Unofficial Copy 2004 Regular Session
J1 4lr0503

By: **Delegates Boutin ~~and Mandel~~, Mandel, Benson, Boteler, Bromwell, Donoghue, Elliott, Goldwater, Hammen, Hubbard, Hurson, Kach, McDonough, Morhaim, Murray, Nathan-Pulliam, Oaks, Pendergrass, Rosenberg, Rudolph, Smigiel, V. Turner, and Weldon**

Introduced and read first time: January 29, 2004
Assigned to: Health and Government Operations

Committee Report: Favorable with amendments
House action: Adopted
Read second time: March 9, 2004

CHAPTER_____

AN ACT concerning

Prescription Drug Safety Act

FOR the purpose of requiring ~~certain health practitioners to print or type written prescriptions in a legible manner, include certain information on the prescription, and sign the prescription; prohibiting certain health practitioners from writing prescriptions in a certain manner; authorizing certain licensing boards to take disciplinary action against certain health care practitioners; and generally relating to health practitioners and written prescriptions~~ prescriptions to be legible; providing that certain penalties do not apply to a violation of this Act; requiring the Secretary of Health and Mental Hygiene, in conjunction with certain other groups, to convene a certain workgroup to study the legibility of prescriptions and report to certain committees on or before a certain date in a certain manner on the recommendations of the workgroup; requiring the study to include certain items; and generally relating to legibility of prescriptions.

BY repealing and reenacting, with amendments,
Article - Health - General
Section 21-220 and 21-1215
Annotated Code of Maryland
(2000 Replacement Volume and 2003 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article - Health - General

21-220.

(a) A drug that is intended for use by human beings and is in any of the following classifications may be dispensed by a pharmacist only on a written or oral prescription from a health practitioner authorized by law to prescribe the drug:

(1) A habit-forming drug to which § 21-218(b)(1) of this subtitle applies.

(2) A drug that because of its toxicity or other potentiality for harmful effect, the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a health practitioner who is authorized by law to administer such a drug.

(3) A drug that is limited by an approved application under § 355 of the federal act or § 21-223 of this subtitle to use under the professional supervision of a health practitioner authorized by law to administer such a drug.

(b) (1) A prescription may be written or oral. However, a pharmacist may not dispense a drug on an oral prescription unless the pharmacist promptly writes out and files the prescription.

(2) A prescription for a controlled dangerous substance within the meaning of Title 5 of the Criminal Law Article may not be written on a preprinted prescription form that states the name, quantity, or strength of the controlled dangerous substance.

(3) When a prescription is written, a separate prescription form is required for each controlled dangerous substance. If a pharmacist is otherwise satisfied that a prescription is valid the pharmacist may fill the prescription if the pharmacist promptly writes out and files a prescription for each substance and also files the original prescription.

~~(4) (I) WHEN A PRESCRIPTION IS WRITTEN, A HEALTH PRACTITIONER AUTHORIZED BY LAW TO PRESCRIBE A DRUG SHALL:~~

~~1. PRINT OR TYPE THE PRESCRIPTION IN A LEGIBLE MANNER SO THAT IT CAN BE READ AND UNDERSTOOD BY THE PHARMACIST FILLING THE PRESCRIPTION;~~

~~2. INDICATE ON THE PRESCRIPTION:~~

~~A. THE DATE OF ISSUANCE, WITH THE MONTH STATED IN TEXTUAL LETTERS;~~

~~B. THE NAME OF THE AUTHORIZING PRESCRIBER;~~

~~C. THE NAME AND STRENGTH OF THE DRUG, WITH THE STRENGTH WRITTEN IN METRIC UNITS;~~

~~D. THE QUANTITY OF THE DRUG IN BOTH TEXTUAL AND NUMERICAL FORMATS;~~

~~E. THE DIRECTIONS FOR USING THE DRUG;~~

~~F. THE REASON FOR PRESCRIBING THE DRUG; AND~~

~~G. FOR CHILDREN UNDER AGE 12, THE AGE AND WEIGHT OF THE CHILD; AND~~

~~3. SIGN THE PRESCRIPTION ON THE DATE THAT THE PRESCRIPTION IS ISSUED.~~

~~(II) WHEN A PRESCRIPTION IS WRITTEN, A HEALTH PRACTITIONER AUTHORIZED BY LAW TO PRESCRIBE A DRUG MAY NOT:~~

~~1. USE LATIN OR APOTHECARY ABBREVIATIONS;~~

~~2. USE LEADING ZEROS BEFORE A DECIMAL POINT FOR NUMBERS LESS THAN ONE;~~

~~3. USE TRAILING ZEROS AFTER A DECIMAL POINT FOR WHOLE NUMBERS; AND~~

~~4. ABBREVIATE THE NAME OR STRENGTH OF A DRUG.~~

(4) A PRESCRIPTION SHALL BE LEGIBLE.

(c) A pharmacist may not refill and dispense a prescription unless the refilling is authorized by:

(1) The health practitioner's specification in the original prescription as to how many times it may be refilled; or

(2) [By an] AN oral order of the health practitioner that promptly is written out and filed by the pharmacist.

(d) The dispensing of a drug without complying with the requirements of this section is the dispensing of a misbranded drug.

(e) (1) A drug that is subject to the prescription requirements of this section is misbranded if, at any time before it is dispensed, its label does not bear the statement "Caution: Federal Law Prohibits Dispensing Without Prescription", or "Caution: State Law Prohibits Dispensing Without Prescription".

(2) A drug to which the prescription requirements of this section do not apply is misbranded if, at any time before it is dispensed, its label bears the caution statement quoted in paragraph (1) of this subsection.

(f) (1) The prescription requirements of this section do not apply to any drug that is exempted under a rule or regulation adopted by the Secretary.

(2) The Secretary, by rule or regulation, may exempt any drug from the requirements of this section if the Secretary finds that, as to the drug, the requirements of this section are not necessary for the protection of the public health.

(3) The Secretary, by rule and regulation, may exempt from the requirements of this section any drug that is removed from the prescription requirements of the federal act by a rule or regulation adopted under that act.

~~(G) A HEALTH PRACTITIONER AUTHORIZED BY LAW TO PRESCRIBE A DRUG WHO FAILS TO COMPLY WITH SUBSECTION (B)(4) OF THIS SECTION MAY BE SUBJECT TO DISCIPLINARY ACTIONS BY THE APPROPRIATE LICENSING BOARD.~~

21-1215.

(a) THIS SECTION DOES NOT APPLY TO A VIOLATION OF § 21-220(B)(4) OF THIS TITLE.

(B) A person who violates any provision of Subtitle 2 of this title or any regulation adopted under Subtitle 2 of this title is guilty of a misdemeanor and on conviction is subject to:

(1) A fine not exceeding $10,000 or imprisonment not exceeding 1 year or both; or

(2) If the person has been convicted once of violating Subtitle 2 of this title, a fine not exceeding $25,000 or imprisonment not exceeding 3 years or both.

[(b)] (C) In addition to any criminal penalties imposed under this section, a person who violates any provision of Subtitle 2 of this title, any rule or regulation adopted under Subtitle 2 of this title, or any term, condition, or limitation of any license or registration issued under Subtitle 2 of this title:

(1) Is subject to a civil penalty not exceeding $5,000, in an action in any District Court; and

(2) May be enjoined from continuing the violation.

[(c)] (D) Each day on which a violation occurs is a separate violation under this section.

SECTION 2. AND BE IT FURTHER ENACTED, That:

(a) The Secretary of Health and Mental Hygiene, in conjunction with the Maryland Health Care Commission, the Board of Physicians, and the Board of Pharmacy, shall convene a workgroup of authorized prescribers, including physicians, dentists, and nurses; pharmacists; hospitals; long-term care facilities; and local health departments to study the issue of legibility of prescriptions and make recommendations for any statutory or regulatory changes needed to improve prescription legibility in order to enhance patient safety.

(b) The study shall include:

(1) The appropriate content and format of a prescription;

(2) The best means to inform and educate prescribers if changes in prescription format or content are enacted;

(3) The appropriate time frame and procedures for implementation of any changes enacted;

(4) Mechanisms for enforcement of any changes enacted;

(5) The impact of any changes in the content or format of prescriptions on oral prescriptions;

(6) Whether pharmacists should be prohibited by statute from dispensing illegible prescriptions; and

(7) The use and cost of computerized physician order entry and the feasibility of eliminating handwritten prescriptions after a specified date.

(c) The workgroup shall report its recommendations on or before November 1, 2004, in accordance with § 2-1246 of the State Government Article, to the Senate Finance Committee and the House Health and Government Operations Committee.

SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect ~~October~~ July 1, 2004.