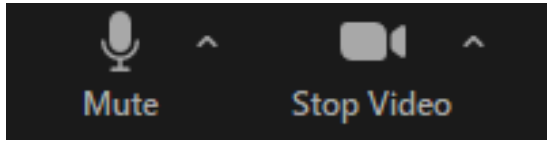
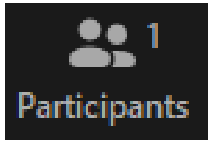
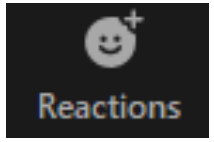
Psychedelic Medicine Task Force

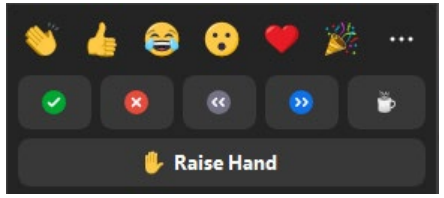
Welcome Psychedelic Medicine Task Force members!

Please use this time to test your Zoom meeting controls located at the bottom of the screen:









Access **Mural** via the link sent to you in your meeting invitation. Only members have access to this shared workspace. Once on the site, minimize the screen for later use during the meeting.

Task Force staff

MDH staff

- **Kari Gloppen**, Epidemiologist Supervisor, Injury and Violence Prevention Section
- **Dr. Caroline Johnson**, Psychedelic Medicine Scientific Researcher

Task Force leadership

- Dr. Jessica Nielson, Chair
- Bennett Hartz, Vice-Chair
- Paula DeSanto, Work Group Chair

MAD staff

- Jessica Burke, Senior Management Consultant
- Nick Kor, Senior Management Consultant
- Stacy Sjogren, Senior Management Consultant

Welcome meeting observers

Thank you for your interest in the work of the

Psychedelic Medicine Task Force!

This meeting will not be recorded. **Minutes will be posted on the task force's website** along with other materials for this meeting:

https://www.health.state.mn.us/people/psychmed/index.html

health.psychedelicmemedicine@state.mn.us

Legislative charge

The Psychedelic Medicine Task Force was established to advise the legislature on the legal, medical, and policy issues associated with the legalization of psychedelic medicine in the state. For purposes of this work, “psychedelic medicine” means MDMA, psilocybin, and LSD.

Task force duties

as outlined in legislation (Subd. 5.)

Scientific Research

1. Survey existing studies in the scientific literature on the therapeutic **efficacy** of psychedelic medicine in the treatment of mental health conditions, including depression, anxiety, post-traumatic stress disorder, bipolar disorder, and **any other mental health conditions and medical conditions** for which a psychedelic medicine may provide an **effective** treatment option.
2. Compare the efficacy of psychedelic medicine in treating the conditions described [above] with the efficacy of treatments currently used for these conditions.

Duties

Develop a comprehensive plan that covers:

1. statutory changes necessary for the legalization of psychedelic medicine.

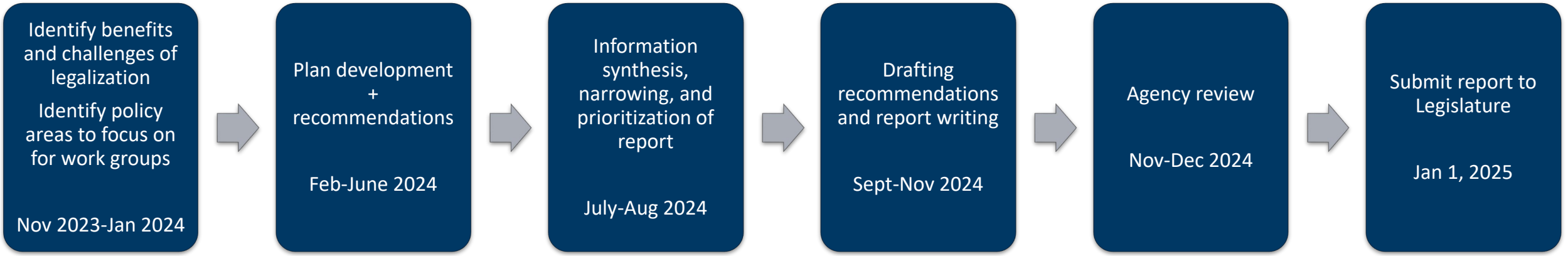
2. state and local regulation of psychedelic medicine

3. federal law, policy, and regulation of psychedelic medicine, with a focus on retaining state autonomy to act without conflicting with federal law, including methods to resolve conflicts.

    - Such as seeking an administrative exemption to the federal Controlled Substances Act under United States Code, title 21, section 822(d), and Code of Federal Regulations, title 21, part 1307.03; seeking a judicially created exemption to the federal Controlled Substances Act; petitioning the United States Attorney General to establish a research program under United States Code, title 21, section 872(e); using the Food and Drug Administration's expanded access program; and using authority under the federal Right to Try Act

4. Education of the public on recommendations made to the legislature and others about necessary and appropriate actions related to the legalization of psychedelic medicine in the state.

Work cadence



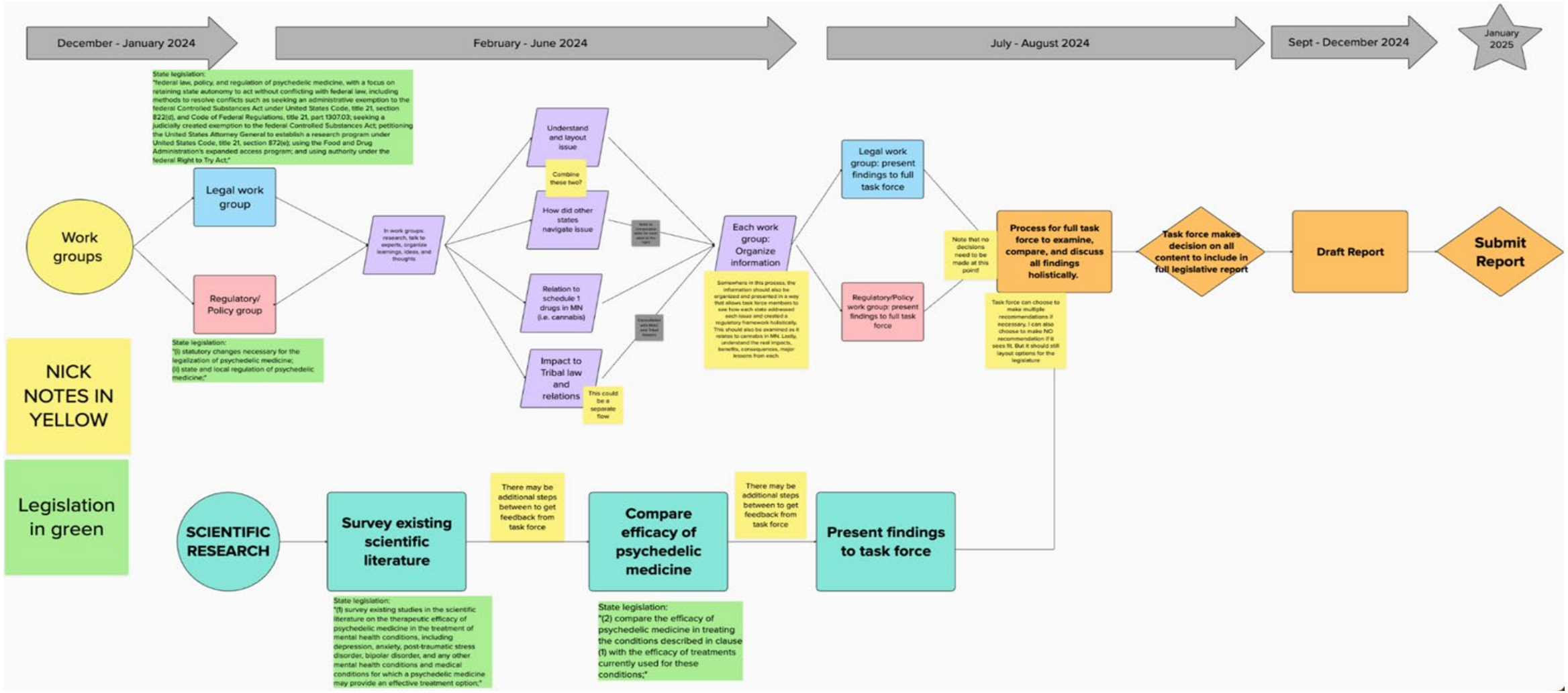
Today’s agenda

- Approve August meeting summary
- Share member-collected feedback
- Decision preparation
- Voting on recommendations
- Task Force report development update

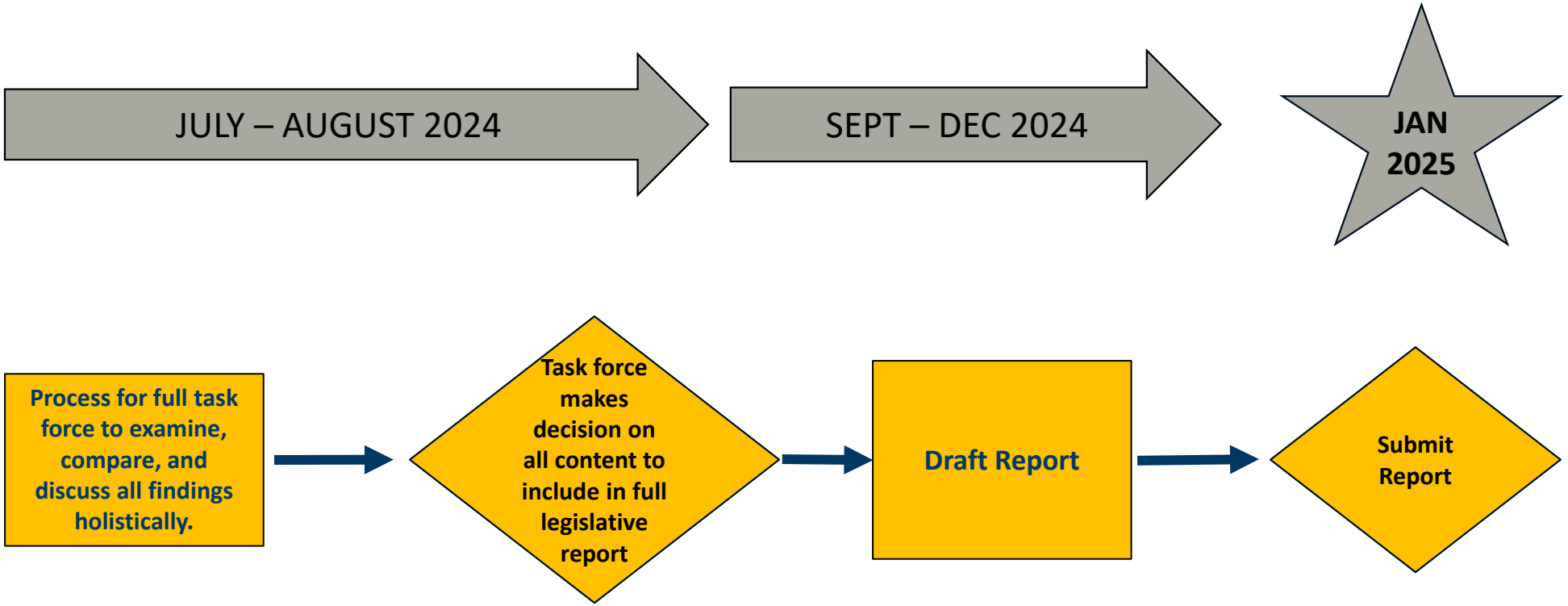
Task Force Status Update – September 2024

Dr. Jessica Nielson | Task Force Chair

Timeline: decision flow chart



Timeline: decision flow chart



Summary of what we've learned

- December – brief introduction to clinical trials and how the Food and Drug Administration (FDA) approves new drugs, and special considerations for psychedelic clinical trials.
- January – learned from Robert Rush and Ismail Ali about the history of drug prohibition, the controlled substances act, "states as labs"
- February – learned from Mason Marks about federal laws and how what Oregon and Colorado are doing could run afoul of certain federal laws regarding data privacy and blending services with schedule 1 drugs into federally supported healthcare systems, noting that decriminalization is the simplest option to implement (e.g. legally, financially), with funding more clinical trials and education programs for the public are the most legal option under current federal law.
- March – learned about cultural genocide of plant medicines and practices from Christine Diindiisi McCleave and Tribal consultation, and ethical guidelines for businesses with psychedelics (lessons learned from Cannabis) from Ariel Clark.

Summary of what we've learned

- April – we learned from Shane Pennington about how state regulated medical programs may help build support for the US Department of Health & Human Services (HHS) to recommend federally rescheduling psilocybin but may delay/limit access for Minnesota; and Caroline Johnson presented clinical trial results with LSD.

- May – we learned from a panel (Mason Marks, Jason Ortiz, Emma Knighton, Dominque Mendiola) about regulating for equity, criminal justice reform, community investment, and economic opportunity, decriminalization must come before/along with legalization (not after), lessons learned and growing pains out of Oregon and Colorado, including involving state licensing boards from the beginning, having more flexibility for allowed facilitation locations to help with accessibility and costs (e.g. home, outdoor use), barriers to access regarding cost for both facilitators (startup fees, tax code complications, licenses) and clients (limited accessibility, payment out of pocket, creates a tourist industry), and requiring the program to fund itself through licensing fees drives up implementation costs across the board; and Caroline Johnson presented clinical trial results with synthetic psilocybin.

- June – we learned from representatives from Lykos Therapeutics about the development of MDMA-AT and what the roll out might look like if FDA approved in August; and Caroline Johnson presented clinical trial results with MDMA.

Noteworthy updates that impact our work

- HHS modified the way they consider "accepted medical use" when making rescheduling recommendations to the Drug Enforcement Administration (DEA) - *recommended rescheduling cannabis to schedule III due to accepted medical use across many states, not because of FDA approval of a specific product.*

- Unfavorable review from external advisory panel for FDA regarding MDMA-AT for PTSD (voted against FDA approval) - *this is a recommendation and FDA isn't bound by their decision. FDA will make their final decision on August 11, 2024.*

- The Chevron Accord was overturned by the Supreme Court, which *may* enable more successful litigation of cases with the DEA around Right to Try (RTT) or religious use (RFRA) access for psychedelic medicines - *previous attempts for Controlled Substances Act (CSA) exemptions to access psilocybin under the RTT have been rejected due to deference to the DEA on whether RTT applies to schedule 1 drugs (they say no). Many churches have also been denied exemptions for similar restrictions with the CSA (with some successes).*

Final voting process review and discussion

DEPARTMENT OF HEALTH

Initial voting process review

- As discussed in the August task force meeting, *all* task force members, regardless of meeting attendance, will be able to vote. Jess will collect votes via email for absent members.
- Members can vote yes, no, or abstain. *Does the task force want to count any abstentions in the total to determine majority/supermajority? Or remove them as non-votes that will not affect the total of yes or no votes?*

Recommendation voting

Final voting on recommendations

- We will be voting via roll call today. There are six recommendations. Please be ready to unmute and cast your vote to help us move through everyone efficiently.
- Depending on when absent members vote, we may not know whether a recommendation passed by a supermajority or not at the meeting. Jess will report to the task force when all member votes have been recorded if that happens.
- There may be additional recommendations that come up in the report-writing process. If that happens, the task force will have an opportunity to vote on them.

Final vote

Broad recommendation 1

Removing criminal penalties for possession of personal use quantities of psychedelic medicines, and for non-commercial (without remuneration) cultivation and sharing of psilocybin-containing mushrooms.

- The Task Force recommends the Minnesota legislature remove criminal penalties for the possession of personal use quantities of mushrooms containing psilocybin, synthetic psilocybin, MDMA, and LSD.
- The Task Force recommends the Minnesota legislature remove criminal penalties for the non-commercial(without remuneration) cultivation and sharing of psilocybin-containing mushrooms.

Broad recommendation 2

Creating a state-regulated clinical program with psychedelic medicines in Minnesota.

- The task force recommends the Minnesota legislature create a state-regulated program for the clinical administration of synthetic MDMA, LSD and psilocybin.
- The task force recommends the Minnesota legislature create a state-regulated program for the clinical administration of psilocybin-containing mushrooms.

Broad recommendation 3

Appropriate funding for clinical research program for psychedelic medicines.

- The Task Force recommends the Minnesota legislature appropriate funding for clinical research regarding the health benefits and treatment of medical conditions through the administration of psilocybin, MDMA, and LSD.

Broad recommendation 4

Creating an adult regulated use program in Minnesota with psilocybin-containing mushrooms.

- The Task Force recommends the Minnesota legislature allow and regulate adult use of psilocybin-containing mushrooms.

Report writing update

Dr. Caroline Johnson | Psychedelic Medicine Scientific Researcher

Timeline

	August	September	October	November	December
At the meeting	Continue drafting and finalizing recommendations	Decide upon high-level recommendations to be included in final report	Discuss the draft, suggest edits, discuss additional recommendations	Discuss draft, edits, recommendations. Approve version to be submitted to MDH	Discuss any returned edits
Rest of month	Review recommendations, discuss with State agencies	Draft comprehensive version of the final report	Continue drafting and polishing report	Submit report to MDH for review of formatting, accessibility. Continue writing	Make final edits

Personal anecdotes

- Possibility for an appendix of personal anecdotes, experiences regarding psychedelic medicine
- Paragraph or so finished by mid-September

Writing process/Q&A

- Additional volunteers for writing? Reviewing?
- Other questions, comments

Work groups updates

- **Upcoming meetings**
  - Second and fourth Thursdays of each month, 4:00-5:00 pm
  - Members writing and reviewing recommendations can meet outside of work group meetings to work on their sections, as long as the number of meeting attendees is below quorum and no major decisions are made.

Next steps and adjournment

- **Opportunity for member feedback:** please leave your feedback in Mural.
- **Questions between meetings:** contact Jess Burke (jessica.burke@state.mn.us)
- Next meeting: Monday, September 9, 2024, 9:30 am – 12:30 pm