?

Any person entering a compounding area where Category 1, Category 2, or Category 3 CSPs are prepared must be properly garbed including sterile gloves.

134. If an IV bag has tubing attached in one hood and compounding is done in a second hood, does the IV bag need to be wiped with sterile 70% IPA before bringing into the second hood?

Yes. Just before any item is introduced into the PEC, it must be wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use.

135. Do personnel have to wipe gloves with sterile 70% IPA every time their hands enter the ISO Class 5 PEC even if not touching contaminated surfaces (e.g., throwing out trash without touching trash can or grabbing a supply that was disinfected for them prior to touching)?

Application of sterile 70% IPA to gloves must occur immediately before compounding and regularly throughout the compounding process. The facility SOPs should describe this process. For example, gloves might be wiped with sterile 70% alcohol before beginning to stage items into the hood then re-wiped before beginning compounding, after handling trash, when retrieving items outside the hood, etc. Handling trash or retrieving a supply item outside the hood could contaminate gloves so they should be re-wiped with sterile 70% alcohol after performing these tasks.

Equipment, Supplies, and Components

136. Why are active pharmaceutical ingredients (APIs) required to be obtained from an FDA-registered facility and components other than APIs only recommended to be obtained from an FDA-registered facility?

The Federal Food, Drug, and Cosmetic Act requires compounded preparations to be prepared from bulk drug substances that are obtained from FDA-registered facilities. The Expert Committee recognizes that there may be some components other than APIs that cannot be obtained from an FDA-registered facility, thus, it is a recommendation that these components be obtained from an FDA-registered facility.

137. How often do I need to calibrate my temperature monitoring equipment or verify its accuracy?

Section *9.3.4 Component handling and storage* states that all monitoring equipment must be calibrated or verified for accuracy as recommended by the manufacturer or every 12 months if not specified by the manufacturer. For example, if the manufacturer specifies to calibrate every 2 years, then that would be the correct interval. If a manufacturer does not specify the calibration interval, then it must occur at least every 12 months.

138. Does API refer to conventionally manufactured drug products?

The term "API" refers to any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body. Also referred to as *Bulk drug substance*. A conventionally manufactured drug product is not an API but is typically manufactured from an API(s).

139. If a CSP is stored outside of the pharmacy, do we need to monitor and document temperature readings for nursing unit floor refrigerators or remote-access Pyxis refrigerators?

Once a CSP is dispensed, you should handle this as you would any other medication (manufactured or compounded). Temperature storage conditions in healthcare facilities such as hospitals have requirements from other regulators and accreditors concerning maintaining and documenting temperatures of medication storage areas. Generally, this requires at least daily monitoring and documentation.

140. "All monitoring equipment must be calibrated or verified for accuracy as recommended by the manufacturer or every 12 months if not specified by the manufacturer." Does this statement apply to humidity sensors, pressure monitors, and thermostats?

Yes. Those are examples of monitoring equipment.

141. Do we need a certificate of quality for each lot of sterile empty bags we use? <797> states "Each lot of commercially available sterile, depyrogenated containers and container closure systems must be accompanied by a COA or other documentation showing conformance with established specifications (i.e., sterility and depyrogenation requirements)."

Sterile empty bags obtained from suppliers are described as such in the product labeling. The lot number is traceable back to the manufacturer/supplier if any concerns would be identified.

Sterilization and Depyrogenation

142. What is the difference between aseptic processing and terminal sterilization?

USP General Chapter <1229> *Sterilization of Compendial Articles* summarizes the common requirements for sterilization process: design, development, validation, and process control. *USP* <1229.4> *Sterilizing Filtration of Liquids* states, "Sterilization processes are divided broadly into two categories: destruction of microorganisms, and their physical removal from the material to be sterilized. Terminal sterilization (e.g., autoclaving) is an example of the former, and sterilizing filtration is an example of the latter."

Aseptic processing includes either 1) compounding with only sterile starting ingredient(s), or 2) compounding with nonsterile ingredient(s) followed by sterilization by filtration. Filtration sterilization is not terminal sterilization because it is not a lethal process of microbial destruction.

Terminal sterilization includes compounding with sterile and/or nonsterile starting ingredient(s) and subsequent sterilization with a lethal process intended to achieve a probability of a nonsterile unit (PNSU) of 10^{-6} (e.g., steam, dry heat, irradiation).

143. Can stoppered and crimped empty vials be sterilized using steam heat?

Sealed containers must be able to generate steam internally to be sterilized by steam heat. Stoppered and crimped empty vials must contain a small amount of sterile water to generate steam (see also *<1229> Sterilization of Compendial Articles*).

144. Does a sterile filter with a pore size of 0.2 µm meet the requirement of the chapter ("0.22 µm or smaller")?

Yes. For the purposes of <797> and *USP–NF* compounded preparation monographs, 0.2 µm and 0.22 µm filters are interchangeable, as they pass the same performance criteria.

145. Why is a prefiltration step with a filter of a pore size of 1.2 µm required before sterilization procedures?

A prefiltration step with a filter of a pore size of 1.2 µm removes particulate matter in the solution before sterilization. This is only required if CSPs are known to contain excessive particulate matter, which may also be an indication that the formulation may be problematic and therefore the formulation and the process should be assessed and modified if necessary.

146. What is the PNSU for CSPs sterilized by filtration?

A PNSU value cannot be applied to CSPs that are sterilized by filtration because sterilization by filtration is not terminal sterilization.

147. Is a biological indicator required for each sterilization cycle using steam or dry heat?

Yes, the effectiveness of the steam and dry heat sterilization method must be verified and documented with each run or load using an appropriate biological indicator.

148. Why does the chapter continue to exclude terminal filtration container systems from its definition of terminal sterilization?

Filtration-based methods of sterilization are not considered to be a method of terminal sterilization because they are not a lethal process of microbial destruction.

Each method of sterilization must take into consideration the container closure system that holds the compounded preparation. Since there are many container closure systems and methods of terminal sterilization, it becomes a complex matrix that is specific to the container closure system and the method of sterilization. The permutations are too numerous to include in the chapter.

149. What is depyrogenation?

Pyrogens are organic compounds that are soluble in water and not removed by filtration or steam sterilization. They are endotoxins; lipo-polysaccharides produced by Gram-negative bacteria. Depyrogenation is the destruction or elimination of endotoxins (i.e., pyrogens). There are several methods that can be used to accomplish depyrogenation.

Master Formulation and Compounding Records

150. Do I need a master formulation record (MFR) for repackaged conventionally manufactured components?

Repackaging conventionally manufactured components is within the scope of the chapter. General Chapter <797> requires a master formulation record for CSPs created for more than 1 patient and for CSPs prepared from nonsterile ingredients. If the CSP is created for more than 1 patient, such as repackaging several units, a master formulation record is required.

151. Are master formulation records required for patient-specific CSPs?

A master formulation record must be created for CSPs prepared for more than 1 patient and for CSPs prepared from nonsterile ingredient(s). If the CSP is only for a single patient and does not contain nonsterile ingredients, a master formulation record is not required.

152. When is a compounding record needed for immediate-use CSPs?

If the immediate-use CSPs are prepared in a batch and are intended for use in more than one patient, then a compounding record as described in Section *11.2 Creating Compounding Records* is required.

153. Does a change in any of the information listed as MFR requirements in *Box 9* when compounding the same drug require an entirely new MFR, or can an MFR be created to contain the differences?

Any change to the process, ingredients, or packaging specified in an MFR are to be noted on a compounding record. The MFR is not changed.

If a preparation is made repeatedly that has differences in process, ingredients, or packaging, consideration should be given to creating a new MFR for that version of the preparation. Otherwise, all changes are to be noted on a compounding record.

154. Where does the documentation of compounding occur (in process, in the buffer room, outside of classified areas)?

The master formulation record would be established prior to compounding a CSP, usually outside of the cleanroom suite. The compounding record should be initiated before the components of the CSP are assembled. When documented on paper, this is usually performed outside of the cleanroom suite. Depending on your work practices, final sign-off on the CR would be done in the most appropriate area. While labels need to be available for placement on the completed CSP in the buffer room, exposure of paper records should be minimized in the buffer room. Those organizations with workflow technology that supports completion of the CR in the buffer room will likely have a different process than those with only manual records.

Release Inspections and Testing

155. What is required to be documented for the visual inspection of the CSP and the container closure system?

All CSPs must be visually inspected to determine whether the physical appearance of the CSP is as expected. The master formulation record must list specific requirements for a particular CSP. Examples of visible quality characteristics might include discoloration, visible particulates, or cloudiness. Examples of visual inspection of the container closure system might include checking for leakage, cracks in the container, or improper seals.

156. Why should CSPs administered epidurally have the same endotoxin limit as that of intrathecally administered CSPs?

CSPs delivered by implanted pumps may be administered over a long period of time and may be compounded from nonsterile components. Bacterial endotoxin testing helps ensure that CSPs do not contain excessive bacterial endotoxins. Although <797> refers to General Chapter <85> *Bacterial Endotoxins Test* for calculating endotoxin limits for the appropriate route of administration, <85> does not address products administered epidurally or administered directly into the central nervous system. Compounders should be aware that endotoxin testing is also important for CSPs administered epidurally due to the close proximity of the epidural and intrathecal spaces.

157. Do all Category 2 CSPs need to undergo bacterial endotoxins testing?

No. General Chapter <797> Section *12.3 Bacterial Endotoxins Testing* requires Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing per *Table 13* to undergo bacterial endotoxins testing. For example, ophthalmic compounded preparations are not required to undergo bacterial endotoxins testing because they are not Category 2 injectable CSPs. Category 2 injectable CSPs made from one or more nonsterile component(s) and assigned a BUD that does not require sterility testing are recommended to be tested for bacterial endotoxins.

158. How is the endotoxin limit of CSPs for non-human species determined?

Endotoxin limits for non-human species are calculated as described in *USP* <85> based on the largest recommended dose and weight (or average weight for more than a single animal) of the target animal species unless a different limit is scientifically supported. The formula to calculate endotoxin limit is: K/M where K = the threshold pyrogenic limit for the dosage form (expressed as EU or endotoxin units), and where M = the largest dose/patient or per species average weight in kg per hour. K has been defined by route of administration as follows: injections = 5 EU/kg, radiopharmaceutical injections = 175 EU/dose, intrathecal injections = 0.2 EU/kg, and radiopharmaceutical intrathecal injections = 14 EU/dose. To calculate the endotoxin limit for compounded morphine sulfate 50 mg/ml injection in a 5 kg cat, the following calculations are performed. The maximum dose of morphine sulfate in cats is 0.25 mg/kg. K = 5 EU/kg/hr (as defined for injections) M = 0.25 mg x 5 kg x 1hr = 1.25 mg/kg/hr K/M = 5 EU/kg/hr / 1.25 mg/kg/hr = 4 EU/mg.

The average representative weights for non-human species can be found here: https://www.fda.gov/media/102469/download.

159. Why is there a maximum batch size of 250 units for CSPs requiring sterility testing?

Sterile compounding within 503A facilities is largely a manual process. The chapter sets a minimum standard for quality assurance that encompasses a wide variety of practice sites. These quality assurance parameters are not intended for outsourcing facilities or pharmaceutical manufacturers, as they were created to accommodate the equipment and processes normally performed by 503A facilities. The risk of contaminating a CSP is likely to increase as the batch size increases, especially for a manual process. For example, equipment limitations (such as the size of a PEC) may only permit a portion of a large batch to be packaged in one continuous process. If 25 units are packaged in one continuous process, a batch of 250 units would require repeating this process 10 times. A batch of 1000 units would require repeating this process 40 times.

Smaller batches reduce the potential for operator error due to fatigue. To help ensure sterility assurance, batch size is limited to 250 final dosage units for CSPs that require sterility testing. Sterility testing does not guarantee that an entire batch is sterile, only the units tested. The possibility of detecting a contaminated preparation is about 10% for batch sizes between 10 and 100 but drops to about 4% for a batch size of 250 and only 2% for a batch size of 500.

160. Why is there not a batch size limit in <71> *Sterility Tests*?

USP General Chapter <71> *Sterility Tests* falls under the Microbiology Expert Committee and was created for facilities that follow current good manufacturing practices (CGMP). Following CGMP requires a level of quality assurance significantly higher than what is required by 503A facilities who follow <797>. Modifications have been made in <797> to require a fewer number of test samples with batch sizes 1 to 39 units and to limit batch size to 250 final dosage units. Other aspects of <71>, including method suitability, number of units to be tested (for batch sizes 40 to 250), and quantity per unit tested, are required.

161. How many additional units of CSPs must be compounded to perform sterility testing if there are less than 40 units, and does this apply to ophthalmics, large volume parenteral (LVP) solutions, etc.?

If 1–39 CSPs are compounded in a single batch, the sterility testing must be performed on a number of units equal to 10% of the number of CSPs prepared, rounded up to the next whole number. This applies when the number of CSPs to be compounded in a single batch is less than the number of CSPs needed for testing as specified in <71>, *Table 3*. *Table 3* requires testing 5% or a minimum of 2 ophthalmic preparations, whichever is greater, so this would apply to ophthalmic preparation batch sizes of 1 or 2 units. If compounding more than 2 units of ophthalmic preparation, use the numbers in <71>, *Table 3*.

162. Do I have to wait for the results of the sterility tests before releasing the CSP?

Sterility testing is not required for Category 1 CSPs. Category 2 and Category 3 CSPs that require sterility testing may be administered or dispensed prior to receiving the results of release testing (including sterility testing).

In order to do this, the facility must have procedures in place to:

- Immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (e.g., sterility, strength, purity, bacterial endotoxin, or other quality attributes)
- Recall any unused dispensed CSPs and quarantine any stock remaining in the pharmacy
- Investigate if other lots are affected and recall if necessary

An SOP for recall of out-of-specification dispensed CSPs must contain:

- Procedures to determine the severity of the problem and the urgency for implementation and completion of the recall
- Procedures to determine the distribution of any affected CSP, including the date and quantity of distribution
- Procedures to identify patients who have received the CSP
- Procedures for disposal and documentation of the recalled CSP
- Procedures to investigate and document the reason for failure

163. <797> states, "When a CSP will not be released or dispensed on the day of preparation, a visual inspection must be conducted immediately before it is released or dispensed to make sure that the CSP does not exhibit any defects such as precipitation, cloudiness, or leakage, which could develop during storage." Would this prohibit stocking CSPs on the floors in automated dispensing cabinets (i.e., Pyxis) to no more than a 24-hour supply?

No, releasing a CSP to the floor is similar to dispensing to a patient so a second check is not required by a pharmacist. Nurses should be educated to check all types of sterile preparations – manufactured, from a registered outsourcer, prepared by pharmacy, or those that they activate or mix – prior to administration to a patient.

164. After a CSP has been verified by a pharmacist and placed in an area to be picked up for a specific patient in a specified timeframe, does the CSP need to be re-checked by a pharmacist before going out to a patient?

<797> requires that "at the completion of compounding, before release and dispensing, the CSP must be visually inspected to determine whether the physical appearance of the CSP is as expected". If the pharmacist has performed the release check and dispensed the CSP, and it is only awaiting pick-up or delivery, a re-check is not required.

165. Why is bacterial endotoxin testing required for Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing and Category 3 injectable CSPs compounded from one or more nonsterile component(s)?

The purpose of the bacterial endotoxins test is to ensure the source material does not contain excessive endotoxins and ensure any mitigation steps that were performed are adequate. Bacterial endotoxins entering patients' bloodstreams in sufficient concentrations can cause harmful effects such as fever and septic shock and can be fatal in the most severe cases.

Establishing Beyond-Use Dates

166. What is the difference between the beyond-use date (BUD) and "hang time" (e.g., administration time, infusion time)?

The BUD is the date, or the hour and date, after which the CSP must not be used. BUDs apply to CSPs and are not intended to limit the time during which a CSP is administered (e.g., infused). "Hang time" is often used to refer to the amount of time during which a CSP or conventionally manufactured product (e.g., pre-mix, large volume parenteral solution) may be infused before which either the tubing or the medication must be changed. General Chapter <797> does not address administration time (e.g., hang time).

167. Can a CSP be administered beyond the assigned BUD?

Administration cannot begin past the assigned BUD; however, it is not intended to limit administration that began before the BUD lapsed (see *14.1 Terminology*). For example:

- An intravenous preparation begins 1 hour before the BUD lapses; however, it is scheduled to continue infusing for a total of 2 hours. The BUD is not intended to limit the dose from being completed.
- An ophthalmic preparation is scheduled to be given once daily for 14 days; however, the BUD will lapse in 10 days. The medication can continue to be administered up until the assigned BUD in 10 days, beyond which the preparation must not be used and must be discarded.

168. After the CSP has begun to infuse, does it need to be taken down and discarded after the BUD is met?

No. Administration must begin before the BUD. The administration process is outside the scope of <797>. Standard precautions such as the Centers for Disease Control and Prevention (CDC) safe injection practices apply to administration. See <800> for additional recommendations for the administration of hazardous drugs.

169. How does the storage condition affect the BUD of a CSP? What is the relationship between storage temperature and BUDs?

Generally, longer BUDs are permitted for CSPs stored in colder conditions than for CSPs stored at controlled room temperature as colder temperatures have been shown to slow the growth of most microorganisms.

Temperature affects chemical reaction rates; thus, storage at higher temperatures will accelerate degradation and reduce a BUD. The accepted rule of thumb is reaction rates increase two-fold for every 10 degree increase in temperature. This means that 1 year storage at 30 °C is equivalent to approximately 6 months at 40 °C and approximately 3 months at 50 °C. Correlating this concept to a refrigerated product (stored at 5 °C) estimates the BUD to be one-fourth at room temperature (25 °C). The exact mechanism of degradation and rate of reaction will determine the actual difference, which can only be determined through a stability evaluation over time.

170. Are BUDs cumulative?

No, BUDs must not be additive. The storage time of a CSP must not exceed the original BUD placed on the CSP for its labeled storage condition.

For example, a CSP that is assigned a BUD based on storage at room temperature cannot subsequently be refrigerated or frozen in order to extend the original BUD assigned. Likewise, the BUD of a frozen CSP must not be extended based on storage at room temperature when it is thawed.

171. Can the BUDs of Category 2 CSPs be extended beyond those in *Table 13. BUD Limits for Category 2 CSPs*?

The chapter states that BUDs for Category 2 CSPs must be established in accordance with *Table 13*. However, if there is a compounded preparation monograph for a particular CSP formulation, that BUD may be assigned if the CSP is prepared according to the monograph and all monograph requirements are met (e.g., Specific Tests). *General Notices 3.10* states that where the requirements of a monograph differ from the requirements in an applicable general chapter, the monograph requirements apply and supersede the general chapter.

Category 3 CSPs may be assigned longer BUDs than those set for Category 2 CSPs but not exceeding the limits in *Table 14*, if compounded in accordance with all applicable requirements for Category 3 CSPs.

BUDs must be assigned conservatively and must take into account factors such as validated stability-indicating analytical methods and testing for sterility, endotoxins, container closure integrity, and particulate matter.

172. Why is the BUD for aseptically prepared Category 2 CSPs using only sterile ingredients 4 days when stored at controlled room temperature?

The previous version of <797> specified a storage time of 48 hours and 30 hours at controlled room temperature for low- and medium-risk level CSPs, respectively. The longer BUD in the revised chapter is based on a risk-based approach to balance the need for quality CSPs and to facilitate patient access. Further, the revised chapter contains additional requirements (e.g., facility and engineering controls and surface sampling) to help mitigate risks of inadvertent contamination.

173. Is mixing MVI vial 1 and vial 2 compounding? What is the BUD?

No. Compounding does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling or supplemental materials provided by the product's manufacturer. Refer to the approved labeling for use of MVI once mixed.

174. If the compounding facility meets the requirements for compounding Category 3 CSPs, can a CSP still be given a Category 2 BUD to avoid sterility testing that particular CSP?

Yes. The chapter does not prohibit a compounder from assigning a shorter BUD than is specified in the BUD Limits tables (*Table 14* for Category 3 CSPs). As these are BUD limits, they are the date and time after which a CSP must not be used, stored, or transported, and a BUD shorter than the limit may be assigned to a CSP.

175. What is an example of a CSP requiring a shorter BUD based on stability and sterility?

Shorter BUDs must be assigned when the CSP's stability and/or sterility is less than the hours or days established in BUD limits for each CSP Category. For example, per guidelines, parenteral nutrition compounded as a total nutrient admixture (TNA) at a final concentration of amino acid > 4%, monohydrated dextrose > 10%, and lipid injectable emulsion > 2% are more likely to remain stable for up to 30 hours at room temperature or for 9 days refrigerated followed by 24 hours at room temperature.

176. Are there special considerations for CSPs that contain lipid emulsions?

Manufacturer recommendations regarding administration times and filtering must be followed for CSPs containing lipid emulsions. Some lipid-containing products should not exceed an administration hang time exceeding 12 hours and many require the use of a 1.2-micron filter.

177. Do Category 3 CSP BUDs have to be based on published stability studies?

The USP Compounding Expert Committee has compiled the Formulation and Stability Reference Document for Pharmaceutical Compounding posted here to help compounders understand when a stability study is suitable for assigning Category 3 BUDs to CSPs. While every CSP must meet release testing requirements for each batch to ensure sterility, evidence to prove the physicochemical stability of a CSP may be obtained from any stability-indicating assay method study, either published or unpublished, and does not have to be repeated for each batch as long as the formula, procedures, and container closure systems in the study are exactly the same for the CSP being prepared.

178. Describe when <51> testing is necessary.

An aqueous multiple-dose CSP must pass antimicrobial effectiveness testing in accordance with <51> *Antimicrobial Effectiveness Testing*.

179. Is <51> testing required for stock solutions?

No. When a CSP stock solution is used as a component to compound additional CSPs, the original CSP stock solution must be entered or punctured in ISO Class 5 or cleaner air and must be stored under the conditions upon which its BUD is based (e.g., refrigerator or controlled room temperature). The CSP stock solution may be used for sterile compounding for up to 12 h or its assigned BUD, whichever is shorter, and any remainder must be discarded.

180. Must antimicrobial effectiveness testing results be provided by an FDA-registered facility?

The compounder may rely on antimicrobial effectiveness testing 1) conducted (or contracted for) once for each formulation in the particular container closure system in which it will be packaged or 2) results from an FDA-registered facility or published in peer-reviewed literature sources, provided that the CSP formulation (including any preservative) and container closure system are exactly the same as those tested, unless a bracketing study is performed. Outside of the United States, facilities must comply with the laws and regulations of the applicable regulatory jurisdiction.

181. The conversion from high, medium, and low-risk compounding to Category 1 and Category 2 CSPs means that CSPs previously categorized as low-risk (48 hours at room temperature; 14 days refrigerated), now categorized as Category 2 (4 days room temperature; 10 days refrigerated) would increase the BUD at room temperature but decrease the BUD if refrigerated. Why is that?

The Compounding Expert Committee replaced risk levels with categories based on criteria other than just starting ingredients and number of manipulations. In addition to starting ingredients, BUDs are also based on environmental quality, personnel hygiene and garbing, physicochemical stability, and requirements for release testing.

182. If I only compound Category 3 CSPs occasionally, do I still have to follow the Category 3 requirements at all times?

Yes, if a compounder desires to assign a BUD longer than those allowed in *Tables 12* and *13*, then the requirements outlined in Section *14.4 Additional Requirements for Category 3 CSPs* must be met at all times.

183. What BUD should we use if there is no stability data available for the exact concentration of a CSP?

In this case, the maximum allowable BUD limits in <797> must not be exceeded.

184. May a plastic luer lock vial be stored after access?

No. The container closure system must remain intact in order to store a single-dose container after opening. Opened plastic luer lock vials are treated like ampules and must not be stored for any time period.

185. May a vial that has the septum or metal septum ring removed be stored after access?

No. The container closure system must remain intact in order to store a single-dose container after opening. Vials that have the septum or metal septum ring removed are treated like ampules and must not be stored for any time period.

Use of Conventionally Manufactured Products as Components

186. Is a conventionally manufactured single-dose container required to be stored in an ISO Class 5 PEC in order for it to be allowed to be used for up to 12 hours?

No, opened or punctured conventionally manufactured single-dose containers may be stored outside of an ISO Class 5 PEC. However, the chapter does require that the conventionally manufactured single-dose container be entered or punctured inside of an ISO Class 5 PEC. These containers may be used up to 12 hours after initial entry or puncture provided that the storage requirements (e.g., controlled room temperature, cold temperature) are maintained. Opened single-dose ampules must not be stored for any period of time.

187. When determining the BUD for a single-dose vial after puncture, how long can the single-dose vial be stored if the package insert states "use immediately"?

Compounding does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling or supplemental materials provided by the product's manufacturer. When preparing a product per approved labeling, the labeling must be followed.

When compounding a CSP, if a single-dose vial is entered or punctured only in an ISO Class 5 or cleaner air, it may be used up to 12 h after initial entry or puncture as long as the labeled storage requirements during that 12-h period are maintained and based on sterility assurance.

Package inserts are often based on stability assurance and lack sterility data, so if this is the case and the package insert states "use immediately", the same microbiological principles of a 4-hour immediate-use time may apply. Contact the manufacturer for stability information.

188. Are conventionally manufactured sterile topical ophthalmic products considered multiple-dose containers?

No, <659> *Packaging and Storage Requirements* defines multiple-dose containers as a container closure system that holds a sterile medication for parenteral administration (injection or infusion) that has met antimicrobial effectiveness testing requirements, or is excluded from such testing requirements by FDA regulation. Therefore, the requirement that multiple-dose containers not be used for more than 28 days unless otherwise specified on the labeling does not apply to conventionally manufactured sterile topical products.

189. If the approved labeling of a pharmacy bulk package describes a long storage time (e.g., 14 days), can the pharmacy bulk package be stored and used for that period of time?

Users should carefully review the manufacturer's approved labeling for pharmacy bulk packages. Some approved labeling may provide a storage time based on stability (e.g., 14 days) as well as a shorter time (e.g., 4 hours) based on the risk of microbial contamination. Users must use the shorter storage time specified in the manufacturer's approved labeling. The pharmacy bulk package must be used according to the manufacturer's approved labeling.

Use of CSPs as Components

190. How is the BUD of a CSP affected by pH-modifiers or other stock solutions that are used as components?

For CSPs prepared from one or more compounded components, the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CSP exceeds the BUD assigned to compounded components (e.g., pH-altering solutions). If the assigned BUD of the final CSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CSP must not be negatively impacted.

191. What is an example of assigning a BUD to compounded stock solutions and their subsequent CSPs?

A compounder wants to reconstitute a conventionally manufactured sterile product and further dilute it to prepare a subsequent CSP *(see 16.2 Use of Compounded Single-Dose CSPs and CSP Stock Solutions)*.

- Day 1: a 2-gram single-dose conventionally manufactured container of powder for solution is reconstituted with 8 mL of a conventionally manufactured diluent, yielding 10 mL of 200 mg/mL of drug (CSP-A, original CSP). CSP-A is assigned a BUD of 10 days because it is aseptically processed, has not passed sterility testing, was prepared from only sterile starting components, and will be stored in a refrigerator (see *Table 13*).
- Day 3: CSP-A is entered or punctured in an ISO Class 5 PEC, where 10 mL of CSP-A solution is further diluted with 40 mL of diluent, yielding 50 mL solution of 40 mg/mL of drug (CSP-B, a finished CSP). CSP-B is aseptically processed, has not passed sterility testing, was prepared from only sterile starting components, and will be stored in a refrigerator. The BUD of a CSP prepared from one or more compounded components may not exceed the shortest BUD of any of the individual starting components. Therefore, the assigned BUD for CSP-B will be 7 days (10 days minus the 3 lapsed days of CSP-A), because that is the shortest BUD of all of its individual components.
- Additionally, CSP-A must be used within 12 hours of initial entry/puncture or its originally assigned BUD, whichever is shorter, and the remainder must be discarded.

192. What BUD must be assigned to Category 2 or Category 3 CSPs made using a CSP stock solution?

The BUD assigned to a CSP, whether compounded from conventionally manufactured components or from compounded stock solutions, follows the same standards in Section *14. Establishing Beyond-Use Dates*. The one difference found in Section *14.3 Establishing a BUD for a CSP,* is that the BUD of CSPs made from compounded components may, at times, exceed the BUD of compounded components. For example, if a compounded pH-altering solution with a short BUD is used to compound a CSP, the resulting CSP would likely have greater stability, and thus a longer BUD than the pH-altering solution. Another example would be a Category 2 CSP that was not sterility tested and used to make a Category 3 CSP that will be sterilized and sterility tested. If the physical, chemical, and microbiological stability is not negatively impacted, the BUD of the resulting CSP may exceed that of the component. This exception does not exist for commercially available components. It is important to note that the BUD of the final CSP should not be further restricted by the time limits for entering or puncturing components found in Sections *15* and *16*.

193. Once punctured, can a CSP or conventionally manufactured product still be used for the length of its BUD?

Compounders may utilize both conventionally manufactured and compounded components. The chapter specifies the time in which each of these components can be stored and used after first entered. This is often called in-use time, although this term is not used in the chapter. The BUD is not the same as in-use time. A multiple-dose vial may have a BUD of 60 days but must still be discarded no later 28 days after first puncture.

194. The chapter states, "After a multiple-dose CSP is initially entered or punctured, the multiple-dose CSP must not be used for longer than the assigned BUD or 28 days, whichever is shorter. This time limit for entering or puncturing is not intended to restrict the BUD of the final CSP." Can you clarify what the last sentence means?

Each component, whether conventionally manufactured or compounded, must have a time limit for entering or puncturing after first use. For example, a conventionally manufactured multiple-dose vial may not be used after 28 days of first puncture. This 28-day time limit for use is not the same as the BUD of the component and is not intended to restrict the BUD of the resulting CSP. If a CSP is prepared from a multiple-dose vial either 1 day or 10 days after first puncture, the BUD of the resulting CSP would remain the same. For example, let's assume a conventionally manufactured multiple-dose vial with a one-year expiration date is used to compound a CSP with a 60-day BUD. The multiple-dose vial component may be punctured on day 1 to make the CSP and a BUD of 60 days would be given. Now, 27 days later the same multiple-dose vial component is punctured to make the CSP, and still, a 60-day BUD is assigned. In this instance, the time limit for entering or puncturing the MDV component does not further restrict the CSP being compounded.

195. Please explain the requirements as to the appropriate BUD for a reconstituted single-dose vial. For example, a reconstituted vial of daptomycin is stable for 2 days in the refrigerator. Can this vial be saved and reused for multiple preparations if kept in the refrigerator?

See Section *15* of <797>, which describes the different types of components that could be part of a CSP. When using a single-dose vial, <797> says: "If a single-dose vial is entered or punctured only in an ISO Class 5 or cleaner air, it may be used up to 12 h after initial entry or puncture as long as the labeled storage requirements during that 12-h period are maintained."

The vial of daptomycin mentioned in this example may be used for multiple preparations up to 12 hours after initial entry or puncture provided that the storage requirements (e.g., controlled room temperature, cold temperature) are maintained. If reconstituted in advance *as a single dose for a single patient*, then the daptomycin reconstituted solution may be stored per the approved labeling.

Quality Assurance and Quality Control

196. What does "the overall QA and QC program" entail?

A quality assurance program is guided by written procedures that define responsibilities and practices that ensure compounded preparations are produced with quality attributes appropriate to meet the needs of patients and healthcare professionals. The authority and responsibility for the quality assurance program should be clearly defined and implemented and should include at least the following nine separate but integrated components: (1) training; (2) standard operating procedures (SOPs); (3) documentation; (4) verification; (5) testing; (6) cleaning, disinfecting, and safety; (7) containers, packaging, repackaging, labeling, and storage; (8) outsourcing, if used; and (9) responsible personnel.

CSP Handling, Storage, Packaging, Shipping, and Transport

197. <797> states that the temperature in the storage area must be monitored each day, either manually or by a continuous recording device. ("The results of the temperature readings must be documented in a temperature log per facility SOPs or stored in the continuous temperature recording device and must be retrievable.") Does this mean that it would be acceptable to record temperatures on Monday if closed on weekends?

Yes.

198. Do all personnel who "touch" a CSP need to have training?

Yes, but not all personnel require the same training. <797> is specific about training for compounding, but leaves requirements for other personnel up to the organization. Personnel who receive sterile products and preparations, enter orders but do not compound or check CSP preparation, clean compounding areas, transport CSPs, or other activities must have documented competence as defined by the organization.

See related question in Personnel Training and Evaluation.

Compounding Allergenic Extracts

199. What are allergenic extracts?

Allergenic extracts are biological substances used for the diagnosis and/or treatment of allergic diseases such as allergic rhinitis, allergic sinusitis, allergic conjunctivitis, bee venom allergy, and food allergy. Allergenic extract prescription sets are combinations of licensed allergenic extracts which would be mixed and diluted to provide subcutaneous immunotherapy to an individual patient, even though these allergenic extract combinations are not specified in the approved biological license application (BLA) for the licensed biological products.

200. Does *21. Compounding Allergenic Extracts* apply to physician and pharmacy settings?

Yes, the provisions in *21. Compounding Allergenic Extracts* apply regardless of where the allergenic extract is compounded when:

1. The compounding process involves transfer via sterile needles and syringes of conventionally manufactured sterile allergen products and appropriate conventionally manufactured sterile added substances, and
2. Manipulations are limited to penetrating stoppers on vials with sterile needles and syringes and transferring sterile liquids in sterile syringes to sterile vials.

201. Why are the BUDs for compounded allergenic extracts longer than those required for Category 1 and Category 2 CSPs?

Because of certain characteristics of allergenic extracts and allergy practice (e.g., preservative systems and risk of anaphylaxis), preparation of allergenic extract for individual patient prescription sets is not subject to the requirements in this chapter that are applicable to other sterile CSPs. Further, FDA provides additional information for preparation of allergenic extracts in the FDA Guidance for Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application.

202. Does gloved fingertip and thumb sampling need to occur after media-fill testing for personnel who compound allergenic extracts?

No. Unlike personnel training for other CSPs, the goal of gloved fingertip and thumb sampling for personnel who compound allergenic extracts is to evaluate hand hygiene and garbing but not aseptic technique, due to the nature of the CSPs they compound. Therefore, personnel perform gloved fingertip and thumb sampling three times initially before compounding; thereafter gloved fingertip and thumb sampling is performed immediately after donning gloves at least once every 12 months. The action level for these samples is anything greater than 0 CFU per each hand.

203. Can allergenic extracts be prepared for immediate-use?

Yes.

204. Can this section apply for vials that are made for multiple patients?

No. Compounding allergenic extracts is per individual patient prescription set only.