**PUERTO RICO COMMONWEALTH HEALTH DEPARTMENT**

**OFFICE OF REGULATION AND CERTIFICATION OF HEALTH PROFESSIONALS**

**PUERTO RICO PHARMACY BOARD**

STUDY GUIDE FOR THE REVALIDATION EXAM ON LEGALS ASPECTS OF PHARMACY PRACTICE FOR PHARMACIST LICENSE APPLICANTS

**Introduction:**

In accordance with article 4.04, paragraphs (a) and (b) of the Pharmacy Act, the purpose of the pharmacist revalidation is to measure the applicant's competencies to begin practicing the profession.

The revalidation for applicants of a pharmacist license will consist of two exams: one general and the other on legal aspects of pharmacy practice. The second will measure the application of knowledge in legal aspects of the practice of the profession.

This declaration of competencies is a general guide on the subjects that may be the subject of the revalidation exam on legal aspects.

The Board has made the administrative decision to limit the study of the aspects of law to be examined up to six months prior to the date of revalidation.

**Declaration of competencies Area I (approximately 70% of the exam)**

**Practice of the profession, manufacturing, distribution and dispensing of medicines**.

* Puerto Rico Pharmacy Law, Act No. 247-2004, as amended.
* Regulation of the Board of Pharmacy No. 8503 of July 23, 2014
* Administrative Order of the Secretary of Health No. 269
* Regulation Secretary of Health Regulation No. 156 of February 18, 2016, for the Operation of Establishments Dedicated to the Manufacturing, Distribution and Distribution of Medications in Puerto Rico.
* Regulation Secretary of Health Regulation No. 156A of September 8, 2016, For the Exchange of Biological Products
* Secretary of Health Regulation No. 8867 of December 2, 2016, For the Operation of Establishments Dedicated to the Sale, Distribution and Manufacturing of Veterinary Products.
* Resolutions of the Puerto Rico Board of Pharmacy:

o No. 2015-1127

 Distance Continuing Education

o No. 2016-187

The 1,500 hours of practice of a pharmacy intern can be carried out in the different areas of performance of a pharmacist.

o No. 2016-188

Pharmacists with two years of experience are trained to be preceptors.

o No. 2016-207

Eliminates the right to pay for pharmaceutical specialty certification.

o No. 2016-260

Authorizes pharmacy interns to practice administering vaccines.

1. **Pharmacy Profession**
2. Social responsibility
3. Requirements to practice
4. Requirements to obtain the license.
5. Recertification
6. Denial, suspension, cancellation, or revocation of license
7. Reinstallation
8. Features
9. License display
10. Pharmacist:
11. Regent
12. Employee
13. Preceptor
14. Inspector
	* + - 1. Certification of credentials
				2. Conduct that constitutes a crime.
15. **Pharmacy Technician Occupation**
	* + 1. Responsibilities
			2. Requirements to practice
			3. Requirements to obtain the certificate.
			4. Recertification
			5. Denial, suspension, cancellation, or revocation of certificate
			6. Re installation
			7. Features
			8. Conduct that constitutes a crime.
16. **Board of Pharmacy**
	* 1. Composition
		2. Designations
		3. Responsibilities
		4. Powers, functions, and duties
		5. Investigative and adjudicative procedures for complaints
17. **Establishments authorized and registered to acquire, purchase, store, sell, dispense, or administer medications.**
	1. **Licenses and authorizations**
		1. Requirements
		2. Validity
		3. Changes
		4. Denial, suspension, cancellation, or revocation
	2. **First Aid Kit License**
	3. **Triennial Registration Certificate**
	4. **Establishments that require pharmacists**
18. Manufacture
19. Wholesale distribution of prescription drugs
20. Drugstores
21. Pharmacy
22. **Responsibilities**
23. Regent pharmacist
24. Pharmacists employed.
25. Owner, administrator, or manager
26. Non-pharmaceutical personnel
27. Absences
28. Termination of employment
	1. **Pharmacies**
29. Pharmacy
30. Tasks
31. Closure
32. Security
33. Orientation
34. Extemporaneous composition or formulation
35. Equipment
36. Reference sources
37. Staff
38. Pharmacist absences
	* + Emergency
		+ Meal break
		+ Preceptor
39. Pharmacy without a pharmacist
40. Signs
41. **Medications**
42. Without a prescription
43. With prescription
44. With special requirements
45. Radioactive
46. Organic products
47. Vaccines, vaccination
48. In pharmacies
49. Extramural
50. Sterile pharmaceutical products
51. Records
52. Conservation
53. **Prescription**

1. Prescriber

a. Legitimate medical use.

b. Doctor-patient relationship.

* 1. Patient
1. Final consumer
	1. Written.
	2. Electronic.
	3. In emergency situations.
	4. Required information.
	5. Validity.
	6. Repetition.
	7. File.
2. **Dispensing**
3. Responsibility of the pharmacist, non-delegable functions
4. Process
5. Verification
6. Orientation
7. Resignation
8. Delivery
	* + 1. Waiver of delivery by the pharmacist
9. Drug exchange
	* + 1. Bioequivalents
			2. Biologicals, interchangeable biosimilars
10. Pharmaceutical file
11. Return of medicines
12. Packaging and labeling
13. **Secretary of Health**
14. Powers and responsibilities

 a. Pharmacy Law

1. Drug and Pharmacies Division
2. Investigations Office

**Area II (approximately 20% of the exam) Controlled Substances**

* - Federal Controlled Substances Act, “Comprehensive Drug Abuse Prevention and Control Act of 1970” and its DEA regulations
* - Puerto Rico Controlled Substances Law, Law No. 4 of June 22, 1971, as amended
* - Regulation of the Secretary of Health No. 153 of May 29, 2015, for the Control of the Manufacturing, Distribution, Dispensing and Disposal of Controlled Substances
* - Puerto Rico Narcotics Law, Art. 21
* - DEA, Controlled Substances Alphabetical Order

A. **Controlled Substances (18% of 20%)**

1. Supervisory agencies
2. Classifications
3. Records
4. Security measure
5. Purchases, returns
6. Records, inventories, reports, files
7. Prescriber, dispenser, dispense

a. Fair medical use, doctor-patient relationship

1. Final consumer
2. Doctor-patient relationship
3. Prescription
	1. Content
	2. Labeling
	3. Refill
	4. Validity
	5. Dispensing

 1.Partial

 2. Emergency

 f. File

1. Technical violations

**Area III (approximately %5 of the exam)**

**Collegiality and Ethics**

* Law of the College of Pharmacists of Puerto Rico, Law No. 243 of 1958, as amended.
* Regulations of the College of Pharmacists
* Code of ethics
1. **Have knowledge of the terms of:**
2. Morality
3. Ethics
4. Bioethics
5. Professional Ethics
6. Euthanasia
7. **College of Pharmacists**
8. Powers, duties, and obligations of the institution
9. Rights, duties, and ethical obligations of the profession

 a. Code of ethics

1. Right to die with dignity
2. Conscientious objection

b. Complaints

1. College of Pharmacists
2. Pharmacy Board

c. Complaint processing

1. Denial, suspension or revocation of licenses or certificates for ethical reasons

**Area IV (approximately 5% of the exam)**

**General Aspects of Law**

**Constitutional Law**

* + 1. Constitutional Law
1. Supremacy Clause 2
2. The power of the federal government over commerce
3. The application of federal laws in Puerto Rico
4. The structure of the government

 a. The separation of powers

b. Individual rights

c. Rights:

1. Civil
2. Criminal
3. Administrative
	* 1. Extracontractual civil liability (damages and losses)
	1. Elements of the cause of action
	2. Compensable damages
	3. Prescription
	4. Professional malpractice

a. Doctrine of informed consent

b. Manifest incompetence in the exercise of the profession

c. Right to accept or refuse medical treatment