



Pathways to Healing

Opportunities for Providers and Patients in Colorado's State-Regulated Psychedelic Therapies Program

Speakers



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Psychedelic Overview:

Multiple Medicines & Pathways

FEDERALLY LEGAL WITH PRESCRIPTION

- Ketamine

STATE-LEGAL FOR SUPERVISED USE (CO & OR)

- Psilocybin and psilocin from mushrooms (“natural medicine”)

ILLEGAL OUTSIDE APPROVED RESEARCH

- Lysergic acid diethylamide (LSD)
- MDMA
- Other potential medications

DECRIMINALIZED FOR PERSONAL USE (CO)

- Psilocybin and psilocin
- Mescaline unless derived from peyote
- Ibogaine
- Dimethyltryptamine (DMT)



History of Research and Practice with Psychedelics

- Thousands of years of practice in Indigenous cultures: healing, spirituality, ceremony, rites of passage
- 1950's to 1970's
 - Over 1,000 studies with over 40,000 participants
 - Addiction, end of life anxiety, pain
- Halted in 1970 when Nixon classified psychedelics as Schedule I drugs
- 22-year gap in research
- 1994 – resurgence in investigating psychedelics for therapeutic purposes (psilocybin, LSD, MDMA)
- Hopkins, UCLA, NYU, Yale, Arizona, UCSF, UNM



Recent Psilocybin Research

- Studies at **leading medical institutions** show significant promise for depression, end of life anxiety and addiction
- FDA **breakthrough therapy** designation for treatment resistant depression and major depressive disorder
- Evidence of **durable effects** (months to years) following **one to three** high dose sessions, with supportive therapy



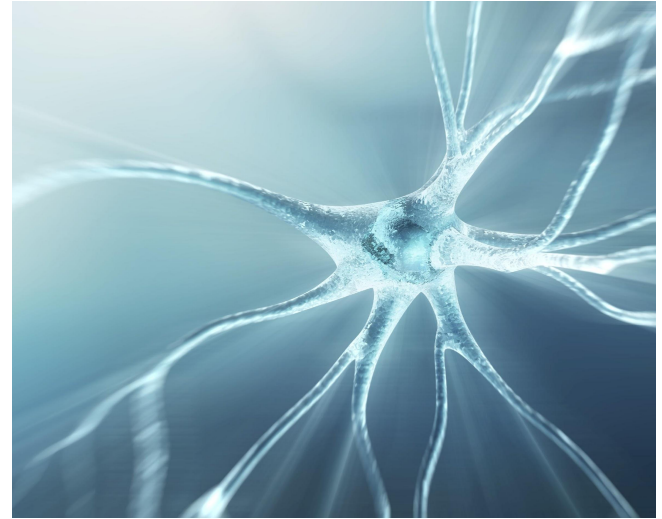
Sampling of Studies

- Psilocybin treatment for major depression **effective for up to a year** in most patients (Hopkins)
- Psilocybin **eases anxiety** in people with life threatening cancer (Hopkins)
- Psilocybin in combination with psychotherapy **decreases heavy drinking days** in people with alcohol use disorder (NYU)
- Psilocybin holds considerable promise in **long-term abstinence from smoking** (Hopkins)
- Psilocybin **compares favorably to SSRI in treating moderate to severe depression** with additional long-term benefits (Imperial College)



Psilocybin Research: Where are we now?

- We are accruing a substantial body of research
- Google Scholar – Psilocybin (1994-2024) = 30,000 citations
- Most of the work is small samples, few RCTs, specific populations
- Not all peer reviewed proposals/protocols, ethical issues around funding sources, criticism about methodology, variability in the interventions
- We need large sample RCTs funded by the NIH, with different populations and focused on specific psychological and medical symptoms/diagnosis to help to establish an evidence-base.



A Phase 2b, Randomized, Double-blind, Placebo-controlled, Multi-center study of the Effects of Psilocybin-assisted Psychotherapy on Psychiatric and Existential Distress in Advanced Cancer

Co-PIs: Fischer (CU Denver) and Ross (NYU), Co-I's: Grigsby and Kilbourn

This study is an important study

- One of the first R01 RCTs funded by NCI
- Testing the efficacy of psilocybin-assisted psychotherapy (PAP) in large sample (N=200)
- Potential to establish an evidence-base of PAP in those with a serious medical illness

Why those with advanced cancer?

- This is a group that faces high levels of distress
- Currently there are very few effective treatments for those with advanced or life-limiting illness

Primary Outcomes:

- Anxiety, Depression, Existential Distress

Exploratory:

- Pain, Psychological mechanisms, Self-compassion, Cognitive fx



Our Model for Psilocybin-Assisted Psychotherapy (PAP)

Therapeutic use of psilocybin requires more than just administering the drug

Contextualized within

- **Set** - intrinsic factors unique to each individual
- **Setting** - environment where the dosing occurs

Create a supportive setting

- Preparation
- Support
- Integration

We utilize a targeted, brief psychotherapeutic platform

Each individual has inner healing intelligence - compassion, openness, clarity



Elements of PAP

Therapeutic Aspects

- Supportive Psychotherapy
- Existential Psychotherapy
- Individual Meaning Centered Psychotherapy (IMCP)
 - Creating new narratives
 - Creating/recreating meaning in life
 - Reflect on hopes and goals
- Meaning-making Intervention
- Life Review/Lifeline Exercise

Process

- Co-therapists (one must be licensed)
- Virtual or in-person sessions
- Dosing day at the medical center
- Sessions 1.5 to 2 hours in length

Manualized Semi-Structured Intervention

- 3 preparatory sessions
- Single day dosing session
- 1 post-dosing day debrief
- 3 post-dosing integration sessions



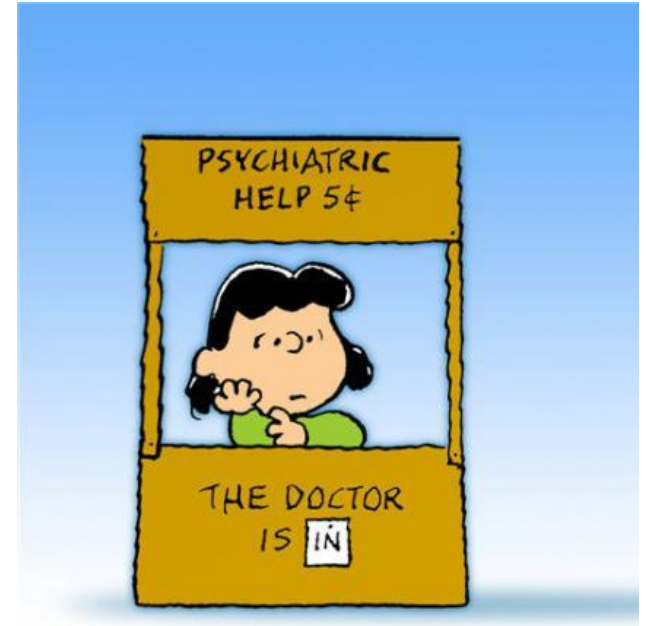
PAP Therapist

Our Therapists

- ◆ Trainees (doctoral students, interns, post-docs, medical residents and fellows), community therapists, clinicians at CU Denver (Psychology, Psychiatry, Family Medicine)

Dyadic teams

- ◆ One therapist must be a licensed healthcare provider with training and experience in psychotherapy (FDA rule)
- Need to have knowledge and experience working with seriously ill individuals
- Emotionally mature, grounded, self-aware with sound clinical judgement and psychological flexibility
- Familiarity with a range of therapeutic interventions
- Skilled at managing distressing and overwhelming emotions
- Ability to follow a manualized semi-structured intervention



Role of the Therapist(s)



- Is not the expert but a facilitator to the person's healing
- Does not give advice or render interpretations
- Model curiosity, openness, compassion
- Prepares participants for the dosing experience
- Creates and maintains a safe therapy container

Overview of PAP Sessions

- Pre-dosing sessions (3)
 - Sessions 1 and 2 focus on a life review, values, coping strategies, sense of meaning and purpose, spiritual history, medical history, etc.
 - Session 3 focuses on preparing for dosing
- Dosing Day (8+ hours)
 - Study team is there to help and support
- Integration sessions (4)
 - First session must occur the day after dosing
 - Integration varies depending on the dosing experience and participants history etc.
- All participants receive the same treatment regardless of their randomization (double-blind)
- After completing the RCT arm, they are eligible to go into the Open Label Arm where they receive the same intervention but they are guaranteed to get psilocybin



Dosing Day

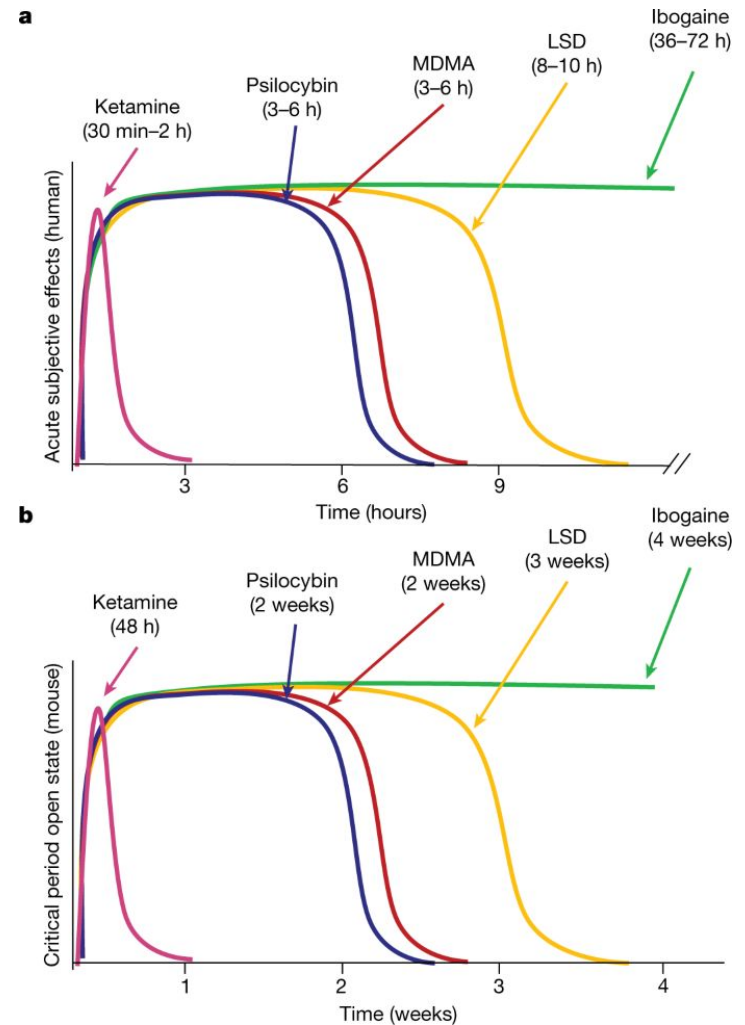
- Anschutz Medical Campus
- Start with intention setting
- Music - specific playlist that cannot be changed or forwarded
- Default position – eye mask, headphones
- Monitor vitals
- Rescue meds – psychosis, high anxiety, blood pressure, nausea
- Onset of experience – 45-90 mins
- Peak – 1.5 to 3.5 hours
- Descent – 3.5 to 6 hours
- Return – 6+ hours
- Most have support person pick them up at the end of the day



Why is post-dosing “integration” so important?

- Allows the participant to make meaningful connections from the dosing experience
- Shaking of the snow globe
- Unclear if dosing without integration can lead to meaningful, lasting changes
- Critical period = Neuroplasticity*
 - Psilocybin -2.5 weeks
 - Important that at least some integration occurs within this critical period

*Dolen, Nature 2023



Risk Factors & Screening

Exclusions:

- Primary psychotic or affective psychotic disorders
- Family history of psychotic or serious bipolar spectrum illnesses
- Active SUD
- High risk of suicide
- Serious CNS disease
- Concurrent meds: anti-depressants*, anti-psychotics, mood stabilizers, centrally acting serotonergic medications

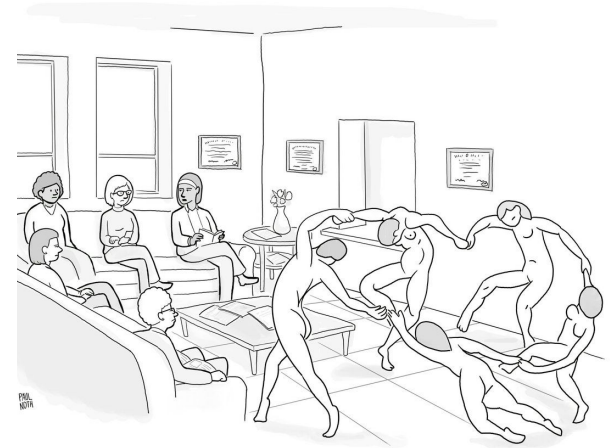
Important things to know:

- Past use of psychedelics
- Expectations for dosing
- Trauma history
- Coping styles



Challenges of a large, multisite RCT

- Two sites (UC Denver and NYU)
- Schedule 1 drug - many FDA rules and regulations
- Challenge of standardizing the therapy and trying to control as much variability as possible
- Heavy assessment burden for the participants and the study team
- Managing participant expectations
- Lack of resources
- Dealing with the various issues around the placebo arm



"So I'm guessing we're in the placebo group."

Additional Areas of Research & Inquiry

- Addiction (e.g., recent NIH funding: psilocybin for methamphetamine addiction)
- Obsessive-Compulsive Disorder (OCD)
- Traumatic Brain Injury (TBI)
- Bipolar II
- Eating disorders
- Long COVID
- Cognitive disorders
- Pain conditions
 - Headache disorders, fibromyalgia, chronic regional pain syndrome



Colorado's Natural Medicine Health Act (Nov 2022)

Regulated Access

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Personal and Community

Civil Protections

Colorado Natural Medicine Health Act

Regulated Access

Supervised Use Only (No Sales)

- Program launches January 2025
 - Psilocybin & psilocin
- Other medicines?

DORA – Facilitators

- Facilitators
- Clinical Facilitators
- Standards of Care / Scope of Practice

DOR– Businesses

- Healing Centers
- Cultivation
- Manufacturing
- Micro-Healing Center / Micro-Cultivation
- Testing

Colorado Natural Medicine Health Act

Personal and Community Use

Decriminalization of “Personal Use”

Community Healing

- Bona Fide Support Services and Harm Reduction
- Prohibition on commercial activity

Unlawful practice of facilitation

Colorado Natural Medicine Health Act

Civil Protections

Child Rearing

Insurance /
Organ
Transplants

Professional
Licenses

Other federal
benefits

Employment

Probation
and Parole

Record
Sealing

State-Legal Psilocybin Care

Colorado's regulated natural medicine program is modeled after the clinical research



1: SCREENING

Participants complete a screening process and match with a psilocybin facilitator based on individual needs and fit.

2: PREPARATION

Facilitator meets with participant to explain the process, incorporate participant goals and develop an individualized safety plan.

3: ADMINISTRATION

Participant consumes psilocybin and remains under the supervision of a trained facilitator for 4-6 hours.

4: INTEGRATION

Participant meets with their facilitator to integrate insights and learnings from the psilocybin experience into daily life, and to plan for further support.





Likely Location Types



Complementary
businesses (e.g.,
therapist's office)



Existing
healthcare
facilities



Retreat Centers



Participant homes
(additional safety
requirements apply)

Two Full Scope Facilitator License Types

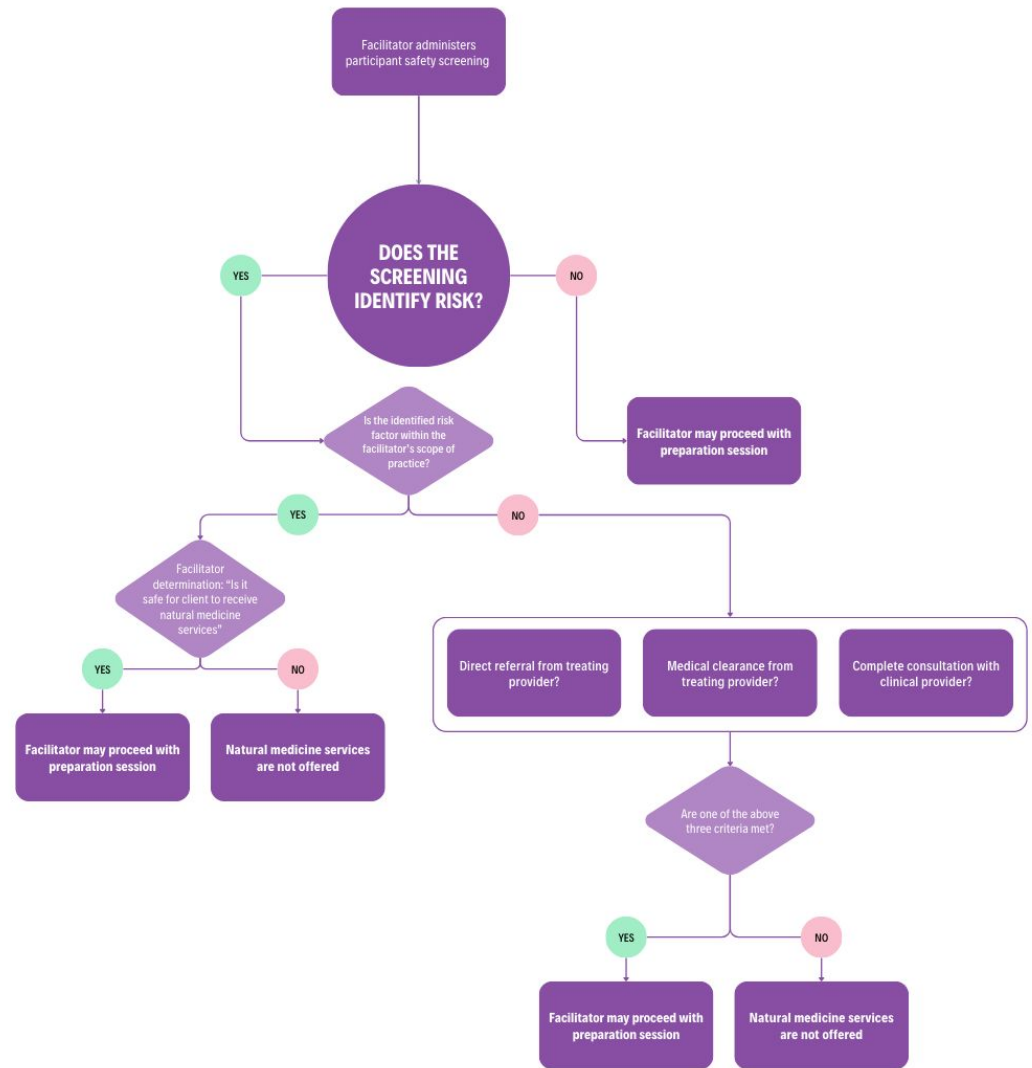
Clinical Facilitator

- Separate clinical licensure
- Can provide natural medicine services for purpose of treating physical or mental/behavioral health conditions

Facilitator

- Education requirements
- Can integrate secondary licensure, if applicable
- No separate license required
- Cannot practice medicine or psychotherapy

Required Safety Screen

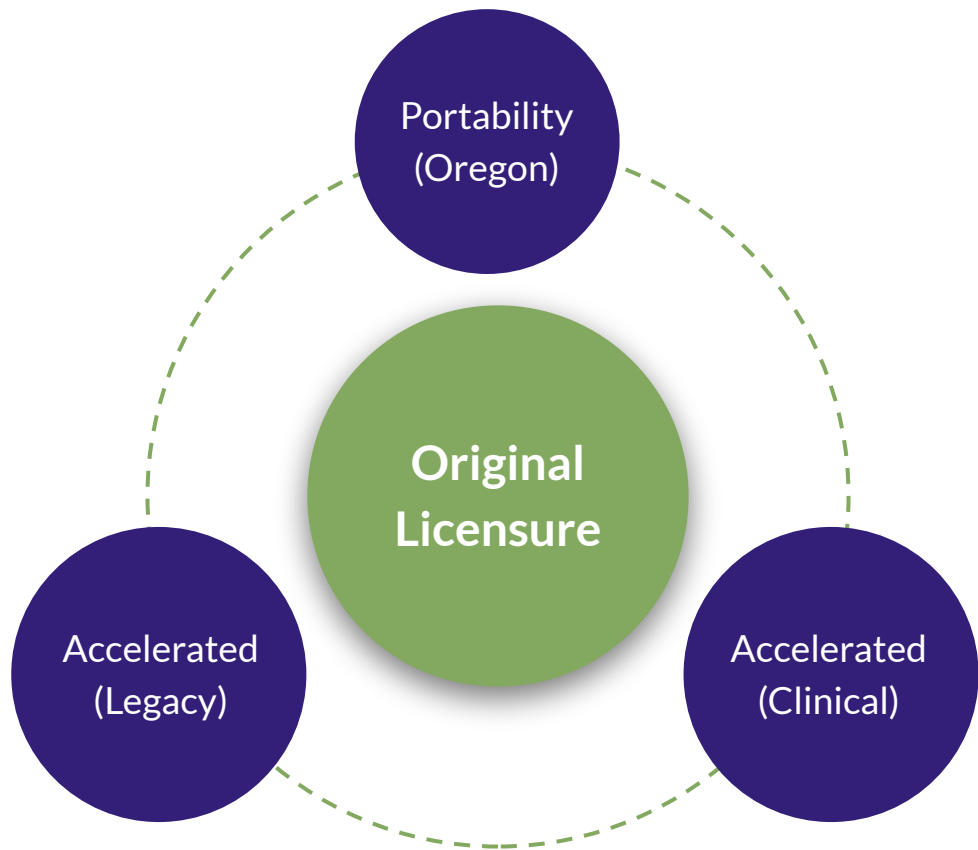


Required Training

- 150 hours of coursework (remote or in person)
- 40 hours of supervised practice (in person)
- 50 hours of consultation over 6 months while actively providing natural medicine services
- Basic Life Support (BLS) certification



Training Pathways



Required Coursework (150 hours)

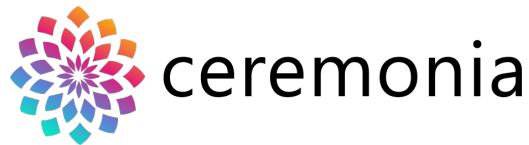
Ethics and Colorado Natural Medicine Rules and Regulations (25 hours)	Relational Boundaries and Introduction to Physical Touch (10 hours)	Preparation (10 hours)	Administration (10 hours)	Integration (10 hours)
	Intro to Trauma Informed Care (10 hours)			
Physical and Mental Health and State (25 hours)	Indigenous, Social, and Cultural Considerations (10 hours)	Group Facilitation (10 hours)	Facilitator Best Practices (5 hours)	Drug Effects, Contraindications and Interactions (5 hours)
		Facilitator Development and Self-Care (10 hours)	Intro to Suicide Risk (5 hours)	Screening (5 hours)

Colorado Approved Facilitator Training Programs

soundmind



Elemental
Psychedelics



CHANGA INSTITUTE

*Note that several additional programs are finalizing their applications and will likely be approved in the near future.

Standards of Practice

Informed Consent,
Disclosures

Boundaries & Use
of Physical Touch

Screening, Safety &
Support Plans

Preparation,
Administration,
Integration

Dosage Guidelines

Group Sessions

Real-World Research in the State-Access Model

- Greater diversity of participants, settings, approaches (fewer exclusion criteria)
- Less expensive than clinical research
- Opportunities to understand efficacy and safety for understudied conditions & populations
- Cultivated mushrooms (i.e., full spectrum) versus synthesized psilocybin
- Challenges around federal illegality, but not insurmountable!



Are you a woman who has been diagnosed with fibromyalgia?

Are you interested in participating in research on psilocybin as a treatment for fibromyalgia?

You may be eligible to participate in this study if:

- You are a US citizen between ages 18 and 45
- You are not currently experiencing severe psychopathology (e.g. bipolar, schizophrenia, major depression, etc.)
- You speak fluent English
- You are able to spend 60-120 minutes on audio or video calls with the researcher

Eligible participants will experience psilocybin treatments with a licensed facilitator at a licensed service center in the state of Oregon.

QUALIFIED VOLUNTEERS WILL BE CONTACTED AND INTERVIEWED BY THE RESEARCHER (A CLINICAL PSYCHOLOGY STUDENT) FOR HER DOCTORAL DISSERTATION. PARTICIPATION IS CONFIDENTIAL, VOLUNTARY, AND WILL INCLUDE COMPLETING FORMS, QUESTIONNAIRES AND INTERVIEWS IN ENGLISH.

Contact the researcher, Sierra Warren, M.A. at (541) 821-0372 or sierra.warren@my.pacificu.edu

HAF Community Impact Pilots

- Deepen understanding of safety, efficacy and cost-savings
- Build a population specific service model
- Learnings to strengthen rules, regulation, and best practices



Pilot Details in Oregon

- Cohorts of **8-10** participants
- Comprehensive **community engagement** and stakeholder outreach process
- **Rigorous screening** and eligibility requirements
- **Additional preparation and integration sessions** - both individual and group - above state-mandated requirements
- **Quantitative and qualitative data** collection

Initial CIPS in Oregon:

- Substance use
- End of life/palliative care
- Justice-impacted
- Veterans

We will be looking for partners in Colorado!

Legal Considerations with the State Access Model

Federal Legality

- Criminal / Civil liability
- DEA Registrations
- Insurance
- Banking
- Immigration

Legal Considerations with the State Access Model

State Issues

- Changing Regulations
- Local Governments
- Licensing Boards
- Unknowns

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Thank you!
And Q&A

healingadvocacyfund.org