

Part XVI. Legend Drugs

[Editor's Note: A new Part XVI, consisting of R.S. 40:1237 and 40:1238, was created by Act 872 of 1982 Legislature, effective January 1, 1984. Subsequent amendments are noted herein.]

§1060.11. Definitions

- A. For the purpose of this Part:
- (1) "Code imprint" means a series of letters or numbers assigned by the manufacturer or distributor to a specific drug, or marks or monograms unique to the manufacturer, distributor, or both. The National Drug Code may be used as a code imprint.
 - (2) "Distributor" means any corporation, person, or entity not engaged in the manufacture of a legend drug product, who distributes for resale and distribution a legend drug product under the label of such corporation, person, or entity.
 - (3) "Legend drug" means any drug or drug product bearing on the label of the manufacturer or distributor, as required by the Federal Food and Drug Administration, the statement "Caution: Federal law prohibits dispensing without prescription."
 - (4) "Solid dosage forms" means capsules or tablets intended for oral administration.

(HCR 84 of 2015 Legislature re-designated the original Section 1237 as R.S. 40:1060.11)

§1060.12. Legend drug imprint

- A. No legend drug in solid dosage form may be manufactured or distributed for sale in this state unless there is clearly marked or imprinted on the dosage form a code imprint identifying the drug and the manufacturer or distributor of the drug. The Louisiana Department of Health, upon application by a manufacturer or distributor, may exempt a particular drug product from the requirement to be imprinted on the grounds that imprinting is not feasible because of said drug product's size, texture, or other unique characteristics.
- B. On or before January 1, 2014, manufacturers or distributors of legend drugs shall provide to the Louisiana Department of Health a list of their legend drugs and the description of the code imprint each bears. The department shall provide for the distribution of the information required to be submitted under this Part to all poison control centers in the state. The department shall provide to any licensed healthcare provider, upon request, lists of legend drugs and code imprints provided to the department under this Section, but may charge a reasonable fee to cover copying and postage costs. Manufacturers and distributors shall provide updated lists to the department annually or as changes or revisions occur.
- C. A legend drug that does meet the above requirements shall be deemed misbranded.
- D. Whoever manufactures or distributes for sale or otherwise provides to any other person for dispensing any legend drug in solid dosage form that fails to comply with this Section shall be fined twenty-five thousand dollars, or imprisoned for five years, or both.
- E. The provisions of Subsections A, B, C, and D of this Section shall not apply to any of the following:
- (1) Drugs purchased by a pharmacy, pharmacist, or licensed wholesaler prior to January 1, 2014, and held in stock for resale.
 - (2) Drugs which are manufactured by or upon the order of a practitioner licensed by law to prescribe or administer drugs and which are to be used solely by the patient for whom prescribed.

(HCR 84 of 2015 Legislature re-designated the original Section 1238 as R.S. 40:1060.12)

§1060.13. Sale, distribution, or possession of legend drug without prescription or order prohibited; exceptions; penalties

- A. It shall be unlawful for any person to sell, deliver, or possess any legend drug except upon the order or prescription of a physician or licensed healthcare practitioner as defined in R.S. 40:961(33). This Section shall not apply to sale, delivery, or possession by drug wholesalers or drug manufacturers, or their agents or employees, or to any practitioner acting within the scope of his license, or to a common or contract carrier or warehouseman, or any employee thereof, whose possession of any legend drug is in the usual course of business or employment.
- B. *[Repealed by Act 360 of 2010 Legislature]*
- C. Any person who violates the provisions of this Section shall be imprisoned, with or without hard labor, for not more than five years and may be sentenced to pay a fine of not more than five thousand dollars.

(Section was added by Act 565 of 2006 Legislature as R.S. 40:1238.1; HCR 84 of 2015 Legislature re-designated the original Section 1238.1 as R.S. 40:1060.13)

§1060.14. Prescription requirements; penalties

- A. A prescription, in order to be effective in legalizing the possession of legend drugs, shall be issued for a legitimate medical purpose by one authorized to prescribe for the use of such legend drugs. An order purporting to be a prescription issued to a drug abuser or habitual user of legend drugs, not in the course of professional treatment, is not a prescription within the meaning and intent of this Section. Any person who knows or should know that he or she is filling such a prescription or order to a drug abuser or habitual user of legend drugs, as well as the person issuing the prescription, may be charged with a violation of this Section. A legitimate medical purpose shall include use of the drug in the course of a bona fide research program in conjunction with a hospital or university.
- B. Any person who violates the provisions of this Section shall be imprisoned, with or without hard labor, for not more than five years and may be sentenced to pay a fine of not more than five thousand dollars.

(Section was added by Act 565 of 2006 Legislature as R.S. 40:1238.2; HCR 84 of 2015 Legislature re-designated the original Section 1238.2 as R.S. 40:1060.14)

§1060.15. Obtaining legend drugs by misrepresentation or fraud; penalties

- A. It shall be unlawful for any person knowingly or intentionally to acquire or obtain possession of a legend drug by misrepresentation, fraud, forgery, deception or subterfuge.
- B. Any person who violates the provisions of this Section shall be imprisoned, with or without hard labor, for not more than five years and may be sentenced to pay a fine of not more than five thousand dollars.

(Section was added by Act 565 of 2006 Legislature as R.S. 40:1238.3; HCR 84 of 2015 Legislature re-designated the original Section 1238.3 as R.S. 40:1060.15)

§1060.16. Prescriptions; electronic questionnaires

- A. As used in this Section, the following terms shall have the following meanings unless the context clearly indicates otherwise:
 - (1) “*Electronic questionnaire*” means a computer-assisted system for collecting a person’s healthcare data.
 - (2) “*Valid physician-patient relationship*” means a medical relationship that exists when the practitioner has conducted at least one medical evaluation with a person in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other practitioners.
- B. A prescription issued solely upon the results of answers to an electronic questionnaire, in the absence of a documented patient evaluation including a physical examination, shall be considered issued outside the context of a valid physician-patient relationship and shall not be a valid prescription.
- C. If a pharmacist knowingly dispenses a prescription authorized solely on the result of an electronic questionnaire, he shall be in violation of this Section.
- D. A pharmacist who knows that a prescription has been authorized in the absence of a valid physician-patient relationship, or otherwise in violation of the prescriber’s standard of practice, shall not fill such prescription.
- E. A pharmacist who dispenses prescription drugs in violation of this Section is not acting in the best interest of the patient and is dispensing outside the course of the professional practice of pharmacy.
- F. A pharmacist who violates the provisions of this Section shall be imprisoned, with or without hard labor, for not more than five years and may be sentenced to pay a fine of not more than five thousand dollars.

(Section was added by Act 318 of 2007 Legislature as R.S. 40:1238.4; HCR 84 of 2015 Legislature re-designated the original Section 1238.4 as R.S. 40:1060.16)