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Closing your GBP/DEA License

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Research Compliance
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Research Administration

In this presentation

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- What should I do with my drugs?
- What steps do I need to take ?
- What if I don't close my license properly?
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- Q & As



Do I really need to close my license?



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Why can't I just let my license expire?

The Georgia Board of Pharmacy (GBP) and the Drug Enforcement Administration (DEA) have regulatory requirements to properly "retire" or close a license.

GBP Regulations	DEA Regulations
<p>Rule 480-7-.04 - Researcher's Permit</p> <p>(6) Licensees shall notify the <u>Board in writing</u> of the occurrence of any change to any of the information submitted to the Board as part of the licensee's initial application for licensure or application for renewal of licensure. This shall not apply to any event the occurrence of which these rules require immediate notification to the Board, in which event such immediate notification shall be made.</p>	<p>§ 1301.52 Termination of registration; transfer of registration; distribution upon discontinuance of business.</p> <p>(a) Except as provided in paragraph (b) of this section, the registration of any person, and any modifications of that registration, shall terminate, without any further action by the Administration, if and when such person dies, ceases legal existence, discontinues business or professional practice, or surrenders a registration. <u>Any registrant who ceases legal existence or discontinues business or professional practice shall notify the Administrator promptly of such fact.</u> In the case of a surrender, termination shall occur upon receipt by any employee of the Administration of a duly executed DEA form 104 or any signed writing indicating the desire to surrender a registration.</p>

What should I do with my drugs?

Both Agencies require the Registrant to notify them in writing that the business activities will be discontinued.

However, you must destroy all the drugs you acquired with your respective licenses prior to notifying GBP/DEA of discontinuing business.

How do I do that?

Destruction of Dangerous Drugs

Fill out [Form I](#): Destruction of Dangerous Drugs log

Then request a pickup through the Emory University Environmental Health and Safety Office (EHSO). Contact EHSO at <http://www.ehso.emory.edu/> and go to “Waste Collection.”

Complete the required information, and a representative from EHSO or Republic will remove and properly dispose of the drug.

Maintain the destruction records in your GDNA Ready Binder for 2 years.

Destruction of Controlled Substances

All CI-V Controlled Substances must be destroyed by a licensed reverse distributor like the Rx Exchange.

CI-II drugs are required to have a DEA Form 222 form. You may also use Form 4: [Controlled Substance Destruction Log](#)

CIII-V drugs are to be documented on Form 4: [Controlled Substance Destruction Log](#)

CS obtained via a prescription like BUP ER should be disposed of via EHSO. **For Controlled Substances obtained by prescription** (like Buprenorphine SR), fill out [FORM 13](#) to document the receipt, use, and disposition. When the CS expires or is no longer needed, update the record.

Maintain the destruction records in your DEA Ready Binder for 2 years.

Now that I destroyed my drugs, what are the next steps?

Georgia Board of Pharmacy Requirements

This can be done by writing a letter on Emory letterhead to the Georgia Board of Pharmacy requesting that the license be officially retired on the date you are leaving Emory or discontinuing research.

You must state in the letter that do not have any controlled substances or dangerous drugs on hand.

Email the letter to Ms. Annie Ruth Parks at Georgia Board of Pharmacy (aparks@dch.ga.gov).

Please cc ORIC oric@emory.edu

Now that I destroyed my drugs, what are the next steps?

DEA Requirements

Call the DEA Duty Line at (571)362-3537 and ask to speak with a Diversion Investigator (DI).

Explain that you would like to retire your DEA license.

Obtain the DI's name and email address then send an email documenting desire to retire DEA license (cc: ORIC@emory.edu)

Write a letter on Emory letterhead to the DEA requesting that the license be officially retired on the date you are leaving Emory or discontinuing research. Send back your DEA Registration and any unused DEA Form 222s to:

Drug Enforcement Administration

Attn: DI **First and Last Name**

75 Ted Turner Drive SW

Room 800

Atlanta, GA 30303-3311

Required Recordkeeping

Even after retiring or closing your license, you are still responsible for your recordkeeping for a two-year period.

Record retention of:

Inventories (only applicable to CS)

Receiving records

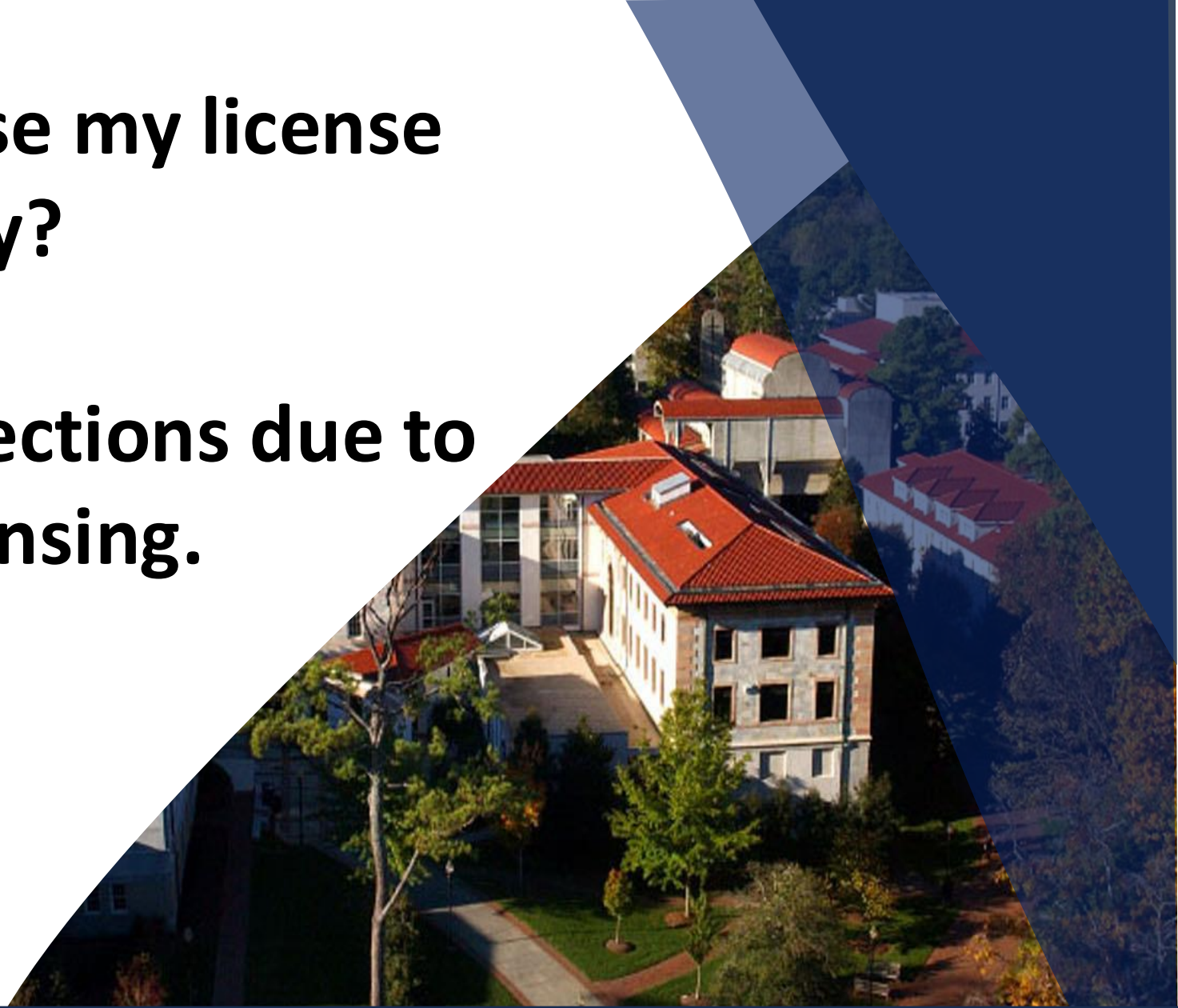
Dispensing records

Destruction records

Closure of license requests

What if I don't close my license properly?

Risk of agency inspections due to lapse in licensing.



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Required to renew or terminate

If you don't terminate your license properly as required by Rule 480-7-.04(6) and § 1301.52, then your license appears to be in a lapsed status to state and federal regulators. All registrants are either required to terminate the license or renew.

GBP Renewal Requirements

Rule 480-7-.04(7) Permits are renewable every two (2) years and expire on June 30th of the even-numbered years. Permits may be renewed upon the payment of the required renewal fee and the filing of the renewal application form. If the application is not made and the fee not paid before September 1st of the even-numbered year, the permit shall lapse and shall not be renewable except by application for a new permit.

DEA Renewal Requirements

21 CFR 1301.13(e)(1)(v), (vi). Any person who is required to be registered and who is not so registered, shall make application for registration for one of the following groups of controlled substances activities, which are deemed to be independent of each other...

Oh no! Somebody left Emory without closing their license properly and disposing of their drugs .

What Should I do?



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Don't Panic!



Abandonment of Drugs

Contact ORIC at ORIC@emory.edu. We have procedures in place for these actions.

If you leave Emory without properly destroying your drugs, we have an obligation to report these drugs as abandoned.

16-13-3. Penalty for abandonment of dangerous drugs, poisons, or controlled substances.

Any person who shall abandon, in a public place, any dangerous drug, poison, or controlled substance as defined by Article 2 or Article 3 of this chapter shall be guilty of a misdemeanor.

Recap

Review

Make sure records are in order

Dispose of Drugs

Notify GBP/DEA

Surrender license & Forms 222

Keep all records for a two-year period

Questions?



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