### **Public Health Division**

### Office of the State Public Health Director



Tina Kotek, Governor

DATE: October 9, 2025

TO: Hearing Attendees and Commenters –

Oregon Administrative Rules chapter 333, division 333

Oregon Psilocybin Services

FROM: Brittany Hall, Administrative Rules Coordinator

Public Health Division

SUBJECT: Presiding Hearing Officer's Report on Rulemaking Hearings and Public

**Comment Period** 

# **Hearing Officer Report**

Date of hearings: September 16, 2025 and September 18, 2025 via Zoom

**Purpose of hearings and public comment period:** To receive testimony and comments regarding the Oregon Health Authority (OHA), Public Health Division's proposed permanent amendment of Oregon Administrative Rules in chapter 333, division 333 related to Oregon Psilocybin Services. The proposed rules implement ORS chapter 475A, the Oregon Psilocybin Services Act ("the Act"); Oregon Laws 2025, Chapter 147 (HB 2387); and Oregon Laws 2025, Chapter 236 (SB 907).

ORS 475A created the nation's first regulatory framework for the production and sale of psilocybin products and provision of psilocybin services to clients. OHA adopted rules in 2022, 2023, and 2024 that addressed a variety of issues, including requirements for licensure, storage and security, standards for psilocybin products, packaging and labeling requirements, safety standards and guidelines for provision of psilocybin services, client rights and informed consent processes, facilitator duties, compliance, product tracking and transportation. These proposed rules supplement prior rules and make further refinements to requirements for training programs, licensees, and permittees. The proposed rules address all

aspects of implementation and support the Act's goals of promoting access and equity while protecting health and safety. The proposed rules are necessary to effectively implement the Act because they make important changes to the previously adopted rules that will provide greater clarity and efficiency of operations for both licensees and the Oregon Psilocybin Services Section (OPS) of the Oregon Health Authority. The rules also implement Oregon Laws 2025, Chapter 236 (Senate Bill 907) and Oregon Laws, 2025, Chapter 147 (House Bill 2387). The proposed rules make changes to align with revised statutory language, address requirements for facilitators who hold other license types, require additional information on product labels, additional reporting by licensees, and additional requirements for verification of property ownership.

Hearing Officer: Samie Patnode

Comments and testimony received: In OHA's Notice of Proposed Rulemaking, OHA announced that individuals could submit written comments by sending them to OHA's designated email address for receiving such comments, or by fax or mail. In addition, OHA took public testimony at the public hearings that were held on September 16, 2025 and September 18, 2025. OHA received oral testimony from 10 individuals at the public hearings (some individuals testified at more than one hearing) and received timely comments from five individuals. OHA staff have considered the public testimony and written comments received prior to the deadline on September 22, 2025, at 5:00 p.m. Pacific Time. OHA thanks all Oregonians who provided public comment and appreciates the varied input they have provided to the rulemaking process.

Themes of the testimony and written comments relevant to the current proposed rules, in no particular order, are summarized below. Copies of audio recordings of the hearings are available online at <a href="https://oregov/psilocybin">oregov/psilocybin</a>. Written comments received prior to the deadline on September 22, 2025, at 5:00 p.m. Pacific Time are attached to this report as EXHIBIT 1.

OHA received comments expressing opposition to the proposed amendment to OAR 333-333-2030(1) (adding the word "transfer"), "which would prohibit manufacturers from transferring finished and packaged extracts and edibles to one another."

## **Agency response:**

This comment misunderstands the requirements of the rule. The existing text of OAR 333-333-2030(1) requires that a manufacturer may only produce or sell psilocybin products if they hold the appropriate endorsement for that product type. The 2025 amendment adds the word "transfer." It is not a prohibition but rather a requirement that manufacturers hold an endorsement for the products they transfer.

➤ OHA received comments requesting that presenters of educational material (at continuing education workshops and conferences, for example) receive continuing education credit for presenting.

## **Agency response:**

Revised language in OAR 333-333-3030(8) allows facilitators to claim continuing education hours for providing trainings that qualify under the rule.

➤ OHA received comments requesting specificity or clarification around requirements for continuing facilitator education in OAR 333-333-3300. The commentor noted that there are conflicting sections of the rule regarding the type of content that is considered valid and would count as continuing education. Section (2) references continuing education described in OAR 333-333-3050 and OAR 333-333-3060, while subsections (5)(c) and (6)(d) cites continuing facilitator education under ORS chapter 475A. The commentor questioned "is it any relevant content relevant to the provision of psilocybin services under ORS chapter 475A [as stated in subsections (5)(c) and (6)(d)]?" "Or is it any content as listed specifically in OAR 333-333-3050 and OAR 333-333-3060 [as stated in section (2)]?"

# **Agency response:**

OAR 333-333-3300 has been amended to use consistent references throughout the rule.

> Also regarding OAR 333-333-3300, Continuing Facilitator Education, OHA heard in oral testimony and received written comments stating that there are limited options and strict requirements on what continuing education (CE) is considered valid, referencing subsections (3)(a) and (b), which say continuing education must be offered by training programs with curricula approved by the Oregon Health Authority and offered by organizations or conferences that have been approved to offer continuing education for other types of professional licenses or certifications. Written comments opine that the limited CE considered valid for facilitator CE requirements "places a possibly confusing and undue burden on facilitators trying to meet with requirement for relicensing." Written comments request that the rules "remove the limited requirements of who is considered 'valid' to offer CE" in order to "expand what is considered valid CE for facilitators in the re-licensing requirement" and to increase access and affordability. As an alternative, written comments requested that Oregon Psilocybin Services (OPS) "consider offering their own trainings and educational opportunities to disseminate to facilitators that would meet the aforementioned definitions and would be free of cost" or, if approval and validity is still desired, "perhaps OPS could open up its own sub-set of rules governing programs specifically for CE" in order to allow OPS to retain some oversight.

# Agency response:

OPS lacks resources to offer its own training and educational opportunities or preapprove offerings provided by outside organization. The rule limits which programs and organizations may offer training and by doing so provides clarity to facilitators regarding which trainings will qualify for continuing education.

➤ OHA heard in oral testimony and received written comments voicing concern about proposed changes to OAR 333-333-4820(1)(c), Record Retention, which has been amended to add "If additional documentation regarding client participation in preparation, administration and integration sessions that is not required by these rules is created, it must be promptly incorporated into the client records." The commentor noted that, as a licensed facilitator, there are things that a client may not want to write down or add to a client information form but are verbally discussed with the facilitator in the trust building process. The facilitator offers to write notes for the client during the preparation and

integration session(s) and under this new rule as it is written, those notes would be required to be added to a client record for retention. The commentor opined that this "has the possibility to negatively impact a client seeking services, who may opt out if they knew documentation of very private and sensitive information relating to them will be added to their record with no understanding of the reasons why, what will be done with that information, and the integrity of safety mechanisms in place to protect that documentation." It was also noted in oral testimony that there is a potential privacy issue if records are included that are covered by HIPAA (Health Insurance Portability and Accountability Act) due to creation by a dual licensed facilitator. It was requested that the addition of new language in subsection (1)(c) be omitted or that the rule be amended to clarify and specify exactly what is meant to be incorporated in the client records in addition to what is already required.

## **Agency response:**

The records described in this comment are client records as defined in OAR 333-333-1010(20). Existing rules require these documents to be stored at the service center. The proposed amendment merely states that these records must be incorporated with other client records promptly. OPS has revised OAR 333-333-4820(1)(c) for clarity in response to this comment.

OPS is unable to address concerns regarding compliance with other record keeping requirements for dual licensed facilitators. OAR 333-333-4820 operates independently from any requirements imposed by other licensing bodies and regulations, and dual licensed facilitators are responsible for understanding and complying with any applicable record requirements in addition to complying with OAR 333-333-4820.

➤ OHA heard in oral testimony a request for rewording changes to OAR 333-333-5120(3), Facilitator Conduct, in order to make rule more readable and easier to understand.

# **Agency response:**

OAR 333-333-5120 has been revised for readability.

➤ OHA heard oral testimony the request to eliminate the requirement to conduct final preparation sessions 24 hours in advance of the administrative session for doses under 2.5mg (microdoses/subperceptual doses), as well as a request to eliminate transportation plan requirements for doses under 2.5mg.

## Agency response:

The requirement that a preparation session be held at least 24 hours before the client's first administration session is found in OAR 333-333-5000. This rule was open in the current rulemaking to make technical adjustments for references to other rules that had been amended. The rules advisory committee did not have an opportunity to consider substantive changes. Therefore, this comment is more appropriate for future rule making.

OPS declines to amend OAR 333-333-5150 to eliminate transportation plans for doses under 2.5mg. A transportation plan is necessary to protect public health and safety, regardless of the dose consumed. This requirement is supported by Oregon law, ORS 813.040, which was amended in 2023 to add psilocybin to the list of intoxicants identified in Oregon law prohibiting driving under the influence of intoxicants.

➤ OHA heard in oral testimony the request to allow service centers to serve food and beverages that have not been sealed in protective packaging, like a banana or an orange for instance. It was suggested that instead of requiring food to be in original, sealed packaging that a food handler permit requirement for someone serving food in a service center could be implemented.

## Agency response:

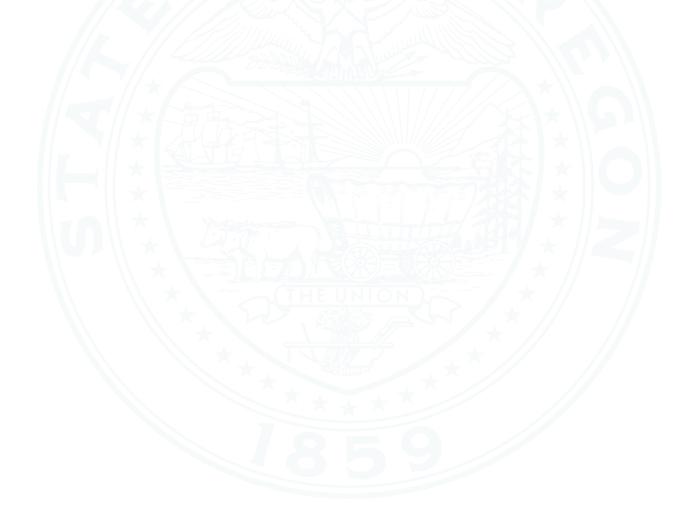
OAR 333-333-4300 prohibits issuing a license at a facility licensed under ORS chapter 624. The requested change to OAR 333-333-4480 is inconsistent with this prohibition.

➤ OHA heard in oral testimony the need to change the way numbers are assigned for dosing, especially for microdosing. Currently, the client dose is based on psilocybin analyte. However, there are products containing psilocin that can lead to higher doses than the listed value for psilocybin analyte only.

Subperceptual doses (microdoses) under the rules may not be subperceptual in reality. Oral testimony encourages the use of a formula and education about the combination of psilocybin and psilocin content in products.

# **Agency response:**

OPS has revised OAR 333-333-2400 and 2410 to require additional information regarding potency formulas on product labels and production information documents. OPS has also amended OAR 333-333-5000 to require that clients review a Psilocybin Product Potency Information Document during their preparation session.



Oregon Health Authority - Public Health Division

Public Health Division Rules Coordinator
Oregon Psilocybin Division
800 NE Oregon Street, Suite 930
Portland, Oregon 97232

#### RE: Public Comment on Proposed Rule Changes for Division 333-Psilocybin

To Whom It May Concern,

Thank you for the opportunity to provide input on the proposed rules changes for OAR 333-333. I am writing to express some of my concerns, particularly with the proposed changes affecting **333-4820 Record Retention** and **333-333-3300 Continuing Facilitator Education**.

A new proposed rule was added to **333-333-4820 Record Retention** which states:

(c) If additional documentation regarding client participation in preparation, administration and integration sessions that is not required by these rules is created, it must be promptly incorporated into the client records.

This new rule is incredibly broad. It is unclear why this rule was created and what the intent is behind it. What additional client information does OPS need to have record of outside of the *significant* amount of required documentation that is already created and completed by the client?

If the impetus behind the addition of this rule is tied to the recent legislative changes encompassing the allowance of dual-licensure during preparation and integration sessions, then more clarity and specificity should be added. However, I also see a potential conflict with the required retention if this is the case, as it might contain information that should be regulated under HIPAA.

As a licensed facilitator, there are things that a client will divulge to me during preparation that they will not add to their client information form, for a multitude of reasons. They may not want to write down to have on record things like traumatic experiences, current mental health struggles or their reasons for seeking services. However, in the trust building process, they will verbally discuss things that they hadn't added to their forms, and I may jot down some notes as it relates to things to keep in mind for their session(s). This applies to their integration session(s) as well.

Additionally, I offer to write notes for the client during their session should they want, things that come up in their journey, and I give the client these notes immediately following their

administration session end. I do not keep copies. But under this new rule, as it is written, those things would be subject to be added to a client record for retention.

This seems like an unnecessary overreach as well as additional undue administrative burden. It also has the possibility to negatively impact a client seeking services, who may opt out if they knew that documentation of very private and sensitive information relating to them will be added to their record with no understanding of the reasons why, what will be done with that information, and the integrity of safety mechanisms in place to protect that documentation.

Recommendation/Request: I would like to recommend that the proposed rule addition is <u>omitted</u> until more specificity about type and clarity on intent can be communicated.

For rule changes proposed affecting 333-333-3300 Continuing Facilitator Education:

#### My concerns are highlighted with explanations following the full rules text:

As is written now and with the proposed changes marked in red this section states:

### 333-333-3300 Continuing Facilitator Education

- (1) For renewal applications received on or after January 1, 2026, facilitator licensees must have completed four hours of continuing facilitator education during their annual license period in order to be eligible for license renewal.
- (2) Continuing facilitator education must consist of skills and knowledge that are relevant to the core curriculum described in OAR 333-333-3050 and OAR 333-333-3060.
- (3) The Oregon Health Authority (Authority) will consider continuing education hours to be valid if they meet the requirement in section (2) of this rule, and the education was offered by:
- (a) Training programs with curricula approved by the Authority.
- (b) Organizations or conferences that have been approved to offer continuing education for other types of professional licenses or certifications.
- (4) Facilitator licensees must record and report continuing facilitator education hours in a form and manner prescribed by the Authority.
- (5) For continuing facilitator education hours received from training programs with curricula approved by the Authority, documentation must include, including:
- (a) Date of continuing facilitator education.
- (b) Name of training program, organization or conference offering that offered the continuing facilitator education.

- (c) A description of how the continuing facilitator education is relevant to the provision of psilocybin services under ORS chapter 475A.
- (6) For continuing facilitator education hours received from an organization or conference, documentation must include:
- (a) Date of continuing facilitator education.
- (b) Name and contact information for the program, organization or conference offering the continuing facilitator education.
- (c) Name of the organization that approved the continuing education for other types of professional licenses or certifications.
- (d) A description of how the continuing facilitator education is relevant to the provision of psilocybin services under ORS chapter 475A.
- (75) Training programs that offer continuing facilitator education must notify the Authority in form and manner prescribed by the Authority.

### Concern #1 (sections highlighted in yellow)

- Conflicting information: Here in section 2 the specificity of the type of content that is considered valid and would count as CE is defined in the referenced OAR's. However, the requirements for documentation later states in 5(c) and 6(d) "A description of how the continuing facilitator education is relevant to the provision of psilocybin services under ORS chapter 475A." Which is far broader than the specifics listed in OAR 333-333-3050 and OAR 333-333-3060 referenced in section 2.
- Specificity/continuity may be needed to clarify which content is considered valid and counts as CE. Is it any relevant content relevant to the provision of psilocybin services under ORS chapter 475A? Or is it any content as listed specifically in OAR 333-333-3050 and OAR 333-333-3060?

### Concern #2 (sections highlighted in blue)

- <u>Limited Options/Strict Requirements on what CE considered valid:</u> Here in section 3 it states that the only CE that will be considered "valid" are those offered by:
  - (a) Training programs with curricula approved by the Authority.
  - (b) Organizations or conferences that have been approved to offer continuing education for other types of professional licenses or certifications.
- **For option (a)**, training programs with curricula approved by the authority: These training programs already have a litany of requirements to meet to be approved, including a \$500

- application fee and HECC approvals. As such, I imagine that those training programs who already hold this approval may require a fee for any CE they offer, IF they offer it.
- **For option (b)** Organizations or conferences that have been approved to offer continuing education for other types of professional licenses or certifications:
  - 1. Approved by whom? To my knowledge there are no official qualifications, institutions or organizations to approve who can award CE's (generally speaking.) I know that requirements vary for CE's for other state licensed individuals (i.e. Therapists, Nurses, etc...) including approval by specific CE accreditation bodies in those professions in order to qualify as CE. But the regulated psilocybin industry has none of those checkpoints to my knowledge. Additionally, for the requirements in documenting CE obtained from the aforementioned "organizations or conferences" not only is the name and contact information for the program, organization or conference offering the continuing facilitator education required to be documented, but further requested is the "name of the organization that approved the continuing education for other types of professional licenses or certifications." How will most people know, let alone be able to document whom the organization was "approved" by? Especially since, as mentioned earlier, there is no single approval organization for the oversight of who can offer CE's. This seems like it is an additional unnecessary complexity or barrier to justifying CE so it can be considered "valid" by OPS.
  - 2. This level of specificity on "organizations or conferences" <u>has the potential to be cost-prohibitive to facilitators</u>. Most traditional conferences require a fee for entry, and I would imagine any "organizations" who are "approved" to offer CE for "other types of professional licenses or certifications" would require some type of payment as well.
- The fact that OPS has limited the CE considered valid for the facilitator CE requirements starting January 2026 places a possibly confusing and undue burden on facilitators trying to meet this requirement for re-licensing. The sheer cost of annual licensure is already cost prohibitive due to the existing fee-based funding structure, but an added monetary burden for CE seems unnecessary.

#### Recommendation/Request: I would like to request the following:

- Expand what is considered valid CE for facilitators in the re-licensing requirement
  - Remove the limited requirements of who is considered "valid" to offer CE. As long as the CE is relevant to the skills and knowledge previously defined by OPS, this would open up far more options, including free or less cost prohibitive educational opportunities. The facilitator is already being asked to record a fair amount of detail

to report to OPS on the CE they are submitting, surely that information in itself is to some degree valid enough.

#### Alternatives

- If this is not amenable to OPS, perhaps they could consider offering their own trainings and educational opportunities to disseminate to facilitators that would meet the aforementioned definitions and would be free of cost.
- Additionally, if some sort of approval or validity checkpoint is still desired, then
  perhaps OPS could open up its own sub-set of rules governing programs specifically
  for CE. That way it would be a less prohibitive version of licensing an entire training
  program but would allow OPS to retain some oversight.

In conclusion, I urge the Oregon Psilocybin Services Division to reconsider the proposed rule changes and take into account some of the concerns raised and its impact on facilitators and the clients we serve.

I appreciate the opportunity to provide input and remain available for further discussion.

Sincerely,

Sera R. Miller

Licensed Psilocybin Facilitator-

From: Ms Mii

To: <u>Public Health Rules</u>

Subject:Oregon Psilocybin Services CommentDate:Wednesday, September 3, 2025 1:42:11 PM

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I reside in Brookings, Oregon and I am upset that Psilocybin services have been banned in Curry County.

However, my own county voted against it out of sheer ignorance.

Brookings is known as a place for people to retire and a good portion of the retired population are Vietnam veterans. Knowing history of the war and how the drafted troops were shamed upon returning home, they need it much more and that makes me upset on their behalf.

If there is any way to convince Curry County to allow Psilocybin distribution, please do so.

I definetly want Vietnam veterans willing to be treated to enjoy their sunset years in peace.

From: CHRISTOPHER WARREN
To: Public Health Rules
Subject: Micro-Dosing

Date: Tuesday, September 2, 2025 4:35:12 PM

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Hello! I heard about MICRO-DOSING without spending another Housing level deposit for the service You know \$2800 Bucks? SO I HEARD OF A CALIFORNIA SERVICE WHILE NOT CHEAP ARE STILL RELATIVELY EXPENSIVE AT \$400 a delivery! AND ADDITIONALLY, THE SHIT THEY SELL might just kill you! At least here in Oregon at Epic you get the PROVENENCE OF ITS CREATION AND A SUBSTANCE COUNT ON THE AMOUNT YOU ARE INGESTING! So, that's the reason for my request that we have opened the use of Psilocybin as a treatment but the price point makes it unavailable for most of us in Oregon unless you use the uncontrolled providers with no safety procedures or testing regimen which means somebody could get killed by a bad mushroom spore or somebody sticking FENTANYL to give a product some boost that gave them an OVERDOSE! I don't think the Public would be served by your ignoring this issue SO I EXPECT YOU TO COME UP WITH A SOLUTION TO KEEP THIS AVAILIBLE AND NOT GET PEOPLE KILLED! Thanks for working for the State AND US! Christopher Warren

From: <u>Harrison</u>

To: <u>Public Health Rules</u>

**Subject:** Public comment psilocybin draft rules 2025 **Date:** Tuesday, September 16, 2025 11:58:19 AM

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**Think twice** before clicking on links or opening attachments. This email came from outside our organization and might not be safe. If you are not expecting an attachment, contact the sender before opening it.

Dear Members of the Rulemaking Committee,

I am writing to express my opposition to the proposed amendment to rule 333-333-2030 (1) which would prohibit manufacturers from transferring finished and packaged extracts and edibles to one another.

While I understand the committee's intent to promote safety and accountability in regulated industries, this specific restriction would have adverse consequences without offering any demonstrable improvement to consumer safety. In fact, it threatens to undermine the very goals of fairness, equity, and sustainability that should guide thoughtful regulation.

#### 1. No Tangible Benefit to Client Safety

Prohibiting transfers between manufacturers does not inherently make products safer for consumers. Licensed manufacturers already operate under strict compliance requirements for quality control, packaging, and traceability. These existing safeguards ensure that all finished products—regardless of which compliant manufacturer produced them—meet the same rigorous standards. There is no evidence to suggest that transfers of packaged products between manufacturers introduce new risks to product integrity or consumer health.

#### 2. Harm to Industry Equity

This rule disproportionately affects the smallest manufacturers—particularly those without their own commercial kitchens—who rely on collaboration to remain viable in a competitive market. Larger operations may have the resources to internalize all stages of production and distribution, but smaller businesses often need to partner with others to meet client demand efficiently. Eliminating the ability to transfer finished goods hinders these partnerships, tilts the playing field in favor of vertically integrated firms and risks stifling innovation and reducing market diversity.

#### 3. Environmental Consequences

Forcing each manufacturer to manage end-to-end logistics independently will result in redundant trips, increased energy consumption, and greater greenhouse gas emissions. Transfers between manufacturers can significantly reduce transportation distances and resource use. By contrast, this proposed rule may lead to longer, more fragmented distribution chains, directly undermining both state and federal climate goals.

### 4. Regulatory Inconsistency and Competitive Imbalance

The proposed rule creates an inconsistency by restricting transfers between manufacturers but not between service centers. Under the new language, any service center could sell or transfer an edible or extract to another, but a licensed manufacturer without the endorsement could not do the same thing. This loophole creates a regulatory imbalance that certain vertically integrated businesses could exploit, gaining a competitive advantage that others cannot access.

#### Suggested Revision

To address these issues while preserving the rule's intent, I propose a simple change to the current language from rule 333-333-2030 (1), so that it reads:

"A manufacturer may only produce psilocybin products if the manufacturer has received an endorsement from the Oregon Health Authority (Authority) for that type of product. Any manufacturer may possess, transfer and sell packaged psilocybin products of any type."

This change would maintain appropriate oversight while allowing finished and packaged products to be transferred between licensed entities, preserving equity and sustainability in the industry.

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In summary, this proposed change would not enhance safety but would increase costs, harm small businesses, and create environmental harm through unnecessary logistical inefficiencies. I respectfully urge the committee to reconsider this amendment and maintain the ability of licensed manufacturers to transfer finished and packaged products to one another under current regulatory oversight.

Thank you for your time and thoughtful consideration of this important matter.

From: <u>Daniel Golletz</u>
To: <u>Public Health Rules</u>

**Subject:** Public comment on proposed rules for Oregon Psilocybin Services

**Date:** Tuesday, September 23, 2025 8:19:44 AM

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#### Hello OPS -

I would like to comment on the proposed rules regarding continuing education for facilitators. In other professions governed by the Oregon Health Authority, it is common for continuing education credit to be granted to *presenters* of educational material (such as at CE workshops, conferences, etc.). As I read the proposed rules, it did not appear to me that the rules included this as an option. Please clarify whether CE credit for presenters is available, and if not, please consider adding that as an option for earning CE credits. Thank you.

Daniel Golletz Licensed Facilitator