

From: [Brown, James](#)
To: [Clark, Jacob, DOH](#); [Brown, James](#)
Subject: [EXTERNAL] Additional Comments on Definitions for Submission on the Producer and Laboratory Requirements
Date: Tuesday, April 14, 2026 4:37:45 PM
Attachments: [9605.pdf](#)

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Jacob,

I wanted to submit the following comments on the Definitions for the Producer and Lab Requirements. My comments are in Red.

Thank You,
James Brown

Referring Clinician - Definition: A licensed clinician acting within their scope of practice who possesses diagnostic authority. Please include examples of who this would be ie: Physicians, CNP, PA, Psychiatrist, other Specialized Clinicians – Pharmacist & Other Specialist. The participant has been provided medical clearance by the participant's referring clinician.

- The Referring Clinician must document and maintain reasonable evidence of a consultation and risk review taking place, and if the consultation and risk review identifies heightened risk associated with a specific condition, the participant must work with the referring clinician to develop a safety plan, informed by the consultation and risk review, and provide written informed consent to work with the Clinician.

Determining Clinician - Definition: A clinician operating within their authorized scope, responsible for determining medical appropriateness for psilocybin treatment. Please include examples of who this would be ie: Physicians, CNP, PA, Psychiatrist, other Specialized Clinicians – Pharmacist & Other Specialist.

- The Determining Clinician must document and maintain reasonable evidence of a consultation and risk review taking place, and if the consultation and risk review identifies heightened risk associated with a specific condition, the participant must work with the Determining Clinician to develop a safety plan, informed by the consultation and risk review, and provide written informed consent to work with the Clinician.

Guides or Facilitators - Definition: A licensed or certified individual trained in psilocybin facilitation and therapeutic support. Please include examples of who this would be ie:

Physicians, CNP, PA, Psychiatrist, Licensed Social Works, Caplins, Death Dulas, Natural Medicine Doctor, Pharmacist, Nursing, & Other Healthcare Professionals.

- The Guide/Facilitator must document and maintain reasonable evidence of a consultation and risk review taking place, and if the consultation and risk review identifies heightened risk associated with a specific condition, the participant must work with the Facilitator to develop a safety plan, informed by the consultation and risk review, and provide written informed consent to work with the Facilitator.

Integration Provider - Definition: A clinician or trained professional providing post-session therapeutic integration. Please include examples of who this would be ie: Focus would be on Therapist, Licensed Social Workers, Physicians, CNP, PA, Psychiatrist, Psychologist, other Specialized Clinicians – Pharmacist & Other Specialist and Healthcare Professionals.

From: Brown, James <jbrown9@phs.org>

Sent: Tuesday, April 14, 2026 4:33 PM

To: jacob.clark@doh.nm.gov <jacob.clark@doh.nm.gov>; Brown, James <jbrown9@phs.org>

Subject: Fw: Comments for Submission on the Producer and Laboratory Requirements

To: Jacob Clark

Here are my comments for submission and addition to the following section (in Red) :

Thank You,
James Brown

M. Recall and Destruction:

PURPOSE:

To define a method by which psilocybin & psilocin recalls for substances discontinued for safety reasons will be handled.

RECALL DEFINITIONS:

- Class 1 recall: a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequence or death.
- Class 2 recall: a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- Class 3 recall: a situation in which use of or exposure to violative product is not likely to cause adverse health consequences.

STATEMENT OF POLICY:

- All psilocybin and psilocin involved in a recall notice will be handled per New Mexico Department of Health regulations.
- Recall notices are available from many sources which may include wholesalers, manufacturers, the N.M. Department of Health. Each will be treated as a potential harmful until proven otherwise.
- Once a notice is received, the facility personnel will inspect all the products and floor stock for the specific product recalled.
- If any psilocybin or psilocin is found on the recall notice, anywhere within the facility, it will be immediately removed from circulation and quarantined.
- The facility has a quarantine area for recalled and expired psilocybin and psilocin within the facility. The container is labelled "OUTDATED/RECALLED/DO NOT USE" wording.
- At this time the class of the recall will determine what course of action needs to be taken.
- All class 2 and 3 recalls will be processed as per recall instructions.
- For a class 1 recall, patients must be notified of the recall, it may be done by registered mail, phone, or whatever it takes.
- Facility system sale records will be reviewed back as far as necessary to protect patient safety. (I.e.; Facility Name; address; contact info)
- Copies of recall notices received by the facility will be kept within the facility whether we had the product or not. The recall paperwork will be signed and dated as to whether we had the product or not.
- All recall notices will be filed within the facility, these records will be available for inspection for 5 years.
- All recall notices will be reported to the Safety Committee at the next scheduled meeting and scanned into the DOH electronic system.
- Incident reports will be done on any patient receiving class 1 recall psilocybin or psilocin prior to recall.
- When psilocybin or psilocin are recalled or discontinued for safety reasons prescribers and those who dispense or administer the medication will be notified.

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