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Tony Evers, Governor
Dan Hereth, Secretary

HYBRID (IN-PERSON/VIRTUAL)
PHARMACY EXAMINING BOARD
N208, 4822 Madison Yards Way, Madison, WI
Contact: Brad Wojciechowski (608) 266-2112
April 25, 2024

Notice: The following agenda describes the issues that the Board 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 description of the actions of the Board. A quorum of the Board may be present during any committee meetings. Be advised that board members may attend meetings designated as "Hybrid" in-person or virtually.

AGENDA

11:00 A.M.
(OR IMMEDIATELY FOLLOWING THE PHARMACY RULES COMMITTEE)

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. Adoption of Agenda (1-4)

B. Approval of Minutes of February 29, 2024 (5-8)

C. Reminders: Conflicts of Interest, Scheduling Concerns

D. Introductions, Announcements, and Recognition

E. Administrative Matters – Discussion and Consideration
1) Department, Staff and Board Updates
2) Board Members – Term Expiration Dates
   a. Kleppin, Susan – 7/1/2025
   b. O'Hagan, Tiffany – 7/1/2024
   c. Peterangelo, Anthony – 7/1/2027
   d. Walsh, Michael – 7/1/2024
   e. Weitekamp, John – 7/1/2026
   f. Wilson, Christa – 7/1/2025

F. Psychedelics and Mental Health – Discussion and Consideration (9-26)
1) Presentation by Cody Wenthur, PharmD, PhD

G. Administrative Rule Matters – Discussion and Consideration (27-42)
1) Adoption Order: Phar 18, Relating to Licensure of Third-Party Logistics Provider **(28-34)**
2) Preliminary Rule Draft: Phar 15, Relating to Pharmaceutical Compounding **(35-39)**
3) Scope Statement: Phar 7, Relating to Electronic Prescriptions, Prescription Labeling, CPR for Pharmacists, Epinephrine Delivery Systems, Controlled Substances

Prescription Transfers, Remote Dispensing, and Definition of Managing Pharmacist **(40-41)**

4) Pending or Possible Rulemaking Projects **(42)**

H. Legislative and Policy Matters – Discussion and Consideration

I. Credentialing Matters – Discussion and Consideration

1) 2024 Renewal Period

J. Improving Pharmacist Workplace Satisfaction – Discussion and Consideration

K. NABP Pulse Regulator Monthly Champions Call – Discussion and Consideration

L. NABP Expedited Testing Solutions – Discussion and Consideration

M. Liaison Reports – Discussion and Consideration

N. Speaking Engagements, Travel, or Public Relation Requests, and Reports

O. Pilot Program Matters – Discussion and Consideration

P. Discussion and Consideration on Items Added After Preparation of Agenda

1) Introductions, Announcements and Recognition
2) Nominations, Elections, and Appointments
3) Administrative Matters
4) Election of Officers
5) Appointment of Liaisons and Alternates
6) Delegation of Authorities
7) Education and Examination Matters
8) Credentialing Matters
9) Practice Matters
10) Legislative and Policy Matters
11) Administrative Rule Matters
12) Public Health Emergencies
13) Pilot Program Matters
14) Variances
15) Liaison Reports
16) Board Liaison Training and Appointment of Mentors
17) Informational Items
18) Division of Legal Services and Compliance (DLSC) Matters
19) Presentations of Petitions for Summary Suspension
20) Petitions for Designation of Hearing Examiner
21) Presentation of Stipulations, Final Decisions and Orders
22) Presentation of Proposed Final Decisions and Orders
23) Presentation of Interim Orders
24) Pilot Program Matters
25) Petitions for Re-Hearing
26) Petitions for Assessments
27) Petitions to Vacate Orders
28) Requests for Disciplinary Proceeding Presentations
29) Motions
30) Petitions
31) Appearances from Requests Received or Renewed

32) Speaking Engagements, Travel, or Public Relation Requests, and Reports

Q. Public Comments

CONVENE TO CLOSED SESSION to deliberate on cases following hearing (s. 19.85(1)(a), Stats.); to consider licensure or certification of individuals (s. 19.85(1)(b), Stats.); to consider closing disciplinary investigations with administrative warnings (ss. 19.85(1)(b), and 440.205, Stats.); to consider individual histories or disciplinary data (s. 19.85(1)(f), Stats.); and to confer with legal counsel (s. 19.85(1)(g), Stats.).

R. Deliberation on Review of Administrative Warning

1) **12:30 P.M. APPEARANCE:** Julie Zimmer, DLSC Attorney; Maria Kysely Schneider, Attorney for Respondent; and K.M.L., Respondent: WARN00003678 – 23 PHM 060 – K.M.L. **(43-57)**

S. Credentialing Matters

1) **Application Reviews**
   a. E.P. – Pharmacy (Out-of-State) **(58-252)**

T. Deliberation on Division of Legal Services and Compliance Matters

1) **Administrative Warning**
   a. 23 PHM 109 – J.R.B. **(253-254)**
   b. 23 PHM 116 – C.A.W.P. **(255-256)**
   c. 23 PHM 117 – C.A.W.P. **(257-258)**
   d. 23 PHM 121 – M.H.E.S. **(259-260)**
   e. 23 PHM 121 – W.C. **(261-262)**
   f. 23 PHM 123 – S. **(263-264)**
   g. 23 PHM 142 – B.D.J. **(265-266)**
   h. 24 PHM 005 – H.A. **(267-268)**
   i. 24 PHM 011 – A.H.G. **(269-270)**
2) **Case Closings**
   a. 22 PHM 080 – C. **(271-274)**
   b. 22 PHM 090 – H.A.Z. **(275-282)**
   c. 22 PHM 131 – P.L. **(283-286)**
   d. 22 PHM 185 – V.C.P. **(287-290)**
   e. 22 PHM 194 – R.A.G. **(291-294)**
   f. 23 PHM 084 – O.R. **(295-300)**
   g. 23 PHM 038 – J.R.N. **(301-304)**
   h. 23 PHM 099 – C.O.A. and W.M.P. **(305-309)**
   i. 23 PHM 109 – W. **(310-314)**
   j. 23 PHM 132 – E.H.P.S.C. **(315-319)**
   k. 23 PHM 188 – W. **(320-324)**
   l. 24 PHM 018 – K.C. **(325-328)**
3) **Proposed Stipulations, Final Decisions and Orders**
   a. 22 PHM 067 – Abdelrahman H. Alarga **(329-334)**
   b. 22 PHM 067 – Susan O. Coady **(335-340)**
   c. 22 PHM 067 – Mohammed H. Elghannam **(341-346)**
   d. 23 PHM 101 – Stephanie L. Nehls **(347-358)**
4) **Monitoring Matters (359-404)**
   a. Kyle J. McGilligan, R.Ph. – Requesting Full Licensure **(361-370)**
   b. Jin Ryu, R.Ph. – Requesting Modification of Monitoring Order **(371-404)**

U. Deliberation of Items Added After Preparation of the Agenda
   1) Education and Examination Matters
   2) Credentialing Matters
   3) Application Reviews
   4) DLSC Matters
   5) Monitoring Matters
   6) Professional Assistance Procedure (PAP) Matters
   7) Petitions for Summary Suspensions
   8) Petitions for Designation of Hearing Examiner
   9) Proposed Stipulations, Final Decisions and Orders
   10) Proposed Interim Orders
   11) Administrative Warnings
   12) Review of Administrative Warnings
   13) Proposed Final Decisions and Orders
   14) Matters Relating to Costs/Orders Fixing Costs
   15) Case Closings
   16) Board Liaison Training
   17) Petitions for Assessments and Evaluations
   18) Petitions to Vacate Orders
   19) Remedial Education Cases
   20) Motions
   21) Petitions for Re-Hearing
   22) Appearances from Requests Received or Renewed

V. Consulting with Legal Counsel

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

W. Vote on Items Considered or Deliberated Upon in Closed Session if Voting is Appropriate

X. Open Session Items Noticed Above Not Completed in the Initial Open Session

ADJOURNMENT

NEXT MEETING: JUNE 20, 2024

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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 disciplinary hearings may be changed by the examiner for the convenience of the parties. 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
PHARMACY EXAMINING BOARD
MEETING MINUTES
FEBRUARY 29, 2024

PRESENT: Susan Kleppin, Tiffany O'Hagan, Anthony Peterangelo, Michael Walsh, John Weitekamp, Christa Wilson

STAFF: Brad Wojciechowski, Executive Director; Whitney DeVoe, Legal Counsel; Nilajah Hardin, Administrative Rules Coordinator; Brenda Taylor, Board Services Supervisor; and other Department staff

CALL TO ORDER

John Weitekamp, Chairperson, called the meeting to order at 11:01 a.m. A quorum was confirmed with six (6) members present.

ADOPTION OF AGENDA

MOTION: Michael Walsh moved, seconded by Anthony Peterangelo, to adopt the Agenda as published. Motion carried unanimously.

APPROVAL OF MINUTES OF JANUARY 18, 2024

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to approve the Minutes of January 18, 2024, as published. Motion carried unanimously.

IMPROVING PHARMACIST WORKPLACE SATISFACTION

Presentation: 2022 NABP Report of the Work Group on Workplace Safety, Well-Being, and Working Conditions – Reggie Dilliard, NABP President

MOTION: John Weitekamp moved, seconded by Tiffany O'Hagan, to acknowledge and thank NABP Chairperson Reggie Dilliard, for his appearance and presentation relating to NABP's Work Group on Workplace Safety, Well-bring, and Working Conditions to the Pharmacy Examining Board. Motion carried unanimously.

FDA ADVISORY LETTER TO NABP CONCERNING COMPOUNDED SEMAGLUTIDES

MOTION: John Weitekamp moved, seconded by Michael Walsh, acknowledge and thank Dr. Sumeet Goel, Vice Chairperson, Wisconsin Medical Examining Board for his appearance at the Pharmacy Examining Board meeting. Motion carried unanimously.

MOTION: John Weitekamp moved, seconded by Anthony Peterangelo, to authorize Susan Kleppin to attend the Medical Examining Board meeting on March 20, 2024, on behalf of the Pharmacy Examining Board. Motion carried unanimously.

ADMINISTRATIVE RULE MATTERS

Adoption Order: Phar 7 and 10, Relating to Required Disclosures to Consumers

MOTION: Susan Kleppin moved, seconded by Tiffany O'Hagan, to approve the Adoption Order for Clearinghouse Rule 23-015 (Phar 7 and 10), relating to Required Disclosures to Consumers. Motion carried unanimously.

NABP EXPEDITED TESTING SOLUTIONS

MOTION: John Weitekamp moved, seconded by Michael Walsh, to acknowledge and thank Secretary Dan Hereth for his efforts to expediate licensure of pharmacists in Wisconsin. Motion carried unanimously.

MOTION: John Weitekamp moved, seconded by Anthony Peterangelo, to recommend and approve DSPS to work with NABP and pharmacy schools located in Wisconsin on accelerating the eligibility to apply, and sit for the MPJE prior to clinical semesters. Additionally, DSPS take into consideration the ability of pharmacy schools to attest that graduating students have the ability to apply for the NAPLEX examination during their final semester. Motion carried unanimously.

CLOSED SESSION

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to convene to Closed Session to deliberate on cases following hearing (s. 19.85(1)(a), Stats.); to consider licensure or certification of individuals (s. 19.85(1)(b), Stats.); to consider closing disciplinary investigations with administrative warnings (ss. 19.85(1)(b), and 440.205, Stats.); to consider individual histories or disciplinary data (s. 19.85(1)(f), Stats.); and to confer with legal counsel (s. 19.85(1)(g), Stats.). John Weitekamp, Chairperson, read the language of the motion. The vote of each member was ascertained by voice vote. Roll Call Vote: Susan Kleppin-yes; Tiffany O'Hagan-yes; Anthony Peterangelo-yes; Michael Walsh-yes; John Weitekamp-yes; and Christa Wilson-yes. Motion carried unanimously.

The Board convened into Closed Session at 1:15 p.m.

CREDENTIALING MATTERS

Application Reviews

Corinne Never - Pharmacy Technician

MOTION: John Weitekamp moved, seconded by Christa Wilson, to request additional information from Corinne Never and to authorize Tiffany O'Hagan to make a final determination on the application of Corinne Never. Motion carried unanimously.

DELIBERATION ON DIVISION OF LEGAL SERVICES AND COMPLIANCE (DLSC) MATTERS

Administrative Warnings

23 PHM 142 – B.D.J.

MOTION: Michael Walsh moved, seconded by Susan Kleppin, to refer back DLSC Case Number 23 PHM 142, B.D.J., for further investigation by DLSC. Motion carried unanimously.

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to issue an Administrative Warning in the following DLSC Cases:
22 PHM 008 – E.S.P.
23 PHM 060 – K.M.L.
23 PHM 105 – A.A.K.
23 PHM 105 – N.R.W.
23 PHM 125 – C.L.
Motion carried unanimously.

Case Closings

MOTION: Michael moved, seconded by John, to close the following DLSC Cases for the reasons outlined below:
22 PHM 044 – W. – No Violation (NV)
22 PHM 089 – CVS – Insufficient Evidence (IE)
22 PHM 101 – CVS – No Violation (NV)
22 PHM 101 – M.H. – No Violation (NV)
22 PHM 117 – W. Prosecutorial Discretion (P1)
22 PHM 127 – W. – Insufficient Evidence (IE)
23 PHM 018 – M.M.P. – No Violation (NV)
23 PHM 037 – E.S.P. – No Violation (NV)
23 PHM 105 – D.J.M. – No Violation (NV)
23 PHM 105 – W. – No Violation (NV)
23 PHM 125 – W. – Prosecutorial Discretion (P2)
23 PHM 142 – W.R.H.P. – No Violation (NV)
23 PHM 148 – O.E. – Insufficient Evidence (IE)
23 PHM 162 – H.P. – Prosecutorial Discretion (P7)
Motion carried unanimously.

Proposed Stipulations, Final Decisions and Orders

22 PHM 044 – Erik C. Simonson

MOTION: John Weitekamp moved, seconded by Anthony Peterangelo, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of Erik C. Simonson, DLSC Case Number 22 PHM 044. Motion carried unanimously.

22 PHM 120 – Triad Rx, Inc.

MOTION: Michael Walsh moved, seconded by Christa Wilson, to adopt the Findings of Fact, Conclusion of Law and Order in the matter of disciplinary proceedings against Triad Rx, Inc., DLSC Case Number 22 PHM 120. Motion carried unanimously.

RECONVENE TO OPEN SESSION

MOTION: Michael moved, seconded by Tony, to reconvene into Open Session. Motion carried unanimously.

The Board reconvened into Open Session at 2:45 p.m.

VOTING ON ITEMS CONSIDERED OR DELIBERATED UPON IN CLOSED SESSION

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to affirm all motions made and votes taken in Closed Session. Motion carried unanimously.

(Be advised that any recusals or abstentions reflected in the Closed Session motions stand for the purposes of the affirmation vote.)

ADJOURNMENT

MOTION: Susan Kleppin moved, seconded by Christa Wilson, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 2:47 p.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: 4/4/2024 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: Pharmacy Examining Board			
4) Meeting Date: 4/25/2024	5) Attachments: ☒ Yes ☐ No	6) How should the item be titled on the agenda page? Presentation: Psychedelics and Mental Health, Cody Wenthur, PharmD, PhD	
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 Cody Wenthur ☐ 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		4/4/2024 Date	
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.

Psychedelics and Mental Health

Cody J. Wenthur, PharmD, PhD

Director, Psychoactive Pharmaceutical Investigation Programs

Executive Committee Member, Transdisciplinary Center for Research in Psychoactive Substances

Assistant Professor of Pharmacy

University of Wisconsin - Madison

Psychedelic Research Centers and Programs in the USA

University of Wisconsin – Madison

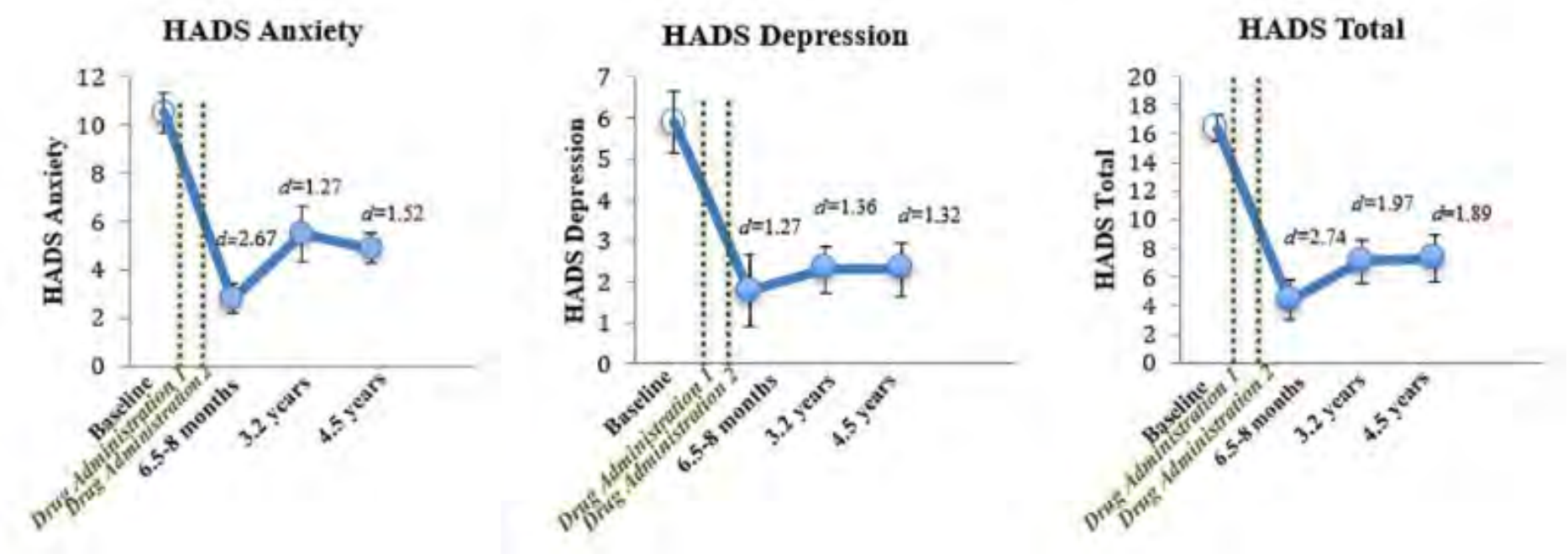
Usona Institute

Ohio State University
University of Michigan
University of Minnesota
Johns Hopkins University
New York University
Mount Sinai
University of California – Berkeley
University of California – San Francisco
University of California - Davis

University of Texas – Austin
Duke University
University of Pennsylvania
Yale University
Harvard University
Colombia University
Medical University of South Carolina
Emory University
University of Alabama – Birmingham
University of New Mexico
Heffter Research Institute
California Institute for Integral Studies
Alexander Shulgin Research Institute

(a partial list)

Persisting Effects from Psilocybin-Assisted Therapy for End-Of Life Depression and Anxiety



The psilocybin experience changed my thoughts about myself in the world. I see myself in a less limited way. I am more open to life. It has taken me out from under a big load of feelings and past issues in my life that I was carrying around.

There's a reckoning, which came with cancer, and this reckoning was enhanced by the psilocybin experience. I have a greater appreciation and sense of gratitude for being alive.

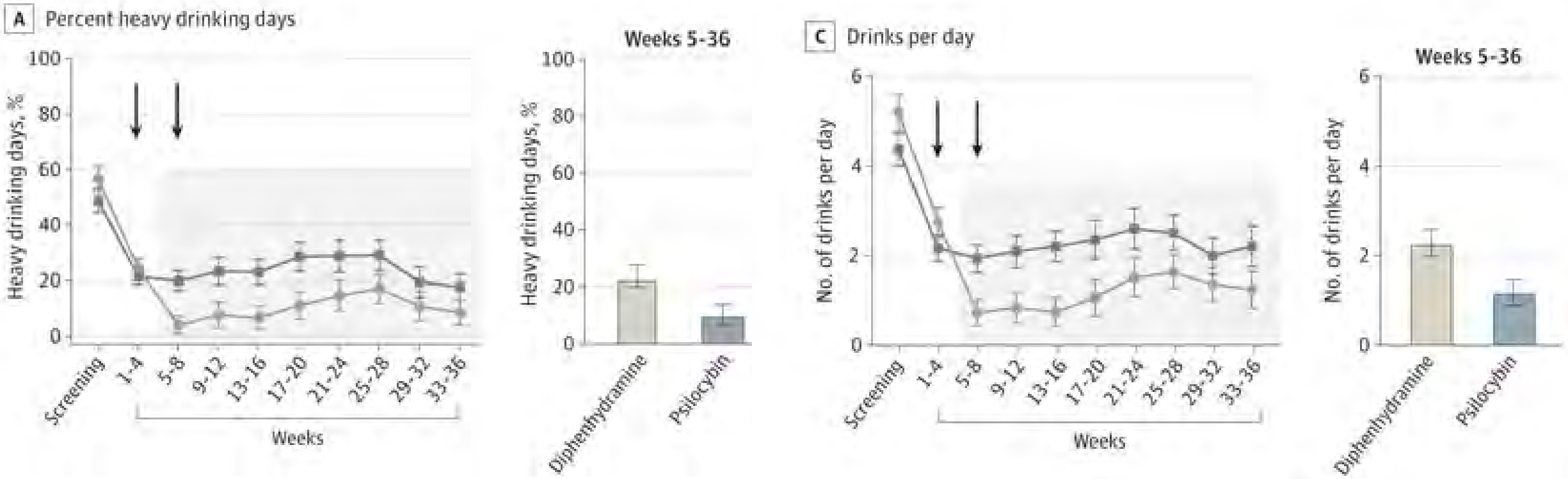
DATA FROM: Agin-Liebes et al. J Psychopharmacol. 34(2): 155–166. 2020.

Psilocybin for Treatment-Resistant Depression

DATA FROM: Compass Pathways. 2021 (https://www.sec.gov/Archives/edgar/data/0001816590/000162828021022397/exhibit992-compass6xk.htm)

NYU

Psilocybin and Alcohol Use

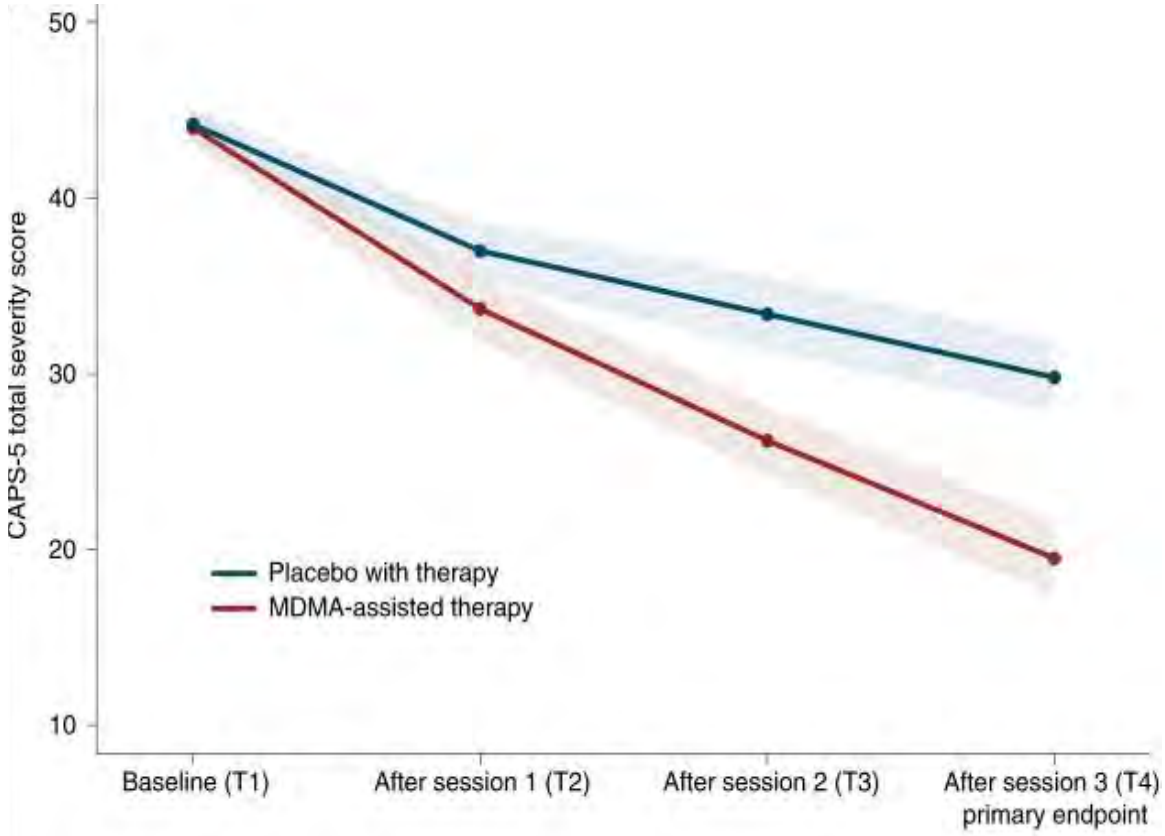


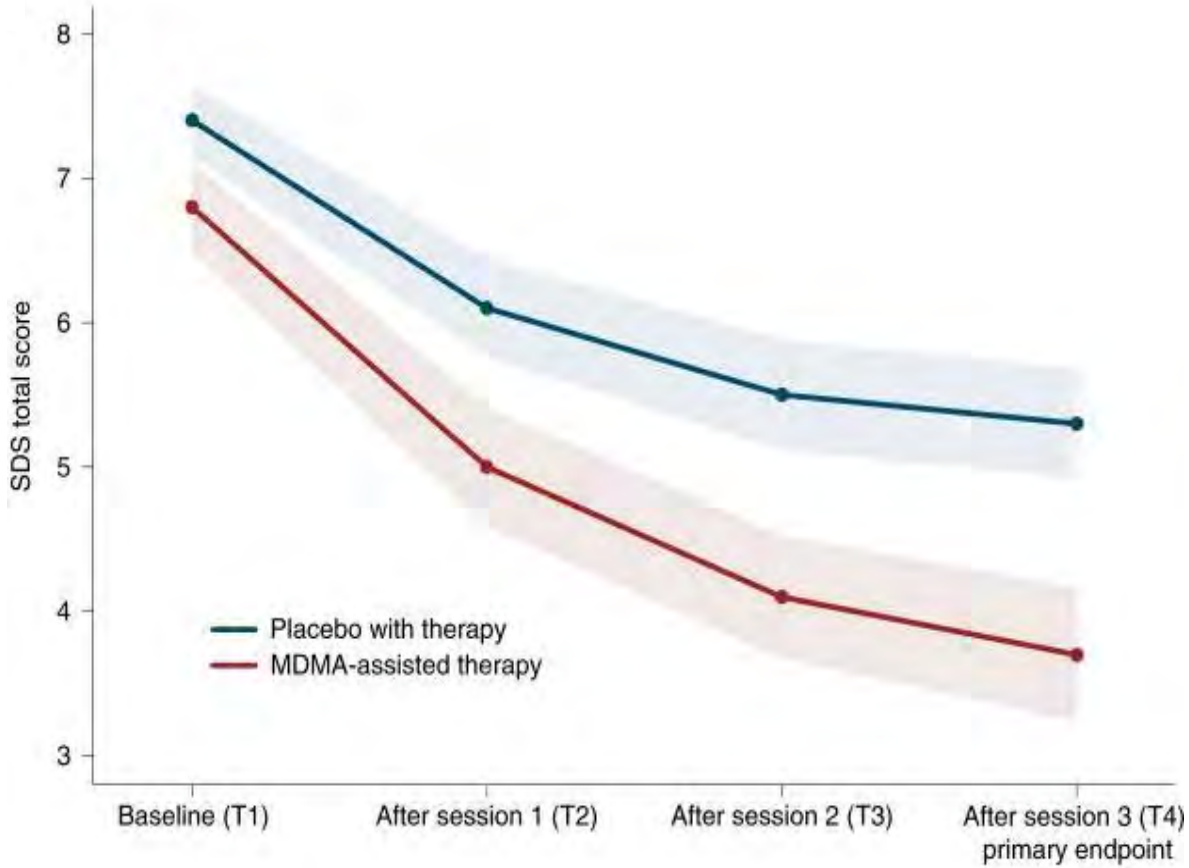
	Follow-up period	No. (%)[a] Diphenhydramine (n = 45)	Psilocybin (n = 48)	NNT	OR (95% CI)[b]	*P* value[b,c]
Abstinence	Weeks 5-36	4 (8.9)	11 (22.9)	7.1	3.05 (0.89-10.40)	.06
	Weeks 33-36	11 (24.4)	23 (47.9)	4.3	2.84 (1.17-6.89)	.02
No heavy drinking	Weeks 5-36	5 (11.1)	16 (33.3)	4.5	4 (1.32-12.10)	.01
	Weeks 33-36	18 (40.0)	30 (62.5)	4.4	2.5 (1.08-5.76)	.03

DATA FROM: Bogenschutz MP et al. *JAMA Psychiatry*. 2022;79(10):953-962.

MDMA-assisted therapy for severe PTSD

Multidisciplinary Association for Psychedelic Studies





DATA FROM: Mitchell JM, et al. *Nat Med*. 2021;27(6):1025-1033.

Example Psychedelic-Assisted Therapy Structure

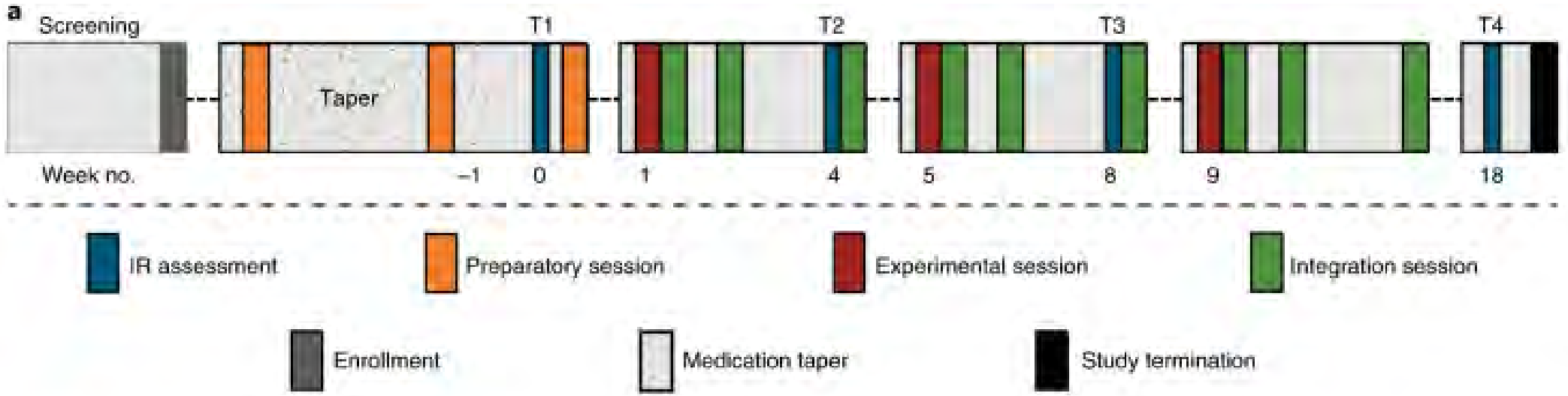
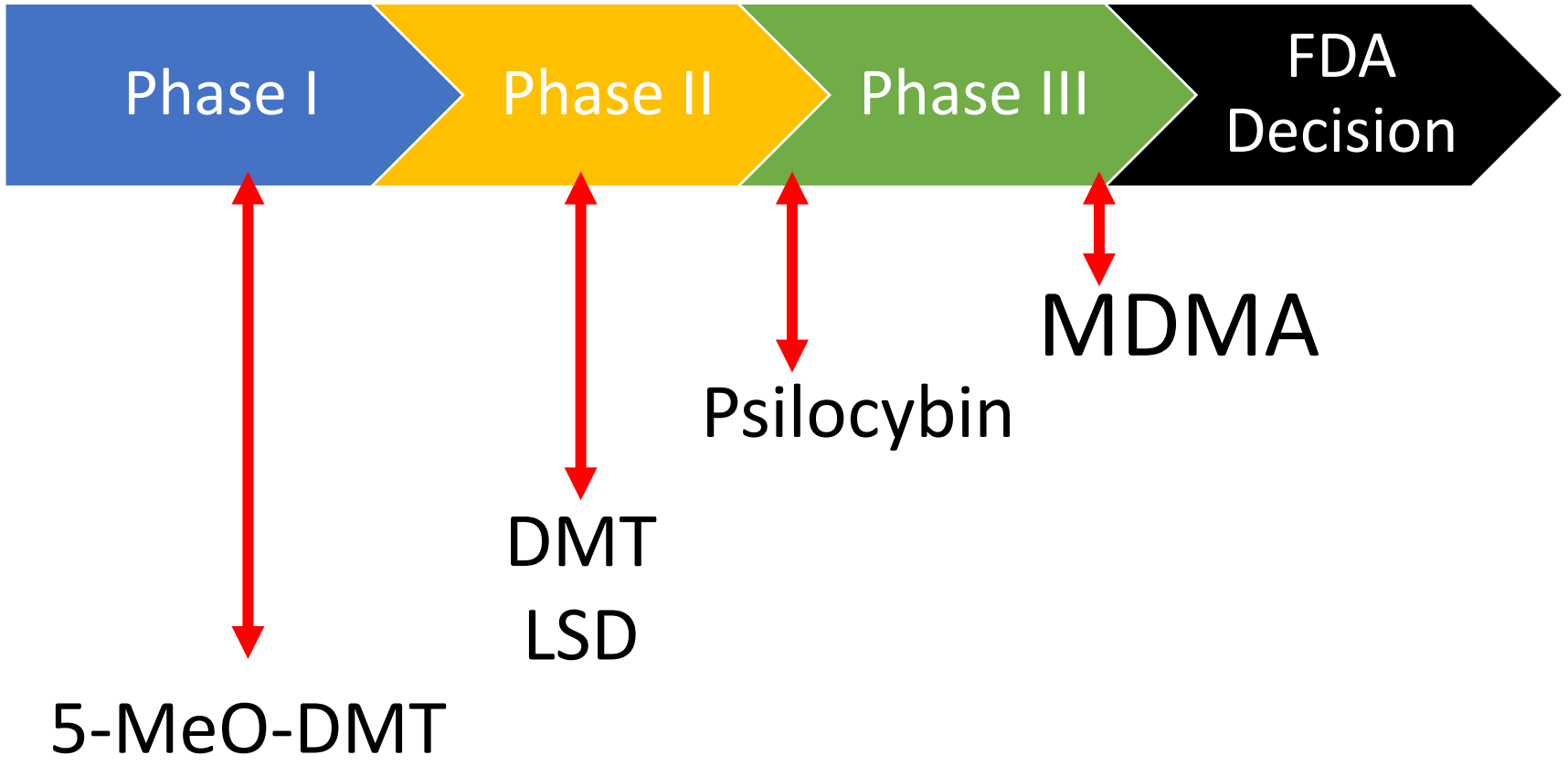


FIGURE FROM: Mitchell JM et al. *Nat Med*. 2021;27(6):1025-1033. ; MDMA-Assisted Psychotherapy Treatment Manual v.8. 25 May 2016

Progression toward FDA Decision for Medical Use

The FDA accepted a new drug application (NDA) for 3,4-Methylenedioxy-methamphetamine (MDMA) to be used in combination with psychological interventions, including psychotherapy and other supportive services from a health care provider, for individuals with posttraumatic stress disorder (PTSD). The agency has also granted priority review to the NDA and assigned a prescription drug user fee act target action date of August 11, 2024.

Progression toward FDA Decision for Medical Use



FDA Draft Guidance for Research Studies with Psychedelics

Safety monitoring should include the following:

<u>Observation by two monitors for the duration of the treatment session</u>

A healthcare provider with graduate-level professional training and clinical experience in psychotherapy, licensed to practice independently, serving as the **lead monitor**.

An **assistant monitor** with a bachelor's degree and at least 1 year of clinical experience in a licensed mental healthcare setting.

Notable Adverse Effects in Psychedelic Trials

Elevated heart rate (15-20 bpm) and elevated blood pressure (+20-25/10-25 mmHg) in the first 60-90 minutes following psychedelic administration

Headache is common with classical psychedelics, often occurring after waning of psychoactive effects; treatable with acetaminophen 325 mg PO

Nausea is present for classical psychedelics in some individuals; vomiting is more common and pronounced with Ayahuasca

MDMA induces muscle tightness, decreased appetite, sweating, dizziness, chills

<u><1% of individuals: potentially risky disorientation or delayed / lingering psychological symptoms</u>

DATA FROM: Grob CS, et al., eds. *Handbook of Medical Hallucinogens*. The Guilford Press; 2021:413-448. Liechti ME. *Temperature (Austin)*. 2014;1(3):192-200. Carbonaro et al. J Psychopharmacol. 30(12): 1268–1278. 2016

Clinical Training, Accreditation, and Certification

Presently there is virtually no guidance on what appropriate clinical training looks like, or how it would be accredited

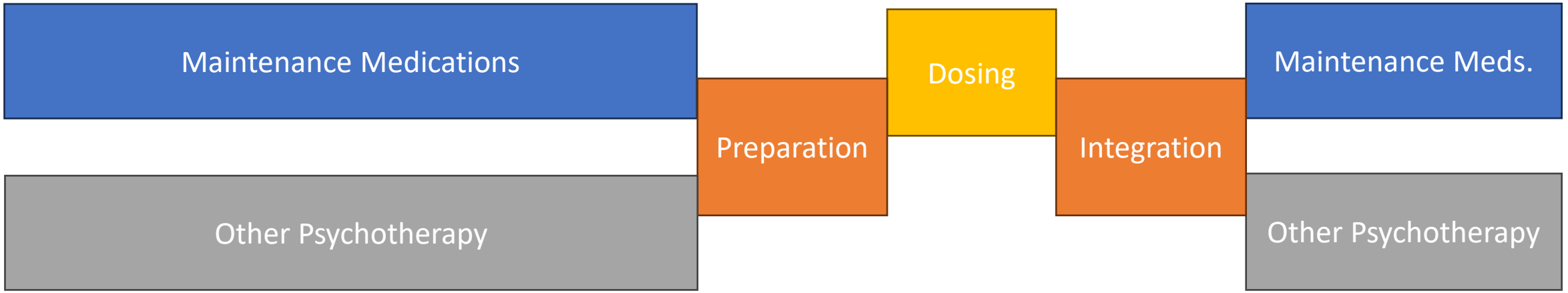
No current state or federal guidance on certification requirements or intersection with scope of practice

Existing billing models are adapting to accommodate new roles and activities (extended monitoring during dosing, for example: CPT 0820T, 0821T, 0822T)

UW-Madison has more than a decade of experience in psychedelic-assisted therapy delivery and world-leading expertise in psychedelic graduate education through our Transdisciplinary Center for Research in Psychoactive Substances.

We are excited to work with state regulators and licensing boards to create safe, effective, and equitable models for clinical training and delivery of care that will deliver needed certainty of quality to practitioners, payers, and patients

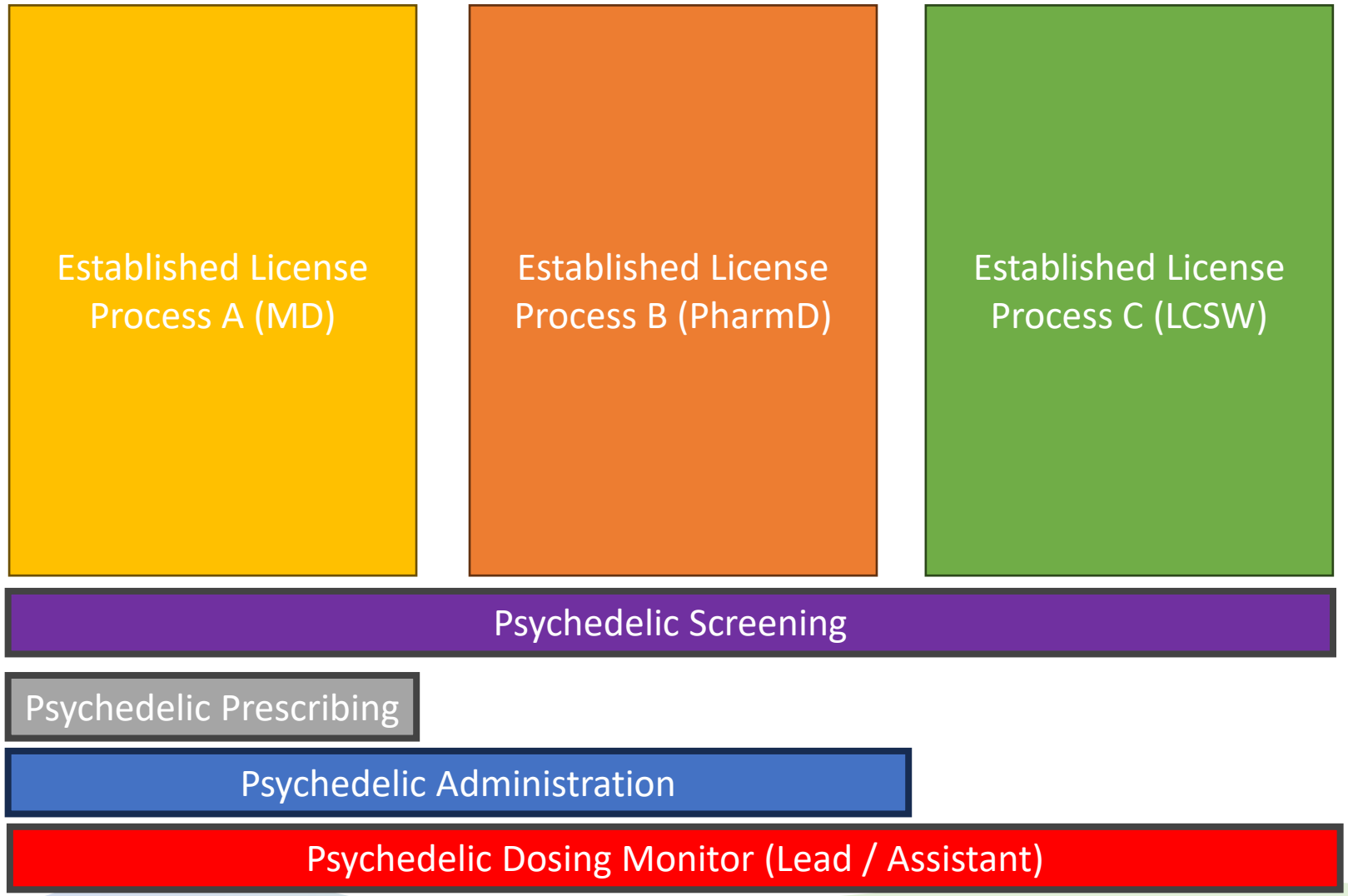
Psychedelic-Assisted Therapy and Coordination of Care



Many Roles to Manage: Prescribing, Tapering, Dispensing, Preparation, Administration, Integration, Maintenance
Multiple Providers: MD/DO, Psych NP, PharmD, PsyD, MSW / LCSW, LCPC / LMFT

Creating an effective model with proper oversight, coordination, delivery, and follow-up will likely require input from multiple professions, perhaps through creation of a focused workgroup across relevant licensing boards

Creating Clear Practice Activities Under Existing Licenses



Pharmacy Practice Impacts and Opportunities

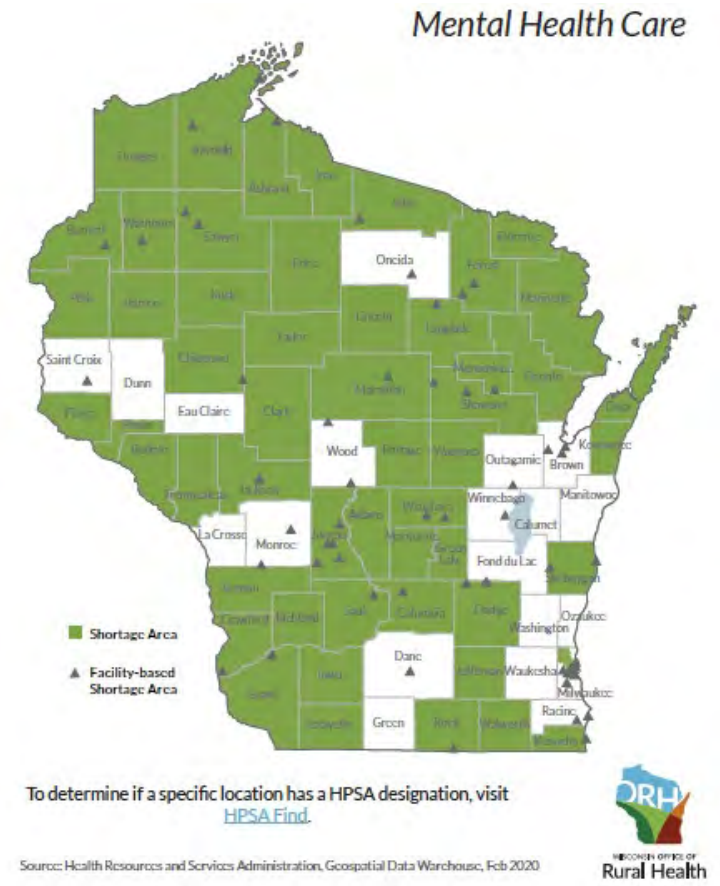
Existing activities provided under WI Statues 450.01 (16) (a-j) “Practice of Pharmacy” are directly applicable to MDMA, Psilocybin, etc. in the event of FDA approval

Opportunities to define appropriate training for pharmacist administration of prescribed psychedelics, analogous to injectables or vaccines, under (450.035 (1r) / (2) *“ …a course of study and training in administration technique conducted by a course provider approved by [ACPE] or the board… A pharmacist who administers a prescribed drug product or device under this subsection shall comply with the requirements and procedures established in rules promulgated by the board…”*

Pharmacist service as a provider for purposes of monitoring appears straightforward under (450.033), services delegated by physician. ”*A pharmacist may perform any patient care service delegated to the pharmacist by a physician...”*

Additional rulemaking might be considered under 450.02 (3)(a) *“The board may promulgate rules relating to the distribution and dispensing of prescription drugs”* and pharmacy pilot programs (such as in-pharmacy administration for Mental Health Care Facility shortage areas) may be authorized by the board via (450.02)(3r).

<u>Supporting pharmacist administration and monitoring during psychedelic-assisted therapy will enhance access to real-time drug safety expertise and improve care equity</u>



Take-Home Messages

Hundreds of thousands of Americans are dying every year from mental health issues

Psychedelic-assisted therapy trials confirm safety and have shown positive efficacy data for treating mental illnesses like end-of-life anxiety, PTSD, depression, and substance misuse

MDMA-assisted therapy is scheduled for review by FDA on Aug 11th, 2024

Creating accountability mechanisms to minimize risks and harms is critical for licensure and regulatory agency roles when considering psychedelic use impacts to the public at large

Licensure processes that acknowledge and support multiple interconnected roles in psychedelic delivery to maximize safety and yield equitable therapeutic outcomes across populations

Proactive support of pharmacists to facilitate effective and safe delivery of psychedelic-assisted therapies through their full scope of practice could help overcome barriers to effective mental healthcare access in many areas of Wisconsin

Questions and Discussion

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request: **Nilajah Hardin** **Administrative Rules Coordinator**		2) Date when request submitted: **04/12/24** 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: Pharmacy Examining Board		
4) Meeting Date: **04/25/24**	5) Attachments: ☒ Yes ☐ No	6) How should the item be titled on the agenda page? **Administrative Rule Matters – Discussion and Consideration** **1. Adoption Order: Phar 18, Relating to Licensure of Third-Party Logistics Provider** **2. Preliminary Rule Draft: Phar 15, Relating to Pharmaceutical Compounding** **3. Scope Statement: Phar 7, Relating to Electronic Prescriptions, Prescription Labeling, CPR for Pharmacists, Epinephrine Delivery Systems, Controlled Substances Prescription Transfers, Remote Dispensing, and Definition of Managing Pharmacist** **4. Pending or Possible Rulemaking Projects**
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 ☒ No	9) Name of Case Advisor(s), if required: **N/A**
10) Describe the issue and action that should be addressed: Attachments: 1. Phar 18 Adoption Order 2. Phar 15 Preliminary Rule Draft 3. Phar 7 Scope Statement 4. Rule Projects Chart Copies of current Board Rule Projects Can be Viewed Here: https://dsps.wi.gov/Pages/RulesStatutes/PendingRules.aspx		
11) Authorization Nilajah D. Hardin — Signature of person making this request 04/12/24 — Date Supervisor (if required) — Date Executive Director signature (indicates approval to add post agenda deadline item to agenda) — Date		
Directions for including supporting documents: 1. This form should be attached to any documents submitted to the agenda. 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.		

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD	:	ORDER OF THE PHARMACY EXAMINING BOARD ADOPTING RULES (CLEARINGHOUSE RULE 23-031)

ORDER

An order of the Pharmacy Examining Board to create Phar 18, relating to licensure of third-party logistics providers.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 450.075 (4), Stats.

Statutory authority: ss. 15.08 (5) (b), 450.02 (3) (a), 450.02 (3) (d), and 450.075 (4), Stats.

Explanation of agency authority:
Section 15.08 (5) (b), Stats. states that "The Board shall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains, and define and enforce professional conduct and unethical practices not inconsistent with the law relating to the particular trade or profession."

Section 450.02 (3) (a), Stats. Authorizes the board to "promulgate rules relating to the manufacture of drugs and the distribution and dispensing of prescription drugs."

Section 450.02 (3) (d), Stats. provides that the board "may promulgate rules necessary for the administration and enforcement of this chapter and Ch. 961."

Section 450.075 (4), Stats. says: "The board shall promulgate rules implementing this section. The rules shall ensure compliance with the federal drug supply chain security act, 21 USC 360eee, et seq. The board may not promulgate rules that impose requirements more strict than the federal drug supply chain security act or any regulations passed under the federal drug supply chain security act. The board may not promulgate rules that require a license under this section."

Related statute or rule: Wisconsin Administrative Code Chapter Phar 18

Plain language analysis: The object of the proposed rule is to implement the statutory changes from 2021 Wisconsin Act 25. This was accomplished by creating chapter Phar 18, entitled Third-Party Logistics providers, a new chapter in the Wisconsin Administrative Code that outlines requirements for a new optional state license.

Summary of, and comparison with, existing or proposed federal regulation: 21 U.S. Code s. 360eee includes national standards for third-party logistics providers. These standards include guidelines for a federal licensure program issued by the Secretary of the U.S. Department of Health and Human Services. This section also includes clarifications for those states that have a licensure program. Third-party logistics providers must either be licensed at the state level, if such a licensure program exists, or federally. On February 4, 2022, the U.S. Food and Drug Administration announced a proposed rule in National Standards for Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers. This rule has not been finalized yet.

Comparison with rules in adjacent states:
Illinois: The Illinois Department of Financial and Professional Regulation is responsible for the licensure and regulation of wholesale distribution in Illinois, with input from the Illinois Board of Pharmacy. The Illinois Wholesale Distribution Act contains requirements for licensure of resident and non-resident third-party logistics providers. In addition to obtaining licensure, each third-party logistics provider must also submit the information of a designated representative responsible for operations at each site [225 Illinois Complied Statutes ch. 120 s. 25.5].

Iowa: The Iowa Board of Pharmacy is responsible for the licensure and regulation of Pharmacy practice in Iowa. The Iowa Pharmacy Practice Act rules are contained in the Iowa Administrative Code and include requirements for licensure of third-party logistics providers. In addition to obtaining licensure, each third-party logistics provider must also submit the information of a facility manager responsible for operations at each site [657 Iowa Administrative Code ch. 43].

Michigan: The Michigan Board of Pharmacy is responsible for the licensure and regulation of pharmacy practice in Michigan. Act 368 Article 15 Part 177 of the Michigan Compiled Laws includes the regulations for wholesale distribution in Michigan, among several other occupations. Wholesale distributor-brokers serve the same function as third-party logistics providers. In Michigan, wholesale distributor-brokers are required to be licensed and must designate a facility manager or pharmacist-in-charge to be responsible for each site [Michigan Compiled Laws s. 333.17748].

Minnesota: The Minnesota Board of Pharmacy is responsible for the licensure and regulation of pharmacy practice and wholesale distribution in Minnesota. Chapter 151 of the Minnesota Statutes, or the Pharmacy Practice and Wholesale Distribution Act, also includes licensure requirements for third-party logistics providers. In Minnesota, the facility manager or designated representative responsible for each third-party logistic provider license cannot have any felony convictions relating to wholesale distribution and must be fingerprinted as authorized by the Minnesota Board. [Minnesota Statutes s. 151.471].

Summary of factual data and analytical methodologies:
The Board reviewed the statutory changes from 2021 Wisconsin Act 25 and added to the Wisconsin Administrative Code accordingly.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:
The rule was posted for 14 days on the Department of Safety and Professional Services website to solicit economic impact comments, including how the proposed rules may affect businesses, local municipalities, and private citizens. No comments were received.

Fiscal Estimate and Economic Impact Analysis:
The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:
These rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-2112.

Agency contact person:

Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8366; telephone 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

TEXT OF RULE

SECTION 1. Chapter Phar 18 is created to read:

CHAPTER PHAR 18
THIRD-PARTY LOGISTICS PROVIDERS

Phar 18.01 Authority and Applicability.(1) The rules in this chapter are adopted pursuant to the authority delegated by ss. 15.08 (5) (b), 450.02 (3), and 450.075 (4), Stats. **(2)** Pursuant to s. 450.075 (7) (b), the rules in this chapter only apply if the Pharmacy Examining Board makes a determination on a biennial basis, that continued licensure by this state of third-party logistics providers is required.

Phar 18.02 Definitions. In this chapter:

(1) "Designated representative" means an individual who functions on behalf of a third-party logistics provider or an out-of-state third-party logistic provider as specified in Phar 18.05.

(2) "Facility" has the meaning given in s. 450.01 (11m), Stats.

(3) "Out-of-state third-party logistics provider" has the meaning given s. 450.01 (13w), Stats.

(4) "Third-party logistics provider" has the meaning given in s. 450.01 (21s), Stats.

Phar 18.03 Licensure, Renewal, and Reinstatement.

(1) LICENSE ALLOWED. A person acting as a third-party logistics provider or an out-of-state third-party logistics provider of any drug or device may apply to obtain a license from the board.

(2) LICENSURE. Except as provided under Phar 18.03 (4), the board shall grant a license to operate as a third-party logistics provider or out-of-state third-party logistics provider, to any applicant that satisfies all of the following requirements, as determined by the Board:

(a) Submits a completed application form.

Note: Application forms are available from the department of safety and professional services' website at http://dsps.wi.gov.

(b) Pays the fee specified in s. 440.05, Stats.

(c) Submits all of the following information relating to a designated representative:

1. Name, address, and telephone number.
2. Date and place of birth.
3. A photograph of the person taken within the 12-month period immediately preceding the date of the application.
4. A personal information statement that includes all of the following for the 7-year period immediately preceding the application:
   a. Place of residence.
   b. Occupations, positions of employment, and offices held.
   c. The name and addresses for each business, corporation or entity listed in subpar b.
   d. Whether the person has been the subject of any proceeding for the revocation of any business or professional licensure and the disposition of that proceeding.
   e. Whether the person has been enjoined by a court, either temporarily or permanently, from possessing, controlling, or distributing any prescription drug, and a description of the circumstances surrounding the injunction.
   f. A description of any involvement with any business, including investments other than the ownership of stock in a publicly traded company or mutual fund, that manufactured, administered, prescribed, distributed, or stored pharmaceutical products or drugs, and list of any lawsuits in which such a business was named as a party.

5. A description of any misdemeanor or felony criminal offense of which the person was, as an adult, found guilty, whether adjudication of guilt was withheld, or the person pleaded guilty or no contest. If the person is appealing a criminal conviction, the application shall include a copy of the notice of appeal, and the person shall submit a copy of the final disposition of the appeal not more than 15 days after a final disposition is reached.

6. Verification that the requirements in Phar 18.05 (1) have been met.

7. A statement that each facility used by the applicant for third-party logistics provider services has been inspected in the 3-year period immediately preceding the date of the application by the board, a pharmacy examining board of another state, the National Association of Boards of Pharmacy, or another accrediting body recognized by the board, with the date of each such inspection.

(d) Subject to ss. 111.321, 111.322, and 111.335, Stats., the applicant does not have an arrest or conviction record.

(e) Where operations are conducted at more than one facility, a person acting as a third-party logistics provider or out-of-state logistics provider may apply for a license for each such facility.

(3) RENEWAL. **(a)** Each licensee may elect to renew biennially. Renewal is required to maintain a license issued under this chapter. The renewal date and fee are specified by s. 440.08 (2), Stats.

(b) Every even-numbered year, each licensee shall complete a renewal application and return it with the required fee prior to July 1 of that year.

Note: Instructions for renewal applications can be found on the department of safety and professional services' website at http://dsps.wi.gov.

(4) REINSTATEMENT. A licensee who has unmet disciplinary requirements and failed to renew the license within 5 years or whose license has been surrendered or revoked may apply to have the license reinstated in accordance with all of the following:

(a) Evidence of completion of the requirements in Phar 18.03 (2) if the license has not been active within 5 years.

(b) Evidence of completion of disciplinary requirements, if applicable.

(c) Evidence of rehabilitation or change in circumstances warranting reinstatement.

Phar 18.04 Inspections. Pursuant to s. 450.075 (6), a third-party logistics provider or out-of-state third-party logistics provider regardless of licensure status shall permit the board or its authorized representatives and authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law. Such officials shall be required to show appropriate identification prior to being permitted access to the third-party logistics provider or out-of-state third-party logistics provider's premises and delivery vehicles.

Phar 18.05 Responsible Persons. (1) DESIGNATED REPRESENTATIVE. The individual acting as the designated representative for a third-party logistics provider or an out-of-state third-party logistics provider shall meet all of the following requirements:

(a) Is at least 21 years old.

(b) Has been employed full-time for at least three years in a pharmacy or with a wholesale prescription drug distributor in a capacity related to the dispensing of and distribution of, and recordkeeping related to, prescription drugs.

(c) Is employed full-time in a managerial position.

(d) Is physically present at the third-party logistics provider's or out-of-state third-party logistics provider's facility during regular business hours. This subsection does not preclude the person from taking authorized sick leave and vacation time or from being absent from the facility for other authorized business or personal purposes.

(e) Is actively involved in and aware of the daily operation of the third-party logistics provider or the out-of-state third-party logistics provider.

(f) Is a designated representative for only one applicant at any given time. This subsection does not apply if more than one third-party logistics provider or out-of-state third-party logistics provider is located at the facility and the third-party logistics provider or out-of-state third-party logistics providers located at the facility are members of an affiliated group.

(g) Has not been convicted of violating any federal, state, or local law relating to distribution of a controlled substance.

(h) Has not been convicted of a felony.

(i) Submits to the department 2 fingerprint cards, each bearing a complete set of the person's fingerprints. The department of justice shall provide for the submission of the fingerprint cards to the federal bureau of investigation for purposes of verifying the identity of the person and obtaining the person's criminal arrest and conviction record.

(2) OFFICERS, DIRECTORS AND MANAGERS. A third-party logistics provider or out-of-state third-party logistics provider licensed under this chapter shall maintain a list of officers, directors, and managers, including a description of their duties and a summary of their qualifications.

Phar 18.06 Facility and Storage Requirements. All facilities licensed as third-party logistics providers or out-of-state third-party logistics providers shall:

(1) Maintain access to warehouse space of suitable size to facilitate safe operations, including a suitable area to quarantine suspect product.

(2) Have written policies and procedures to:

(a) Address receipt, security, storage, inventory, shipment, and distribution of a product.

(b) Identify, record, and report confirmed losses or thefts.

(c) Correct errors and inaccuracies in inventories.

(d) Provide support for manufacturer recalls.

(e) Prepare for, protect against, and address any reasonably foreseeable crisis that affects security or operation at the facility, such as a strike, fire, or flood.

(f) Ensure that any expired product is segregated from other products and returned to the manufacturer or repackager or destroyed.

(g) Maintain the capability to trace the receipt and outbound distribution of a product, and supplies and records of inventory.

(h) Quarantine or destroy a suspect product if directed to do so by the respective manufacturer, wholesale distributor, dispenser, or an authorized government agency.

Phar 18.07 Security Requirements. All facilities shall require the following:

(1) Access from outside the premises is kept to a minimum and is well controlled.

(2) The outside perimeter of the premises is well lighted.

(3) Entry into areas where prescription drugs are held is limited to authorized personnel.

(4) An alarm system is maintained to detect entry after hours.

(5) A security system is maintained that will provide suitable protection against theft and diversion, including, when appropriate, a system that provides protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

Phar 18.08 Compliance. A third-party logistics provider or an out-of-state third-party logistics provider who elects to be licensed under this chapter and fails to comply with all applicable federal and state laws and regulations may be subject to disciplinary action by the board under s. 450.10, Stats.

SECTION 2. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

Dated _____ Agency _____

Chairperson
Pharmacy Examining Board

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD	:	PROPOSED ORDER OF THE PHARMACY EXAMINING BOARD ADOPTING RULES (CLEARINGHOUSE RULE)

PROPOSED ORDER

An order of the Pharmacy Examining Board to repeal and recreate chapter Phar 15, relating to Compounding Pharmaceuticals.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 450.01 (16), Stats.

Statutory authority: ss. 15.08 (5) (b), and 450.02 (3) (d) and (e), Stats.

Explanation of agency authority:
Section 15.08 (5) (b), Stats. states that "The Board shall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains, and define and enforce professional conduct and unethical practices not inconsistent with the law relating to the particular trade or profession."

Section 450.02 (3) (d), Stats. says that the board "may promulgate rules necessary for the administration and enforcement of this chapter and ch. 961."

Section 450.02 (3) (e), Stats. provides that the board "may promulgate rules establishing minimum standards for the practice of pharmacy."

Related statute or rule: N/A

Plain language analysis:
The Pharmacy Examining Board recently completed a revision to Wisconsin Administrative Code Chapter Phar 15 which became effective on August 1, 2022. The objective of this rule is to repeal and recreate the recent version of Phar 15 to incorporate by reference United States Pharmaceopeia (USP) General Chapters 795 and 797, published on November 1, 2022. The Board will also be incorporating USP General Chapter 800, published on December 1, 2019, as well as USP General Chapter 825, published on December 1, 2020.

Summary of, and comparison with, existing or proposed federal regulation:
The practice of pharmacy is not regulated by the federal government and Wisconsin has its own controlled substances schedules. However, the federal government does regulate federally controlled substances and the vast majority of Wisconsin controlled substances are also federally controlled substances. Title 21 CFR Chapter II governs federally scheduled controlled substances, including: registration of manufacturers, distributors and dispensers of controlled substances; prescriptions; orders for schedule I and II controlled substances; requirements for electronic orders and prescriptions; and disposal.The states are primarily responsible for the oversight of compounding in pharmacies. Pursuant to the Drug Quality and Security Act, the federal government is responsible for outsourcing facilities, which by definition are not pharmacies, and are subject to current good manufacturing practice requirements, labeling requirements and may distribute compounded drugs in response to an order that is not patient specific. The Food, Drug and Cosmetic Act requires drugs to be prepared, packed or held under sanitary conditions.

Summary of public comments received on statement of scope and a description of how and to what extent those comments and feedback were taken into account in drafting the proposed rule: N/A

Comparison with rules in adjacent states:
Illinois: For patient-specific prescriptions, sterile and unsterile pharmaceutical compounding is governed by the USP 42-NF 37 from the 2019 USP Compounding Compendium, except for USP Chapter 800. Additionally, all pharmacies that compound drugs must maintain a set of minimum standards and equipment. These requirements include a specific area for compounding materials, accurate scales or measuring equipment, a separate area for compounding, a record keeping system for tracking compounded drugs, drug distribution procedures, and labelling. Additional requirements for sterile compounding include current reference materials, pharmacist availability at all times to answer patient and health care professional questions, and emergency medications for adverse drug reactions to compounded sterile drugs. [Illinois Administrative Code s. 1330.640]. In Illinois, the definition of “compounding” excludes flavorings [225 Illinois Compiled Statutes 85 s. 3 (o)].

Iowa: Iowa requires compliance with the current revisions of USP Chapters 795 and 797. Additionally, Iowa includes requirements for the use of flavoring agents. These requirements include that pharmacist may add flavoring in the amount of not more than percent of the total volume of the drug. The beyond-use date of the flavored drug must be no greater than 14 days and the pharmacist must document that a flavoring agent was added ot a drug. Compliance with USP Chapter 825 is not required, however Iowa does have its own rules for radiopharmaceuticals and nuclear pharmacy [Iowa Administrative Code ss.657.16 and 657.20].

Michigan: Michigan requires a pharmacy that provides compounding services to be licensed as a pharmacy and authorized to provide compounding services. The pharmacy must be accredited through a national accrediting organization and be in compliance with USP standards [Michigan Compiled Laws s. 333.17748a to c]. In Michigan, the definition of "compounding" does not include flavoring agents that are nonallergenic, inert, and not more than 5% of the drug's total volume [Michigan Administrative Rules R 338.501 (1) (e)].

Minnesota: Minnesota requires pharmacies compounding nonsterile drug preparations to follow USP chapter 795 standards. Pharmacies compounding sterile drug preparations are required to follow USP chapter 797 standards. [Minnesota Administrative Rules s.6800.3300]

Summary of factual data and analytical methodologies: In addition to the four adjacent states listed above, the Pharmacy Examining Board also reviewed statutes and regulations regarding compounding pharmaceuticals from other states including Arizona, California, Colorado, Connecticut, Idaho, Kentucky, Lousiana, Massachusetts, Mississippi, Missouri, Nebraska, New Hampshire, New Jersey, North Carolina, Ohio, Pennsylvania, South Carolina, South Dakota, Texas, Utah, West Virginia, and Wyoming.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:
The rule will be posted for 14 days on the Department of Safety and Professional Services website to solicit economic impact comments, including how the proposed rules may affect businesses, local municipalities, and private citizens.

Fiscal Estimate and Economic Impact Analysis:
The Fiscal Estimate and Economic Impact Analysis will be attached upon completion.

Effect on small business:
These rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-6795.

Agency contact person:
Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8366; telephone 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:
Comments may be submitted to Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received on or before the public hearing, held on a date to be determined, to be included in the record of rule-making proceedings.

TEXT OF RULE

Section 1. Chapter Phar 15 is repealed and recreated to read:

Chapter Phar 15
PHARMACEUTICAL COMPOUNDING, SAFE HANDLING OF HAZARDOUS DRUGS, AND RADIOPHARMACEUTICALS

Phar 15.01 Definitions. In this chapter:
(1) "USP-NF" means the United States Pharmacopeia-National Formulary published by the United States Pharmacopeial Convention.

Phar 15.02 Incorporation of Standards. (1) PHARMACEUTICAL COMPOUNDING - NONSTERILE PREPARATIONS. USP-NF general chapter 795, official as of November 1, 2023, is incorporated by reference into this chapter, subject to the exception that nonsterile compounding does not include the addition of nonallergenic, therapeutically inert flavoring agents to a conventionally manufactured drug product. The pharmacist shall also comply with the following requirements when adding flavoring agents to a drug product:

(a) The pharmacist shall ensure that the flavoring agent is not more than 5 percent of the product's total volume.

(b) The pharmacist shall label the flavored prescription with a beyond-use-date that shall be no longer than fourteen days if stored in a refrigerator unless otherwise documented.

(c) The pharmacist shall document the addition of flavoring as part of the prescription record. The documentation shall include the type of flavoring agent, manufacturer, lot number, and expiration date.

(d) A prescription is required before a pharmacist may add flavoring to an over-the-counter product.

(2) PHARMACEUTICAL COMPOUNDING - STERILE PREPARATIONS. USP-NF general chapter 797, official as of November 1, 2023, is incorporated by reference into this chapter.
(3) SAFE HANDLING OF HAZARDOUS DRUGS. USP-NF general chapter 800, official as of July 1, 2020, is incorporated by reference into this chapter.
(4) RADIOPHARMACEUTICALS. USP-NF general chapter 825, official as of January 1, 2024, is incorporated by reference into this chapter.

Note: Copies of the above standards are on file in the office of the legislative reference bureau. A copy of the USP-NF can be purchased from the United States Pharmacopeial Convention at https://usp.org.

Phar 15.03 Compliance. Noncompliance with ch. Phar 15 may be considered a violation of s. Phar 10.03 and may result in disciplinary action by the Board against a credential holder.

SECTION 2. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

STATEMENT OF SCOPE

PHARMACY EXAMINING BOARD

Rule No.: Phar 7

Relating to: Electronic Prescriptions, Prescription Labeling, CPR for Pharmacists, Epinephrine Delivery Systems, Controlled Substance Prescription Transfers, Remote Dispensing, and Managing Pharmacist Definition.

Rule Type: Permanent

1. Finding/nature of emergency (Emergency Rule only): N/A

2. Detailed description of the objective of the proposed rule: The objective of the proposed rule is to update requirements in Wisconsin Administrative Code Phar 7 to align with current pharmacy practice in the areas of electronic prescriptions, prescription labelling, CPR for pharmacists, controlled substance prescription transfers, remote dispensing, and the definition of a managing pharmacist. Additionally, the rule will implement the statutory changes from 2023 Wisconsin Act 27 by updating requirements for epinephrine delivery systems.

3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:
Wisconsin Administrative Code Phar 7 includes requirements for the practice of pharmacy. These requirements have the potential to become outdated on a regular basis. If the Board does not make regular updates via the permanent rules process, there will be inconsistencies between current pharmacy practice and what is required in the Wisconsin Administrative Code. This project will ensure that the Wisconsin Administrative Code continues to be current in the practice areas listed above.

4. Detailed explanation of statutory authority for the rule (including the statutory citation and language):
15.08 (5) (b), Stats., states that the Board "shall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains, and define and enforce professional conduct and unethical practices not inconsistent with the law relating to the particular trade or profession."

450.02 (2), Stats., states that "the Board shall promulgate rules that do all of the following:
(a) The board shall adopt rules defining the active practice of pharmacy. The rules shall apply to all applicants for licensure under s. 450.05.
(b) Define the activities that constitute the practice of a pharmacy technician for purposes if the registration requirement under s. 450.68."

450.02 (3) (a), Stats., states "[t]he Board may promulgate rules relating to the manufacture of drugs and the distribution and dispensing of prescription drugs."

450.02 (3) (b), Stats., states "[t]he Board may promulgate rules establishing security standards for pharmacies."

450.02 (3) (d), Stats., states "[t]he Board may promulgate rules necessary for the administration and enforcement of this chapter and ch. 961."

450.02 (3) (e), Stats., states "[t]he Board may promulgate rules establishing minimum standards for the practice of pharmacy."

450.02 (5), Stats., states “[t]he Board may promulgate rules governing pharmacies that are operated as remote dispensing sites.”

5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule:
120 hours

6. List with description of all entities that may be affected by the proposed rule:
Licensed Pharmacies, Pharmacists, Manufacturers, and Distributors; Registered Pharmacy Technicians

7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule:
The practice of pharmacy is not regulated by the federal government and Wisconsin has its own controlled substances schedules. However, the federal government does regulate federally controlled substances and the vast majority of Wisconsin controlled substances are also federally controlled substances. Title 21 CFR Chapter II governs federally scheduled controlled substances, including: registration of manufacturers, distributors and dispensers of controlled substances; prescriptions; orders for schedule I and II controlled substances; requirements for electronic orders and prescriptions; and disposal.

8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):
None to minimal. It is not likely to have a significant economic impact on small businesses.

Contact Person: Nilajah Hardin, Administrative Rules Coordinator, (608) 267-7139

Approved for publication:

Authorized Signature

Date Submitted

Approved for implementation:

Authorized Signature

Date Submitted

Pharmacy Examining Board
Rule Projects (updated 04/12/24)

CH Rule Number	Scope Number	Scope Expiration Date	Code Chapter Affected	Relating Clause	Stage of Rule Process	Next Step
23-072 (EmR 2303)	052-22	12/27/2024	Phar 1, 5, 7, 10, and 19	Registration of Pharmacy Technicians	Legislative Review ; Emergency Rule Effective 02/03/23-05/01/24	Board Approval of Adoption Order at a Future Meeting
23-054 (EmR 2213)	053-22	12/27/2024	Phar 1, 5, 6, 7 and 8	Remote Dispensing	Legislative Review; Emergency Rule Effective 11/01/22-05/01/24	Board Approval of Adoption Order at a Future Meeting
Not Assigned Yet	Not Assigned Yet	TBD	Phar 7	Electronic Prescriptions, Prescription Labeling, CPR for Pharmacists, Epinephrine Delivery Systems, Controlled Substance Prescription Transfers, Remote Dispensing, and Definition of Managing Pharmacist	Updated Scope Statement Reviewed at 4/25/24 Meeting	Board Approval of Scope Statement for Publication and Submission to the Governor's Office for Review
23-015	102-21	05/01/2024	Phar 7 and 10	Consumer Disclosures	Effective on 05/1/24	N/A
Not Assigned Yet	044-23	01/10/2026	Phar 8	Controlled Substances Requirements	Updated Emergency Rule Reviewed by Rules Committee on 04/25/24	Drafting Preliminary Permanent Rule
Not Assigned Yet	007-23	07/23/2025	Phar 15	Compounding Pharmaceuticals	Review of Updated Preliminary Rule Draft at 04/25/24 Meeting	Board Approval of Permanent Preliminary Rule Draft for Posting for EIA Comment and Submission to Clearinghouse for Review
23-031	097-21	04/18/2024	Phar 18	Third Party Logistics Providers	Board Review of Adoption Order at 04/25/24 Meeting	Submission for Publication; Anticipated Effective date of 07/01/24