DISTRICT OF COLUMBIA

OFFICIAL CODE

TITLE 48.

FOODS AND DRUGS.

CHAPTER 8B.

OFF-LABEL INFORMED CONSENT.

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§ 48-841.01. SHORT TITLE.

This chapter may be cited as the "Off-Label Informed Consent Act of 2008".

(Mar. 26, 2008, D.C. Law 17-131, § 201, 55 DCR 1659.)

HISTORICAL AND STATUTORY NOTES

Legislative History of Laws

Law 17-131, the "SafeRx Amendment Act of 2008", was introduced in Council and assigned Bill No. 17-364 which was referred to the Committee on Health. The Bill was adopted on first and second readings on December 11, 2007, and January 8, 2008, respectively. Signed by the Mayor on February 1, 2008, it was assigned Act No. 17-282 and transmitted to both Houses of Congress for its review. D.C. Law 17-131 became effective on March 26, 2008.

Delegation of Authority

Delegation of Authority pursuant to D.C. Law 17-131, the SafeRX Amendment Act of 2008, see Mayor's Order 2008-94, July 3, 2008 (55 DCR 9375).

§ 48-841.02. DEFINITIONS.

For the purposes of this chapter, the term:

(1) "FDA" means the federal Food and Drug Administration.

(2) "Off-label use" means the use of a prescription drug for human use to treat a condition that is not included in the labeling for that medication, as approved by the federal Food and Drug Administration.

(3) "Prescriber" means a person who is licensed, registered, or otherwise authorized by the District to prescribe and administer prescription drugs for human use in the course of a professional practice.

(Mar. 26, 2008, D.C. Law 17-131, § 202, 55 DCR 1659; Mar. 25, 2009, D.C. Law 17-353, § 309(b), 56 DCR 1117.)

HISTORICAL AND STATUTORY NOTES

Effect of Amendments

D.C. Law 17-353, in par. (2), substituted "prescription drug for human use" for "prescription drug"; in par. (3), substituted "prescription drugs for human use" for "prescription drugs".

Legislative History of Laws

For Law 17-131, see notes following § 48-841.01.

Law 17-353, the "Technical Amendments Act of 2008", was introduced in Council and assigned Bill No. 17-994 which was referred to the Committee of the Whole. The Bill was adopted on first and second readings on December 2, 2008, and December 16, 2008, respectively. Signed by the Mayor on January 15, 2009, it was assigned Act No. 17-687 and transmitted to both Houses of Congress for its review. D.C. Law 17-353 became effective on March 25, 2009.

§ 48-841.03. OFF-LABEL USE OF MEDICATION.

Before prescribing, administering, or furnishing a prescription medication for an off-label use, a prescriber shall make every reasonable effort to:

(1) Explain to the patient, in easily understood terms, that the medication is not within the uses

approved for that medication by the FDA; and

(2) Provide the patient with information regarding the potential risks and side effects associated with using the medication for the off-label use.

(Mar. 26, 2008, D.C. Law 17-131, § 203, 55 DCR 1659.)

HISTORICAL AND STATUTORY NOTES

Legislative History of Laws

For Law 17-131, see notes following § 48-841.01.

§ 48-841.04. PENALTIES.

Failure to comply with this chapter may be used by a health-occupation board as a factor when determining licensure status for a prescriber; provided, that a prescriber shall not be subject to an adverse licensure action if the Board of Medicine determines that the prescribing, administering, or furnishing of the prescription medication for the off-label use was clearly evidence-based and the common practice within the medical community.

(Mar. 26, 2008, D.C. Law 17-131, § 204, 55 DCR 1659.)

HISTORICAL AND STATUTORY NOTES

Legislative History of Laws

For Law 17-131, see notes following § 48-841.01.