

APPLICATION FOR INDIANA CONTROLLED SUBSTANCES REGISTRATION FOR NON-PRACTITIONERS

State Form 52616 (R10 / 8-21)

INDIANA BOARD OF PHARMACY PROFESSIONAL LICENSING AGENCY

402 West Washington Street, Room W072 Indianapolis, Indiana 46204 Telephone: (317) 234-2067 E-mail: pla14@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					
ate of approval (month, day, year) Registration number			Date of issuance (month, day, year)					
	DO NOT	WRITE ABOVE THIS	LINE					
Г <u>-</u>								
Please check appropriate box below and send proper fee as no			000()	04-4-	OCD	O 00D II.		
New store Change of ownership Change of location	Remodel	Fee exempt (for	CSR only)	State	CSR	Current CSR license	e number	
(All applicants mu	at complete this	SECTION I section. Practitioners	a abould us	o Stata Form	24647)			
· · · · · · · · · · · · · · · · · · ·	si complete tilis s	section. Practitioners	s snound us	se State Form	34017.)			
Please check one box.		_			_			
Analytical Laboratory K9 Training		☐ Non-P	ractitioner O	wner	∐ Sı	urgery Center		
Correctional Facility Law Enforcer	ment	Pharm	асу		□w	holesale Distributor		
Hospital / Clinic Limited Perm						mbulance Service Pro	vider	
							, vidoi	
Humane Society Manufacturer		Resea	rcner			ther		
Name of facility (include doing business as (DBA), is applicable.)								
Name of pharmacy manager or person responsible for controlle	ed substances (att	ach 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 (nu.	mber and street)	City		State		ZIP code		
	,	,						
Name of contact person		Title						
Trains of contact porcon		15						
Telephone number E-r	nail address							
	iiaii auuress							
Drug schedules (check all that apply)	2 Naro	cotic 3	\Box	Narcotic	П4	П ₅		
	∠ Nard	cotic3		Narcotic	LJ 4	□ 5		
If your answer is "Yes" to any of the following, explain fully	in a sworn affida	vit, including all relat	ed details, a	and provide c	opies of all rele	evant arrest or court	documents.	
Describe the event including the location, date and disposi								
pursuant to this application.								
1. Has there been an eccasion where you have not mainta	inad affactive cor	strole against divorsi	on of contro	alled cubetane	200			
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	
<u> </u>						† <u> </u>		
Has there been an occasion where you have not been in complete compliance with all state and local laws pertaining to controlled substances?4						Yes	☐ No	
3. Have you been convicted, pled guilty, or pled <i>nolo contendere</i> , under any federal or state laws relating to any controlled						Yes	☐ No	
substances that has <i>not</i> been expunged under IC 35-38-9?								
4. Have you had any action, discipline, revocation, or surrender of your Drug Enforcement Registration or entered into any						Yes	☐ No	
settlement or Memorandum of Understanding (MOU) with respect to said registration?						+		
5. Have you had any action, discipline or revocation or surrender of any professional license in any jurisdiction related to					Yes	☐ No		
controlled substances?								
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		HEDULE NUMBER	FORM / CONCENTS		eeded.) QUANTITY			
NAME OF SUBSTANCE	SCF	1EDULE NUMBER	FORM / CONCENTR	KATION	QUANTITY			
TYPE OF CONTAINED	PR		ONTROLLED SUBSTANC	ES	DEDCOMO MITH ACCECC			
TYPE OF CONTAINER		HOW SECURED		PERSON(S) WITH ACCESS				
TVP5 (PAGE 6405 FT05T55	4)		RY STORAGE	T	PEDOOM/O/MITH ACCESS			
TYPE (ROOM, CAGE, ETCETERA)		HOW SECURED			PERSON(S) WITH ACCESS			
Who documents use / inventory?								
How? (Describe procedure for documentation	1.)							

SECTION III - ADDITIONAL INFORMATION REQUIRED FOR CERTAIN NON-PRACTITIONERS

Ambulance Service Providers:

- Specific protocols for drug monitoring, drug usage, inventory control, destruction, security storage, and access;
- Names, credentials, past training, and copies of current DEA registration of staff;
- Application is required to be signed by Medical Director;
- Policies and procedures to ensure controlled substances are dispensed in a manner that complies with laws, rules, and regulations;
- Must provide training documentation of personnel administering the controlled substances.

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 RE	LEASE 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	Date (month, day, year)						