Wisconsin Department of Safety and Professional Services
Division of Policy Development
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Tony Evers, Governor
Dan Hereth, Secretary

VIRTUAL/TELECONFERENCE MEETING
INTERDISCIPLINARY ADVISORY COMMITTEE
Virtual, 4822 Madison Yards Way, Madison
Contact: Brad Wojciechowski (608) 266-2112
April 30, 2025

The following agenda describes the issues that the Council plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. Please consult the meeting minutes for a record of the actions of the Council.

AGENDA

9:30 A.M.

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. Adoption of Agenda (1-2)

B. Approval of Minutes of February 26, 2025 (3-4)

C. Conflicts of Interest, Scheduling Concerns

D. Introductions, Announcements and Recognition – Discussion and Consideration

E. Administrative Matters – Discussion and Consideration

1. Department, Staff and Council Updates
2. Election of Officers
3. Committee Members – Committee Member Status
    a. Englebert, Doug – Controlled Substances Board Representative
    b. Kane, Amanda K. – Board of Nursing Representative
    c. Schmeling, Gregory – Medical Examining Board Representative
    d. Streit, Tara E. – Physician Assistant Affiliated Credentialing Board Representative
    e. Watkins, Alexis – Cosmetology Examining Board Representative
    f. Weitekamp, John G. – Pharmacy Examining Board Representative
4. Alternates
    a. Bloom, Alan – Controlled Substances Board Representative
    b. Edwards, Jacqueline K. – Physician Assistant Affiliated Credentialing Board Representative
    c. Malak, Jennifer L. – Board of Nursing Representative
    d. McIntosh, Dana – Cosmetology Examining Board Representative
    e. Wilson, Christa M. – Pharmacy Examining Board Representative
    f. Yu, Emily S. – Medical Examining Board Representative

F. Medical Aesthetics and IV Hydration – Discussion and Consideration (5-9)

1. Presentation by Dr. Jen Yeager, DNP, APNP, AGACNP-BC, CCRN - Co-Founder Wisconsin Aesthetic Providers Coalition **(6-9)**

G. IV Hydration Clinics – Discussion and Consideration (10-16)

1. FDA highlights concerns with compounding of drug products by medical offices and clinics under insanitary conditions **(11-16)**
2. IV Hydration Guidance

H. Future Topics – Discussion and Consideration

I. Public Comments

ADJOURNMENT

NEXT MEETING: JUNE 25, 2025

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MEETINGS AND HEARINGS ARE OPEN TO THE PUBLIC, AND MAY BE CANCELLED WITHOUT NOTICE.

Times listed for meeting items are approximate and depend on the length of discussion and voting. All meetings are held virtually unless otherwise indicated. In-person meetings are typically conducted at 4822 Madison Yards Way, Madison, Wisconsin, unless an alternative location is listed on the meeting notice. In order to confirm a meeting or to request a complete copy of the board's agenda, please visit the Department website at https:\\dsps.wi.gov. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of any agenda item may be changed by the board for the convenience of the parties. The person credentialed by the board has the right to demand that the meeting at which final action may be taken against the credential be held in open session. Requests for interpreters for the hard of hearing, or other accommodations, are considered upon request by contacting the Affirmative Action Officer or reach the Meeting Staff by calling 608-267-7213.

VIRTUAL/TELECONFERENCE
INTERDISCIPLINARY ADVISORY COMMITTEE
MEETING MINUTES
FEBRUARY 26, 2025

PRESENT: Doug Engelbert, Gregory Schmeling, Tara Streit, Alexis Watkins, John Weitekamp

ABSENT: Amanda Kane, Shelly R. Sabourin

STAFF: Brad Wojciechowski, Executive Director; Whitney DeVoe, Legal Counsel; Renee Parton, Administrative Rule Coordinator; Brenda Taylor, Board Services Supervisor; and other DSPS Staff

CALL TO ORDER

Brad Wojciechowski, Executive Director, called the meeting to order at 9:30 a.m. A quorum of five (5) members was confirmed.

ADOPTION OF AGENDA

MOTION: Tara Streit moved, seconded by John Weitekamp, to adopt the Agenda as published. Motion carried unanimously.

APPROVAL OF MINUTES OF OCTOBER 22, 2024

MOTION: Alexis Watkins moved, seconded by Tara Streit, to approve the Minutes of October 22, 2024, as published. Motion carried unanimously.

ADMINISTRATIVE MATTERS

Election of Officers

Slate of Officers

NOMINATION: Tara Streit nominated the 2024 slate of officers to continue in 2025. All officers accepted their nominations.

Brad Wojciechowski, Executive Director, called for nominations three (3) times.

The Slate of Officers was elected by unanimous voice vote.

2025 OFFICERS	
Chairperson	Doug Englebert
Vice Chairperson	Tara Streit
Secretary	John Weitekamp

ADJOURNMENT

MOTION: Tara Streit moved, seconded by John Weitekamp, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 11:13 a.m.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Brad Wojciechowski, Executive Director		**2) Date when request submitted:** 4/23/2025 **Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting**
3) Name of Board, Committee, Council, Sections: Choose an item. **Interdisciplinary Advisory Committee**		
4) Meeting Date: 4/30/2025	**5) Attachments:** ☒ Yes ☐ No	**6) How should the item be titled on the agenda page?** Medical Aesthetics and IV Hydration – Discussion and Consideration 1) Presentation by Dr. Jen Yeager, DNP, APNP, AGACNP-BC, CCRN – Co-Founder Wisconsin Aesthetic Providers Coalition
7) Place Item in: ☒ Open Session ☐ Closed Session	**8) Is an appearance before the Board being scheduled?** *(If yes, please complete Appearance Request for Non-DSPS Staff)* ☒ Yes Dr. Jen Yeager ☐ No	**9) Name of Case Advisor(s), if applicable:** <Click Here to Add Case Advisor Name or N/A>
10) Describe the issue and action that should be addressed: <Click Here to Add Description>		
11) Authorization Signature of person making this request		Date: 4/23/2024
Supervisor (Only required for post agenda deadline items)		Date
Executive Director signature (Indicates approval for post agenda deadline items)		Date

Directions for including supporting documents:
1. This form should be saved with any other documents submitted to the Agenda Items folders.
2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.
3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.

Wisconsin Aesthetic Providers Coalition

Presentation to the Interdisciplinary Advisory Committee

Dr. Jen Yeager, DNP, APNP, AGACNP-BC, CCRN

Co-Founder WAPC

Medical Grade Aesthetics

Who is the Wisconsin Aesthetic Provider Coalition?

The Wisconsin Aesthetic Provider Coalition (WAPC) is the collaboration between aesthetic medicine practices in the state of Wisconsin. WAPC was established through a collaborative effort to protect the scope of practice rights for aesthetic medicine providers through educational and compliance standards supported by license designation.

WAPC membership emcompasses the multi-displinary staff that work in aesthetic medicine - including the APRN, MD, PA, RN, LPN, aestheticians, laser technicians, and cosmetologists

Our Goals

- Establish clear, state-level safety standards for the medical aesthetics field rooted in specialty training and experience
- Develop educational and compliance practice standards by establishing minimum requirements that include accredited continuing education in aesthetics, nursing, and medicine ***specific to specialty of medical aesthetics***.

IV Hydration

- Who uses IV Hydration?
- Why do they want it?
- How does our field provide the services?
- How do we work with providers?
- How does compounding work?
- What does it look like if we go backwards?
- What is in the best interest of our patients, their safety and our scope of practice?

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Whitney DeVoe, Board Counsel		**2) Date when request submitted:** 4/18/25 **Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting**	
3) Name of Board, Committee, Council, Sections: Interdisciplinary Advisory Committee			
4) Meeting Date: 04/30/2025	**5) Attachments:** ☒ Yes ☐ No	**6) How should the item be titled on the agenda page?** Discussion and Consideration – Rough Draft IV Hydration Guidance Document	
7) Place Item in: ☒ Open Session ☐ Closed Session	**8) Is an appearance before the Board being scheduled?** ☐ Yes ☒ No	**9) Name of Case Advisor(s), if applicable:**	
10) Describe the issue and action that should be addressed: Discussion and consideration of the rough draft of the IV hydration guidance document.			
11) **Authorization**			
Whitney DeVoe		04/18/25	
Signature of person making this request		Date	
Supervisor (Only required for post agenda deadline items)		Date	
Executive Director signature (Indicates approval for post agenda deadline items)		Date	

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State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Whitney DeVoe, Board Counsel		**2) Date when request submitted:** 4/18/25 **Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting**	
3) Name of Board, Committee, Council, Sections: Interdisciplinary Advisory Committee			
4) Meeting Date: 04/30/2025	**5) Attachments:** ☒ Yes ☐ No	**6) How should the item be titled on the agenda page?** **Discussion and Consideration – FDA highlights concerns with compounding of drug products by medical offices and clinics under insanitary conditions**	
7) Place Item in: ☒ Open Session ☐ Closed Session	**8) Is an appearance before the Board being scheduled?** ☐ Yes ☒ No	**9) Name of Case Advisor(s), if applicable:**	
10) Describe the issue and action that should be addressed: Discussion and consideration of FDA highlights.			
11) **Authorization**			
Whitney DeVoe			**04/18/25**
Signature of person making this request			**Date**
Supervisor (Only required for post agenda deadline items)			**Date**
Executive Director signature (Indicates approval for post agenda deadline items)			**Date**

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FDA highlights concerns with compounding of drug products by medical offices and clinics under insanitary conditions

October 25, 2021

Background

Human drug compounding is generally a practice in which ingredients of a drug are combined, mixed, or altered to create a medication tailored to the medical needs of an individual patient. Section 503A of the Federal Food, Drug and Cosmetic Act (FD&C Act) describes the conditions under which compounded human drug products are exempt from the following three sections of the FD&C Act:

- Section 505 concerning approval prior to marketing
- Section 501(a)(2)(B) concerning current good manufacturing practice (CGMP) requirements
- Section 502(f)(1) concerning labeling with adequate directions for use

One of the conditions to qualify for these exemptions is that the drug is compounded by a licensed pharmacist in a state-licensed pharmacy or federal facility, or by a licensed physician, based on the receipt of a valid patient-specific prescription. Compounded drugs that meet the conditions of section 503A are still subject to section 501(a)(2)(A) of the FD&C Act which states a drug is considered adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

FDA has become increasingly aware of drug products compounded at medical offices and clinics that were prepared under insanitary conditions. FDA has also become aware of business models, such as intravenous (IV) hydration clinics, medical spas, and mobile IV infusion services, that are compounding drugs that may not meet the conditions of section 503A of the FD&C Act or comply with state regulations. Contaminated, or otherwise poor quality, compounded drug products can lead to serious patient illnesses, including death.

Case Examples and Discussion of Risk

The extent to which compounding of drug products is occurring in medical offices is not fully known as compounders seeking to compound drugs under section 503A generally do not register with FDA. Adverse events associated with drug products compounded at medical offices under insanitary conditions have been reported, but it is likely that these events are underreported. The compounding case examples below illustrate some of the risks associated with drug products prepared, packed, or held under insanitary conditions.

Cases of drug product compounding at medical offices under insanitary conditions are well documented. In 2016, a series of fungal infections were linked to an oncology medical practice where 38 patients were exposed and 17 patients were infected with *Exophiala dermitides*, a thermophilic black yeast. FDA communicated with state regulators and conducted an inspection of the medical office where sterile compounding was occurring. Insanitary conditions observed at the medical office during the inspection included contamination in the form of brownish soiled material inside the bottom edges of the ISO-5 classified hood used for sterile drug compounding. FDA also observed that the cleanroom design was inadequate to prevent microbiological contamination of drug products intended to be sterile as the ISO-5 classified hood was located adjacent to a refrigerator and in close proximity to a sink without any air quality control of the surrounding area. ISO-classified areas that meet standardized levels of cleanliness[1] help ensure an appropriate environment for sterile drug compounding.

More recently, in July 2020, FDA was made aware of drug products intended to be sterile that were being compounded under insanitary conditions at Advanced Nutriceuticals, LLC dba The Guyer Institute of Molecular Medicine. The Guyer Institute of Molecular Medicine is a medical clinic operating under a physician's license and offering services such as platelet-rich plasma therapy, IV vitamin therapy, hormone replacement therapy, and laboratory testing. FDA worked with state regulators and conducted an inspection during which numerous deficiencies involving insanitary conditions were observed (/media/144544/download) including, but not limited to:

- Personnel in street clothes with ungloved hands filling drug products intended to be sterile into syringes outside of an ISO-5 classified area. These drug products were scheduled for shipment to patients across the country.
- Personnel performing sterile drug compounding within the ISO-5 classified area failed to sanitize or change gloves after contact with non-sterile items including a face mask and trash can.
- Personnel in the ISO-5 classified area moved rapidly and blocked first pass (clean) air in the vicinity of open sterile units, increasing risk of product contamination.

- High efficiency particulate air (HEPA) filters located in the ISO-5 classified area and cleanroom were discolored and/or damaged.
- The ISO-5 classified cleanroom workbench where sterile drug compounding occurs was constructed of laminated wood which was peeling.
- A heating vent located below the ISO-5 classified hood was visibly dirty and had no filtering device attached.
- Hazardous drugs were handled without providing adequate containment, segregation, or cleaning of work surfaces and utensils to prevent cross-contamination.
- Stock solutions intended to be sterile were exposed to lesser quality than ISO-5 classified air after the stopper had been punctured multiple times.
- Use of expired active pharmaceutical ingredients to prepare drug products intended to be sterile.

In addition, in February 2021, FDA was made aware of a 50-year-old female patient who was hospitalized and treated for suspected septic shock with multi-organ failure after receiving an IV-vitamin infusion in her home. The patient's blood cultures grew *Pseudomonas fluorescens,* a gram-negative bacterium. The IV-vitamin infusion was compounded by Age Management Institute Santa Barbara, a medical clinic providing services including IV therapies and vitamin injectables, sexual health products, hormone replacement therapy, weight loss/management products, and diagnostic laboratory assays. FDA collaborated with multiple state regulators and conducted an inspection of the firm during which several deficiencies involving insanitary conditions were observed (/media/152075/download) including, but not limited to:

- Lack of a certified ISO-5 classified area for sterile compounding.
- Contamination in compounding areas including peeling paint, stained work surfaces, visibly dirty equipment, and air vents with dust and grime.
- Difficult to clean equipment and surfaces such as carpeting in the IV storage and mixing room.
- Standing water in a refrigerated storage area used to store sterile vials.
- Use of expired active pharmaceutical ingredients to prepare drug products intended to be sterile.

Furthermore, FDA has become aware of sterile compounding activities, such as adding vitamins to IV infusion bags, being performed by business entities such as IV hydration clinics, medical spas, and mobile IV infusion companies. It is unknown if drug products are prepared, packed, or held under insanitary conditions by these entities and whether a licensed practitioner is on-site

to evaluate patients and write prescriptions for the drug products intended to be sterile being administered. It is also uncertain whether entities producing these sterile products are following state regulations. It is FDA's understanding that entities such as these can be found nationwide; however, the number of these entities and the compounding practices occurring at these entities are not fully understood given that compounders seeking to compound drugs under section 503A generally do not register with FDA.

The extent to which compounding of drug products is occurring at medical offices and business entities such as IV hydration clinics is not fully known; however, compounding, packing or holding drug products intended to be sterile under insanitary conditions at any facility significantly increases the risk of serious product quality concerns, such as product contamination. Compounding drug products intended to be sterile under insanitary conditions, including employing poor aseptic practices, using dirty equipment, or working in a facility not properly designed to maintain appropriate levels of cleanliness, as noted in the examples described above, increases the risk of product contamination. Use of contaminated drug products intended to be sterile has led to serious patient illnesses, hospitalization, and death.

Conclusion

The above examples of compounding performed at medical offices highlight the crucial need for compounding to be performed in accordance with best practices and not under insanitary conditions to ensure the public has access to quality compounded drugs. Patients can be significantly harmed when drugs are compounded in a way in which sterility or quality cannot be assured. In addition, sterile compounding activities being performed by business entities such as IV hydration clinics present risk and require continued evaluation.

FDA is committed to continued evaluation of these practices and collaboration with state regulatory authorities to address identified and emerging risks to public health and promote the quality of compounded drugs. FDA urges compounders, including physicians' offices and emerging compounding entities, to comply with all state and federal laws and regulations related to compounding and take necessary actions to protect patients who receive their compounded drug products. It is critical that any manipulation of medications, particularly those required to be sterile, occurs in accordance with conditions and practices designed to prevent contamination and other quality concerns.

FDA encourages consumers, patients, and health care professionals to report any adverse events or quality problems experienced with the use of compounded drug products to FDA's MedWatch Adverse Event Reporting program:

- Complete and submit the report online at www.fda.gov/medwatch/report.htm (http://www.fda.gov/medwatch/report.htm); or
- Download and complete the form, then submit it via fax at 1-800-FDA-0178.

References

1. International Organization for Standardization (2015). *Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration* (ISO Standard No. 14644-1:2015).