APPLICATION FOR INDIANA CONTROLLED SUBSTANCES REGISTRATION FOR NON-PRACTITIONERS

State Form 52616 (R9 / 4-19)

INDIANA BOARD OF PHARMACY
PROFESSIONAL LICENSING AGENCY
402 West Washington Street, Room W072
Indianapolis, Indiana 46204
Telephone: (317) 234-2067
E-mail: pla4@pla.IN.gov

INSTRUCTIONS:
1. *The fee for this application is $100.00, payable to the Indiana Professional Licensing Agency, in accordance with 856 IAC 2-3-9(a)-(e).*
2. *Completed application and fees should be mailed to the address listed in the upper right hand corner of this form.*
3. *All fees are non-refundable and non-transferable.*
4. *Please refer to the instructions on our website, www.pla.in.gov, for the licensing requirements.*

FOR OFFICE USE ONLY		
Application fee	Date fee paid (*month, day, year*)	Receipt number
Date of approval (*month, day, year*)	Registration number	Date of issuance (*month, day, year*)

DO NOT WRITE ABOVE THIS LINE

Please check appropriate box below and send proper fee as noted on instructions.

New store	Change of ownership	Change of location	Remodel	Fee exempt (*for CSR only*)	State CSR	Current CSR license number
☐	☐	☐	☐	☐ County or state ownership	☐ Application is enclosed	

SECTION I
(All applicants must complete this section. Practitioners should use State Form 34617.)

Please check one box.

☐ Analytical Laboratory ☐ K9 Training ☐ Non-Practitioner Owner ☐ Surgery Center
☐ Correctional Facility ☐ Law Enforcement ☐ Pharmacy ☐ Wholesale Distributor
☐ Hospital / Clinic ☐ Limited Permit ☐ Out Patient Clinic ☐ Other _____
☐ Humane Society ☐ Manufacturer ☐ Researcher

Name of facility *(Include doing business as (DBA), is applicable.)*

Name of pharmacy manager or person responsible for controlled substances (*attach curriculum vitae*)

Physical address of controlled premises (*number and street)*	City	State	ZIP code	County

If change of location, old location if different street address (*number and street)*	City	State	ZIP code

Name of contact person	Title

Telephone number	E-mail address
( )	

Drug schedules (*check all that apply*) ☐ 1 ☐ 2 ☐ 2 Narcotic ☐ 3 ☐ 3 Narcotic ☐ 4 ☐ 5

If your answer is "Yes" to any of the following, explain fully in a sworn affidavit, including all related details, and provide copies of all relevant arrest or court documents. Describe the event including the location, date and disposition. Falsification of any of the following is grounds for permanent revocation of the license or permit issued pursuant to this application.

1. Has there been an occasion where you have not maintained effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels? ☐ Yes ☐ No
2. Has there been an occasion where you have not been in complete compliance with all state and local laws pertaining to controlled substances? ☐ Yes ☐ No
3. Have you been convicted, pled guilty, or pled *nolo contendere,* under any federal or state laws relating to any controlled substances that has *not* been expunged under IC 35-38-9? ☐ Yes ☐ No
4. Have you had any action, discipline, revocation, or surrender of your Drug Enforcement Registration or entered into any settlement or Memorandum of Understanding (MOU) with respect to said registration? ☐ Yes ☐ No
5. Have you had any action, discipline or revocation or surrender of any professional license in any jurisdiction related to controlled substances? ☐ Yes ☐ No
6. Has the applicant, any of the agents, or the listed pharmacist been treated for drug or alcohol abuse? ☐ Yes ☐ No

SECTION II

(All applicants, with the exception of pharmacies, must complete this section.)

List procedures to be performed that directly involve controlled substances (*attach additional sheet, if needed*).
Limited permit applicants do not need to list procedures.

TYPES AND QUANTITIES OF DRUGS TO BE STORED (***Attach additional sheet, if needed.***)

NAME OF SUBSTANCE	SCHEDULE NUMBER	FORM / CONCENTRATION	QUANTITY

PRIMARY STORAGE OF CONTROLLED SUBSTANCES

TYPE OF CONTAINER	HOW SECURED	PERSON(S) WITH ACCESS

SECONDARY STORAGE (***location of primary***)

TYPE (***ROOM, CAGE, ETC.***)	HOW SECURED	PERSON(S) WITH ACCESS

Who documents use / inventory?

How? (*Describe procedure for documentation.*)

SECTION III - ADDITIONAL INFORMATION REQUIRED FOR CERTAIN NON-PRACTITIONERS

Hospitals / Clinics, Wholesale Distributors, and Analytical Labs:
- A list of procedures to be performed;
- Types and quantities of controlled substances to be stored on site organized by schedule number;
- Specific protocols for monitoring drug usage, inventory control, destruction, security, storage, and access.

Surgery Center:
- A list of procedures to be performed;
- Types and quantities of controlled substances to be stored on site organized by schedule number;
- Specific protocols for drug monitoring drug usage, inventory control, destruction, security, storage, and access;
- Names, credentials, past training, and copies of current DEA registrations of all medical staff;
- A copy of the agreement for pharmacy services, if applicable;
- Application is required to be signed by the Medical Director.

Researchers and Teaching Institutions:
- A list of procedures to be performed;
- Types and quantities of drugs to be stored on site (formulary) organized by Schedule number;
- Specific protocols for monitoring drug usage, inventory control, destruction, security, storage, and access;
- A one page summary of research objectives, research protocol, and curriculum vitae.

Manufacturers:
- A list of procedures to be performed;
- Types and quantities of drugs to be stored on site (formulary) organized by Schedule number;
- Specific protocols for monitoring drug usage, inventory control, destruction, security, storage, and access;
- Must describe their products and manufacturing procedures.

Non-Practitioner Owner CSR Applicants:
- A list of procedures to be performed;
- Types and quantities of controlled substances to be stored on site organized by schedule number;
- Specific protocols for monitoring drug usage, inventory control, destruction, security, storage, and access;
- Names, credentials, past training, and copies of all practitioners employed or contracted to dispense controlled substances
- A copy of the contract or employment agreement between the non-practitioner owner and the dispenser
- Documentation describing the ownership of the facility
- Policies and procedures that ensure controlled substances are dispensed in a manner that complies with laws, rules, and regulations

Humane Societies or Animal Control Facilities:
(If you are only requesting sodium pentobarbital, ketamine and ketamine products, and/or a combination product containing tiletimine and zolazepam, please see the section entitled "Limited Permits" below.)
- A list of procedures to be performed;
- Types and quantities of controlled substances to be stored on site organized by schedule number;
- Specific protocols for monitoring drug usage, inventory control, destruction, security, storage, and access;
- Must provide written documentation of the training of the personnel administering the controlled substances *(copies of training certificates will be sufficient)*;
- The name and license number of the veterinarian associated with the facility (*a written statement from the DVM acknowledging the association and a copy of licenses will be sufficient)*.

Limited Permits ($50 fee):
Any humane society, animal control agency, or governmental entity operating an animal shelter or other animal impounding facility may apply to receive a limited permit only for the purpose of buying, possessing, and using:
1. sodium pentobarbital to euthanize injured, sick, homeless, or unwanted domestic pets and animals;
2. ketamine and ketamine products to anesthetize or immobilize fractious domestic pets and animals; and
3. a combination product containing tiletimine and zolazepam as an agent for the remote chemical capture of domestic pets or animals that otherwise cannot be restrained or captured.

The applicant shall submit following information:
- Type of facility;
- Documentation describing the ownership of the facility;
- Specific protocols for monitoring drug usage, inventory control, destruction, security, storage, and access;
- Written policies relating to storage, security, and procedures for access, handling, and administration of drugs;
- Proof that the employees of the applicant who will handle a controlled substance are sufficiently trained to use and administer the controlled substance *(copies of training certificates will be sufficient)*;
- Proof that a licensed Indiana veterinarian holding a valid Indiana controlled substances registration and federal DEA registration has been retained to provide technical advice to the facility *(a written statement from the DVM acknowledging the association and a copy of licenses will be sufficient)*.

SECTION IV - APPLICATION AFFIRMATION

I hereby swear or affirm under the penalties of perjury that the statements made in this application are true, complete and correct.

Signature of applicant	Date (*month, day, year*)

Printed name of applicant	Title

AUTHORIZATION FOR RELEASE OF INFORMATION

I hereby authorize, request, and direct any person, firm, officer, corporation, association, organization or institution to release to the Professional Licensing Agency or the Indiana Board of Pharmacy any files, documents, records or other information pertaining to the undersigned requested by the Agency or Board, or any of its authorized representatives in connection with processing my application for licensure.

I hereby release the aforementioned persons, firms, officers, corporations, associations, organizations, and institutions from any liability with regard to such inspection or furnishing of any such information.

I further authorize the Professional Licensing Agency and the Indiana Board of Pharmacy to disclose to the aforementioned persons, firms, officers, corporations, associations, organizations, and institutions any information which is material to my application, and I hereby specifically release the Agency and Committee from any and all liability in connection with such disclosure.

A photostatic copy of this authorization has the same force and effect as the original.

AFFIRMATION

I hereby swear or affirm that I have read the above statements and agree to the same.

Signature of applicant	Date signed (*month, day, year*)