

# Strategic Roadmap for Collective Philanthropy

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February 2025

## Letter from the Board

Dear PSFC community,

We are thrilled to share this strategic roadmap for collective philanthropy in the psychedelic field, to guide our actions in the years ahead. It reflects insights from more than 100 experts in the psychedelic field, in addition to numerous PSFC members, to all of whom we are deeply grateful.

Psychedelic research restarted in the 1990s following decades of dormancy in the hope that it would lead to legal therapeutic access. In 2017, we were inspired to found PSFC when the promise of making a psychedelic into a prescription medicine had come into sharp focus. Seven years later, the field has made remarkable progress toward the goal of expanding access to psychedelic healing to all who can benefit.

We are so excited by the growing body of evidence that will help us to realize the benefits of psychedelic substances, and to responsibly address their risks. At the same time, the path toward medical and state-regulated access to psychedelics has brought surprises and setbacks. But as we have seen time and time again, these setbacks have created new imperatives for the field to come together in a broad coalition of funders, operators, and advocates, and to level up our collaboration with eyes firmly on our long-term goals. It is in this spirit that we share the roadmap as a rallying point for philanthropy in service of broadening safe and equitable access to psychedelic healing.

We crafted this roadmap in response to a request from PSFC's membership for guidance on collective philanthropy. It outlines a strategy for advancing opportunities that are essential for the long-term success of the field, and balances a coherent set of core priorities with the acknowledgment of many other promising efforts. And it makes clear that the work ahead requires a coordinated funding effort across diverse priorities—from research to implementation, from public education to policy reform, from access to safety, and more.

While it was developed to provide insight and guidance to PSFC's membership, we are pleased to make it generally available to participants in the psychedelic field, and particularly to philanthropists whose actions will have significant influence on the future landscape. However, it is inevitably incomplete, given the vast diversity of activity and the dynamism of the field. We therefore see this roadmap as a living document, and look forward to supporting philanthropists in acting on its recommendations, while also gathering insights for its evolution. We invite you as funders to join us on the next stage of this journey. Together, we can make a decisive contribution to the future of mental health and human wellbeing.

Sincerely,

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Board of Directors, Psychedelic Science Funders Collective





# Table of Contents

<b>Letter from the Board</b>	<b><u>2</u></b>
<b>Executive Summary</b>	<b><u>4</u></b>
<b>Introduction</b>	<b><u>8</u></b>
<b>Our North Star Goal</b>	<b><u>11</u></b>
<b>Approach and Methodology</b>	<b><u>12</u></b>
<b>Overview of Strategic Roadmap Priorities</b>	<b><u>15</u></b>
<b>I. Expanding Legal Pathways</b>	<b><u>19</u></b>
<b>II. Medical System Integration</b>	<b><u>37</u></b>
<b>III. Communications &amp; Public Health Education</b>	<b><u>49</u></b>
<b>IV. Supporting Ethical Psychedelic Cultures</b>	<b><u>62</u></b>
<b>Summary: Proposed 3-year Investment and its Impact</b>	<b><u>72</u></b>
<b>Summary: Timeline to our North Star</b>	<b><u>73</u></b>
<b>Operationalizing the Roadmap</b>	<b><u>76</u></b>
<b>Acknowledgments</b>	<b><u>79</u></b>





# Executive Summary

## Introduction and Context

Recent years have seen rapid acceleration of research into the potential of psychedelics both to alleviate the current mental health crisis and to address broader societal challenges. However, there remain many unknowns about the true potential impact of psychedelic-assisted healing, about optimal delivery to realize that impact, and about inherent risks. The Psychedelic Science Funders Collaborative (PSFC) was established in 2017 to enable philanthropic funders to identify opportunities to advance the field and to collaborate with organizations doing essential work. With the explosion of philanthropic opportunities in the field, PSFC recognized the need to prioritize those with the greatest potential to advance its mission of making psychedelic healing available to all who can benefit.

To that end, PSFC undertook an effort to develop this **strategic roadmap for collective philanthropy** in the psychedelics field. The objectives of this roadmap include helping funders prioritize areas of focus, unlocking new funding for the field, improving communication among stakeholders about the state of the field, helping operators shape their strategies in a way that advances the entire ecosystem, and defining and incubating new initiatives needed to fill gaps.

PSFC's approach to development of the roadmap began with a set of guiding principles aligned with both our mission and the needs of this still-nascent field. The PSFC team consulted with more than 150 different psychedelics researchers, for-profit and non-profit operators, journalists communicating about the field with the interested public, advocates working to find pathways to integrate psychedelic care into the mental health system, and philanthropists with deep personal connections in the field. We have sought to consistently prioritize funding opportunities based on their potential to expand legal access to psychedelic care, their ability to reduce risks to individuals and to the field, and to catalyze future government or market investment.

The result of this work is a clear and actionable framework for advancing the psychedelics field, and ensuring that efforts are strategically aligned and responsive to emerging challenges. This plan can radically advance the field toward availability of psychedelic healing in the U.S. over the next 5-7 years. Importantly, *the roadmap is not intended to identify all areas in the field that are worthy of philanthropic funding*. While the roadmap is focused on collective opportunities to make necessary structural changes, we recognize the importance of many other individual funding priorities, particularly those that are still in their earliest stages, or are providing help and healing to groups with immediate needs.

## Overview of Roadmap Priorities

Roadmap focus areas are meant to support emerging or established pathways to access psychedelics:

- As FDA-approved prescription medicines, delivered under professional supervision
- In state-regulated supervised use programs
- Via unregulated or self-regulated paths (including both Indigenous medicine traditions and other religious practices)

Deep exploration of these paths has revealed four focus areas for our roadmap.

The first is **expanding legal pathways** to psychedelic care. Psychedelic substances are widely available in the U.S., despite legal prohibition, but we consider it essential to expand opportunities for access without fear of criminal sanction. A promising emerging path that is highly dependent on philanthropy is the establishment of state-regulated access programs. The work of ensuring success of state-regulated programs – as established in Oregon, soon to launch in Colorado, and likely extended to new states in future years – is being pursued in complementary ways by the Healing Advocacy Fund and the National Psychedelics Association. Beyond current programs, there is a range of efforts in ~30 other U.S. states to advance policies that will put them on an eventual path to psychedelic access for those most in need. To help these efforts realize their full potential, the roadmap calls for the formation of a Psychedelic Policy Institute to shape national strategy for state policy, to enable analysis of proposed policies, to support learning across state efforts, and to better harness the energy of local advocates to ensure that the right policy efforts receive the full support that they need. Finally, beyond any particular policy successes, sustained legal access to psychedelics requires the continued advancement of pragmatic research and real-world evidence generation. These are widely distributed efforts that do not currently have a ‘center of gravity’ for large-scale collective funding, but PSFC will seek opportunities to guide interested donors to research efforts that will generate evidence needed to sustain and improve all legal paths to access.

With a growing understanding of the power of psychedelic substances, it is more important than ever to lay groundwork for **integrating psychedelics into the medical system**. Even if only a minority of users will access psychedelics in this way, among them will be those with the greatest need for broader medical and mental health care offerings. However, we are still at the early stages of establishing key infrastructure, including: education for front-line mental health workers; advanced training for psychedelics practitioners in medical settings; credentialing systems to provide assurance of competence to patients and to referring medical professionals; development of clinical practice guidelines to support use of best-practices; and reimbursement not only of psychedelic medicines but of the surrounding care required to deliver good outcomes. While these efforts to influence and support health systems broadly are in early stages, there has been significant progress in the largest U.S. integrated health system - the Veterans Administration. Supporting access to psychedelic care for veterans is both an ethical and strategic imperative, being advanced by the dual efforts of the Heroic Hearts Project to model and scale robust community-based psychedelic care for veterans, and of its recently merged program Healing Breakthrough to prepare the VA to deliver MDMA- and psilocybin-assisted care. Looking more broadly toward populations most in need, we see an opportunity to prepare the field for equitable access to psychedelic care, through the work of the Psychedelic Mental Health Access Alliance. This is a catalytic effort to develop culturally-tailored treatment models, to integrate psychedelic care into Medicaid and community-based health systems, and to align the research and advocacy ecosystems toward supporting historically underserved populations.

The third focus area for the roadmap is **communications and public health education**. With increasing public awareness of the healing potential of psychedelics, there are dual risks from, on the one hand, increasingly vocal opposition to any kind of engagement with psychedelics beyond prohibition; and on the other hand, overly enthusiastic voices that would incautiously downplay the risks of psychedelics. The field very much needs narratives crafted for different stakeholder groups that navigate between these extremes, so that all those with interest in psychedelics can readily form an

accurate understanding of what they are, what uses they may have, what risks they carry, and what resources they can access to learn more. Several organizations play distinct roles in crafting and disseminating these narratives, from different perspectives and toward different audiences. These include the Healing Advocacy Fund, the Multidisciplinary Association for Psychedelic Studies, New Approach PAC, the Coalition for Psychedelic Safety and Education, and the Psychedelic Communications Hub (recently integrated into the Psychedelic Safety Institute). While their efforts to date have been valuable, in the period ahead they will benefit from greater resourcing and more effective coordination in the context of a national communications and education strategy.

Finally, the current dynamic period in the ecosystem gives us the unusual opportunity to actively support the formation of **ethical psychedelic cultures** that will thrive in a future world of broad access. This includes several imperatives. The first is the establishment and upholding of ethical norms for many different types of actors in the psychedelics field. This is both a moral imperative and a strategic priority for maintaining public and policymaker support. Several groups are attempting the challenging project of developing systems of ethical norms and accountability covering large portions of the field, and PSFC will itself adopt an ethical framework to govern its grantmaking. We additionally note a set of self-regulated communities that have pioneered codified ethics and accountability systems, and believe the field can learn from them. A further critical ethical dimension in the evolution of the field is conservation of Indigenous plant medicine traditions and ensuring continued access to healing through them for Indigenous communities. Increasing public interest in psychedelics is amplifying cultural and ecological harms to these Indigenous traditions. In addition to the moral obligation to support the communities whose traditions have stewarded much of our current knowledge of psychedelics, we are also putting at risk future opportunities to learn about effective, healthy, ethical practices in the use of natural medicines. The Indigenous Medicine Conservation Fund, and the International Center for Ethnobotanical Education, Research, and Service, are two of the leading organizations working to slow or reverse threats to major plant medicine traditions, and to strengthen legal recognition of the rights of Indigenous communities to practice their traditions.

## Operationalizing the Roadmap

The psychedelics field is not one in which long-term predictions can be confidently made. However, the roadmap includes a set of goals in each major focus area, for 2025, with some confidence; for 2027, as feasible targets, assuming the earlier goals and funding needs are met; and for 2030, admittedly more aspirational, but realistic if we stay on course in the earlier period. These 2030 goals include multiple FDA approvals (including MDMA, psilocybin, and LSD, for various conditions), an abundant flow of pragmatic research results and real-world evidence to support care delivery optimization, a diverse set of state Medicaid programs and community-based care organizations enabling access to psychedelic care, a public that is widely educated to at least a basic level on the benefits and risks of psychedelics, health education efforts supported by substantial government funding, and ethical practices embedded into research conduct, practitioner training, and service operations, among other goals.

We have estimated the philanthropic costs for the first 3-year period of this program of activity, and found that \$125MM will be sufficient to deliver on the target goals for 2027, if deployed and managed wisely. This is a similar rate of philanthropic giving than we have seen recently (\$350-400MM over the past decade, in the U.S.), but it would require greater focus on core priorities.

The effort to deploy and manage funds judiciously, and to maintain that focus, will benefit greatly from a strong operational plan from PSFC. Some hallmarks of this plan are:

- Attention to ethical philanthropy, holding ourselves and our grantees to the highest standards, that will help us build trust with stakeholders outside of today's psychedelics ecosystem

- A flexible funding model that enables some philanthropists to support a general roadmap fund and leverage PSFC expertise, and enables others to continue giving directly to organizations, but with visibility and alignment with fellow funders
- Governance of grantmaking that leverages the expertise and experience of both knowledgeable, committed donors in respective focus areas, and subject-matter experts from the field, who together can help to maximize the impact of roadmap grants
- Robust grant management and reporting, building on PSFC experience gained to date in this unique field
- Flexibility to evolve the roadmap on a regular basis, as organizations learn to operate at higher levels, as inevitable setbacks occur, and as new opportunities emerge

We gratefully acknowledge the many contributors of ideas and insights that enabled the development of this roadmap. We also thank its readers, whom we hope will be inspired to take action to advance the field in enduring ways, toward our vision of making psychedelic healing available to all who can benefit.



# Introduction

## Why Psychedelics

There is abundant clinical and historical evidence that psychedelics hold enormous promise for human wellbeing, particularly in addressing the current mental health crisis, where traditional treatments often fall short. Clinical trials have demonstrated psychedelics' potential in treating conditions like depression, anxiety, and PTSD, providing hope for those who have not found relief through conventional therapies. Moreover, psychedelics could play a role in tackling broader societal challenges by fostering interconnectedness and empathy, potentially reducing conflict and enhancing cooperation. These substances have been used for thousands of years in various cultural and spiritual practices, indicating their longstanding value in personal and communal healing.

However, the contemporary science behind psychedelics is still evolving, with many unknowns about their true potential for different needs, their optimal delivery, and their inherent risks. The resurgence of interest in psychedelics reflects a reawakening to their potential, but it is crucial to approach this with caution and rigorous scientific inquiry. Integrating psychedelics into therapeutic settings promises new insights into consciousness and mental health, but it also necessitates a balanced perspective that respects both historical uses and modern scientific findings.

As research progresses, psychedelics could not only revolutionize mental health treatments but also offer new ways to understand and address complex societal issues. This exploration represents a merging of ancient wisdom with modern science, offering the potential to reshape how we approach both individual and collective well-being, while acknowledging that much remains to be learned.

## Why PSFC

Since 2017, PSFC has played a crucial role in advancing the psychedelics field and laying groundwork for the large systems changes needed to fully realize the potential of psychedelic healing. Despite their promising therapeutic benefits, psychedelics face stigma that impedes mainstream acceptance and investment, deterring many for-profit entities from entering the field. This stigma, coupled with minimal government support, creates a substantial funding gap that hampers research and development.

Philanthropists whose own lives have been positively impacted by psychedelics, and institutional donors seeking



to seed transformative change in mental health, are uniquely positioned to drive progress, bringing both personal passion and financial resources to the cause. PSFC provides an opportunity for donors to learn from one another, share insights, and develop coordinated strategies to overcome the challenges facing this emerging field. The collaborative approach not only amplifies individual contributions but also fosters a cohesive effort to drive change, making it a vital component in advancing psychedelic science and expanding its therapeutic potential.

## Why a Strategic Roadmap

We are seeing rapid acceleration and diversification in the ecosystem of psychedelic funders and operators in the US. The FDA pipeline is increasingly robust (despite a recent setback), the first state-regulated supervised use program has gained more than a year's experience, state policy efforts regarding psychedelic access and research are widespread, federal agencies have taken initial steps toward funding psychedelic research, and training programs for psychedelic care providers have emerged in both university and independent settings.

While these are positive developments, they create complexity and risk for the field. Challenges arise from a combination of discoordination among related efforts, inadequate funding for critical priorities, and enthusiasm drowning out experienced voices of caution. The transformational change that we're seeking to catalyze requires a true movement, not a disparate collection of independent efforts. This is precisely the situation that calls for collective philanthropy, defined as *aligned deployment of funding, expertise, and influence across multiple donors toward common specific objectives, in order to amplify positive impact*.

Therefore, PSFC has developed this **strategic roadmap for collective philanthropy** in the psychedelics field, with several objectives:

- Help funders prioritize areas of focus for the near- and long-term, clarifying what is needed from collective philanthropy in terms of funding, leadership, talent, partnerships, and strategic support
- Unlock new funding for the field, by helping active and new donors see the full context and paths to success, with implications for mental health and human wellbeing
- Improve communication among stakeholders about the state of the ecosystem, with an objective of helping to organize this still-nascent field
- Help operators to shape their strategies and tactics in a way that doesn't only optimize for their own missions in isolation, but rather "ladders up" to larger goals
- Define and incubate new initiatives to address identified gaps or at-risk efforts

The importance of a long-term roadmap is particularly emphasized by the recent setbacks to Lykos' efforts to secure FDA approval for MDMA-assisted therapy and to Massachusetts voters' rejection of Question 4 to set up a state-regulated supervised use program. This event was a disappointing wake-up call to many advocates for psychedelic healing, and resets some elements of our timeline. However, we do not see it as a terminal failure for the broader effort toward legal access to psychedelic healing, for any paths under consideration. Instead, it reminds us of the need to take the long view, to advance multiple paths, and to build broader support and infrastructure than we have to date.

This is the essence of what this roadmap is all about. Key operators today have been limited by the continual demands of fundraising, with relatively few institutional funders making long-term commitments. By characterizing the multi-year costs of advancing the most impactful work in the field, we hope to secure line-of-sight to the required funding through a mix of contributions and contingent pledges. This will free up the most essential field organizations to undertake the bold initiatives that are required, and to deliver on their operational goals. This aggregation of multi-year

funding commitments is a novel approach to deploying the power of collective philanthropy to accelerate not just an organization or alliance, but a full ecosystem.

Importantly, the roadmap is not meant to characterize all positive philanthropic opportunities in the field. Enablement of individual giving has been, and will continue to be, at the heart of PSFC's activity. The roadmap makes mention of some of these promising opportunities for individual philanthropy for the benefit of funders, even as it more deeply assesses those that are essential for collective philanthropy.



# Our North Star Goal

The overall 'North Star' goal of the roadmap is consistent with the mission of PSFC: to make psychedelic healing available to all who can benefit. This requires interpretation - Which substances? What is 'healing'? Who is 'all'? Our discussions with many PSFC members and external advisers have helped us to refine our goal to include the following commitments:

- We will support legal access to multiple psychedelics, without fear of criminal penalties. Ongoing legal access efforts in the near-term visibly lean toward psilocybin, while groundwork is being laid for other classic psychedelics, as well as ibogaine, MDMA, and ketamine. The latter is already being used legally to provide healing to many in the U.S., but faces many of the same challenges as the rest.
- We will support a variety of settings of care that meet the different needs of individuals and communities, from diagnosed mental health conditions to personal growth and development. We seek to lay foundations for a full spectrum of benefits to individuals, communities, and society, and not leave psychedelics compartmentalized as only a medical tool for those deemed 'sick'.
- We need to ensure that individuals considering using psychedelics have the resources to confidently choose the path that is right for them, across regulated and unregulated options. They should be informed on how to realize benefit and manage risk, recognizing that some paths are 'safer' than others, but that there is no promise of absolute safety.
- We recognize an obligation to ensure equity of education, access, and support to populations that may face unique barriers, be at increased risk of harm, or confront ecological or cultural threats to access.

We see psychedelics as tools for individuals and groups to put to many possible uses, with some uses already well recognized and many still to be understood. The recommendations of our roadmap for collective philanthropy will focus on making these tools available in effective, risk-reduced, equitable ways that do not seek to privilege any particular purposes over others.



# Approach and Methodology

The range of opportunities to advance the psychedelics field is vast. Identifying and connecting opportunities for collective philanthropy that are essential for attaining our North Star goal described in the next section required us to define a clear set of guiding principles, to consult with a wide range of field actors, and to prioritize opportunities based on impact, risk, and sustainability.

## Guiding Principles

These were set at the start of this effort, to reflect PSFC's spirit of collective action.

1. **Field catalyst:** PSFC engaged directly with organizations operating in the field, to understand their capacities, gaps, and opportunities for enhancement, for the purpose of finding the right path to responsibly drive population-level impact.
2. **Relevance to funders:** The roadmap is intended to motivate and enable philanthropic funders, including those new to psychedelics, on the basis of well-researched facts, data, and analysis.
3. **Actionability:** The roadmap provides a clear agenda for moving rapidly toward a future world of widely available psychedelic healing. It calls for resourcing promising operators, and for forming new alliances or infrastructure as needed. Where possible, recommendations include ambitious KPIs and milestones, to track progress and to support intervention as challenges arise.
4. **Systems perspective:** The psychedelic sector is large and complex, and interdependent with other cultural and natural systems (e.g., U.S. mental health care; political networks; ecological systems). We are mindful of these connections, and seek to anticipate unintended consequences of well-intentioned actions.
5. **Engaged Advisory Committee:** The team has benefited from the support of an advisory committee of engaged PSFC members, with a remit to represent the philanthropic community's perspective, make connections in their networks to access new insights, and provide candid feedback on working recommendations.



## Discovery

We spoke with more than 150 different actors in the psychedelics field, of many kinds, in an effort to deeply understand needs in the field, and to identify organizations or teams working to address these needs. Academic researchers shared insights into the implications of their work for scaled implementation of psychedelic care, acknowledging the high level of rigor needed to bring along mainstream mental health researchers. Non-profit and for-profit operators highlighted the many ‘missions within the mission’ that could contribute to a healthier psychedelic ecosystem in the near- and long-term, with great creativity and passion. Journalists and commentators provided valuable historic and cultural context, emphasizing the immense need for information and education to reach the broader public. Mental health advocates illuminated the avenues in the U.S. health system, particularly community health infrastructure, where psychedelics could in time be incorporated. And of course, many philanthropists explained their personal connections to psychedelics, how this informed their priorities for the field, and insights from their broader spheres of professional and philanthropic activity to enrich our strategy.

## Framing the Issues

We used the many insights that this discovery process yielded to distill a prioritized view of the needs of the psychedelics field, over an extended time horizon. This amounted to asking a sequence of questions in each major area of activity:

- What is the future that we collectively wish to see, in 2030 or shortly afterward? These are ‘mini-North Star’ goals for specific domains (legal access, risk reduction, awareness, ethics, etc).
- What is the current state in each of these areas? How near or far are we from that 2030 goal?
- What is likely to happen without collective philanthropic intervention, i.e., what is the “momentum case”? This is a critical question - while it is difficult to answer, it is ill-advised to advocate for significant collective philanthropy in areas where we expect market or government investment to shape the future environment.
- Combining the preceding questions: what is the gap between the future that we wish to see in 2030, and the likely future without collective philanthropy?

This enabled us to discern a set of areas where we see significant risk of inadequate progress in the “momentum case”, and therefore a need for collective philanthropy. This is the set of topics addressed in the roadmap.

## Prioritizing Opportunities

The diversity of exciting work underway in the field calls for clear-eyed prioritization, though this is not straightforward, as disparate goals do not lend themselves to a single ‘scorecard’ of metrics. But we have in all areas attempted to apply a few overarching considerations:

- Which are the organizations whose missions or activities are relevant to the identified long-term gaps? The field actors who provided so much insight into the state and needs of the field were particularly helpful here, although we undoubtedly missed some organizations.
- Which of these organizations are best positioned to meaningfully contribute to closing those gaps? This is a complex question that involves several considerations. While none of these is a ‘must have’ criterion, they collectively helped us to triage and select organizations for deeper collaboration, and in some cases, recommendations for collective funding. Some considerations here were:

- Organizational capacity: What is an organization's track record of impact in the field? What distinct capabilities have they exhibited? What is their 'reach' to influence the field, either directly or through an existing network of partners?
- Expanding legal access: How much will an organization's strategy grow legal access? To what extent will it reduce burdens on individuals and society? How equitable across marginalized populations will the benefits be?
- Risk reduction: What reach will efforts to educate the public and health care communities on risks and responsible use have? What impact will these have on adverse outcomes? What about risk to the field as a whole - what will maintain or grow public support, and avoid backlash?
- Catalytic philanthropy: What is truly transformational, and could 'change the game' in the psychedelics field? What moves would be catalytic, allowing timely replacement of philanthropy by market or government investment, each of which is starting to show some promise?

The team's analysis of these questions led us to identify and engage more deeply with a set of the organizations that emerged as most promising. We worked with them to understand and characterize not only their strategies, but also the support they will require and the risks they face in delivering their full potential impact. This forms the basis for the roadmap recommendations.

## Context for Additional Opportunities

These considerations have led us to a plan that will leave a major mark on the ecosystem over a 5-7 year timeframe, and is unlikely to be achieved without collective philanthropy. In aggregate, the roadmap provides a clear, actionable framework for advancing the psychedelics field, and ensuring that efforts are both strategically aligned and responsive to emerging challenges. That being said, the roadmap excludes many very positive philanthropically funded endeavors, that have either not developed to the point where their path to impact is sufficiently clear, or are directed at goals for the ecosystem that differ from those prioritized for the roadmap.

To contextualize these, it is helpful to distinguish between collective and individual philanthropy. Our *collective* work is focused on building the infrastructure that is needed for access channels to thrive, with a high likelihood of materially advancing the whole field by the early 2030s. At the same time, donors should be encouraged to hold and act on *individual priorities*, including opportunities that are extremely promising for the field, but not roadmap priorities. Our aspiration is that at least half of member giving in psychedelics is toward roadmap priorities, while the remainder is directed to worthy individually-supported initiatives. The range of options for the latter is very broad, but we encourage directing support toward promising early stage efforts that are relevant to roadmap goals and may, with limited philanthropic support, mature to the point where they are suitable for collective philanthropy and prioritization in this roadmap.

Furthermore, there are a few areas in which we cannot yet identify a focused opportunity with line of sight to our long-term goals. This is generally because efforts in some areas are quite diffuse, without one or more clear 'anchor' organizations where significant collective philanthropy could be usefully deployed at this time (research, safety, and ethics are examples). In this roadmap, we mention many of these more nascent or limited-scope efforts. We do this not only because they may be suitable for individual philanthropy, but also because we can envision their maturation or consolidation into anchor organizations for future versions of this roadmap. The PSFC team will monitor events and trends in the field for periodic roadmap updates, and in parallel, seek opportunities to bring additional organizations into the broader strategy for our collective efforts.



# Overview of Strategic Roadmap Priorities

Our work starts by recognizing the importance of future channels of access, and then defining the necessary infrastructure for these channels to thrive. The channels in our consideration are:

- FDA-approved prescription drugs delivered with appropriate care through the medical system
- State-regulated supervised use programs, currently in Oregon, soon Colorado, more to come
- Unregulated or self-regulated use, occurring in a wide range of contexts (including both Indigenous medicine traditions and other religious practices)

While the latter may always comprise the majority of psychedelics use, the first two are key drivers of growing awareness, education, and acceptance of psychedelics by policymakers, by the medical community, and by U.S. society as a whole – thus, it is critical that these succeed. Note that PSFC is not promoting use of psychedelics outside of legal structures, but is aware of the need to reduce risk to individuals and to the broader movement from such use.

For these channels to function at their full potential, in alignment with our North Star goal, an array of different supporting structures is needed. An ecosystem of psychedelic organizations and businesses is evolving to meet those needs. The PSFC team’s mapping of these efforts, and the underlying needs that they represent, highlight four broad pillars where collective philanthropy is essential to unlock a future in which psychedelic healing is available to all who can benefit. These are summarized below, with more detail in the following sections.

## I. Expanding Legal Pathways

A fundamental goal for the field is expanding opportunities for people to benefit from psychedelics without fear of criminal sanction. The philanthropic community has worked toward two complementary legal pathways for this: establishing state-regulated access programs, and supporting advancement of a pipeline of candidates for FDA approval. Despite recent setbacks in both – which we should expect from time to time – each is independently important, and promising in the long run.

With this in mind, one of our top roadmap priorities is **ensuring the success of state-regulated access programs**, namely Oregon, which has been operating for more than one year, and Colorado, to launch in 2025. These programs

serve as platforms for delivery of psychedelic care in ways that will not fit into a medical model, including but not limited to serving those without a specific mental health diagnosis. But they face challenges related to economic viability for service providers, and data collection to validate the benefits and risks of regulated offerings. Two important organizations, [Healing Advocacy Fund](#) (HAF) and the [National Psychedelics Association](#) (NPA), are leading the way with strategies for addressing these challenges and ensuring that these programs flourish in the years ahead.

Beyond current programs, the field has seen a wave of policy and advocacy activity related to psychedelics, at state and federal levels. With at least 30 states having considered legislation reflecting the promise of psychedelics, the need for a systematic strategy to **advance state policy** is stronger than ever. However, policy initiatives have not always been well-informed by an understanding of drug policy or health care system dynamics. Also, efforts have not been well-coordinated, and have missed opportunities to harness the energy of grassroots supporters. Our roadmap addresses the imperative to build mechanisms to develop and pursue a coordinated policy agenda.

Beyond early policy success, sustained legal access to psychedelics will depend on the advancement of research that demonstrates their benefits and risks in various implementation contexts. This kind of **pragmatic research** comprises distributed, uncoordinated efforts. While we expect for-profit drug developers to continue working toward regulatory approval and insurance reimbursement of medications, more philanthropically funded implementation and optimization research will help the practitioner community deliver the best outcomes for patients. Once delivery systems are up and running, collection and analysis of **real world evidence** will help to validate individual and societal benefits of psychedelics, and will further refine care delivery practices.

## II. Medical System Integration

Integration of psychedelics into the mainstream medical system is essential to making them accessible to those with mental health conditions representing the greatest need. It is also essential to the longer path of widespread acceptance and destigmatization. However, we are still in the early stages of unlocking this, with a series of challenges ahead, including: building awareness among front line health care and mental health workers; establishing and evolving clinical practice guidelines for psychedelic care that are accepted by key mental health professions; expanding high-quality training and credentialing of psychedelic care providers; developing referral networks between front line health care providers and psychedelic care providers; and securing sufficient reimbursement to make provision of psychedelic care economically viable at scale. There are numerous opportunities for philanthropists to support these goals, but most remain in early stages, serving as learning and alliance-building opportunities, rather than having a clear line of sight to scaled impact.

An essential element of future medical system integration for which we *can* lay groundwork now is **health equity** - working towards a future where social, economic, and cultural barriers do not limit access to psychedelic care, nor lead to lesser outcomes. The Psychedelic Mental Health Access Alliance is a catalytic philanthropic effort to advance three strategies related to this vision: development of culturally-tailored treatment and therapist practice models; integration of psychedelic-assisted therapy into Medicaid and community-based health systems; and aligning the broader research and advocacy ecosystems toward enabling positive impacts on historically underserved populations.

Finally, there is a unique opportunity to build out systems to provide **access to psychedelic care for veterans**: this will establish applicable learnings on how to scale care, it will help a large patient group with high prevalence of relevant mental health conditions, and it will contribute to destigmatizing psychedelics across a politically polarized society. Two nonprofits, the [Heroic Hearts Project](#) and [Healing Breakthrough](#) have been working to spearhead research, access, and advocacy initiatives to broaden veteran access to psychedelic healing and merged into a single organization in 2024. Heroic Hearts Project has developed and is now refining a community-based care model specifically for veterans and their spouses that leverages legal access in state-regulated systems, beyond what is likely to be possible



within the VA itself. Healing Breakthrough, recently merged into Heroic Hearts Project as a flagship program, is the external non-profit partner to the Veterans Health Administration (VHA) that undertakes impactful federal advocacy for research and access to psychedelic care for veterans, and is helping to bring resources and insight to prepare for effective integration of psychedelic-assisted care as medicines become legally available through the FDA process.

### III. Communications and Public Health Education

The psychedelic ‘renaissance’ is still in early days, and open opposition to access to psychedelics is becoming a more potent force. As this opposition grows, robust and coordinated **communication** efforts are essential to reduce risk to the movement. This needs to shape the larger cultural narrative about the public health benefits and risks of psychedelics, and raise awareness of available paths to access them.

Closely related is the expansion of **public health education** about risks, contraindications, and safer-use practices related to psychedelics. Without high-quality public health education, it will be impossible for most individuals to make well-informed decisions on whether and how to access psychedelic care. This is particularly important for an interested public that skews toward individuals who are young, who are suffering from mental health challenges, and who may be naive to psychedelics use. While the greatest impact on risk reduction can be had through upstream education, some residual risk leading to harms is inevitable, requiring the field to continue to support several elements of **safety net infrastructure**.

Several organizations have distinctive missions oriented toward essential facets of communications and public health education: Healing Advocacy Fund (HAF), the Multidisciplinary Association for Psychedelic Studies (MAPS), New Approach PAC, the Coalition for Psychedelic Safety and Education (CPSE), and the Psychedelic Communications Hub (PCH, now a program within the Psychedelic Safety Institute), in addition to many more that seek to play important roles at local or specialized levels. Our roadmap calls for supporting both the expansion of these leading groups’ efforts, and their integration into a strategic alliance.

### IV. Supporting Ethical Psychedelic Cultures

Much discussion in the psychedelics field is concerned with the ideals and values that we wish to see the field embody. What culture do we want to create, sustain, and pass forward? There may be no single answer that works across all areas, as the relevant norms, behaviors, beliefs, institutions, etc., will differ between the mainstream medical model, regulated but not-necessarily-medical settings, and the many different forms of unregulated settings for psychedelic use. Nevertheless, we see several priorities that are relevant across psychedelic cultures.

In all settings, **establishing and upholding ethical norms** are essential to maintaining public trust and to reducing individual and movement harms. The range of ethically sensitive areas within psychedelics is broad, across research, training, business, care delivery, and more. Several groups are doing promising early work to shape ethical standards to ensure that patient welfare is prioritized and that societal impacts of expanded access are carefully considered. A particularly promising path to reducing risks of abuse through ethical best practices lies in **self-regulated communities**, where we have an opportunity to elevate those (both religious and secular) that are developing and modeling the highest ethical community practices.

We propose ongoing engagement with these groups’ development efforts, and potentially future collective funding of their implementation. In the meantime, PSFC will systematically apply ethically-informed grantmaking into our work, to amplify attention to ethical issues and provide assurance to funders that their resources are contributing to the elevation of ethical practices.

We also recognize that plant medicine healing traditions have roots dating back thousands of years, and that increased demand from the resurgence of interest in psychedelics is amplifying ecological pressure on wild sources of plant-based psychedelics, as well as harms to the communities for whom these psychedelics provide essential psychospiritual support. Beyond the resulting ethical imperative for **Indigenous medicine conservation & access**, our efforts to bring psychedelic care into U.S. culture would benefit from learning from the corpus of wisdom and experience around plant medicine healing held by traditional practitioners through reciprocally beneficial dialogue. The [Indigenous Medicine Conservation \(IMC\) Fund](#) is a crucial organizational partner that has made multi-year investments in building relationships with the Indigenous plant medicine communities, with a host of on-the-ground capacity-building projects and a forward-looking strategy to slow or reverse threats to major plant medicines while ensuring access to healing for Indigenous communities. In parallel, the [International Center for Ethnobotanical Education, Research, and Service \(ICEERS\)](#) focuses on addressing the complexities and challenges of the globalization of Indigenous plant medicine traditions. ICEERS's work centers around research, mitigating harms to people and communities through legal defense, integration support, and Indigenous rights advocacy, as well as partnership-building to support protection of traditional knowledge.

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These are areas that must be addressed to deliver equitable, risk-reduced access to psychedelic healing. In some, we see activity underway with a clear path to scaled impact in the hands of organizations that have the capacity to absorb and deploy collective philanthropic funding. These are our core roadmap priorities, and for each of them, the strategic roadmap addresses the following:

- Why is this important, and what are our long term goals in this area?
- Where are we today, and what is the plan to achieve these long term goals?
- What risks might this plan carry, and how can they be mitigated?
- What are the proposed timelines and milestones for our goals?
- What philanthropic support is needed in the next ~3 years to meaningfully advance toward achieving our goals?

Other areas have a range of promising early-stage activity, but are not yet developed to the point where collective philanthropy is the right instrument. Our roadmap attempts to bring attention to their work, as a starting point for engaged individual funders to learn more. At the same time, PSFC will continue to engage with the teams behind this activity, and look forward to a time when they have developed sufficiently to be recommended as core collective funding recipients.

A full-page background image showing a desert landscape at night. A large, bright full moon is in the upper right sky, surrounded by many small stars. In the foreground, there is a saguaro cactus on the right and a cholla cactus on the left. The ground is dark and sandy, with some low-lying desert vegetation. The overall color palette is dark blue and black, with the white and yellow of the moon and stars providing contrast.

# I. Expanding Legal Pathways

Psychedelic substances are widely available in the U.S. despite legal prohibition. Nevertheless, we consider it essential to expand opportunities for access without fear of criminal sanction. So far, philanthropy has focused on a few approaches: supporting advancement of a pipeline of candidates for FDA approval, and establishing state-regulated access programs (while, in some cases, allowing limited personal possession, sharing, and use). Despite recent setbacks, each path is independently important, and promising in the long run. These are discussed below, along with the research and real-world evidence that are vital fuel for their continued progress.

## Ensuring State-regulated Program Success

State programs have the potential to provide access to the benefits of psychedelics without the need for a medical diagnosis. They also provide opportunities to learn and optimize care delivery, research novel use cases (particularly those with an unclear path to regulatory approval, e.g., end-of-life distress), experiment with group models, and demonstrate real world efficacy. And, as the only legal access pathway for most people for at least the next two years, state programs represent the best opportunity to demonstrate the profile of psychedelics and prepare to integrate them into broader care systems. If successful, these programs can contribute to a shift in public perceptions, in support of eventual federal policy change.

But the viability of state programs is far from guaranteed. State licensees face significant challenges due to state & federal regulatory environments, the novelty of the business model, and an underdeveloped local client base. There is no benefit from a state program in which licensees cannot succeed.

### Long-term goals

State-regulated psychedelic services should be accessible to all eligible individuals in states hosting such a program, within two years after licensing begins. Here, ‘accessible’ means that services are affordable, are geographically accessible, have capacity, and are staffed with qualified personnel.

Beyond benefits to clients, programs must also be economically sustainable for licensees, and for state governments (potentially with subsidies justified by evidence of the societal benefit of the program).

Characteristics of programs that can achieve these goals are that they:

- Have licensing boards to both set standards of care and hold licensees accountable
- Allow licensed mental health professionals to practice, with integration into broader care systems
- Nurture a diverse network of licensees with adequate capacity to meet demand
- Serve a sustainable market of local clients that receive and benefit from psilocybin services
- Enable collection and reporting of outcomes data
- Produce minimal adverse events, in relation to the aggregate benefit delivered
- Have robust public education on psychedelics and psychedelic services, with legitimacy in the eyes of local healthcare institutions
- Generate an evidence base to support eventual insurance reimbursement

### Plan to achieve goals

The two organizations best positioned to bring about the conditions for success of state-regulated programs are [Healing Advocacy Fund](#) (HAF) and [National Psychedelics Association](#) (NPA). They are advocates in policy implementation and development, support licensees with resources and services, and educate the public and healthcare providers to increase awareness and accelerate mainstream adoption of psychedelic therapy.

HAF has a proven track record in Oregon and Colorado over the past four years, including successful strategic communications and advocacy with policymakers around rulemaking and implementation. To achieve our goals, HAF must continue to evolve and grow to best serve state-level stakeholders and the broader psychedelics field. They support the effectiveness, viability, and safety of state programs; demonstrate the potential of psychedelic care through pilot research and advocacy for outcome measurement; protect programs by working with states to deploy safety and accountability measures and run communication strategies; and transmit learnings from existing to emerging state programs.

HAF's work in Oregon and Colorado has been critical to improving the regulatory environment for licensees while ensuring quality, safety (e.g., adequate screening and contraindications), and data collection. In 2024, the HAF Oregon team focused on key improvements to continue boosting safety and to better integrate the program with traditional mental and behavioral health care. This work will evolve as the programs do - with new learnings, policy improvements will be pursued. In the near-term, HAF is focused on adding dual licensure to Oregon (a key success factor for legitimacy in the medical community) as well as other safety measures, such as extending the required adverse event reporting period, addressing concerns around potency labeling and dosage, and allowing public-facing anonymity for clients reporting misconduct or other complaints to the OHA.

HAF has also developed Community Impact Pilots to create real-world proofs-of-concept for the efficacy of psychedelic therapy access, starting with showing efficacy of psilocybin for addiction treatment. People Science, a contract research organization (CRO) with expertise in executing real-world research related to non-pharmaceutical interventions, is partnering with HAF on this pilot. HAF has also received initial funding for a pilot designed to serve justice system-impacted individuals, and has had preliminary discussions with a leading palliative care clinician on a potential end-of-life pilot. Pilot programs like these present opportunities to capture efficacy and other learnings which are essential to achieving many of our goals within state programs and beyond.

HAF continues to be a primary source of information for media covering both the state programs and the psychedelics field overall. They have invested in relationships with local and national media, who view HAF as an informed



source about the details of state programs. In coordination with other anchor organizations, HAF will continue to lead responsible proactive and reactive strategic communications around state programs. HAF also is undertaking a targeted awareness and education campaign designed to accelerate mainstream adoption of psychedelic therap

Complementing the mission of HAF, NPA consists of three parts. NPA Services Inc. provides solutions to support licensee business needs, such as financial services, compliance management, data management, professional services, with insurance to be added in the future. This support is vital because of continued federal illegality, which discourages national service providers from supporting service centers. NPA Services recently completed its formal launch in Oregon, and has 14 service center members; PSFC staff has heard favorable testimonials from several. Second, there is a 501c6 component of NPA which, as a trade association, unifies members around a set of core values that will normalize psychedelic-assisted services, including professional self-regulation, standards for education, ethical practice guidelines, unified lobbying voice, and peer-to-peer engagement. Lastly, NPA Foundation (NPAF) is the 501c3 that seeks to support progress and advocate for expanded access through awareness initiatives, legal advocacy, and accreditation of training programs.

Philanthropically-funded NPAF can help achieve our goals in a few ways, detailed below:

- Raising awareness and understanding of psilocybin services, which will increase access and facilitate integration with other systems of care.
- Creating robust training standards that will attract better students, improve the quality of facilitators and provide a more respected credential, increase credibility of service centers, and ensure high-quality, safe care reducing risks for all stakeholders.
- Improving access and reducing impact of federal policies through legal advocacy.

NPAF's Psychedelic Education Liaisons (PEL) initiative will hire and deploy medical science liaisons (MSLs) to educate licensed mental health professionals about Oregon's regulated psilocybin services, with the goal of enabling appropriate referrals. This initiative will equip mental health professionals with essential knowledge about psilocybin as a therapeutic intervention, whom it is appropriate for, and how to communicate with clients about it within the boundaries of state law. As a result, the PEL initiative will foster a more robust in-state market by ensuring that psilocybin services are understood and accessible to those who need them.

At the same time, NPAF plans to launch a targeted digital ad campaign aimed at attracting out-of-state clients. This is necessary due to the risk of Oregon losing a large portion of its out-of-state clientele (75-95% of the market) as other states begin to offer similar services.

Regarding training, we observe numerous frictions related to a lack of standardized accreditation for training programs, which will become radically worse as new states come online with patchwork standards. NPAF's 'Seal of Approval' for Training Excellence will leverage Beckley Academy's learning framework as a starting point to set standards for quality, safety, and trust. For facilitators, it means top-notch training and respected credentials. For training programs, it attracts students and funding while ensuring legal compliance. For service centers, it ensures safe, high-quality care and boosts credibility.

Finally, NPAF's legal advocacy efforts are aimed at opening access to psilocybin therapy for patients with life-threatening conditions. This advocacy includes a three-pronged approach: leveraging right to try (RTT) laws; building evidence to support rescheduling psilocybin from Schedule I to a lower level (there are arguments that [justify moving as low as Schedule IV](#), though higher levels may be more readily attained); and challenging state regulations to allow in-home services for hospice and palliative care patients.

It's worth noting that, as NPA Services becomes profitable, a percent of those profits will be directed to the NPA Foundation, and reduce the need for philanthropy.

#### Risks in the plan to mitigate

Even with intervention, the regulatory and business environments may prove to be too challenging, forcing operators out of the market, reducing access and the impact of the program. In either case, realizing full sustainability for state-regulated programs may require national shifts, such as rescheduling psilocybin (reducing costs of doing business), and unlocking meaningful insurance coverage (increasing client volume and revenue), each of which is a very long-term goal.

There is also a risk that an accumulation of sensationalized adverse events or instances of abuse could turn public sentiment against the program. HAF's policy work can help ensure suitable guardrails for safety and create an environment to minimize such instances. Additionally, NPA's work to accredit training programs will help ensure quality facilitators and instill confidence in service centers that graduates are capable and competent. Eventually, there may be a need for a licensing board to develop best practices, certify practitioners, and hold them accountable to further mitigate risks.

Even if adverse events or harms happen outside of the regulated programs, in recreational or non-regulated guided contexts, these events could be misattributed in the public narrative to the regulated program. Strategic communications and public education, carried out by multiple organizations in coordination (discussed below) can help to mitigate the risk posed by such events by deploying targeted proactive and crisis communications alongside public health education.

Finally, if data standardization and reporting is not broadly adopted, we will know very little about the risk/benefit profile of state programs. HAF has consistently advocated for systematic data collection (SB303 advocacy in Oregon, and development of promising frameworks from the start in Colorado) and must continue these efforts to ensure comprehensive outcomes data is collected and reported.

#### **Timeline and Milestones**

We anticipate that Healing Advocacy Fund (HAF), with the required funding described below, and adequate support from partnership organizations, should be able to achieve the following milestones:

- 2025 (near-term):
  - In Oregon, passing program improvement bills, including dual licensure.
  - In Colorado, heading off pre-launch efforts to limit access; and ensuring funding for a proposed outcome measurement program.
  - Track and report on information derived from SB303 reporting.
  - Complete first cohorts of Oregon pilots, publish results, and leverage them to support favorable access policies. Additionally, launch at least one pilot in Colorado and extend existing Oregon pilots into additional cohorts.
  - Support coalition work to develop a uniform data variable set for research consistency in similar pilots across the field.
  - Launch market-research backed and agency-driven mainstream awareness and adoption campaigns (impact to be estimated after initial market research results are available).

- 2027
  - Leveraging lessons learned, HAF should be engaged in the implementation of multiple new states (beyond Oregon and Colorado) that have passed some form of significant psychedelic policy change (legislative or ballot initiative). Each new state will benefit from the lessons learned in previous states.
  - Community impact pilots are expanded to new states, demonstrating real-world outcomes with targeted populations, and at a lower cost per-pilot due to greater efficiencies. Pilot studies are providing direct healing to the hundreds of participants and supporting advocacy and policy change efforts.
  - A majority of the public and behavioral health professionals in states with regulated psychedelic programs are aware of these programs and generally understand the benefits and risks are for specific use cases.
- 2030
  - There are at least eight established, active state-level psychedelic care programs, representing a spectrum of policy models, with at least another 3-5 preparing to launch or in early stages of execution - pending validation of success in earlier states. An additional ten states are actively considering or working to establish psychedelic care programs.
  - HAF continues to lead policy development toward models that prioritize safety, efficacy, and field viability. There is a network of partner organizations that target specific, critical issues (e.g., equity and reimbursement) and constituencies (e.g., veterans, health care providers).
  - There is an extensive body of evidence developed through the Community Impact Pilot program and other data analysis to prove safety and efficacy to policymakers, community leaders, and the general public. Broad communications efforts that raise awareness and mainstream acceptance of psychedelic therapy as a valid mental health and wellness tool are driving sustainable growth of viable and effective state-level psychedelic care programs.

The National Psychedelics Association's (NPA's) concrete metrics and milestones relate to the sustainable functioning of on-the-ground licensee businesses.

- 2025
  - 2-3 medical liaisons engaging licensed mental health professionals across Oregon
  - National digital B2C campaign completed, with all KPIs and ROI reported and informing future campaigns
  - At least 5 training programs have received NPA recognition for training excellence
  - Ongoing legal advocacy around right to try (RTT), reclassification, and ADA litigation for hospice and palliative care access
- 2027
  - >50% of Oregon's 4.5K licensed mental health professionals have been educated about regulated psilocybin services, with impact evaluation and recommendations for future initiatives
  - Digital B2C campaign has generated at least 25% lead growth at member centers, with similar campaign launched for Colorado, if needed
  - Majority (>50%) of licensed facilitators have obtained training from programs with NPA's training excellence recognition
  - Psychedelics in phase 3 clinical trials are available for those who qualify for RTT

- Oregon has amended its rules to allow reasonable accommodation for hospice and palliative care patients
- 2030
  - 75% of Oregon and Colorado licensed mental health professionals have been educated on their state's PAC programs
  - Digital B2C campaign continues to generate lead growth of at least 25% at OR and CO member centers, with differentiation among states to balance legacy market viability with new state market entrants
  - NPA training excellence has been adopted as the standard for best in class training, with at least 50% of licensed facilitators graduated from recognized programs

### **3-year Funding Required**

#### *Healing Advocacy Fund (HAF): \$19M*

After significant expansion in 2025 (\$4.8M) to support a broader set of programs and priorities serving the field, HAF expects more modest growth in 2026 (\$6.7M) and 2027 (\$7.5M). These increases are largely driven by expansion of programmatic work. This includes dedicating staff for policy analysis and government engagement to ensure good outcomes, as well as an expanding portfolio of community impact pilots. HAF further plans to expand adoption and awareness programs, including community engagement, to each new state. However, we expect them to achieve significant cross-state efficiencies, reducing the resources required per state over time. By 2030+, as state-level psychedelic policy programs become more common, the need for hands-on program support will decrease.

#### *National Psychedelics Association (NPA): \$9.2M*

NPAF costs over the next three years are driven by a combination of expanding awareness initiatives (PEL and B2C campaigns), and expansion into new state-regulated programs (Colorado in 2025, others TBD). NPAF does expect to maintain internal operating expenses at less than 10% of total expenses, regardless of the number of states. Additionally, NPAF anticipates that the required budget for legal advocacy will decrease over time by 25% each year, and the accreditation program is highly front-loaded with development costs, decreasing by 50%+ after year 1. Moreover, NPAF will be able to earn fees from the accreditation program to cover ongoing costs, and expects in-kind contributions (from NPA Services, Agency, and Legal) to increase year-over-year. As a result, we anticipate that the milestones through 2027 could be delivered at a total cost of \$9.2M over three years: \$2.0M in 2025, \$2.4M in 2026, and \$3.4M in 2027.

## **Advancing State Policies**

For 97% of the U.S. population who live outside of Oregon or Colorado, there is no legal pathway to access psychedelics under state law. The lack of legal access blocks the establishment of regulatory safeguards, increases underground use, and perpetuates social stigma. Reforming laws to advance psychedelic healing and promote public health is an urgent and important goal.

When a state enacts policies to allow legal access, it helps advance the overall movement in several ways. As more people access psychedelic healing, personal stories spread through social networks via friends and families, changing perspectives and opening more hearts and minds along the way. As more states come online, we have more opportunities to experiment with policies and learn about what works. They also mobilize state resources towards development of infrastructure to train facilitators and engage professional associations.



Even when not successful, policy reform campaigns have ancillary benefits. They create opportunities to amplify stories of psychedelic healing and educate the public. They bring together diverse stakeholders to engage in important conversations about how psychedelics can be responsibly integrated into society. They also work as a recruitment tool to bring more people—including opinion leaders and philanthropists—into the movement.

Public support for reforming laws related to psychedelics is significant. Surveys find that 50-70% of American voters favor some kind of reform to enable legal access. Additionally, bipartisan coalitions of state legislators are forming all across the country to introduce new legislation related to psychedelics. The topic of psychedelic policy is gaining legitimacy within intellectual circles as we've seen with the publication of reports from [RAND](#) and [Transform](#). It's also an exciting time, as the range of policy ideas being proposed is diversifying, with several thoughtful frameworks that differ from the existing models in Oregon and Colorado.

While there is a tremendous opportunity, there are also risks and challenges. We need careful, nuanced analysis and reflection to incubate a state policy movement that will be successful in the long run. Developing a strategic plan for advancing state policies over the next five years requires complex thinking that incorporates a broad range of perspectives. With incubation support from PSFC a **Psychedelic Policy Institute** can help guide and coordinate a national state policy movement for psychedelics in collaboration with a broad range of allied groups and stakeholders in the field. The proposed Institute is designed to fill major gaps and establish the infrastructure necessary to maximize the impact and long-term success of state psychedelic policies.

## **Key gaps and challenges in the state policy movement**

### **Improving the quality of policy proposals**

While it is encouraging that dozens of states are introducing and considering policies to advance psychedelics, these proposals are often not written in a clear or thoughtful way, or in the most advantageous way to advance the movement's overall goals. Rather than starting from scratch, policymakers and advocates would benefit greatly from a resource that could provide a menu of model policies (permitting different approaches depending on what is politically viable) and concise analyses that can clarify decisions about policy design and improve the quality of legislation being proposed.

### **Developing coordinated leadership**

The national landscape for state policy reform efforts around psychedelics is fragmented. Across the country, disconnected hubs of local advocates and lawmakers have come forward to push a wide variety of policies at both the state and municipal level. National advocacy organizations tend to pursue strategies without input and communication with other groups. While this groundswell of support has been mostly helpful and beneficial, there is a clear need for leadership to facilitate greater collaboration and coordination and to provide technical assistance to ensure that reforms are implementable, aligned with best practices, and work to advance larger movement goals.

### **Learning from existing state programs and experimenting with different models**

Thousands of people have participated in Oregon's psilocybin services program, and this fact itself is a tremendous milestone for our movement. However, there is still much to learn about state-regulated programs and how we can ensure their long-term success. Proactive policy reform efforts in other states must be updated and informed by our best understanding of current models, so that we can continually improve these programs over time. Furthermore, policies that enable access will likely look different in Indiana versus California—and the pace of change won't be the same in every state. We must develop policies and programs suited to the different environments of each state and region.

### **Ensuring safety and protecting against the risk of political backlash**

We must be vigilant and proactive against scenarios that could lead public opinion to swing back against the psychedelic

movement. One way this might happen is a rise in adverse outcomes attributable to state policy reforms. While [we are not seeing any evidence of a noticeable rise in public health or safety problems in Oregon or Colorado](#), we must continue to take efforts to mitigate this risk, by supporting responsible implementation, robust public health education, and safety net infrastructure. We should also be careful to ensure policy reform efforts have bipartisan support. Our movement will be significantly hindered if we do not make intentional efforts to be politically inclusive.

### **Promoting synergy between state and federal policy**

Many movements, including cannabis legalization and marriage equality, begin in the states which eventually build toward reform at the federal level. State policy reform can significantly influence what happens at the federal level and vice versa. The design of state programs, for example, can influence future deliberations around [federal rescheduling](#) of psychedelic medicines. We need national and state policy experts to help guide collaborative efforts at both levels to achieve the best results.

### **Building bridges with academics and non-psychedelic policy organizations**

Leaders of state psychedelic reform efforts should be in regular dialogue with academic researchers who study psychedelics as well as organizations that play an influential role in shaping public policy (e.g., the National Conference of State Legislatures and Republican Governors Association). We need education to flow both ways.

### **Psychedelic Policy Institute**

Many other successful social movements have benefited from a national policy organization leading state-by-state efforts. The Psychedelic Policy Institute is a new project bringing together leaders in the psychedelic policy community to solve the challenges described above. It will be led by individuals who have many years of experience advancing state policy reform and aims to develop and execute a strategic plan over the next five years to help guide the success of the state-by-state psychedelic movement.

The Institute will work collaboratively with a large coalition of organizations in the psychedelics field, including:

- **National partner organizations** that share a focus on ensuring the success of state-regulated programs, including Healing Advocacy Fund, MAPS, and Heroic Hearts Project.
- **Other core national allies** whose mission significantly overlaps with state-based efforts, including the Coalition for Psychedelic Safety and Education, the Psychedelic Safety Institute, Psychedelic Mental Health Access Alliance, and Reason for Hope.
- A broader network of **organizations who play an important role in advocacy and public education**, including the Chacruna Institute, Clusterbusters, Drug Policy Alliance, Law Enforcement Action Partnership, Reason Foundation, Sacred Plant Alliance, SIREN Project, Students for Sensible Drug Policy, and VETS.
- **Local and state-based advocacy coalitions** such as the Clarity Project (Hawaii), Illinois Psychedelic Society, Natural Medicine Alaska, Natural Medicine Maine, Nevada Coalition for Psychedelic Medicines, New Mexico Psychedelic Science Society, New Yorkers for Mental Health Alternatives, Open Circle Alliance (Massachusetts), Psychedelic Association of Arizona, Psychedelic Medicine Alliance of Washington, and Psychedelic Society of Vermont.

The mission of the Institute is to learn from existing state programs and iteratively improve policies, facilitate a coordinated and strategic national coalition, and guide strategic investments into state campaigns. The overarching goal is to promote public health and wellness, and to the extent possible, the Institute will analyze data and research to assess the impact of state policies. The organization intends to cultivate long-term institutional knowledge and play four key roles in the psychedelic policy movement:

- 1. Policy analysis and development:** build movement capacity to address complex policy questions and lead the development of thoughtful models.
  - Evaluate outcomes of existing state programs;
  - Engage with academic literature that is relevant to psychedelic policy;
  - Monitor and analyze new state and federal legislation;
  - Publish articles and reports that advance understanding and cost-benefit analyses of psychedelic policies;
  - Help state policymakers and advocates draft thoughtful and responsible policies.
- 2. Support and incubate strategic state policy campaigns:** bring experienced leadership and resources to support successful policy reform efforts.
  - Identify ripe opportunities across states and execute a multi-year national strategy;
  - Advance politically viable policies that align with the organization's mission;
  - Build a speakers bureau with powerful advocates who can use their voice to advance state policies;
  - Develop institutional knowledge and a national network of experienced leaders and organizers to spearhead coalitions and manage successful policy campaigns.
- 3. National coalition leadership:** promote coordination with allies and other leaders to advance an inclusive, strong, and successful policy movement.
  - Facilitate alignment among leading organizations in the psychedelic ecosystem;
  - Host regular meetings and in-person policy summits;
  - Develop a collaborative national policy strategy.
- 4. External engagement and strategic partnerships:** go outside the psychedelic bubble to learn from and build alliances with other movements and institutions.
  - Establish strong relationships and communication channels with:
    - scientific researchers
    - public health leaders
    - mental health organizations
    - public policy institutions
    - advocacy/constituency groups
  - Educate audiences about psychedelic policy at conferences and other public events;
  - Develop strategic initiatives in partnership with organizations outside the psychedelic ecosystem

### **Psychedelic Policy Institute organizational structure, 2025 goals, and budget**

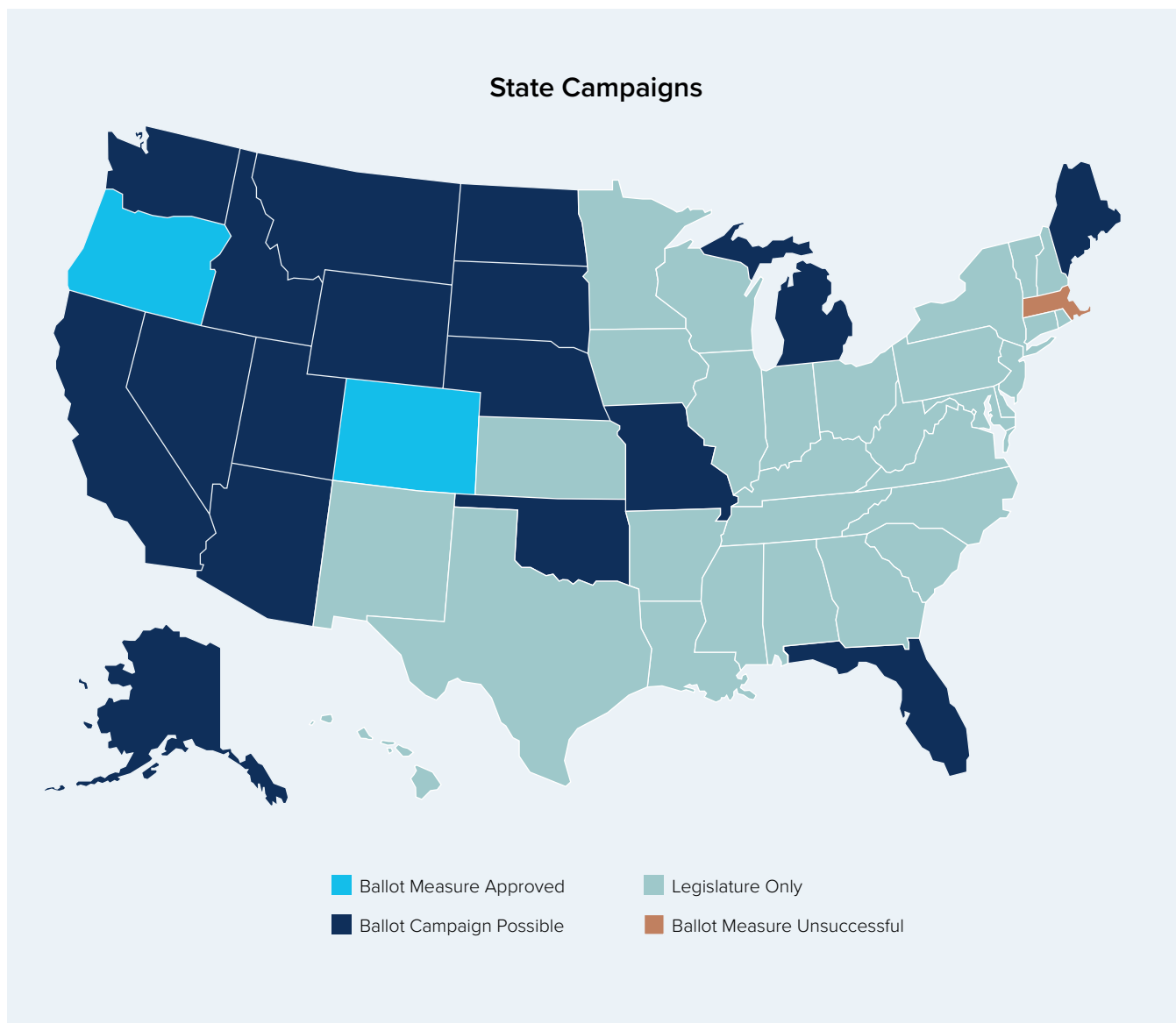
The Institute will be driven by a core group of operational staff including a national policy director and deputy director,

a policy research and academic engagement director, and a strategic partnerships coordinator. Additional support staff will be hired as the project expands, contingent on funding. The Institute will launch in 2025, hiring a minimal number of full-time staff during the first six months while developing initial project infrastructure. The total operating budget for the first year is \$1.2m, with the yearly budget plateauing at \$1.8m by 2027.

Goals of the Psychedelic Policy Institute for 2025

- Build an advisory board of experts and leaders in the field;
- With input from a diverse range of stakeholders, develop a set of model state policies;
- Publish policy briefs on important topics;
- Identify and engage nationally influential organizations (e.g., state government institutions, public health organizations, think tanks) as they develop views on how to engage with the psychedelic policy movement;
- Conduct of a national qualitative opinion research report assessing the views of key voting constituencies on psychedelic policies;
- Develop a national strategy based on opinion research, policy analysis, and input from national coalition partners.

Projected Funding Needs for State Policy Advancement, 2025-2028				
	2025	2026	2027	2028
Operating budget (Institute, c3)	\$1,200,000	\$1,600,000	\$1,800,000	\$1,800,000
Direct lobbying and ballot initiatives (New Approach, c4)	Low: \$800,000 High: \$15,000,000	Low: \$1,500,000 High: \$25,000,000	Low: \$1,500,000 High: \$30,000,000	Low: \$1,500,000 High: \$50,000,000



## National state policy strategy

While growing public support for legal access to psychedelics creates an exciting opportunity to move us closer to our North Star, the role of the Institute is not to pass as many new laws as quickly as possible. Rather, the Institute will support the nascent state policy movement by providing thoughtful analysis, facilitating a broad and inclusive coalition, and developing a national strategy.

Pursuing reforms in particular states offers unique advantages. The Institute will develop and iteratively refine a national plan that incorporates multiple objectives into a cohesive strategy. For example:

- **Arizona, Indiana, Missouri, and Utah** are states where there's strong Republican leadership on psychedelic policy reform; it's critical that we incubate a national bipartisan strategy in order to avoid the pitfalls of partisan gridlock that plague other social movements.
- **New Mexico** presents an opportunity to partner with government stakeholders who have expressed interest in state-funding and possibly Medicaid coverage for state-regulated therapy in conjunction with psychedelic services.

- **New Jersey** and **New York** are states where innovative “medicalized” psilocybin programs have been proposed; these policies, if enacted, could influence future decisions related to rescheduling psilocybin. There is a precedent with cannabis whereby state policies allowing “medical” access have been cited as a reason to justify federal rescheduling.
- **California** has the largest population of any state (39MM) and arguably the strongest base of support in the country; passage of policy in California would have a tremendous national impact.
- **Alaska, Arizona, and Maine** are worth considering for the next wave of ballot measure campaigns; each has a less liberal—but more libertarian—political climate, and above-average veteran populations compared to other states.

### Legislative efforts versus ballot campaigns

Half of U.S. states allow citizens to place an initiated measure on the ballot; half do not. In the development of a national strategy, it's crucial to consider the tradeoffs between pursuing a ballot campaign versus legislative paths. A ballot initiative requires filing a measure, influencing the ballot title and summary, collecting signatures to qualify, and communicating with voters to earn their support. Legislative bills involve building a coalition with elected state legislators, navigating through committees and the legislative process, and getting the governor's signature (or at least avoiding a governor's veto). Proponents of ballot measures have more control in the process, but the campaigns are significantly more expensive. Legislative efforts tend to cost much less, but take longer, face more pitfalls, and tend to be more modest reforms.

## Research Agenda

As psychedelic therapies advance toward FDA approval, a critical and timely endeavor looms: translating clinical trial results into the real world. Currently, there are significant gaps in understanding and implementing these therapies. Addressing these gaps through coordinated research and pragmatic studies is vital to ensure the safe and effective rollout of these treatments. Funding targeted research is crucial; without intervention, the promise of these therapies could be significantly delayed or unrealized in everyday clinical practice, especially for marginalized communities.

### Long-term goals

By 2030, significant federal funding will have been unlocked, with all relevant federal agencies having research officers knowledgeable about psychedelics. A thriving portfolio of pragmatic and implementation research will bridge the significant gaps identified, ensuring that the transition from clinical trials to real-world application is both effective and widespread. We envision a well-funded, credible, network of collaborations that not only advances the understanding of psychedelic therapies but also integrates these insights into everyday clinical practice, having successfully addressed critical areas such as the economic impact of therapies, optimal therapeutic models, and the specifics of patient care, including considerations for marginalized populations.

### Current State

There is a notable lack of comprehensive and organized research efforts in the psychedelics field and to some extent in mental health at large, in contrast with more mature medical fields. Despite growing interest in psychedelic research, efforts remain fragmented, under-funded and under-coordinated, with critical areas such as health economics, the role and optimal modality of therapy and group models being under-researched. Philanthropy has the opportunity to bridge this gap by funding pragmatic and implementation research, crucial for the safe and effective rollout of these treatments.

There is growing interest from funding bodies and private foundations, including an encouraging recent series of significant grants by government agencies:



- NIH and affiliated institutes
  - (2021) \$4M [from NIDA](#) to John Hopkins on psilocybin for smoking cessation (first federal grant for human psychedelic treatment research in 50 years)
  - (2023) \$600k [from NCI](#) to NYU on psilocybin for end-of-life anxiety in cancer patients
  - (2023) NIH launched a [targeted R01 grant program](#) on “Advancing Psychedelics Research for Treating Addiction”
  - (2024) \$3.8M [from NIAAA](#) to NYU on psilocybin for alcohol use disorder, in partnership with B.More
  - (2024) \$14M [from NIDA](#) to Gilgamesh Pharmaceuticals to develop an ibogaine analog for opioid use disorder
  - (2024) \$15M [from NIDA](#) to NYU to support a phase 2 trial of psilocybin in the treatment of OUD, in partnership with B.More
- Defense funding
  - (2021) \$27M [from DARPA](#) to North Carolina University to design non-psychoactive psychedelic medications for mental health
  - (2024) [the DOD](#) currently has an active psychedelic Request for Proposal (RFP)
  - The 2024 National Defense Authorization Act includes [a new provision](#) funding psychedelic trials to study their medical effects on troops.

Other positive signals of federal agency interest are emerging:

- The NIH convened a [workshop](#) in 2022 to cover mechanistic understanding of psychedelics, discuss the necessity and nature of concomitant psychotherapies for treating depression, post-traumatic stress, and substance and alcohol use disorders.
- The National Academy of Science convened a 2022 [workshop](#) to discuss the neurobiology of the therapeutic effects, strategies for optimizing the safety, efficacy, and patient stratification.
- The U.S. Department of Health and Human Services (HHS) held a [convening](#) in 2023 exploring the ethical and practical considerations of psychedelic research, focusing on issues such as informed consent, study design, and the protection of vulnerable groups.
- The NIH launched in January 2023 a [Psychedelic Science and Medicine interest group](#) for the purpose of fostering collaboration among researchers from various disciplines.
- In August 2024, the [Congressional Psychedelics Advancing Therapies \(PATH\) Caucus](#) issued an [RFI](#) seeking specific recommendations on the implementation of programs and policies related to psychedelic-assisted therapies.

Despite these signals, obtaining funding and carrying out psychedelic studies remains challenging for researchers. The regulatory hurdles of working with Schedule I substances add significant cost and time to research initiatives (12-24 month delay in studies). [Apollo Pact](#) and Reason for Hope have been working to reduce research barriers and advocating for federal resources. Only in July 2024 did California start to unlock a year-long logjam of psychedelic study application reviews overseen by the [Research Advisory Panel of California](#) (RAPC). Furthermore, procurement of psychedelics drugs for research is a significant bottleneck that has yet to be solved, as drug developers for MDMA and psilocybin aren’t currently addressing investigator demand, and the government (NIDA) supply program only supplies non-GMP psychedelics even while mandating use of GMP for human trials. Pioneer [Heffter Research Institute](#) is

working on those issues, as well as on an early career award program to help new investigators gather the preliminary evidence needed to unlock federal funding.

Besides Heffter, there are emerging collaborative research networks, either psychedelic-native like the International Society for Research on Psychedelics ([ISRP](#)), psychedelic task forces of larger established networks such as the National Network of Depression Centers ([NNDC](#)), and an informal effort within the [trauma psychology division of the APA](#). NNDC's [psychedelic task force](#) plans to educate clinicians on psychedelic use, and conduct multi-site clinical trials to explore various therapeutic models. Overall, the ecosystem is still largely fragmented and siloed. This situation leaves the field with significant gaps in knowledge in key areas relevant for implementation and care delivery, that will not be fully addressed by commercial actors. More work is needed to convene stakeholders and to establish a pragmatic roadmap for the field.

### Opportunities for PSFC to support advancement of this area

- Engage with regulatory bodies to ease restrictions and unlock more support for a thriving psychedelic research ecosystem. This can be done through strategic partnerships with above-mentioned organizations.
- The [Foundation for the National Institute of Health](#) (F-NIH) offers a possible co-funding mechanism, under which philanthropy can cover a complementary portion of a research study that is ineligible for NIH funding due to scope restrictions that, in some cases, unfortunately prevent trials from measuring treatment efficacy or cost-effectiveness.
- Coordination and collaboration:
  - Support coordination of emerging structures and increased adoption by mainstream hubs
  - Enhance coordination among existing research entities and mainstream organizations, leveraging models from established fields to create a coherent approach to psychedelic research.
  - Support the organization of convenings to foster collaborations.
- Support efforts focused on pragmatic research, especially regarding critical gaps that our team has identified:
  - Health care disparities and enabling equitable access and outcomes; notable work is being done in this area by the Psychedelic Mental Health Access Alliance (PMHAA) , MAPS, and research initiatives discussed in the Health Equity roadmap section
  - Health economics of psychedelic treatments; notable work is being done by the [Collaborative for the Economics of Psychedelics](#) (CEP)
  - Exploring the role of therapy and its impact on patient outcomes and safety when reducing or eliminating the therapeutic component with various substances:
  - Understanding best screening practices, contra-indications and comorbidities
  - Feasibility and impact of group modality models (for sessions and/or support); notable work done at several academic institutions, some being planned by MAPS on couples-therapy and conflict resolution.
  - Role of facilitator competencies and credentials
  - Identifying the right wraparound care, role and type of therapeutic interventions, frequency of dosing for long-lasting outcomes.
  - Understanding the role of Set & Setting
- While some funders value cultivating direct relationships with specific research groups, others might value a more coordinated approach to specifically target and close the most urgent gaps. This could take the form of a Research

Grant Fund.

- This fund would specifically address priority areas where traditional funding mechanisms fall short, adopting a field catalyst approach by issuing targeted Requests for Proposals (RFPs) to support diverse, mission-aligned research initiatives, particularly pragmatic studies with implications for implementation and policy-making.
- The strategy aims to mature the field by ensuring broad inclusion of groups and a holistic approach to tackling identified challenges. Historical precedents, such as the Heffter Research Institute and Beckley Foundation, highlight the power of coordinated philanthropic seed funding to drive progress in priority areas.
- A rigorous review process could be employed, grantees will be expected to share data, collaborate with other grant recipients, and adhere to ethical standards. Eligibility should be broad to include researchers from academia, independent institutions, and other non-profits. Collaborative groups spanning multiple organizations may be incentivized.

### **Risks to monitor**

- Risks of funding biases and potential conflicts of interest can be mitigated with the adoption of the ethics charters for philanthropists and grantees.
- The challenge of translating research findings into practical therapeutic applications can be mitigated by funding projects that embed at least one implementation partner as part of a multi-disciplinary team.

## **Real-World Evidence**

Measuring and analyzing real-world evidence (RWE) is essential for evaluating the effectiveness and safety of psychedelic therapies beyond clinical trials, across diverse real-world settings. This evidence not only helps refine therapeutic protocols and improve patient outcomes but also plays a critical role in monitoring the safety and impact of the wide-ranging, current real-world use of psychedelics. Robust RWE can inform best practices, help refine therapeutic protocols, and support evidence-based policy decisions. Without systematic data collection, there is a risk of insufficient safety measures, fragmented practices, and gaps in knowledge that could erode public trust and hinder the responsible integration of psychedelic therapies.

### **Long-term goals**

By 2030, trusted, interoperable, HIPAA-compliant, and privacy-abiding data infrastructures for psychedelic research will be established, standardizing data across the field and fostering a self-sustaining ecosystem. Collaborative efforts will create comprehensive datasets for psychedelic therapy, managed by transparent non-profit consortia, benefiting researchers and policymakers alike. Furthermore, within 12 months of their launch, newly state-regulated psychedelic therapy programs will implement effective, standardized real-world data collection systems, featuring regularly updated public-facing dashboards to ensure measurement of safety, efficacy, and demographics. Data from all sources—whether federally regulated, state-regulated, or unregulated—will be leveraged to strengthen safety protocols, refine treatment procedures, guide regulatory updates, inform public health policies, and support education and payer reimbursement.

### **Current State**

There is a lack of organized efforts to collect real-world evidence for PAT, both at federal and state levels. This poses significant risks, including safety issues and policy stagnation, which could impede the development of the field and affect public and regulatory acceptance.

Recent FDA activity has emphasized the need for comprehensive long-term post-marketing surveillance of adverse events. The recent [FDA guidelines on real-world data sources](#) offers a new pathway for faster adoption of promising

treatments and potential re-scheduling of natural compounds. Furthermore the recent [DOJ proposal to reschedule cannabis to Schedule III](#) creates a precedent of using state-level data on safety and therapeutic use to inform federal rulings. Since 2021, the Serious illness & psychedelics group (Pallpsysig) gathers about 50 investigators who have started to synthesize information about the trials, methods and measures of each group. The Psychedelic Harms and Adverse Effects Network (PHAEN) recently [published a consensus from 30 psychedelic researchers](#) on key critical research gaps around psychedelic harm and safety. In 2024, 11 of their members published the first [framework for assessment of adverse events](#) occurring in psychedelic-assisted therapies, with a convening planned at Emory University early next year. The [NNDC's ketamine task force](#) (distinct from their [psychedelic task force](#)) has additionally proposed [efforts to collect RWE to support insurance coverage](#).

The Psychedelic Mental Health Access Alliance, in partnership with [UC Berkeley's Collaborative for the Economics of Psychedelics](#), Healing Advocacy Fund and 1440 Foundation, is developing of a uniform data reporting framework, in order to enhance collaboration, information sharing, and research quality. Started in July 2024, this initiative aims to create ecosystem-wide consensus on what and how to measure results of real-world applications of PAT. This involves the development of a standardized set of variables for a database on psychedelic services, which will be broadly accepted and used by a significant number of service providers and clinics within the psychedelic space.

There are additional efforts focused specifically on state regulated-access programs. With the initiation of legal psychedelic services in states like Oregon and Colorado, a structured approach to gather real-world evidence is essential to inform best practices, and guide policy. But existing initiatives are under-funded, lack coordination and face challenges due to the absence of aligned incentives among stakeholders. The Healing Advocacy Fund has worked to provide regular estimates of the number of clients served. In Oregon, non-profit Bendable Therapy was the first to publish [informative anonymized statistics](#) one year into the program. Recently, the [OPEN Initiative](#) has launched an observational survey recruiting through partnership with facilitators with the aim to measure the impact of state legal psychedelic services. The [National Psychedelic Association](#) is working with some service center operators to ensure that they are prepared to implement data collection practices required by Oregon's SB303, mandating anonymized data reporting. The idea of measuring the outcomes of the program in Colorado is gaining traction, with several local stakeholders well equipped to support data collection efforts collaboratively: such as the [Rocky Mountain Poison and Drug Safety \(RMPDS\)](#), University of Colorado and spinoff [Althea](#), and [Unlimited Sciences](#).

### Opportunities for PSFC

Philanthropic action can change the current challenging scenario by aligning incentives and supporting real-world data collection. Supporting interventions like developing comprehensive data platforms, funding targeted research projects, and fostering collaborations among operators and regulatory bodies are crucial.

- **State-Level Coordination:** Collaborate with state-level stakeholders to standardize and streamline data collection efforts in states with legal psychedelic therapies.
  - Support efforts in Oregon to improve service centers' readiness for SB303 and enhance the detailed assessment of safety and outcomes.
  - Support the emerging alliance of stakeholders in Colorado to help create a blueprint for optimal real-world evidence (RWE) collection in state-model psychedelic therapy programs and ensure that it can be adapted and replicated in other states.
  - Work with HAF and NPA to encourage collaborations in other jurisdictions.
- **National and Beyond:** Develop frameworks for a national data infrastructure that can serve as a model for other jurisdictions.
  - Support projects working on the standardization of data collection and reporting across research initiatives

to ensure consistency and reliability of findings. (PMHAA uniform data project, Ketamine RWE initiatives, Pallpsysig and PHAEN)

- Support convening an annual forum to support collaborative initiatives and update practices based on real-world evidence.
- Work with the Psychedelic Policy Institute to ensure inclusion of real-world evidence provisions in future policy initiatives.

### Risks to Mitigate

- **Concerns around data privacy and ownership:** This can be mitigated only over time, through communication and coordination efforts, regular convening of local stakeholders aiming to develop and promote a transparent solution acceptable to all.
- **Data Collection Preparedness:** Inadequate readiness among relevant parties to execute effective data collection strategies. This can be mitigated by the provision of technical assistance and resources to aid local stakeholders in implementing data collection strategies, and integrating real-world insights into clinical practice.

## Future FDA Approvals

Ensuring the availability of safe and effective psychedelic treatments aligns directly with our mission to expand access to psychedelic healing. Currently, ketamine is the only FDA-approved psychedelic, but the anticipated approval of additional substances—such as psilocybin, MDMA, LSD, and 5-MeO-DMT—by 2030 presents a crucial opportunity to transform mental health care and destigmatize the medical use of psychedelics. Despite the setback from the FDA's rejection of Lykos' MDMA-assisted therapy application, there are strong indications that the FDA is open to exploring the potential of psychedelics, including ongoing breakthrough therapy designations and the encouragement of additional MDMA studies.

### Long-term goals

By 2030, the FDA is expected to have approved multiple psychedelic compounds for various medical indications. Concurrently, a well-developed regulatory framework will be in place, designed to support patient safety and deliver optimized outcomes through comprehensive wrap-around care services. This framework will also ensure that these transformative treatments remain widely accessible to all who may benefit from them.

### Current State

The FDA has never been as engaged with psychedelic trials as they are today. In June 2023, FDA issued its first guidance document on psychedelics, [“Psychedelic Drugs: Considerations for Clinical Investigations”](#). Its non-profit arm, the Reagan-Udall Foundation for the FDA, has convened two relevant workshops in 2024: January saw [“Advancing Psychedelic Clinical Study Design,”](#) that explored empirical approaches to address key issues in psychedelic drug development and research; and September saw [“Advancing Treatments for Post-Traumatic Stress Disorder,”](#) featuring a panel discussion with federal partners to explore efforts to accelerate treatment development for PTSD, including psychedelic drug development.

From a regulatory perspective, the FDA decision to issue Lykos a Complete Response Letter (CRL) has complex ramifications across the psychedelic industry. It is expected that Lykos would need at least three years and a major cash injection to complete the requested trial. Given the content and tone of the June 4, 2024 Psychopharmacologic Drugs Advisory Committee meeting and following, there is some risk that new trajectory might lead to a diminished focus on the non-pharmacological elements of psychedelic therapies, potentially resulting in lesser therapeutic outcomes and safety concerns; this should be an important factor in assessing ongoing drug development efforts.

Another point of engagement is the FDA's current crackdown on off-label generic ketamine, disrupting the emerging tele-prescription sector. While this might initially limit access, it could stimulate initiatives to enhance safety and establish critically lacking standards of care and reimbursement guidelines for KAP practitioners.

With this backdrop, there continues to be significant progress in randomized controlled trials on paths toward FDA new drug applications. Multiple drug-indication combinations are moving towards FDA approval in the next 3-5 years, with five breakthrough therapy designations:

- Treatment-resistant depression: [COMPASS](#) (psilocybin),
- Major depressive disorder: [Usona](#) (psilocybin), [Cybin](#) (psilocybin)
- Post-traumatic stress disorder: [Lykos](#) (MDMA)
- Generalized anxiety disorder: [MindMed](#) (LSD)

Several non-profit drug development initiatives are actively working toward approval of low-cost, non-patented versions of psychedelics. These could represent promising directions for philanthropy. The most advanced non-profit efforts with psilocybin are Usona and [B.More](#). Usona is currently in Phase 3, and with Compass announcing an approximate one-year delay, is poised to be among the first to secure FDA approval for psilocybin in treating depression. After a successful Phase 2a boasting impressive efficacy to treat Alcohol Use Disorder (AUD), B.More is launching an innovative clinical trial design done in a residential rehab setting, aided by a \$3.8M grant from NIAA.

Regarding generic ketamine, the [Bodhi Project](#) is a collaborative effort to increase access to ketamine therapy with appropriate psychological support. They are currently evaluating various paths forward including FDA approval for generic ketamine for depression and creating a registry of treatments and outcomes.

[Vilomah Foundation](#) is gearing up for a multi-site trial on generic ibogaine for substance use disorder. A University of Alabama at Birmingham Principal Investigator will manage the Investigational New Drug (IND) process and oversee the FDA submission. To support these efforts, the Foundation is exploring philanthropic contributions and leveraging state opioid settlement funds in discussions with Bryan Hubbard.

Non-profit drug development initiatives face numerous challenges, with fundraising being the most significant hurdle. However, if successful, they could offer substantial benefits. Funders may find these initiatives of interest, and they could potentially become targets for collective philanthropy, supporting broader access and innovation in the field of psychedelic treatments.

Another challenge could be posed by the for-profit drug development sector. Namely, there is a concern that [overly broad patents could severely restrict innovation and access](#) if certain recent patent claims are granted. [Porta Sophia](#) works to promote fair patent policies to ensure optimal access and facilitate future research. They plan to propose policy changes to the U.S. Patent and Trademark Office based on their data and develop new tools for the ecosystem.

Finally, we draw philanthropists' attention to [North Star](#) project's work to form a trade association to set high industry standards that include suitable psychological support and minimizes harm.

### **Opportunities for PSFC**

We are currently lacking in-depth diligence to assess the potential for generic drug development to become a core funding area. The PSFC field building team will continue to assess non-profit drug development initiatives involving substances such as psilocybin, ketamine, and ibogaine. Additionally, the team will explore how to best support high standards of care, whether through government engagement or collaboration with industry trade associations.





## II. Medical System Integration

### Partnering with the Mental Health Establishment

The media narrative around FDA's review of Lykos' application for MDMA-assisted therapy highlighted the woeful lack of engagement and buy-in from the medical community. This needs to change. The actions of a variety of large institutions that shape mental health care in the U.S. will determine whether and how psychedelics are integrated into mainstream care. And on the ground, the preparedness and capacity of practitioners will determine the quality, safety, and accessibility of care. Therefore, engaging the mental health community in the development of practice guidelines, referral networks, practitioner training, credentialing, and reimbursement are critical for making psychedelic assisted care available to treat diagnosed conditions. This is especially true for the more severe, complex conditions that would not be suitable for treatment outside of a medical setting.

#### Long-term goals

Our goals for 2030 cover several areas:

- Awareness: All mental health professionals should have awareness and knowledge of psychedelic-assisted care (PAC) that is comparable to other modalities in their profession's scope of practice, and be prepared to discuss it with patients. All care professionals should have basic awareness of psychedelic care, and at least one referral point in their network for patients to learn more.
- Training: Although there won't be enough practitioners to meet demand (especially if there are 4-5 FDA approvals by 2030), we should have: (a) all mental health care graduate programs providing exposure to information about PAC; (b) universities offering residency tracks to produce 200-400 PAC practitioners per year; (c) adequate CE/CME for 2,000-3,000 current mental health professionals to become prepared to deliver psychedelic-assisted care.
- Credentialing: Mainstream mental health organizations should have PAC credentialing for their respective disciplines, to validate preparedness to provide care, safeguard patients, and enable accountability.
- Clinical Practice Guidelines: Evidence-based PAC should begin to appear in clinical practice guidelines from major professional associations (e.g., APA) for select conditions.
- Reimbursement: There is adequate insurance coverage of therapy before and after dosing sessions, from at least 50 major employers and 3 national insurers.

## Current state

The relevant medical community for PAC includes a wide variety of provider specialties: primary care physicians (PCPs), general and specialty nurses, psychologists, psychiatrists, social workers, and counselors, among others. It also includes decision-makers at insurance companies who will ultimately shape how care is provided. However, most of these stakeholders have limited knowledge of the benefits and risks of psychedelics, let alone a position from which to recommend or provide PAC to their patients. Meanwhile, those specialized in mental health operate in a severely challenged system. Roughly two-thirds of Americans with a diagnosed mental health condition were unable to access treatment in 2021. This, in turn, is a consequence of half of existing behavioral health providers not accepting insurance, due to inadequate and unpredictable reimbursement. It will not be easy for them to take on new modalities of care that require different practice models and different economics.

In this context, mainstream professional associations have been reluctant to embrace PAC, or even to provide information on it to their members. Efforts to create new associations dedicated to psychedelic practitioners have been unsuccessful; and there is some question of whether they would ever have reached the level of credibility and influence held by mainstream associations.

However, the attention being given to psychedelics in public discourse, particularly around the FDA's consideration of Lykos' MDMA-assisted therapy application, has been impossible for them to ignore. Many in the mainstream would say that more research is necessary before PAC can be considered 'evidence based', integrated into practice guidelines, and incorporated as a mainstay in professional training. But now there is at least recognition of the hypothetical promise of this modality, and possible need for their organizations to be ready for PAC in the years ahead.

This is a starting point from which stakeholders in the mental health field can be engaged, by appropriate messengers with a credible and growing body of clinical evidence. But it is likely to require a sustained, coordinated effort to accumulate allies who can eventually influence conservative institutions like the American Psychiatric Association, American Psychological Association, National Association of Social Workers, American Psychiatric Nurses Association, and more.

One area in which we cannot wait for these organizations to move is in practitioner training. We need all graduates of relevant degree programs to have exposure to information about PAC, a significant number of reputable universities with dedicated tracks to produce PAC practitioners, and for existing practitioners, adequate CE/CME and channels for PAC training. Despite the Lykos outcome, we still expect multiple FDA approvals for psychedelics, ultimately requiring tens of thousands of practitioners to treat patients with PTSD, TRD, MDD, AUD, and more. This will require not only training existing psychologists, but creating multiple career tracks for a diverse workforce that centers allied professions like nursing, social work, and counseling. While several universities have launched initiatives around psychedelics, most are dedicated to research, not to education and training of future practitioners. Columbia's Social Work and Penn's Nursing school are engaged in a unique collaboration to scale up the nation's psychedelic assisted care workforce by focusing on the largest and most diverse professions in both mental and physical health. Efforts similar to these, which develop curricula and bring along university leadership, are essential to seeding broader integration into academic institutions. [BrainFutures](#) and [Usona Institute](#) have been supporting coordination and collaboration across early mover universities. Additionally, BrainFutures, Usona, [1440](#), [Sabba](#), and [Beckley Academy](#), are part of an early-stage initiative to provide a comprehensive solution (toolkit for how to start a course/program, open-source online repository, grant funding, faculty education, curricular consulting, etc.) to develop and disseminate evidence-based, culturally appropriate curricular content to universities.

## Opportunities for PSFC

This is a difficult area in which to draw a reliable line of sight from the current landscape to our long-term goals. There is no anchor psychedelic organization in a position to influence mainstream associations, insurance carriers, or related institutions. Smaller-scale efforts have not yet demonstrated much impact, and the prior effort to establish a

professional association specific to psychedelics - that one hoped would grow to have influence in the mainstream - was not successful.

We are therefore in a very early-stage position of needing to cultivate allies, and to solicit ongoing advice from supportive leaders in the field on our efforts to expand support. As such, PSFC will form a member working group to support and provide guidance on efforts to engage the mainstream mental health ecosystem. Additionally, PSFC will convene a senior steering group of influential professionals in the field, composed of thought-leaders who straddle the psychedelic and mainstream, to advise on the work and strategy. The steering group will identify and recommend promising opportunities to achieve our long-term goals, and the member working group will determine which are a good fit for philanthropy. We will provide visibility of organizations and funding opportunities to the broader PSFC community to advance these efforts. PSFC staff will then coordinate with partners and deploy resources ad hoc to support efforts to engage the mainstream mental health ecosystem.

In the absence of a credible anchor organization to drive forward one or more of our goals, we cannot at this time recommend a target for collective philanthropy. However, as individual philanthropic efforts bear fruit, and the community of allies in mainstream mental health grow in influence, we anticipate opportunities to incubate new efforts (analogous to the Psychedelic Mental Health Access Alliance, discussed below) to support mainstream institutions in opening up scaled channels for care.

## Health Equity

The mental health crisis in the U.S. disproportionately impacts marginalized communities and low-income Americans, many of whom receive health insurance through Medicaid. Medicaid covers 78 million individuals, 40% of whom have a mental illness or substance use disorder and 60% of whom are nonwhite. People from marginalized populations (e.g., people of color, LGBTQ+ individuals, and individuals from rural communities, among others) face the highest burdens of trauma, but are some of the least profitable for the U.S. mental health care system to serve, so they typically face the highest barriers to accessing care. Without philanthropic support, the rollout of psychedelic therapy is unlikely to reach these populations. With potential FDA approval of psychedelic treatments still a few years away, we have a window to build health equity into the practice of psychedelic-assisted therapy from the beginning. This would be an exception in the mental health field, but this is also why it's such an important opportunity.

### Long Term Goals

By the late-2030s, psychedelic therapy should be affordable and available to Americans regardless of geographic location, income, and racial background, and measurably improving the lives of individuals from marginalized communities. By 2030, as a step towards this long-term goal, we expect at least five states to cover psychedelic therapy through Medicaid, and 15 community-based organizations to provide psychedelic therapy.

To achieve this vision, progress on three interconnected priorities will be key:

1. ***Development of delivery of care treatment and therapist practice models*** that address the unique needs of people from marginalized communities, with inclusion in training programs for psychedelic therapy professionals.
2. ***Integration of psychedelic-assisted therapy into Medicaid and community based health systems*** through real-world research studying psychedelic-assisted therapy with community-based treatment models to serve historically disadvantaged patient populations.
3. ***Aligning and supporting the broader research, communications, and advocacy ecosystem*** to advance understanding of how psychedelic-assisted therapy can better serve a range of populations that have historically faced the greatest barriers to accessing mental health care.

## Paths to Achieving Goals

A number of organizations and researchers are working to advance equitable access to psychedelics in medical and nonmedical settings, although these efforts are still in their early stages.<sup>1</sup> They include early-stage collaborations to develop culturally-attuned treatment models, pilot studies to persuade Medicaid and other insurers to cover treatment, as well as clinics and training programs focused on serving marginalized populations. Following the FDA's decision on Lykos' MDMA-assisted therapy application, a number of pharma companies are emphasizing drug treatment alone (rather than drug + therapy combinations), so there is a critical need to make sure implementation studies with psychedelics explore and optimize care regimens that include therapy.

### *Key Organizations*

We see the PSFC-incubated Psychedelic Mental Health Access Alliance (PMHAA, formerly known as the Psychedelic Health Equity Initiative) filling a central catalytic and coordinating role for advancing accessibility of psychedelic therapy for marginalized communities. PMHAA's twofold strategy focuses on developing provider training models for psychedelic therapy and conducting pilot studies of Medicaid-fundable, community-based, culturally-attuned care delivery.

PMHAA's first workstream focuses on developing **delivery of care treatment and therapist training models**. In collaboration with clinics and researchers, PMHAA is working to develop best practices for providing culturally-attuned psychedelic-assisted therapy to patients from a range of backgrounds. Understanding and addressing the unique needs of people from marginalized communities is a prerequisite to serving diverse populations. PMHAA's goal is to provide training modules specific to the needs of marginalized communities to add to existing therapist training programs.

PMHAA is also developing **care model pilot studies of psychedelic-assisted therapy with community-based health providers** to demonstrate the efficacy of psychedelic therapy for patients from marginalized backgrounds. We see these studies as a foundational proof-of-concept step toward larger-scale studies aimed at securing Medicaid reimbursement. The community-based care model planned for these studies would enable faster scaling within existing health systems and is a potentially more effective approach to treating marginalized populations than standalone psychedelic-assisted therapy models.

PMHAA's initial pilot study is underway in New Mexico with the support of the New Mexico Legislature and the Department of Health (including Medicaid). The study aims to both advance PMHAA's Medicaid research strategy and support the New Mexico Legislature as they draft [legislation](#) to establish an accessible, state-regulated, and state-funded medical psilocybin access program. The study focuses on psilocybin-assisted group therapy for treating Native American and Hispanic individuals with PTSD, depression, and substance use disorder. The community-based care model planned for the study would enable scaling within existing health systems.

For this study, the University of New Mexico (UNM), with funding from PMHAA, is working with the Bernalillo County Health Equity Council to ensure that the care model design for the study addresses the legislature's goal of implementing a system that effectively addresses the needs of marginalized communities. [Research](#) has shown that involving community members in study design leads to improved outcomes, underlining the importance of effective community participation to maximize the healing benefits and minimize the risks of psychedelic-assisted therapy. The pilot will enable PMHAA and UNM to explore group care options and community support for psychedelic-assisted therapy as well as identify the specific needs of people from marginalized populations. The results of the study will be important for demonstrating the safety, effectiveness, and cost of treatment—which Medicaid decision makers will need to understand in order to move toward funding psychedelic-assisted therapy care models.

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<sup>1</sup> For example, researchers in the U.S. and Canada interested in equity and access issues related to psychedelics include Darron Smith at the University of Washington, Monnica Williams at the University of Toronto, and both AZA Allsop and Alex Belser at Yale, among others. A handful of ketamine and psilocybin clinics or collaboratives currently specialize in access for underserved clients from marginalized communities, including Alchemy and Access to Doorways in Oakland, SoundMind in Philadelphia, and Alma Institute in Oregon, and the Urban Indigenous Collective in New York. And the Deva Collective is a new non-profit focused on research at the intersection of psychedelics and women's health.

### Other Needs

Alongside these PMHAA-led workstreams, advancing health equity in psychedelic therapy will need a number of collaborative initiatives, such as:

- **Data standardization** for real-world research on health equity, which PMHAA is pursuing in partnership with [UC Berkeley's Collaborative for the Economics of Psychedelics](#), [Healing Advocacy Fund](#), and the [1440 Foundation](#). The goal of this collaboration is to create a minimum standard set of uniform data variables for research and practitioners to allow for comparability across studies.
- **Care delivery partnerships** with leading community based care providers such as the Camden Coalition which PMHAA is collaborating with to create the technical assistance tools that community based health care providers will need to successfully incorporate psychedelic therapy into their existing health care models.
- **Accessibility initiatives in state-regulated psilocybin services systems** in Oregon and beyond, which are currently under development by the [Sheri Eckert Foundation](#) and other organizations.
- **Research to address barriers to psychedelic therapy effectively reaching a range of marginalized patient populations** such as patients of color, women, LGBTQ+ patients, and patients from marginalized urban and rural communities. For example, the [Deva Collective](#) works to support psychedelic research focused on women's health.

### Risks to mitigate

- Unclear timeline for availability of psilocybin or MDMA by prescription, given uncertainty around Lykos, Compass, and Usona trials. However, even in the event of delay, more time will only increase the impact of PMHAA's efforts when therapies do become available.
- Elevated risk of adverse events in pilot studies given marginalized patient populations may be at a higher risk for adverse events. PMHAA and their research partners will mitigate this by collaborating with clinics and professionals with extensive experience and expertise in working with these populations.
- Possibility of inconclusive or unpersuasive pilot study results due to novel treatment and research formats—although even disappointing study results would be important learning opportunities for the field.
- As-yet unknown political or administrative barriers to Medicaid administrators covering treatment. However, PMHAA does have the flexibility of selecting states that have the highest likelihood of success and will have multiple chances for success, given the decentralization of Medicaid decision makers.

### Timeline and milestones

#### 2025

- In Spring 2025, participant recruitment begins for the University of New Mexico's pilot study of psilocybin-assisted group therapy of substance use disorder and PTSD.
- In Spring 2025, PMHAA convenes stakeholders from research, clinical, and policy backgrounds to build field buy-in for uniform data standards for care delivery research.
- In May 2025, PMHAA, in collaboration with the New York Medical College, launches an online psychedelic-assisted therapy and health equity workshop for medical trainees to a network of colleges and medical schools.
- In June 2025, the community engagement phase of the University of New Mexico pilot study leads to recommendations from community stakeholders to UNM, the NM legislature and the NM Department Of Health

regarding the community supports needed for effective delivery of psilocybin-assisted therapy.

- In August 2025, PMHAA launches a pilot study in New Jersey of psilocybin-assisted therapy for treating substance use disorder and PTSD in partnership with Cooper University Hospital and the Camden Coalition.
- In October 2025, in collaboration with the University Psychedelic Education Program (U-PEP) and the 1440 Foundation, PMHAA publishes two specialized modules addressing structural inequities and culturally responsive care models in psychedelic therapy. These will be used by U-PEP-affiliated university programs to integrate health equity frameworks into university-based psychedelic practitioner education.

## 2026

- In January 2026, PMHAA and partner organizations finalize uniform data standards for psychedelic-assisted care delivery research and publish a journal article on uniform variables for assessing delivery of care in real world settings.
- In April 2026, the first patients are enrolled in the New Jersey pilot study on psilocybin-assisted therapy for PTSD and substance use disorder.
- In May 2026, results are published from the first cohort of the University of New Mexico's pilot study of group psilocybin therapy for substance use disorder and PTSD.
- In Fall 2026, PMHAA publishes findings from research on best practices for facilitator training programs through U-PEP and other partnerships to support programs in training a culturally responsive psychedelic-assisted therapy workforce to better serve historically marginalized communities.
- In Fall 2026, PMHAA launches a third pilot study and identifies additional potential pilot sites in other states, prioritizing those with influential and interested Medicaid directors.
- In Fall 2026, PMHAA publishes additional health equity education modules for academic and clinical training programs to support the integration of culturally attuned, evidence-based approaches to psychedelic practitioner training.

## Medium-term (3+ years)

- In 2027, PMHAA research partners publish pilot study findings, showing whether psychedelic therapy is a cost-effective treatment for behavioral health conditions in marginalized communities and has a positive impact on other health related problems and equity.
- PMHAA and partners launch national studies to support coverage by public payors, while engagement of state Medicaid directors continues.
- By 2030, 15 community-based organizations provide psychedelic therapy.
- By 2030, at least five states cover psychedelic therapy through Medicaid.

**Projected Costs:** 50%+ of PMHAA's costs are allocated to pilot studies, and this percentage is likely to rise in future years. The total needed to deliver on the milestones above through 2027 are as follows:

- **2025: \$2.7m**
- **2026: \$5.9m**
- **2027: \$6.1m**



# Veteran Healing

U.S. military veterans constitute a population with disproportionate need for innovative mental health treatments, particularly for PTSD, depression, and their comorbidities. A staggering 41% of the 4.2 million service members who returned from recent deployments are identified as needing mental health services, but fewer than half have accessed such services. Even those that have done so find themselves in an overburdened mental health care system that relies heavily on pharmacotherapy and often fails to offer holistic, integrative treatment options. The veteran mental health crisis extends beyond the veterans themselves, profoundly affecting their families through secondary and generational trauma, leading to emotional, psychological, and economic strains.

A limited number of veterans have benefited from psychedelic-assisted care both in the ‘underground’ and through work of several organizations that enable access to retreats outside of the US. However, to make an impact in proportion to the need in this population, much more scalable solutions are required.

At the same time, military veterans are uniquely positioned to act as ambassadors for the benefits of psychedelics, with bipartisan appeal. Many have already stood up to advocate for the advancement of research and access, with resulting expansion of political support; this has happened over years, with an acceleration in the months preceding the FDA decision on MDMA-AT. There is potential for much more advocacy, as veterans are also a highly organized constituency, with major veteran organizations (e.g., American Legion) in a position to wield significant influence, if and when they can be activated to do so.

For these reasons, we see advancement of veteran access to psychedelic healing to be a top priority for collective philanthropy.

## Long-term goals

Our goal is to enable access to affordable, high-quality, state- or federally-legal psychedelic care to all U.S. veterans who may benefit, with 60K+ treated by 2030 - and potentially many more. We plan to achieve this goal in a way that delivers several additional benefits:

- The development of fully integrated care models that specifically address the context and mental health needs that are distinctive to the veteran population, both to optimize outcomes for veterans and to serve as a beacon for development of models for other special populations
- A step-change in public destigmatization, with every American knowing the story of a veteran in their community who has been healed through psychedelic-assisted care
- Majority support in both houses of Congress and throughout VA leadership for access to psychedelic-assisted care at least on par with any medical or surgical care provided in VA
- All major private and community mental health systems following the lead of the VA, and competing on the basis of access to, and quality of, psychedelic assisted care in their treatment offerings

## Paths to achieving goals

These goals require a two-fold path: (1) System-wide adoption of a psychedelic-assisted therapy offering for an area of major unmet need within the VA system, and (2) widespread, equitable, and high-quality veteran access to psychedelic treatments in community settings outside of the VA.

The VA is the largest healthcare provider network in the U.S., providing care to ~50% of U.S. military veterans, and training to ~70% of all physicians practicing in the US. Therefore, it is essential to have treatments rapidly deployed across the VA. Steps already taken include extensive advocacy with VA and Congressional leadership; and philanthropic funding

of training of ~250 VA practitioners and of a suite of pilot clinical studies getting underway in 2024. These have led to positive milestones including the VA's initial commitment to funding their own pilot research through a Request for Applications (RFA) under development, and a mandate to apply \$20M of the VA's budget to research into PAT. Healing Breakthrough (HB), a PSFC-incubated group which merged with the Heroic Hearts Project (introduced below) in 2024, has been instrumental (but not alone) in driving these results. However, we remain far from having the required scale of provider training, resources for delivery, and policies supporting access that are needed to make a material impact for the VA population. The recent negative FDA response to Lykos' application for MDMA-AT is a further setback, creating uncertainty about the path forward within the VA (more below).

At the same time, adoption in the VA should not be our only route for delivering care to veterans. Many receive their care outside the VA; broad dissemination will take until the late 2020s at best; and there is growing evidence that more holistic models of community-based care (beyond what the VA will ever provide) will produce the best outcomes for some veterans and other populations. The Heroic Hearts Project's (HHP) ongoing effort to develop such a model is now active in the U.S. via the Oregon psilocybin program, but has significant work ahead to continue refining the model and growing its facilitator cohort.

As noted above, in late 2024, Heroic Hearts Project and Healing Breakthrough joined together into a single nonprofit. The combined organization is overseen by HHP leadership, although it will retain the HB brand, most HB staff as contractors, and core HB projects as a 'program' under HHP. We discuss the work of HHP and HB separately below and are optimistic that the combined organization will effectively carry forward the missions of both HHP and HB given that the missions and staffing at both organizations complement each other well. However, we anticipate that the details of the activities, milestones, and budgets discussed below may shift during 2025 due to this merger.

## HEALING BREAKTHROUGH AND THE PATH TO VA ADOPTION

In light of the FDA's decision to reject MDMA-assisted therapy for PTSD, it has become more important than ever to support VA research and adoption of psychedelic treatments. Currently, the only active clinical studies with MDMA are being conducted by VA researchers with veterans, a state likely to persist long into 2025. The largest planned program of MDMA clinical work is the VA's Integrated Project Team, launched in January 2024 and projected to continue for several years. Continued advocacy efforts will be critical to ensure that the VA follows through on its intentions to research and roll out psychedelic treatments.

### Mission

Given the VA's decision to include MDMA and psilocybin into its RFP, the fact that the timeline for MDMA-approval has been pushed back, and the strong veteran need for psychedelic treatments across indications (11% of veterans suffer from depression and 7% from PTSD at a high comorbidity rate), Healing Breakthrough (now a program of Heroic Hearts Project following their 2024 merger) is expanding its mission to advance safe, effective, and affordable access to both MDMA-assisted therapy for PTSD and psilocybin therapy for depression. By advancing research, education, and advocacy efforts, HB aims to integrate these therapies into the broader veteran healthcare system, ensuring that veterans receive the most effective mental health treatments while catalyzing the adoption of psychedelic therapies into mainstream mental health care at scale.

### Plan

HB's activities for 2025-2027 will span across three pillars:

1. **Advocacy:** HB will advocate for targeted federal appropriations to the VA's Integrated Project Team (IPT) program to advance VA-led MDMA and psilocybin research. The aim is to secure the future of this multi-year program and expand VA's ability to conduct large-scale research programs, enforcing the VA's leadership role in the rollout of psychedelic therapies.

2. **Research & Education:** HB will gather data from existing VA MDMA studies and state-level psilocybin therapy programs in Oregon and Colorado to conduct meta-analyses to codify best practices and learnings from treating veterans with psychedelic therapy. This data will be designed to help the VA operationalize psychedelic-assisted treatments for veterans at a national scale, bringing aftercare and peer-based models into the VA (especially in light of the anticipated lack of therapy requirements for future FDA-approvals). Research questions will be sourced from key VA stakeholders to ensure that findings are actionable and relevant for policy shifts and implementation. HB will collaborate with key partners to turn findings into comprehensive guidebooks and materials to ensure that both providers and veterans are equipped with the tools and knowledge needed for successful treatment outcomes. This could include setting up an independent veteran portal which provides information, resources and the opportunity for dialogue for veterans to reduce risks and support veterans navigating care options.
3. **Care Delivery:** As MDMA therapy moves forward in the VA, HB plans to stand up clinical demonstration projects with local VA clinics and other sites treating veterans to roll out proposed models for psilocybin and MDMA treatments based on findings from the field. These projects will lay the groundwork for broader adoption and serve as a template for large-scale roll-out. Although this workstream is uncertain as of early 2025, given the delay in MDMA's FDA approval and ongoing shifts in VA leadership it could quickly be reactivated depending on the priorities of the incoming VA leadership.

### Risks and mitigation

Leadership of the VA and its IPT have made clear that they will press on despite the FDA's rejection of MDMA in August 2024. Nonetheless, it is still unclear what specific implications the FDA's decision may have for the programs and timelines of the IPT. HB will work closely with IPT leadership as their plans flex to take into account new timelines for the clinical use of the MDMA and psilocybin.

Following the 2024 election year, a new incoming presidential administration creates both risks and potential opportunities for advocacy on the federal level. In order to ensure that the VA follows through on its intention to fund research and operationalize these treatments, continued advocacy will be critical, alongside education and engagement efforts for the incoming VA secretary and their team. Of particular importance are those elected officials who will remain on House VA Affairs and Senate appropriations committees with jurisdiction over these activities. They will provide the continuity of mission and clarity of intent for the new administration and new members of Congress.

Finally, the VA is a large institution and can be slow to adopt new models of care. To address this, HB will continue gathering research and supporting education programs that make the case for psychedelic treatments through data and advocacy, while supporting key stakeholders in bringing this urgently needed care to veterans across different avenues in the near term (such as state-regulated models).

### Timeline and Milestones

2025:

- Complete integration of Healing Breakthrough staff and workstreams into the Heroic Hearts Project following their 2024 merger.
- Initiate meta-analyses on psychedelic therapy for veterans and codify best practices from VA MDMA research and psilocybin treatments in Oregon & Colorado.
- Collect input from VA on required data and codify learnings from the field into resources for VA research & implementation.
- Launch independent veteran education portal.

2027:

- Publish and disseminate research findings and develop detailed educational and operational materials for VA providers and patients.
- (Pending relaunch of this workstream under new presidential administration) Launch clinical demonstration projects in partnership with local VA clinics and other sites treating veterans to operationalize proposed models of care, with psilocybin and/or MDMA therapy.

2030:

- 10,000+ veterans will have been treated with MDMA-assisted therapy and psilocybin therapy through the VA (exact numbers will depend on FDA approval timelines).
- HB demo clinics will serve as the blueprint for the VA, which by 2030 could have rolled out several of its own pilot psychedelic therapy sites across the nation.
- The large-scale, multi-site trials required for mass dissemination will be underway, funded by federal appropriations resulting from HB's advocacy efforts.

### **Projected philanthropic needs**

HB estimates a total required investment of \$7.5M over the coming three years, although this estimate may shift in 2025 following HB's merger with Heroic Hearts Project. Philanthropic funding in 2025 and 2026 will be critical to maintain momentum, advance the advocacy agenda, research and codify best practices, and prepare demonstration pilots to mitigate doubts about implementation feasibility and empower clinicians and patients through education and outreach. HB expects an annual funding need of \$2.5M throughout 2025-2027. Additional activities towards the tail end of VA adoption may require ongoing funding, but most of the funds will be needed in the next 3 years. Total costs are expected to fall across HB's pillars as follows: 40% public policy and federal agency engagement & education, 30% research & education, 30% care delivery (at an average 15% indirect cost rate across pillars).

## **HEROIC HEARTS PROJECT AND THE GROWTH OF INTEGRATED COMMUNITY-BASED VETERAN CARE**

The emergence of state-regulated supervised use programs creates an opportunity to deploy a state-level strategy to establish meaningful veteran access to robust psychedelic-assisted care offerings, independent of VA infrastructure or funding. The Heroic Hearts Project (HHP) has a long-term program to expand localized access to psychedelic care for veterans in a community model. HHP's approach is groundbreaking, combining access to transformative therapies with sustained community support. They partner with legally operating psilocybin therapy providers to deliver safe, effective, and reasonably priced care, with an emphasis on cultivating cultural competency for work with veterans. Programs include cohort-based preparation, retreat, and integration phases, ensuring continuous support for veterans and their families. These are delivered with a tiered support team comprising a lead facilitator, peer support staff, and professional coaches to guide and mentor veteran participants before and long after retreats; and licensed therapists can be incorporated for more severe cases, as identified by coaches.

HHP's objective is to treat 10,000 veterans & spouses by 2030 in this affordable, state-based community access model with highly trained supervision, eventually achieving all-in costs below \$1K per participant. This will avoid high costs and access barriers seen in other mental health care channels, deliver the benefits of community engagement, raise awareness for the community model with a systematic, highly visible and usable offer that can be applied to other populations, and motivate other states to enable analogous access for their veteran populations.

The HHP model is also designed to deliver research findings that are relevant throughout the provider world. They are partnering with The University of Colorado Boulder and UC Anschutz Medical Campus to evaluate the multidimensional impacts of psilocybin retreats on veterans, first responders, and their spouses. This research establishes foundational data to guide future studies on psilocybin's therapeutic potential within holistic treatment paradigms. Alongside this research, HHP also works to share good practices for facilitator training and participant risk reduction based on its cohort-based community treatment model. In 2024, HHP published a [handbook](#) for Veterans going through psychedelic-assisted treatment and is developing a facilitator training program for practitioners in Oregon.

### **Risks to mitigate**

The most significant risk associated with advancing HHP's U.S. program lies in awareness driving a level of veteran demand that outstrips capacity to serve. The next few years will still be a learning period, as the model is refined in Oregon, and established in Colorado - necessarily with some variations, given the different regulatory environments. Even beyond this, a specialized set of resources needs to come together to run these retreats, and they cannot "0 to 1" scale overnight. An excess of demand for the retreat offering could drive some veterans to alternative psychedelic care providers, either underground in the U.S. or overseas, without the same community-based journey and integration, and without the robust safety protocols that HHP deploys. Harm to veterans in other settings could blow back on the entire veteran psychedelic healing movement. That being said, we have already been living with this risk for some time, and the only appropriate response is to work on building the requisite capacity.

### **Aspirational Timeline and Milestones**

If adequately funded, HHP expects by 2025 to:

- In Oregon, complete 22 retreats, serving 220 veterans & spouses
- In Colorado, complete 10 retreats, serving 100 veterans & spouses (assuming access to suitable licensed providers & facilities by mid-2025, as the regulated program comes online)

Also in 2025, HHP will initiate its observational study on the impact of their group psilocybin program on their participant population, with partners at UC Boulder.

By 2027, HHP would target cumulatively serving more than 1,000 veterans and 250 spouses, including:

- Modest growth in its Oregon program, for a cumulative total ('25-'27) of nearly 70 retreats, serving 700 veterans & spouses
- Faster growth in Colorado, thanks to a larger veteran population and a larger out-of-state catchment area, as well more flexible regulations (factors which will also lead to lower per-veteran costs over time); cumulative total of 62 retreats, serving 620 veterans & spouses.
- Additional opportunities may arise if new access programs emerge through state legislative efforts.

By this time, results of the UC Boulder study, with its 12-month follow-up protocol, will be published and disseminated. In addition, HHP's program will have matured sufficiently for them to work with partner groups to adapt their model to other populations with distinct needs, analogous to veterans.

Projections beyond 2027 are less certain, but even within the first three states, the scaling model suggests that by 2030, HHP could cumulatively treat 10,000 veterans & spouses.

The number of veterans treated is not the only measure of success of the program. If successful, we expect HHP's example to inspire a proliferation of additional fully integrated community-based group psilocybin retreat programs, wherever state-legal access is secured.

### **Projected costs**

Costs for the first three years of the program (2025-2027) are mostly estimated on a per-participant basis, with scale benefits mostly offsetting growth in participants-per-year. During this pilot year (2024), HHP is already delivering the full ~3-month program, with a 5-10 day retreat, at a cost of \$4,600 per participant – already lower than they or other veteran groups have achieved through philanthropically-funded international retreats. They expect unit costs to fall 15% per year through 2027, driven by three tailwinds: the completion of start-up program development and training in 2025 and 2026; the mix shift from Oregon to Colorado, with less restrictive regulation; and the build-up of purchasing scale in hub areas. As a result, we anticipate that the milestones through 2027 above can be delivered at a cost of \$5.0MM over three years: \$1.6MM in 2025, \$1.7MM in 2026, \$1.8MM in 2027.





## III. Communications & Public Health Education

Views about psychedelics are evolving rapidly, which impacts almost every facet of the work being done to advance the field, the causes that PSFC supports, and the future of psychedelics. Communications and public health education are both critical for different reasons:

- *Communications* are necessary to share accurate information about the potential public health benefits and risks of psychedelics and to raise awareness of treatment options available and how to access them.
- *Public health education* is necessary to educate the interested public – including many who are young, suffering, and/or naïve to psychedelics use – about risks, contraindications and safer-use practices related to psychedelics, in order to support informed decision-making that reduces harm and optimizes benefits among people who choose to use them.

Well-coordinated and focused strategic communications and separate but aligned public health education efforts, each with clear messages and distinct calls for action, can advance the objectives above by educating and engaging important targeted audiences and stakeholders including:

- Federal/state/local policymakers and staff
- Voters
- Current and future psychedelic users and family members
- Medical and mental health professionals (e.g., psychiatrists, psychologists, nurses, social workers)
- Media and social media influencers

Of note, the importance of communications among these broad but critical audiences was first brought to the PSFC community's attention by leadership of Psychedelic Communications Hub, starting with its founding in late 2022.

### Long-term goals

By 2030, the North Star for communications and public health education efforts is to have in place an entrenched science- and data-informed shift in cultural (feelings, attitudes, values, and beliefs) and societal (structures, systems, and policies) norms and expectations among target audiences and stakeholders, in support of and in relation to safe,

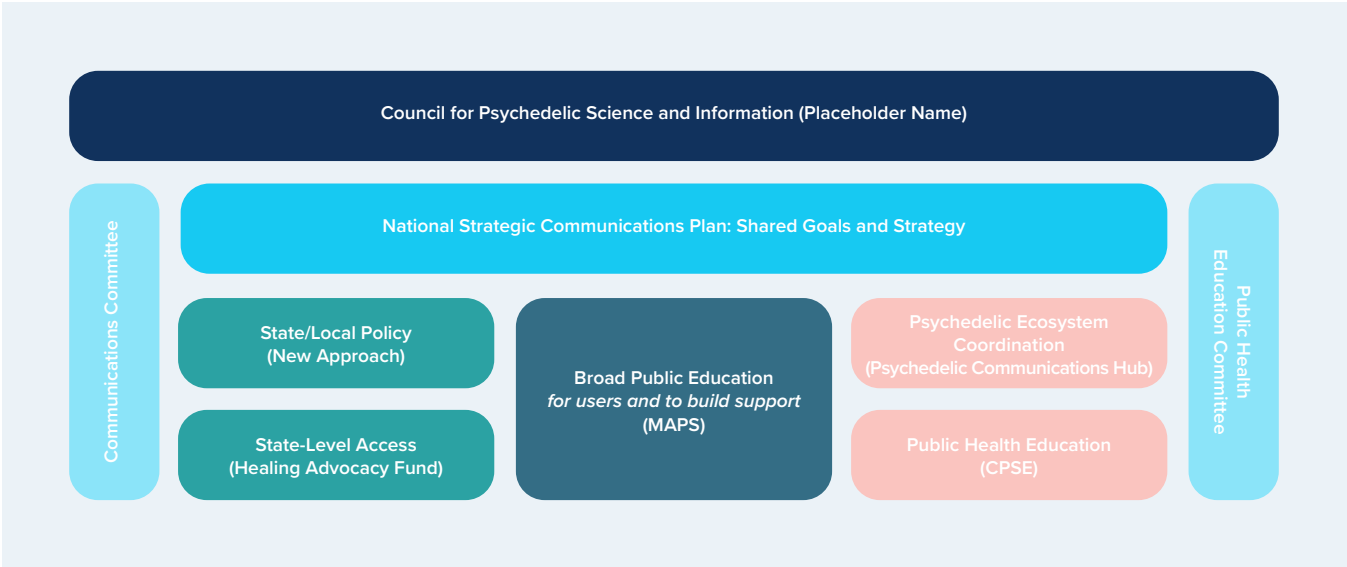
equitable and sustainable access to psychedelics. In addition, we will have demonstrable evidence that our public health education efforts have raised awareness (early phases) and promoted behaviors (later stages) that have reduced health risks. Progress towards these North Star goals will be measured through public opinion tracking, earned and social media sentiment analysis, and other data gathering methods.

**Plan to achieve goals**

A coordinated alliance between the organizations with communications and public health education goals will create a multiplier effect of impact by:

- Facilitating cross-organization discussion and alignment around communication support needed to help achieve the most important goals and objectives for the entire field
- Enabling agile adaptation and revision of strategy and approach across the field, as the external environment shifts
- Allowing each organization to focus its time and resources on advancing its specific mission with support and input from other organizations
- Strengthening resource, information and best practice sharing between the individual organizations
- Minimizing duplicative efforts currently happening within separate organizations across the field

This alliance is visualized below with the organizations that currently have the greatest ability to make significant progress against field-wide communications and public health education goals. This organization set can shift over time as appropriate.



Key components of this alliance include:

- **National strategic communications plan:** A national strategic communications plan will be developed that identifies strategies and collaborative action plans to achieve the shared goals and success metrics for both communications and public health education efforts. The plan will identify clear lines of ownership and accountability for activation. Some actions will be taken in collaboration, and some will be the focus of individual organizations.
- **Communications Committee:** A communications committee will work together to develop the national strategic communications plan and collectively decide when and how to activate resources to support the highest priority

communications activities. Committee members, while collaborating around shared goals, messages, and priorities, will continue to focus in their organizations on communications that advance their own more targeted individual missions.

- **Public Health Education Committee:** A public health education committee will have shared accountability to support the successful activation of joint and/or independent public health education campaigns and to ensure resources are being spent in coordination across campaigns and with approaches and data collection that will most benefit the field.
- **Mission Specific Focus Areas:** In addition to the coordination across the alliance as outlined above, each of the mission areas will be achieved through the focused efforts of individual organizations, which are detailed below.

## COUNCIL FOR PSYCHEDELIC SCIENCE AND INFORMATION (PLACEHOLDER NAME)

Focus	Core Priorities
<p><b>Fieldwide Resources and Coordination:</b> Provide high-impact communication resources and expertise to support the field at large with a goal of driving large-scale awareness through an “always on” operation.</p>	<p>Many of the following priorities were initially envisioned and repeatedly proposed by the foundering leaders of the Psychedelic Communications Hub, Robyn Thomas and Anne Friedman</p> <ul style="list-style-type: none"> <li>• Host and facilitate Communications Committee and Public Health Education Committee meetings and decision points</li> <li>• Overall coordination and accountability for development and successful activation of the national strategic communications plan</li> <li>• Commission national public opinion research (qualitative and quantitative) designed to inform national message strategy and provide a benchmark and tracking of public opinion attitudes over time</li> <li>• Develop message framework and supportive resources to amplify messages throughout the field</li> <li>• Maintain a public-facing informational website, potentially with an externally-facing name (e.g., Council for Psychedelics Information) to communicate shared messaging, supportive data and media coverage, options and access resources, and links to individual organizations across the field</li> <li>• Monitor national news coverage, generate proactive national media stories, and help coordinate responses to inquiries from national media</li> <li>• Monitor social media and influencer feeds and develop content to proactively and systematically push through social and influencer channels to influence the national dialogue</li> <li>• Maintain a speaker’s bureau of trained and ready spokespeople who can be deployed to support comms efforts across the field</li> <li>• Identify and prepare the field to mitigate potential risks and coordinate rapid response initiatives</li> <li>• Coordinate ad hoc fieldwide issue-specific campaigns (e.g., MDMA-AT)</li> <li>• Centrally vet and incubate new ideas for supporting the field (e.g., representation in movies); ensure resources are prioritized on most impactful ideas and actions</li> <li>• Operational note: the launch of this entity depends on recruiting and preparing a suitable leader; this process will be advised and supported by leaders of the Psychedelic Communications Hub, Robyn Thomas and Anne Friedman, whose experience and expertise will be crucial in this matter. The intention in this selection process is to identify a leader committed to building a values-driven organization that prioritizes transparency, trust, respect, and inclusion in all aspects of the work</li> </ul>

## NEW APPROACH

Focus	Core Priorities
<p><b>State/Local Policy Campaign Communications:</b></p> <p>Develop and lead comms strategy focused on reaching state and (potentially) local policymakers and influencers to build support for new policy initiatives.</p>	<ul style="list-style-type: none"> <li>Continue to lead public opinion research, messaging, state policy media outreach and engagement, and policy advertising focused on supporting state and (potentially) local policy campaigns</li> </ul> <p><i>(Additional detail in discussion of state policy agenda)</i></p>

## HEALING ADVOCACY FUND

Focus	Core Priorities
<p><b>Success of State Psychedelic Therapy Programs:</b></p> <p>Develop and lead a communications strategy designed to protect and expand the viability of facilitated psychedelic therapy in state programs. This includes policy communications, particularly after passage and through the implementation period, and marketing communications to generate the demand necessary to bolster viability of the state-regulated model in its early years</p>	<p><i>Strategic Comms and Narrative-Shaping for Psychedelic Therapy Programs</i></p> <ul style="list-style-type: none"> <li>Lead state and local strategic communications efforts to ensure that state-approved psychedelic therapy programs maintain and grow support among policymakers and the general public</li> <li>Manage state-level crisis communications efforts</li> <li>Create and disseminate storytelling that highlights efficacy, cost-effectiveness, and human impact of psychedelic therapy for common mental health challenges – particularly ones that affect state budgets. (This will dovetail with our Community Impact Pilots, which will create significant positive storytelling opportunities.)</li> <li>Grow profile at national level as leading advocate and defender for psychedelic therapy through state programs</li> </ul> <p><i>Awareness and Adoption</i></p> <ul style="list-style-type: none"> <li>Build and execute engagement strategy focused on key practitioner communities (mental health providers, addiction treatment specialists, etc.) to drive integration of psychedelic therapy into traditional mental/behavioral health care</li> <li>Build targeted consumer marketing strategy – including market research, channel identification, content production, events, community engagement, and analytics – designed to drive client demand for active state programs</li> <li>Disseminate with paid media campaign</li> </ul>

## PSYCHEDELIC COMMUNICATIONS HUB

Focus	Core Priorities
<b>Psychedelic Ecosystem Coordination:</b> Coordinate communications education, activation and best practice sharing across the broad field (e.g., APA, Healing Breakthrough, smaller orgs)	<ul style="list-style-type: none"> <li>• Maintain a nationwide network of organizations and individuals to help shape the mainstream narrative of psychedelics</li> <li>• Ensure the field is prepared to respond quickly, accurately and effectively to any adverse events and negative media cascades; circulate updated news information and messaging guidance to allies</li> <li>• Support organizations across the ecosystem by amplifying successes, sowing connections among partners, and providing robust messaging and media support</li> <li>• Create trusting relationships with membership organizations from across the psychedelic ecosystem</li> <li>• Convene partner organizations to discuss and find shared ground on some of the most polarizing communications challenges</li> <li>• Note: many of these activities are synergistic with the newly proposed Council for Psychedelic Science and Information (placeholder name). As a result, we will assess opportunities to merge these two efforts, incorporating the Hub's successful work providing resources to smaller organizations, and creating a forum for engagement across any and all psychedelic organizations, into the new group's portfolio of work</li> </ul>

## MAPS

Focus	Core Priorities
<b>Convener and Clearinghouse:</b> Facilitate and manage multi-org policy coalition; amplify core coalition messages; mobilize broad support aligned to shared goals outlined in the national communications strategy.	<i>Synthesize, Amplify, and Evolve Narrative</i> <ul style="list-style-type: none"> <li>• Leverage MAPS' exceptional earned media presence (3,254 unique media hits, 1k journalist shares, with a combined unique visitor count of 48 billion in 2023) to introduce and engage mainstream audiences on psychedelic topics</li> <li>• Direct media toward mature analysis of psychedelics and evidence-based discussion of risks and benefits; educate psychedelic users to reduce harms and increase benefits regardless of the legal context of their use</li> <li>• Place targeted, impactful stories featuring thoughtful surrogates with aligned messaging</li> </ul>



## MAPS (CON'T)

Focus	Core Priorities
<p><b>Policy Activation and Engagement:</b> Amplify policy messaging and calls to action using MAPS' comms channels; advise New Approach and other ecosystem stakeholders in technical policy elements; guide and train new advocates nationwide to support community-driven (but policy-coalition-influenced) efforts at local and state levels; stay on the pulse of federal policy efforts.</p>	<ul style="list-style-type: none"> <li>Invest substantially in movement building with 15,000 experts and attendees at Psychedelic Science 2025, the premier opportunity for earned media, social media, thought leadership, and MAPS-supported community gatherings, knowledge exchange, and educational content generation in the psychedelic movement with 10% of attendees supported by scholarships</li> <li>Fund, support, and coordinate smaller, mission-focused public health, ethics, and educational efforts (e.g., the Zendo Project, North Star, and dozens of allies and fiscally sponsored organizations) through grants, fiscal sponsorships, and leadership development</li> </ul>
	<p><i>General Audience &amp; Professional Education</i></p> <ul style="list-style-type: none"> <li>Continue and expand delivery of general audience public health education to raise awareness and promote behaviors that reduce risks of social, spiritual, medical, or personal use of psychedelics</li> <li>Expand delivery of the successful Crisis Assessment and Intervention Training piloted in Denver in 2023-24, and by 2030 have established psychedelic crisis response as a core competency of first responders nationwide</li> <li>Sustain and expand the International Therapist Education Program with a goal of training 750 care providers across the globe who serve communities stricken by armed conflict, forced migration, and natural disasters by 2030.</li> </ul>
	<p><i>Grassroots Mobilization at the Intersection of Policy &amp; Education</i></p> <ul style="list-style-type: none"> <li>Deploy MAPS' and Psychedelic Science's sophisticated data infrastructure and integrated data systems to activate supporters online and in-person, find new donors for the movement, and build sustainable support for policy reform</li> <li>Cultivate and grow audience (240k email, 600k social in 2024) toward community education</li> <li>Direct MAPS' channels and audience toward direct political activation (i.e. targeted email lists, calls-to-action) in support of state initiatives and state or federal legislation</li> <li>Establish and regularly update assets for state initiatives and legislative campaigns, including establishing 501c4</li> <li>Expand and manage newly activated cross-country Speaker/Expert bureau from 50 HCPs to 100 LEO, medical / psychological care professionals, researchers, policy experts, faith leaders, and celebrities who will be trained in media and to support drafting, testimony, or committee discussion about high-priority bills, task force discussions / reports, or stakeholder meetings</li> </ul>

## COALITION FOR PSYCHEDELIC SAFETY AND EDUCATION

Focus	Core Priorities
<b>Public Health Education:</b> State and local public health education to reduce harms with a focus on those potentially most at risk: young and emerging adults considering or already taking psychedelics, people struggling with mental or emotional health who are looking for healing/considering self-medicating, people naïve to psychedelics and their use, and their family members	<ul style="list-style-type: none"> <li>Launch public health education pilot/proof of concept campaign focused in two markets: SF/Oakland/Berkeley, CA and Boston/Cambridge, MA, with other markets under consideration.</li> <li>Coordinate efforts of national agency to develop and implement the fully integrated campaign (research, message strategy, media, influencers, paid media, etc.)</li> <li>Reduce harms, with a focus on those potentially most at risk: young/emerging adults considering or already taking psychedelics, people struggling with mental or emotional health who are considering self-medicating</li> <li>Cultivate a more balanced, realistic and nuanced understanding among the interested public to help people make well-informed personal choices about whether or not psychedelics are right for them</li> <li>Raise awareness of research and resources to help people who experience psychedelic-related adverse events</li> <li>Incorporate input from public health education committee and launch broader campaign post pilot phase</li> </ul>

### 3-year funding required, and what it will deliver

Estimates of funding needs collectively across the alliance are **\$14.2M for 2024-2025** and **\$32.2M for 2026-2027**. Funding at this level will allow each organization to focus on its core priorities outlined above, significantly increasing the impact each can make individually, and enable a multiplier effect through the elimination of cross-organizational redundancies. Funding need estimates, by organization, are listed below.

Organization	2024-2025 Funding Needs*	2026-2027 Funding Needs*
<b>Council for Psychedelic Science and Information (Placeholder Name)</b>	2.8M	6.4M
<b>MAPS</b>	8.0M	18.4M
<b>Coalition for Psychedelic Safety and Education*</b>	1.5M	3.9M
<b>Healing Advocacy Fund</b>	1.5M	2.5M
<b>Psychedelic Communications Hub</b>	0.4M	1.0M

*\*CPSE's funding needs include a limited budget for paid media. These estimates may change based on campaign strategy shifts and/or expansions. Paid media campaigns for the other orgs are not included in these budget estimates due to multiple variables and would require separate funding requests as those needs arise.*

Risks in the plan to mitigate

- Lack of active participation and coordination among Alliance members, leading to disjointed messages and duplicative efforts across the field
  - Ensure engaging with the Alliance helps each organization more effectively deliver on their own mission; conduct quarterly pulse checks to assess value; adjust Alliance priorities as needed
- Lack of discipline and accountability around achieving the goals and priorities in the national strategic communications plan, leaving the field in a responsive rather than proactive posture
  - Assign a strong project manager to drive and ensure forward progress against all deadlines and KPIs in the plan; review progress and KPIs with Alliance members on a monthly basis
- Lack of balance in messaging between the potential public health benefits and the risks of psychedelics, leading to continued increase in use (particularly among minors) without adequate information about safety
  - Ensure shared goals, messaging, action plans and KPIs around public health education are prioritized and firmly embedded in the national strategic communications plan that will guide coordinated alliance efforts; through the public health education committee of the alliance, ensure public health education continues to be embedded in the strategies and messaging of the individual alliance member efforts; conduct quarterly analysis of messages and information in the public domain; adjust messages, outreach strategies, and budget allocations as needed to ensure balance

TIMELINE & MILESTONES  
By the end of 2025

Communications	Public Health Education
<ul style="list-style-type: none"><li>• National communications strategy in place, building off learnings from analogous efforts like Plan B, guiding a coordinated approach</li><li>• Clear and compelling research-based message framework actively in use across the field that shares a balanced, but positive, vision and story, and conveys public health guidance aiming to maximize safety, equity, and positive outcomes.</li><li>• Information and data collected informing the most effective ways to educate people about treatment options available, how to access them, and how to mitigate risks.</li><li>• Harmful myths and misinformation, whether positive or negative, proactively and systematically rebutted with truthful, accurate information.</li></ul>	<ul style="list-style-type: none"><li>• Public health education pilot program data and learnings gleaned and informing future harm reduction efforts</li><li>• Public health learnings from other analogous efforts, like cannabis, applied and informing the safer roll out of psychedelics</li><li>• Identification of other public health education efforts and individual learning modules to amplify and support</li></ul>

## TIMELINE & MILESTONES

By the end of 2027

Communications	Public Health Education
<ul style="list-style-type: none"> <li>• Growing number of target audiences and stakeholders, including high-profile influential voices, have a greater understanding of both the potential benefits and risks of psychedelic use</li> <li>• Greater number of people in key communities are aware of treatment options available and exploring them for personal use</li> <li>• Positive shifts in cultural norms and expectations (feelings, attitudes, values and beliefs) among adults (not trying to normalize among underage users), as measured through attitudinal changes in public opinion research tracking</li> <li>• Data showing shifts in societal norms and expectations (structures, systems and policies) as evidenced by the number and types of organizations adopting official positions advocating for change, the number of laws and regulations passed and funded, the number of trained therapists, an increase in the number of successful patient outcomes, among others</li> </ul>	<ul style="list-style-type: none"> <li>• As norms and expectations are shifting, public health education efforts are growing at scale and impact to ensure balance with public health guidance, with tangible harm reduction results that are informing and supporting the field</li> <li>• Increased, measurable public awareness of key risk/safety messages</li> <li>• Local and state public health messages benefit from national-level learnings and shared resources</li> <li>• Local and state harm reduction organizations are considered KOLs and critical partners in development of government-funded public health campaigns</li> </ul>

## TIMELINE & MILESTONES

By the end of 2030

Communications	Public Health Education
<ul style="list-style-type: none"> <li>• Benefits/risks, contraindications and safer-use practices of psychedelics are well known among target audiences and stakeholders</li> <li>• Clear and sustained shifts in cultural norms and expectations as measured through public opinion research tracking</li> <li>• Sustained shifts in societal norms and expectations documented</li> </ul>	<ul style="list-style-type: none"> <li>• Public health education efforts show proof of significantly mitigated harm and are increasingly built into policy initiatives with government funding</li> <li>• Evidence-based public health campaigns and initiatives meet or exceed government funding of anti-drug based models and messaging that reinforce the negative stigma about psychedelics</li> </ul>

# Safety Net Infrastructure

Ongoing expansion in awareness of psychedelics is driving increased use in unregulated spaces, with a possible consequence of increasing harm to individuals. Acting to offset these increasing harms is an ethical imperative, as well as a strategic priority. It is easier to accomplish this in state-regulated programs than in the unregulated market, given the former's regulatory and licensure infrastructure, though there is surely room for ongoing improvement. And in the unregulated market, we have potentially powerful levers to reduce harm through public education on risks of psychedelics, good practices to mitigate these risks, and the elevation of practitioners recognized as providing risk-reduced experiences. But no matter how effective these are, there will be instances of adverse events, including practitioner abuse, sometimes resulting in lasting harms. It is critical as a movement to both acknowledge the real risks of psychedelics, and to help build risk reduction into all psychedelic use.

## Long-term goals

By 2030, every person in the U.S. with active or past challenging psychedelic experiences should know where and how to access appropriate support. Professionals that encounter this population should be prepared to help them. This help should be grounded in robust research on the types of adverse events or long-term harms that can be caused by psychedelics, and best practices for how to effectively treat these instances. This information needs to reach both psychedelic users and medical professionals, in audience-appropriate ways, and to inform the practice of specialized professionals trained in integration and treating psychedelic harm. Similarly, first responders or emergency medicine providers should have information and training on how to properly support those actively experiencing adverse effects from psychedelics, without causing additional harm, and with the ability to point to more specialized integration and harm reduction services.

## Current state

Psychedelic use in the U.S. is growing. [SAMHSA's National Survey on Drug Use and Health](#) finds that from 2018 to 2022 lifetime use of "hallucinogens" increased 14.2% and past year use increased 50.3%. There are also indications of a significant increase in the number of psychedelic-related poison center calls, emergency room visits, and hospitalizations. However, the vast majority of first responders and emergency medicine providers are unprepared to help in these instances. This creates risk of further harm, and may create a perception of psychedelics as an unwanted burden on already strained systems. A comprehensive safety net is essential for people during or after a challenging psychedelic experience, including peer support and integration services, and psychedelic harm reduction training for first responders and medical professionals.

But current offerings are limited, structural gaps exist, and the determinants of safety vary significantly with context. There are organizations and groups focusing on various aspects of what is needed, but they are nascent and the path to scaled impact remains unclear. Nonetheless, there is a promising ecosystem seeking to provide the necessary evidence-based knowledge and resources, to support dissemination and risk-reduced use, to respond to challenging psychedelic experiences and harms, and to train first responders. The following may be of interest for individual philanthropic support for those seeking to foster risk-reduced psychedelic use:

- [The Psychedelic Safety Institute](#) is a strategy lab seeking to facilitate ecosystem alignment to collaboratively address critical safety issues related to the expanding use of psychedelics. Relevant stakeholders include policy-makers, first responders, researchers, training organizations, media, and clinicians, through shared understanding, coordinated actions, and education. PSI's strategy is to:
  1. Clarify what needs to happen to address safety issues at scale
    - a. [Knowledge Base](#): Using clinical and academic literature and available market research to build a comprehensive knowledge base possible on psychedelic harms, risks, and interventions.

- b. Stakeholder Engagement: Working with [diverse stakeholder representatives](#) to upgrade the knowledge base, define gaps and priorities, and develop clarity on collaborative opportunities.
  - c. Strategic Analysis: Analyzing the current ecosystem and what is needed to reduce harm and developing a set of strategic assets, including typologies, an ecosystem map, a knowledge and infrastructure gaps analysis, and a theory of change.
  - d. Summit with UC Berkeley: The [Psychedelic Safety Summit](#), hosted by PSI and UC Berkeley's Center for the Science of Psychedelics and set for March 2025, aims to refine the strategy, develop collaborations, and define specific commitments and agreements by and between participants to reduce psychedelic-related harms and improve safe use.
- 5. Attract sufficient capital and buy-in to execute
  - a. Funder Relations: Present the strategic process results to funders with funding requirements and educate funders on enabling various public health and safety outcomes.
- 3. Execute effectively, building capacity across the ecosystem
  - a. Implement: Implement an action plan, including disseminating findings and best practices and engaging policymakers, first responders, care providers, and other stakeholders.
  - b. Capacity-Build: Work with non-profit teams to ensure they have effective strategies, leadership, and operations to execute their commitments to the action plan. As needed, carry out due diligence, funding thesis, and grant distribution services for funders.
- The [Chacruna Institute](#) has launched its [Certificate in Ceremony, Ethics, and Reciprocity](#), a 6-month course for ceremonial facilitators focused on reducing risks, strengthening community accountability, and cultivating skills for ethical ceremonial leadership. With the first cohort starting in March 2025, it is too soon to estimate the growth and ultimate impact of the program. But Chacruna has assembled an outstanding faculty and in-depth curriculum, and they have the experience and capabilities to deliver a field-leading offering that can seed unregulated settings with ceremonial guides who will elevate safety and ethics to the highest levels.
- [The Challenging Psychedelic Experiences Project](#) works to highlight and research psychedelic harms (especially extended post-psychedelic difficulties) and what helps people avoid or reduce these harms. They also organize and facilitate an online support group for people who have experienced extended difficulties after psychedelic experiences and publish a weekly newsletter, Ecstatic Integration. This work is helping fill critical gaps in what we know about psychedelic harms, how to reduce their likelihood, and how to help those who have been harmed. To broadly reduce risks associated with psychedelic use across contexts, it will be essential for the Challenging Psychedelic Experiences Project to partner with other organizations to disseminate and amplify learnings.
- [Global Psychedelic Society](#) (GPS) empowers local psychedelic societies with resources to build and support their communities with an inclusive, risk-reducing, and benefit-maximizing approach to advocacy, integration, and information. GPS is collaborating with PSI and could be both a 'voice of the customer' in prioritizing harms to address, and a channel for disseminating safety information and best practices. GPS can further bring awareness of other safety net resources, such as SHINE Collective and Fireside Project, to local psychedelic societies and their members. Their plans to reach this level of influence are in their early stages, but could ultimately be of great value to the field.
- [Fireside Project](#) works to minimize the risks of psychedelic experiences by providing compassionate, accessible, and culturally responsive remote peer support (Psychedelic Support Line). Fireside is highly scalable, has a proven track record, and is projecting one million calls per year by 2030. Fireside meets people where they are, providing direct assistance and reducing harm, while also creating opportunities for practitioners to get experiential training in psychedelic harm reduction. Additionally, Fireside can help provide basic safety education through its platform

and provide ongoing integration services.

- [Zendo Project](#) provides peer-based psychedelic and emotional care at events and offers professional education in their compassionate care model. Zendo has scaled its efforts since receiving their nonprofit status in 2023, expanding their partnership with event safety teams to bring their care model to more mainstream festivals. Zendo's newly-founded SIT education program trained over 800 students in its first year, with plans to train 5,000 people annually by 2027. Zendo is also developing specialized training modules for mental health crisis teams, clinicians, and psychedelic facilitators. With a twelve year history of supporting people undergoing complex psychedelic experiences, Zendo is a wealth of knowledge and asset for the field, with the ability to deliver peer-based harm reduction, train others, and inform best practices for psychedelic care.
- [SHINE Collective](#) offers no-cost virtual peer support groups to those who identify as survivors of psychedelic harm. SHINE is building a network of specialized providers capable of addressing the unique needs of this population which will be absolutely essential to have. What scale is achievable is unclear, but growing awareness of the need for these services among the types of practitioners eligible for SHINE training will be essential to building an adequate network.
- [MAPS](#) has piloted a psychedelic response training for over 3,000 first responders in Denver. MAPS seeks to make this available to other cities (emphasizing decrim locations) via a partner that can package and deliver it in a scalable way. MAPS is also positioned to be a useful partner in broadening the reach of any safety resources, as a uniquely credible organization in the field.

#### **Opportunities for PSFC:**

The preceding initiatives are promising for individual philanthropy, and with time and effort, could reach a point of maturity where significant collective funding would have a transformational impact. We encourage funders with an interest in safety net infrastructure to engage with these organizations.

The PSFC team will monitor progress of the above early efforts and conduct regular check-ins with stakeholders. PSFC can leverage our network of partners to work with the preceding initiatives to increase the visibility and accessibility of the safety net, which will be essential for success. And, as educational assets become available, PSFC can help to disseminate these to our network of partners.

With member endorsements, the PSFC team will make specific projects and organizations visible for interested members and facilitate connections.

#### **Risks with this set of activities**

Even if there are robust resources around safety best practices, it may be difficult to gain broad enough adoption to significantly influence safety across contexts. Early engagement and collaboration with entities that are, or we hope will be, part of the safety net long-term will be essential to ensuring adoption of safety best practices within these groups.

It is unclear how much demand is out there, among first responders and emergency medicine providers, for training on psychedelic harm reduction. If these groups aren't trained and become inundated with calls/visits from people having challenging psychedelic experiences, it could be an unwanted strain on an already overburdened system. These groups could become vocal critics of legal access to psychedelics.

If the safety net isn't visible and accessible, when adverse events happen there is risk associated with the perception of "this isn't safe" or "not enough has been done to address safety." Dissemination of safety net resources must be a top priority for our communications and public health education efforts.





## IV. Supporting Ethical Psychedelic Cultures

### Ethical Norms

The psychedelics field has faced many ethical controversies over the decades. To varying degrees, these have eroded public trust in psychedelics and driven sensationalized media coverage. Psychedelic states heighten suggestibility and vulnerability, thereby amplifying existing risks of abuse when psychedelics are used in medical, therapeutic, or spiritual settings. As a result, ethical concerns in the psychedelic field have persisted from the 1950s to the present, encompassing issues from practitioner abuse to scientific misconduct, conflicts of interest, and opaque funding practices, and prompting calls for clear and enforceable ethical norms.

We believe that introducing psychedelics into society without robust ethical principles could cause unanticipated harms and exacerbate some of the problems they aim to address. When it comes to business ethics, a “move fast and break things” approach could jeopardize patient safety. Furthermore, the field of philanthropy itself has faced media scrutiny of its ethics.

Given the heightened public scrutiny faced by the psychedelic field, there’s a strong need for actors within it to adopt exemplary and thorough ethical practices, echoing former director of the National Institutes of Mental Health, Tom Insel’s [powerful call](#) for the field to be “more Catholic than the pope”, or else we risk “poisoning the well for everyone.” A robust ethical framework is vital to enable the field to navigate these issues responsibly and prevent the repeat of historical mistakes, ensuring that the promising benefits of psychedelic therapies are realized while minimizing harms.

#### Long-term goals

By 2030, all stakeholders in the psychedelic ecosystem, including practitioners, businesses, researchers, advocacy organizations, and other nonprofits as well as philanthropists will uphold high ethical standards relevant to their areas of work. These will be guided by comprehensive ethical guidelines and accountability mechanisms developed and enforced by reputable actors. As philanthropy will still play a significant role in the field, philanthropic organizations will lead by example, embracing codes of conduct and using their influence to promote adoption of ethical practices and accountability, starting with their grantees. This proactive engagement will reduce both actual and perceived ethical violations significantly, thereby strengthening public trust in the psychedelic field. Where ethical breaches occur, businesses and nonprofits will be held publicly accountable, fostering a culture of transparency and integrity within the ecosystem. Reflecting the important and ongoing role of Indigenous plant medicine traditions in the psychedelic field, Indigenous leadership will be rightfully included in governance discussions, ensuring that their cultures’ perspectives

and wisdom are integral to shaping the field's ethical landscape.

### Current state

Recently, the psychedelics field has witnessed several high-profile allegations of ethical violations impacting underground psychedelic therapy patients and above-ground clinical trial subjects, among others. Without field-wide action, this pattern is likely to continue, resulting in increasing harms and backlash. [North Star](#) was founded as a direct response to the ethical perils depicted in the striking graphic short story, [We Will Call It Pala](#) in 2019. They crafted an [ethics pledge](#) with insights from 100 stakeholders, establishing seven key principles for psychedelics professionals. A landmark [2020 Lancet paper](#) sounded the alarm on safety and ethical concerns in psychedelic medicine, emphasizing the need for robust ethical frameworks for clinical research and therapy in order to reduce risks of harm to patients and manage growing public and regulatory attention. Attention to these ethical concerns has grown since then, as evidenced by a 2023 convening of researchers and practitioners at Oxford that [yielded the field's first consensus statement](#) recommending the adoption of ethical norms for psychedelic research and clinical practice. Also in 2023, the Lancet published the results of [a global Indigenous consensus process with ethical recommendations](#) for Western psychedelic research and practitioners seeking to engage ethically with traditional Indigenous plant medicine knowledge systems. The U.S. Department of Health and Human Services (HHS) held a [convening](#) in exploring the ethical considerations of psychedelic research, focusing on issues such as informed consent and the protection of vulnerable groups. And in 2024 the [Psychedelic Listening Project](#) spoke with 26 interviewees from across the ecosystem including five philanthropists and identified vital issues in the space, including several ethical recommendations for funders. A Branbury convening led to a [2024 JAMA Open consensus statement focused on ethical clinical care](#).

Proactively establishing ethical guidelines will be imperative to ensure informed consent, uphold practitioner standards, and set ethical guardrails for businesses and nonprofits in the psychedelics field. Several promising publications and convenings have started shaping conversations in the field on ethics, but efforts to establish ethical standards are currently fragmented and lack coordination. As numerous groups are tackling various aspects needed for ethical frameworks, aligning and coordinating these efforts will be an important step towards impact. At the same time, as public scrutiny of philanthropy intensifies in the psychedelic sector, concerns about its ethical implications are growing. Whether these reflect valid concerns or perceptions of ethical misconduct, they have the potential to significantly harm funders' reputations and increase their liability risks.

The ethical challenges facing the psychedelic field are wide-ranging, although in PSFC's view, the most significant and urgent ethical issues in the field center around potential harms to psychedelic therapy patients from practitioner misconduct or adverse experiences more generally. Although the organizations and initiatives outlined below are addressing important issues, there are several critical gaps in these current efforts to develop ethical norms and accountability in the psychedelic field.

- First, there is an urgent need to address research or pilot projects operating outside of Institutional Review Board (IRB) oversight, especially those conducted in settings that are federally illegal (e.g., underground therapy, cities that have decriminalized plant medicine possession, or state-regulated programs), posing significant risks due to the absence of formal ethical review and monitoring.
- Second, a comprehensive, 'umbrella' approach to patient safety is needed. This would cover a wide range of contexts, including regulated research environments as well as less formal settings such as underground therapy, overseas retreat centers, and other unregulated spaces (including concerns around unethical fundraising). Establishing a focus on patient safety across these domains is essential to safeguard individuals wherever they engage with psychedelics.
- Finally, ethics training for psychedelic practitioners and accountability mechanisms remain underdeveloped. While there is some ongoing work in this area, many key elements vital to patient safety—including managing suggestibility, addressing trauma-informed care, and ensuring proper integration support—are still often overlooked. Addressing

these gaps will be critical to fostering a safer and more ethical landscape for psychedelic use.

Below, we categorize a number of organizations and initiatives relevant to ethics in the psychedelic field. Though some are early-stage, they may be of interest for individual philanthropic support for those seeking to support the development and adoption of ethical norms and accountability for the field:

#### ***Initiatives addressing ethical business conduct for psychedelic companies***

- [North Star's latest project](#) seeks to establish a comprehensive framework of best practices for businesses in the psychedelic field, emphasizing ethical principles and public benefit. This initiative will extensively engage stakeholders to tailor guidelines to the industry's unique complexities, focusing on business structures, operational practices, safety, and incentives for responsible behavior.

#### ***Initiatives addressing practitioner ethics and patient safety***

- [The Ethical Legal Implications of pSychedelics in Society \(ELIPSIS\) program at Baylor College of Medicine](#) aims to develop and disseminate comprehensive ethical guidelines for the use of psychedelics in therapy, creating a training program for clinicians, and facilitating community engagement to inform policy development. Additionally, they will carry out research exploring the implications of psychedelic use in various therapeutic contexts, focusing on harm reduction and the integration of these therapies into mainstream medical practices in the US.
- Started in 2023, a promising collaboration between the [University of Pennsylvania](#) and the American Psychedelic Practitioners Association (APPA) was developing the first ethical guidelines for legal psychedelic practitioners. Since APPA disbanded, this project is on hold and could resume under a new suitable host, such as the Psychedelic Medicine Association or BrainFutures.
- The HIVE Initiative (Holistic Initiative for Visionary Ethics): Originating from an underground guild, this initiative is formulating ethical principles specifically for practitioners.
- [Shine Collective](#) and [The Challenging Psychedelic Experiences Project](#) have discussed the need for system-wide accountability mechanisms, with possible mediation and intervention by a psychedelic ombudsman, as the field does not yet have an established mechanism to denounce violations and hold actors accountable.

#### ***Organizations focused on ethical relationships between the psychedelic field and Indigenous plant medicine knowledge systems and knowledge-holders*** *(For more detail on some of these organizations, see the Indigenous Medicine Access and Conservation section):*

- The [Naut sa mawt Centre for Psychedelic Research](#) has developed an [Ethical Research Framework](#) aimed at supporting intercultural collaboration and incorporating Indigenous methodologies into its research practices.
- Groups like the [International Center for Ethnobotanical Education, Research, and Service \(ICEERS\)](#), the [Indigenous Medicine Conservation Fund](#) (IMC Fund), and [Chacruna](#) are working on guidelines for ethical relationships with Indigenous traditions and creating a dialogue to take their voice in consideration.
- The [Othering & Belonging Institute](#) is convening dialogues around ethics between Indigenous elders, researchers and training operators and published in the Lancet Regional, [“Ethical principles of traditional Indigenous medicine to guide western psychedelic research and practice”](#).
- [Common Field](#) focuses on protecting and integrating Traditional Indigenous Knowledge into law, business, and organizational culture. Their mission emphasizes the importance of Indigenous wisdom not just being acknowledged, but actively guiding actions and decision-making in areas like equity, sustainability, and decolonization.

### *Initiatives developing ethical guidelines for self-regulated communities*

- Incubated by Chacruna, [Sacred Plant Alliance](#) is developing ethical guidelines for the self-regulation of psychedelic churches.

### *Ethics for philanthropists supporting psychedelics*

- Scholars have written on how responsible psychedelic organizations should not seek funding from people during or in the days after a psychedelic experience, given that [potential donors might be more suggestible](#) and willing to support a project without proper due diligence.
- Reimagining philanthropic activity to create sustainable impact at the community level, the [pollination approach](#) was developed at the University of Maryland School of Business, to apply an ethics- and sustainability-centered vision to psychedelic organizational development.
- Ethical guidelines for philanthropists such as those set by the [Robert Wood Johnson Foundation](#) and the [National Committee on Responsive Philanthropy](#) illustrate the potential for establishing rigorous ethical conduct in philanthropy, which could be adapted to the psychedelics field.

### *Cross-cutting ethics initiatives addressing multiple areas*

- [Hopkins-Oxford Psychedelic Ethics \(HOPE\) Centre](#), a collaborative effort between Johns Hopkins University and the University of Oxford, established the first international hub dedicated to the development of ethical guidelines and policies for psychedelic research and therapies in 2022, publishing the [first consensus statement](#). They are hosting annual global summits, with key stakeholders—including researchers, ethicists, policymakers, and practitioners—to debate and form consensus on critical ethical standards, to produce pivotal policy briefs and publications that will guide regulation and ethical conduct on an international scale.
- [The Council on Spiritual Practices](#), since 1995, has collaborated with experts across various fields to develop safe and effective approaches in psychedelics, including a [Code of Ethics for Spiritual Guides](#) and a [Statement on Open Science](#).

### **Opportunities for PSFC**

The preceding initiatives are promising for individual philanthropy, and with time and effort, could reach a point of maturity where significant collective funding would have a transformational impact. The PSFC team will monitor progress of the above early efforts and conduct regular check-ins with stakeholders.

Over the near-term, we see a powerful opportunity for PSFC and members of our community to lead by example for the psychedelic field by developing and adopting ethical guidelines for both donors and grantees. Over time, the PSFC team will coordinate the development of ethical guidelines for philanthropy in psychedelics, working with PSFC members, expert ethics advisers and key stakeholders, including some of the organizations mentioned earlier. This process will culminate in clear policies and the establishment of an ad hoc ethics committee that will advise PSFC, its members, and grantees and maintain accountability. Our goal is to develop two complementary ethical guidelines:

- **An Ethical Charter for Philanthropists and Philanthropic Organizations:** This charter will address the specific ethical responsibilities and standards expected from psychedelic philanthropy
- **Ethical Requirements for Grantees:** This set of guidelines will focus on ethical expectations from organizations receiving philanthropic funding, emphasizing adherence to established norms and accountability mechanisms.

Over the longer term, we hope that the psychedelic field will follow the precedent set by the field of genomics and devote three to five percent of total funding in the field to supporting ethics initiatives. Just as the genomics field

recognized the importance of addressing potential ethical concerns—especially given its historical associations with eugenics—psychedelic research must acknowledge and address its own complex history, including instances of unethical experimentation, like those during Project MKUltra. By proactively confronting these historical shadows, the field can build a foundation of transparency and trust. This forward-looking approach not only addresses past controversies but ensures that future advancements are pursued responsibly, with public trust and societal benefit as guiding principles.

## Risks

- *Resistance from stakeholders:* Some stakeholders may resist adopting ethical standards, fearing it could stifle innovation or expose past unethical practices. This resistance may slow the development and enforcement of ethical guidelines, particularly among those who feel they are already operating responsibly or who may prioritize rapid growth over careful ethical considerations. To address this, incentives such as funding opportunities tied to ethical compliance or technical assistance in implementing these standards could encourage broader adoption.
- *Perception of philanthropy as an inappropriate ethics steward:* There may be skepticism about whether philanthropic organizations should take on the role of ethical gatekeepers in the psychedelic space, as some might question their impartiality or expertise. To mitigate this, it will be crucial to clearly acknowledge and learn from past ethical challenges in philanthropy—such as conflicts of interest or inadequate oversight in other fields—and demonstrate the current safeguards in place. A collaborative approach, where the push for ethics is a genuine inclusive multi-stakeholder effort will help demonstrate the positive intent of the initiative.
- *Lack of coordination across ethical initiatives:* With multiple groups working on ethical frameworks for psychedelics, there is a risk that efforts remain fragmented, leading to overlapping or contradictory guidelines. This lack of coordination could confuse stakeholders and reduce the overall effectiveness of these initiatives. A coordinated effort to harmonize these guidelines, possibly through annual summits or a dedicated ethics consortium, could mitigate this risk.

## Indigenous Medicine Conservation & Access

Plant medicine healing traditions have roots dating back thousands of years in what is now the U.S., and globally, and serve an estimated 1-2 million individuals worldwide. Members of these Indigenous communities are the single largest cohort currently receiving supervised psychospiritual support with psychedelics. In the U.S., Native Americans face the highest rates of suicide, mental illness, and substance use disorders in the country and ~350,000 Native American Church members currently access healing through peyote.

Increased demand from the resurgence of global interest in psychedelics has compounded ecological pressure on wild sources of plant-based psychedelics central to these Indigenous traditions. These ecological threats are exacerbated by cultural and legal threats such as the criminalization of traditional plant medicine practices, as well as patenting and misappropriation of traditional plant medicine knowledge, placing the continued survival of Indigenous plant medicine healing systems at risk.

At the same time, the extraordinary depth of knowledge and experience around plant medicine healing held by traditional practitioners has begun to be recognized by Western scientists and policymakers, including in a [2024 Request for Information](#) on psychedelic-assisted therapies from the U.S. Congress. Initiatives to foster connections and dialogue between Indigenous and Western knowledge systems will require a foundation of relational integrity, trust, and care, and should only proceed where mutually beneficial. Efforts to foster dialogue between these knowledge systems around psychedelic healing are still in their early stages, but will be vitally important in order for the globalization of

plant medicines and psychedelics to proceed from a place of right relationship, compassion, and supporting accessible healing within existing traditional and new systems.

## Long Term Goals

By the mid-2030s, ecological declines of key plant medicines have been reversed, and all are on track for long-term sustainability, while acute cultural and legal threats to traditional Indigenous plant medicine traditions have been addressed. This will increase and protect access to plant medicines for the Indigenous communities currently accessing traditional and culturally-appropriate plant medicine healing modalities in the U.S. and globally. Government protections that honor heritage plant rights (e.g., implementation of the [Nagoya Protocol](#) and UN Convention on Biodiversity, two international agreements addressing fair and equitable sharing of genetic resources) will be in place and enacted in the Amazon, on the African continent, and in North America. In parallel to these ecological, cultural, and legal efforts, relationship-building between Western and Indigenous knowledge systems will have enabled Indigenous voices to act as trusted authorities in the conservation field and the field of psychedelic medicine alongside western medical professionals, academics, and policymakers.

## Paths to Achieving Goals

### *Current State*

Several plant medicines face acute ecological threats. For example, wild populations of peyote and iboga are in steady decline due to overharvesting, illegal poaching, and habitat loss, jeopardizing access for traditional practitioners in the U.S. and Mexico (peyote) as well as in Gabon (iboga). Other plant medicines, including ayahuasca, psilocybin-containing mushrooms (specifically, heritage strains native to the Mexican highlands), and the Sonoran desert toad (not a plant, but similarly at risk) also face a range of ecological and social threats, including legal prosecution of practitioners and the loss of knowledge systems that sustain traditional plant medicine practices. Early-stage ecological and cultural knowledge preservation efforts are underway, although most are still small-scale. Some of these have embraced biocultural conservation strategies, which recognize the importance of Indigenous-led ecosystem stewardship. On the legal front, hundreds of traditional plant medicine practitioners around the world have faced prosecution. The policy environment around plant medicines is evolving rapidly worldwide due to decriminalization movements, conflicts over Indigenous rights, and crackdowns in previously unregulated national contexts.

### *Key Organizations*

We see two organizations, the Indigenous Medicine Conservation Fund (IMC Fund) and the International Center for Ethnobotanical Education, Research, and Service (ICEERS) playing complementary roles to address the ecological, cultural, and legal threats to Indigenous plant medicine traditions, while working to foster respectful and reciprocally beneficial dialogue between Western and Indigenous knowledge systems around plant medicines:

- **Supporting the [Indigenous Medicine Conservation Fund \(IMC Fund\)](#) as a field catalyst and capacity builder for bio-cultural conservation initiatives addressing threatened plant medicines and communities.** IMC Fund has an innovative Indigenous-led governance structure and supports biocultural conservation approaches, which recognize the importance of Indigenous-led ecosystem and cultural stewardship. IMC Fund is focused on a multi-year strategy through 2030, collaborating with over 19 organizations to build large-scale, regional initiatives to slow and reverse threats to five key plant medicines (ayahuasca, iboga, mushrooms, peyote, and toad) while deeply supporting associated knowledge systems and community access to healing. Some projects, such as the IMC Fund-supported [Indigenous Peyote Conservation Initiative](#) have already made significant progress towards habitat conservation and cultural revitalization. The fund is conducting an ecological baseline assessment across all five plant medicine biocultures with results anticipated in 2025. IMC Fund also works closely with the broader psychedelic ecosystem on public education initiatives and convenings (e.g., leading plant medicine programming for the MAPS 2025 Psychedelic Science conference) to shape public narrative and foster mutually beneficial



relationships between Indigenous medicine knowledge-holding communities and Western scientific and policy efforts.

- **Strengthening legal and policy protections for Indigenous plant medicine practitioners and weaving alliances to bring together Indigenous and Western knowledge systems.** [The International Center for Ethnobotanical Education, Research, and Service](#) (ICEERS) has played a synergistic role in the psychedelics field addressing the many challenges that have emerged with the globalization of plant medicine. Since its founding 15 years ago, ICEERS's work has included legal defense services for over 350 practitioners—including Indigenous healers—facing prosecution in over 45 countries, policy advocacy to support protection of Indigenous plant medicine traditions, and free integration and crisis support for individuals facing difficulties after plant medicine experiences. ICEERS has built alliances and collaborative processes centering Indigenous knowledge holders to strengthen plant medicine traditions and build support for policies that protect communities that sustain these traditions. Through a process led by Indigenous knowledge-holders, ICEERS is also supporting global convenings including a 2026 global ayahuasca conference bringing together plant medicine communities, researchers, policy makers and Indigenous knowledge holders to foster global intercultural alliances and collaboration.

#### *Other Needs*

Alongside the work of these two organizations, initiatives to promote reciprocity and ethical approaches to intellectual property will be important. Such efforts can mitigate harms from the commercialization of psychedelics and foster benefit sharing with traditions that have stewarded knowledge from which much of the Western use of psychedelics emerged. Notably, two similar organizations, the [North Star Project](#) and [Common Field](#) anticipate creating initiatives to promote ethical business practices and respect for traditional Indigenous knowledge by companies in the psychedelic field. Public education around plant medicine conservation and the protection of Indigenous plant medicine traditions will also be essential. [Chacruna](#) has extensive experience leading public education efforts and coordinating reciprocity initiatives on these issues. Chacruna's conferences are also vital forums for dialogue and learning about plant medicine conservation and reciprocity. Finally, nonprofits such as [Onaya Science](#) are working to support research on plant medicines in partnership with Indigenous knowledge holders.

#### **Risks to mitigate**

- **Program execution risk and need for capacity building** - Global North-South funding collaboration involves a number of technical and capacity-related challenges when granting to small nonprofits in developing countries. IMC Fund mitigates these risks by providing technical advisory support alongside funding to community partner organizations. This has proven successful with IMC Fund's early partnerships focused on ayahuasca conservation in Colombia, where the networks and local knowledge of local partners have enabled grantmaking in 2022-24 to be highly cost-effective in terms of advancing access to healing modalities for survivors of armed conflict and sexual abuse while also addressing cultural and ecological conservation goals.
- **Inherent challenges of conservation efforts** - Some ecological threats are rapidly accelerating (e.g., iboga and toad) and may be exacerbated by outside factors such as climate change-induced habitat loss. So there is a real risk that conservation efforts may be too slow or may be insufficient to address ecological threats. IMC Fund is mitigating these risks through their periodic conservation assessments and investing in long-term partnership building and capacity building among partner organizations to enable them to operate over long periods of time.
- **Policy change and bridge building challenges** - Although ICEERS is well-positioned to support policy advocacy to strengthen Indigenous rights around plant medicines, national and global political dynamics around drug policy are highly volatile, so progress will be uncertain. And while relationship-building between Indigenous and Western knowledge systems around plant medicines is a noteworthy long-term goal, it will proceed at the speed of trust, which is built slowly and is delicate to sustain.



## Aspirational Timeline and Milestones

IMC Fund has developed a six-year planning horizon for its conservation work across five medicine biocultures (ayahuasca, iboga, mushrooms, peyote, and toad), highlights of which are summarized below. In addition to ICEERS' ongoing harm reduction, policy engagement, and legal support programs, they are building towards a key 2026 convening to anchor their intercultural partnership work between Indigenous ayahuasca practitioners and western knowledge systems to support knowledge sharing and global policy change.

### 2024-2025

- Indigenous community partnerships confirmed for all five IMC Fund biocultures and governance bodies established for each.
- Ecological and community-based assessments completed by IMC Fund-supported organizations to evaluate conservation status and needs for each bioculture; results incorporated into conservation strategies for subsequent phases.
- Publication of collaborative papers on IMC Fund ecological assessments; papers presented at conferences and publicized via a media strategy to shape the public narrative on psychedelics and inform consumer choices.
- Best practices for benefit sharing and adherence to international human rights standards and biodiversity protocols within the psychedelics field developed and disseminated with trusted learning partners by IMC Fund.
- ICEERS brings data from plant medicine globalization to the Indigenous Ayahuasca Conference to inform dialogue and analysis by key Indigenous leaders, and consolidates a collaborative plan with the leadership for the convening of a large international gathering in 2026.
- ICEERS completes initial collaborative engagement processes with Indigenous ayahuasca leaders, policymakers, and advocates around potential plant medicine practices and policies that could serve as pathways towards healing and strengthening relationships between Indigenous and Western communities.

### 2026-2027

- Large-scale conservation strategies and goals developed and completed for all five IMC Fund biocultures; Implementation of conservation initiatives underway.
- Second round of ecological and community-based assessments completed by IMC Fund-supported organizations, reflecting newly-developed conservation strategies.
- Additional Indigenous community partnerships confirmed with IMC Fund to align with a scaled-up conservation strategy.
- Under Indigenous leadership, ICEERS hosts the World Ayahuasca Conference in 2026 with coordinated Indigenous and Western participation, leading to coordinated efforts to support intercultural collaboration around key issues, including global plant medicine stewardship, knowledge preservation, knowledge sharing, and policy engagement.

### 2028-2030

- Ongoing assessment, technical support, and new partnership development based on the high-level strategy work for each IMC Fund bioculture in Phase 2.
- Additional Indigenous community partnerships developed by IMC Fund sufficient to reach network strength

needed for long-term bioculture health and medicine community sustainability.

- Public narratives and policymaking/advocacy priorities in the psychedelic field shift towards greater alignment with right relationship between Western and Indigenous perspectives; minimizing pressures from the expansion of access to psychedelics in traditional communities.
- ICEERS's legal support, and policy engagement initiatives yield reductions in legal prosecution of plant medicine practitioners and significant policy reforms. In parallel, ICEERS's integration support and capacity-building work measurably reduces global incidence of adverse events and unattended challenging experiences, a critical step in order to mitigate the risk of backlash.
- ICEERS's initial collaborative plant medicine stewardship strategies centering Indigenous leadership demonstrate progress towards protecting and strengthening community-based plant medicine practices and serve as models for future collaborative work with other communities.

## Projected Costs

Overall costs through 2027 across IMC Fund and ICEERS are summarized below:

**Indigenous Medicine Conservation Fund (IMC Fund):** Total philanthropic investment of \$17m over three years:

- 2025: \$5.5 million
- 2026: \$5.5 million
- 2027: \$6.0 million

**International Center for Ethnobotanical Education, Research, and Service (ICEERS):** Total philanthropic investment of \$5.7m over three years:

- 2025: \$1.7 million
- 2026: \$2.3 million (\$500k for global plant medicine conference)
- 2027: \$1.7 million

## Self-regulated Communities

Most psychedelic use in the U.S. will continue to take place outside of any government-regulated setting for the foreseeable future. Even for those whose entry points are in a medical or state-regulated context, these channels will often not be suitable for an ongoing relationship with psychedelics. Psychedelic use in community enables continuity of interpersonal relationships, and evolving relationships to the substances. This in turn creates opportunities for risk reduction and peer support, as well as ready-made containers for integration. The inevitability of community use, along with these benefits, suggests that we should pursue opportunities to support organizations that can serve as standard-setters and role models in ethics, safety, accountability, and community support.

**Long-term goals.** There should be both religious and secular self-regulated communities throughout the U.S. that operate with high ethical norms and accountability mechanisms. By 2030, any U.S. individuals in search of such a community should be able to identify one accessible to them, and to make educated choices about how to participate. These should operate with greater legal protection than seen today.

**Current landscape.** Positive psychedelic experiences and growth, with reduced risk and safety net infrastructure, can be fostered in formal communities with intentional operating, ethical, and governance structures. Examples include secular psychedelic societies, psychedelic churches, and religious organizations already serving as spiritual homes to many. Churches could in time come to enjoy a degree of legal protection, although to date, this protection has been limited to only a few organizations. Line of sight to a clear legal framework that protects a meaningful number of groups is still unclear, though some seek to apply pressure on the DEA to provide this.

A few pioneering groups have recognized the potential for abuse in underground settings, and are responding by designing models that minimize these and other risks - and sharing them with others.

- Sacred Plant Alliance ([SPA](#)), a membership organization for minimal-dogma psychedelic religious organizations, that provides peer support and collaboration among leaders, sharing of best practices and ethical standards (including annual ethical review and peer review, and a central reporting system), and public education.
- Brooklyn Psychedelic Society ([BPS](#)), a local group (reach ~10K) defining the novel “trellis” operating model to foster community based healing with highly participative governance and strong accountability. This will be open-source, and eventually be a basis for recognition of other groups that show alignment with the core tenets.

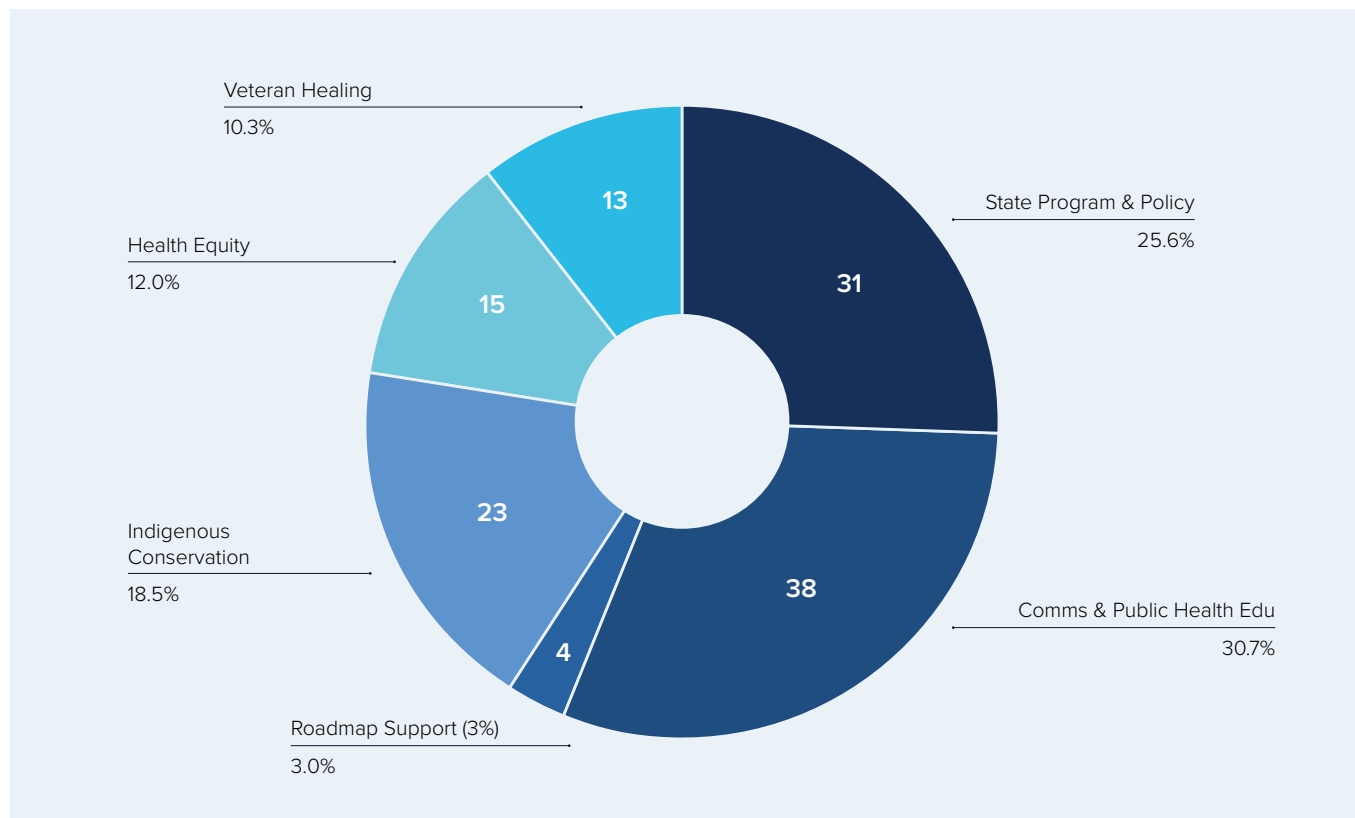
Other organizations are exploring implications of growing awareness of psychedelics as they inevitably intersect with the practice of mainstream religions. [Ligare](#) and [Shefa](#) are education and advocacy organizations that seek to enable existing Christian and Jewish communities, respectively, to responsibly incorporate psychedelic experiences into well-established traditions, when they wish to do so.

These organizations are still early in their journeys, and the scale of their impact thus far is still small. We consider their missions to be high priorities for individual philanthropy by those seeking to foster ethical, responsible community use outside the limits of regulated settings. As these organizations’ models are refined and their footprint grows, the path to large-scale impact will become clearer, and they could become top priorities for collective philanthropy.

# Summary: Proposed 3-year Investment and its Impact


The preceding sections highlight the crucial role that philanthropy will play in the advancement of the psychedelics field. This is not new - earlier stages of psychedelic research and delivery were heavily fueled by philanthropy. We estimate that in the past decade, the 'psychedelic renaissance' has benefited from \$350-400MM in philanthropic support, and while its impact has been broad, the majority of it has been directed toward drug development.

Our analysis shows that philanthropic support will need to be held at these levels, but be directed toward a more concentrated set of priorities, to meaningfully advance toward our north star goal. **Over the next three years, 2025-2027, we call for \$125MM** to advance the following areas:



This level of investment, in the efforts outlined in preceding sections, will be the foundation for a major expansion of access to psychedelic care for those most in need. We anticipate that it will deliver the interim outcomes described in preceding sections. The item for Roadmap Support reflects the cost of ongoing diligence, grant management, and grantee engagement and support, and is estimated at 3% of the total underlying philanthropic support.

It is important to note that not all areas with future funding needs are represented in this analysis. Some are still emerging, with the right 'home' for the most impactful investment not yet ready (e.g., funding the work necessary for mainstream national mental health organizations to embrace and adopt psychedelic care). Others remain very promising areas for individual philanthropy, but are not yet at a scale that calls for collective action (e.g., supportive self-regulated communities). We will stay closely attuned to these areas, to find opportunities to support their maturation, and to eventually be able to partner with anchor organizations as core roadmap priorities.



## Summary: Timeline to our North Star

The following exhibits summarize the timelines for progress toward our north star in the four core areas of the strategic roadmap. Uncertainties abound, inside and outside of the control of PSFC and partner organizations, so we expect that some milestones will be achieved early, some late, and some changed. But it is essential to have a plan to track against, and we are confident that by the end of 2025, there will be real progress across roadmap areas, setting the foundation for the next stage of work. In 2027, we anticipate a stock-taking and reassessment prior to the next 3-year period through 2030.

## EXPANDING LEGAL PATHWAYS

2025

- Oregon service centers publish first SB 303 data
- Oregon service centers have access to core business services and technical assistance, with multiple efforts to build awareness and referrals underway
- Colorado psilocybin program launched,

2027

- Colorado adds 1-3 additional natural medicines to its supervised psilocybin therapy program
- Multiple state access programs advancing based on legislative efforts
- Uniform data collection, awareness & referral, and business support offerings across active state programs
- First FDA approval and resulting rescheduling of a psilocybin product

2030

- Real-world evidence from state regulated psychedelic programs supports psilocybin rescheduling to III+
- State-licensed training program accreditation established as norm, covering 50%+ licensees
- 3-4 additional FDA approvals, including MDMA and LSD, and new psilocybin indications

## MEDICAL SYSTEM INTEGRATION

2025

- Psychedelic working groups established in major mental health practitioner societies
- First state Medicaid study launched, on psilocybin for SUD in Hispanic & NA populations
- Licensed mental health professionals in CO integrating psilocybin care, reimbursed for wrap-around care
- Cultural competency and health equity training curricula incorporated into PAT education.

2027

- 20+ university graduate programs have curricular content on psychedelic healing, and 10 have specialized practitioner training programs
- Robust pilot studies demonstrate cost-effectiveness of psychedelic treatment in marginalized communities
- FDA-approved psychedelic reimbursed by health plans covering 50%+ of insured population
- VA clinical demo projects launched for MDMA and psilocybin

2030

- Psychedelic care recognized as evidence-based therapy in mainstream clinical practice guidelines
- 15 community based orgs provide psychedelic therapy; 5 state Medicaid programs cover psychedelic therapy
- 10,000 veterans treated in VA with large-scale multi-site trials to support dissemination underway

## COMMS. AND PUBLIC HEALTH INFRASTRUCTURE

2025

National coordinated communications strategy in place based on research-based message framework

"Always-on" campaign activated, to proactively develop and disseminate balanced information through multiple channels

Public health education pilot program completed, findings incorporated into scale-up plans

2027

Positive shifts in cultural norms and expectations among adults around psychedelics, as measured through attitudinal changes in public opinion research tracking

Positive shifts manifesting in increasing number of evidence-informed laws and regulations

PS27 exceeds even PS25's record-breaking engagement and positive media coverage

Increased, measurable public awareness and understanding of key risk/safety messages

Government funded education campaigns underway, with partnership of local & state harm reduction orgs

2030

Benefits/risks, contraindications and safer-use practices of psychedelics are well known among target audiences

Public health education efforts show proof of significantly mitigated harm and are increasingly built into policy initiatives with government funding

## ETHICAL PSYCHEDELIC CULTURES

2025

Ecological and community-based assessments for five key biocultures completed (ayahuasca, iboga, mushrooms, peyote, and toad)

Collaboration launches to develop ethical guidelines and establish an accountability system across the psychedelics ecosystem.

Ethics-informed grantmaking standard for PSFC, and adopted by other funders in the psychedelics field

2027

Large-scale conservation strategies developed for all five plant medicine biocultures; Implementation of conservation initiatives underway

Intercultural collaboration on global medicine stewardship, knowledge preservation and sharing, and policy engagement resulting from 2026 World Ayahuasca Conference

Credible and recognized ethics alliance established, leading to adoption of ethical frameworks and guidelines across medical and non-medical settings.

2030

Acute environmental, cultural, and legal threats to traditional Indigenous plant medicine traditions on track to be remediated

Ethical practices deeply embedded in practitioner training, service operations, and research conduct





# Operationalizing the Roadmap

This roadmap is intended as a resource for the philanthropic community. Its impact depends not only on financial support for the roadmap's core initiatives, but also active stewardship of the plan. PSFC will serve as a vehicle to enable this stewardship, in several ways.

## Ethical Philanthropy

At PSFC, we commit to holding ourselves and our grantees to the highest ethical standards, drawing on established best practices in medical, psychedelic, and philanthropic ethics to inform and guide our operations. We will closely monitor discussion and data related to the field's ethical issues, and expect our grantees to have robust mechanisms to navigate challenges relevant to their areas of operation, and to enable accountability when missteps occur. In time, we aim to develop a more comprehensive ethical charter in consultation with experts, setting rigorous ethical standards and including an accountability mechanism that fosters a safe environment for raising ethical concerns. We encourage other funders in the philanthropic community to positively influence the field by joining us in integrating ethical assessments into their own grant-making processes.

## Funding Roadmap Priorities

Our approach to supporting funders' contributions to roadmap priorities will be flexible, reflecting different types of donor-grantee relationships. The PSFC team will be able to support philanthropic giving in three ways:

1. **Direct-to-org contributions:** Many donors and grantees mutually value their direct collaborative relationships, and we anticipate this translating to direct contributions, with PSFC uninvolved in transactions. We fully support this, but recommend that donors stay in dialogue with PSFC expert staff, both for transparency into overall progress against roadmap funding targets, and for thought-partnership in structuring grants to stay in alignment with roadmap goals.
2. **Restricted contributions:** Even with our efforts to focus on the most critical areas of the field, not all donors will be passionate about all of the priorities that this roadmap highlights. For those seeking to give to a particular area, but not to diligence and form a direct relationship with a grantee, PSFC can receive and deploy restricted funds, to be used for a specific donor-designated roadmap focus area or organization.

3. **General roadmap contributions:** Grants to PSFC general funds will be deployed in accordance with the principles of this roadmap. This path is suitable for donors who are seeking collective impact, leveraging the full insight and relationship network of the PSFC team. PSFC will regularly assess and rebalance its view of opportunities to advance the field, providing assurance that our most up-to-date insights will guide use of resources.

## Governance of PSFC Grantmaking

Historically, the vast majority of PSFC philanthropic activity is in the form of individual giving by members to grantees. For funds managed by PSFC, its board of directors exercises governance over grantmaking to the psychedelics field. It will continue to do so in the context of the strategic roadmap, with some enhancements:

- In each major roadmap area, PSFC will convene a bespoke grant committee of donors having experience as actively engaged funders in that area. This will enrich the PSFC team's insight into subtle shifts in the field, and ensure that the donor perspective is always represented in our grantmaking.
- We will bring non-donor subject matter experts to advise on proposed grants whenever possible, ideally in consultation with grant committees. This is particularly important in areas where ethical, technical, or cross-cultural issues are more likely to arise.

## Grant Management & Reporting

PSFC's approach to grant management and reporting for the roadmap will build on our experience and learning from our organization's initial rounds of grants, and from peer grantmaking organizations in the psychedelics field and beyond. We have learned and adapted throughout our grantmaking from 2022-2024, with grants to more than a half-dozen infrastructure initiatives.

These experiences have shaped PSFC's process for roadmap grantmaking, which seeks to balance thorough diligence and monitoring with the needs and capacities of grantees:

- **Diligence:** PSFC tailors its grant application path and diligence process to the context and scope of each organization and project, and will continue to do so in the context of the roadmap, which features organizations at very different stages of development.
- **Grant agreements:** Our grant agreements typically involve milestones and reporting requirements developed in collaboration with each grantee. These often involve extensive and detailed milestones across program areas for mature organizations, or for younger organizations, they can be learning opportunities for goal setting and working with KPIs.
- **Grant management:** Typical grant agreements are 6-12 months in duration and involve distributions of funds contingent upon submission of progress reports and successful completion of grant milestones. We aim for the management process to be as collaborative as possible and typically build in periodic check-in conversations with grantees to review reports, discuss programmatic shifts, setbacks, or challenges.

## Evolving the Roadmap

The psychedelics field is evolving rapidly, more like a new technology field than one with centuries-old origins. This is driven by an accelerating pace of research, the advancement of the FDA drug pipeline, and a combination of media coverage and advocacy driving increasing awareness of potential benefits & risks by the public and policymakers. This pace will continue in the coming years, implying that no roadmap for progress can be static. Timelines for efforts that we support will need regular adjustment, forward and backward. Some organizations that we back may not succeed, and new and unexpected initiatives will arise that present important additions or alternatives to existing ones.

The PSFC team will stay closely engaged with our grantees, and seek paths to support them to meet or exceed current expectations. At the same time, we will closely monitor events and trends in the field, seeking emergent opportunities to further ensure attainment of our north star goal. We will use these to update the roadmap on a regular basis as the future unfolds.



# Acknowledgments

This roadmap would have been impossible to create without the generous gifts of time and insight from several groups. While perspectives differ on the roadmap's recommendations, and not all of those named below would agree with all points, it would have been a much diminished asset without their valuable input.

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# PSFC

Psychedelic Science  
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