DISTRICT OF COLUMBIA OFFICIAL CODE
TITLE 48. FOOD AND DRUGS
SUBTITLE II. PRESCRIPTION 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."

§ 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 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 in the course of a professional practice.

§ 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.

§ 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.