

**WEST VIRGINIA
SECRETARY OF STATE
NATALIE E. TENNANT
ADMINISTRATIVE LAW DIVISION**

Form #2

Do Not Mark In This Box

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2009 SEP 22 PM 1:57
OFFICE OF THE WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE

AGENCY: Governor's Office of Health Enhancement and Lifestyle Planning TITLE NUMBER: 210

RULE TYPE: Legislative CITE AUTHORITY: §16-29H-8(a)

AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: 1

TITLE OF RULE BEING PROPOSED: Prescription Drug Advertising Expense Reporting

IN LIEU OF A PUBLIC HEARING, A COMMENT PERIOD HAS BEEN ESTABLISHED DURING WHICH ANY INTERESTED PERSON MAY SEND COMMENTS CONCERNING THESE PROPOSED RULES. THIS COMMENT PERIOD WILL END ON October 22, 2009 AT 5:00 PM ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS:

GOHELP

1124 Smith Street, Room 105
Charleston, WV 25301

THE ISSUES TO BE HEARD SHALL BE LIMITED TO THIS PROPOSED RULE.


Authorized Signature

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

Prescription Drug Advertising Expense Reporting
TITLE 210, SERIES 1

BRIEF SUMMARY OF LEGISLATIVE RULE

On August 26, 2009, W.Va. Code § 16-29H-1 et seq. became effective. Article 29H established the Governor's Office of Health Enhancement and Lifestyle Planning ("GOHELP") and transferred the rule-making authority previously granted to the West Virginia Pharmaceutical Cost Management Council to GOHELP. The subject Article further mandates GOHELP to promulgate a legislative rule requiring certain entities to annually report pharmaceutical advertising costs. Until August 26, 2009, pharmaceutical advertising reporting was governed by a rule promulgated by the Pharmaceutical Cost Management Council (206CSR1). That rule had a calendar year reporting period. With the repeal of W. Va. Code § 5A-3C-1 et seq., the Pharmaceutical Cost Management Council existence was terminated resulting in the rescission of its rules. To prevent having a period of time in which pharmaceutical advertising reporting is not required by the state, a rule must be filed on an emergency basis. Reporting of drug advertising expenses allows the state to obtain an accurate view of the level and scope of drug advertising and marketing in West Virginia.

Prescription Drug Advertising Expense Reporting
TITLE 210, SERIES 1

STATEMENT OF CIRCUMSTANCES

On August 26, 2009, W.Va. Code § 16-29H-1 et seq. became effective. Article 29H established the Governor's Office of Health Enhancement and Lifestyle Planning ("GOHELP") and transferred the rule-making authority previously granted to the West Virginia Pharmaceutical Cost Management Council to GOHELP. The subject Article further mandates GOHELP to promulgate a legislative rule requiring certain entities to annually report pharmaceutical advertising costs. Until August 26, 2009, pharmaceutical advertising reporting was governed by a rule promulgated by the Pharmaceutical Cost Management Council (206CSR1). That rule had a calendar year reporting period. With the repeal of W. Va. Code § 5A-3C-1 et seq., the Pharmaceutical Cost Management Council existence was terminated resulting in the rescission of its rules. To prevent having a period of time in which pharmaceutical advertising reporting is not required by the state, a rule must be filed on an emergency basis. Reporting of drug advertising expenses allows the state to obtain an accurate view of the level and scope of drug advertising and marketing in West Virginia.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Prescription Drug Advertising Expense Reporting

Rule Title: _____

Type of Rule: Legislative Interpretive Procedural

Agency: Governor's Office of Health Enhancement and Lifestyle Planning

Address: 1124 Smith Street, Room 105
Charleston, WV 25301

Phone Number: (304) 558 0079 Email: GOHELP@wv.gov

Fiscal Note Summary

Summarize in a clear and concise manner what impact this measure will have on costs and revenues of state government.

This rule will have no fiscal impact on costs and revenues of state government.

Fiscal Note Detail

Show over-all effect in Item 1 and 2 and, in Item 3, give an explanation of Breakdown by fiscal year, including long-range effect.

| FISCAL YEAR | | | |
|------------------------------------|--|-------------------------------------|---|
| Effect of Proposal | Current Increase/Decrease (use "-") | Next Increase/Decrease (use "-") | Fiscal Year (Upon Full Implementation) |
| 1. Estimated Total Cost | | | |
| Personal Services | | | |
| Current Expenses | | | |
| Repairs & Alterations | | | |
| Assets | | | |
| Other | | | |
| 2. Estimated Total Revenues | | | |

Rule Title: _____

Rule Title: Prescription Drug Advertising Expense Reporting

3. **Explanation of above estimates (including long-range effect):**
Please include any increase or decrease in fees in your estimated total revenues.

MEMORANDUM

Please identify any areas of vagueness, technical defects, reasons the proposed rule would not have a fiscal impact, and/or any special issues not captured elsewhere on this form.

Date: September 22, 2009

Signature of Agency Head or Authorized Representative

Martha J. Walker

FILED

TITLE 210
LEGISLATIVE RULE
GOVERNOR'S OFFICE OF HEALTH ENHANCEMENT AND LIFESTYLE
PLANNING (GOHELP)

2009 SEP 22 PM 1:58

OFFICE OF THE
SECRETARY OF STATE

SERIES 1
PRESCRIPTION DRUG ADVERTISING EXPENSE REPORTING

§210-1-1. General.

1.1. Scope. -- This rule establishes advertising expense disclosure requirements for all manufacturers and labelers of prescription drugs dispensed in this state who employ, direct or utilize marketing representatives.

1.2. Authority. -- W. Va. Code §16-29H-8(a).

1.3. Filing Date. -- September 22, 2009

1.4. Effective Date. --

§210-1-2. Definitions.

2.1. "Aggregate" or "aggregate data" means information which does not disclose personally-identifiable information about specific prescribers or otherwise identify specific individuals or companies.

2.2. "Aggregate list" means the aggregate data included in the GOHELP annual report to the Joint Committee on Government and Finance.

2.3. "Bona-fide clinical trial" means a clinical trial approved by an institutional review board in compliance with the statutory and regulatory requirements of the federal Food and Drug Administration, including Title 21 of the United States Code, 21 C.F.R., Part 56 and 45 C.F.R. § 46.101, and conducted in connection with a research study the principle purpose of which is scientific research.

2.4. "GOHELP" means the Governor's Office of Health Enhancement and Lifestyle Planning established under the authority of W. Va. Code §16-29H-1 *et seq.*

2.5. "Direct-to-consumer advertising" or "DTC advertising" means advertising prescription drugs directly to residents of this state through radio, television, magazines, newspapers, direct mail or telephone communications.

2.6. "Dispensed" or "dispensing" means that aspect of the practice of pharmacy concerned with the preparation, verification of contents and delivery of a drug or device in an appropriately labeled and suitable container to a patient or a patient's representative pursuant to a lawful order of a practitioner for subsequent administration to, or use by, a patient. A drug or device has not been dispensed until it has been physically delivered to the patient or patient's representative.

2.7. "National aggregate data" means all expenses associated with advertising and direct promotion of prescription drugs through radio, television, magazines, newspapers, direct mail and telephone communications in the United States.

2.8. "Prescription drugs" or "pharmaceutical drugs" means drugs for human use which may be legally dispensed only with a prescription.

2.9. "Prescriber" means a physician or other health care professional licensed to prescribe drugs in the State of West Virginia.

2.10. "Reporting entity" means a drug manufacturer, pharmaceutical manufacturer or labeler.

§210-1-3. Required Disclosures.

3.1. Every drug manufacturer, pharmaceutical manufacturer, and labeler of prescription drugs dispensed in this state, or to a consumer in this state via mail, who employs, directs or utilizes marketing representatives in this state must complete and file with GOHELP, the form contained in Appendix A of this rule, disclosing the reporting entity's expenditures for advertising prescription drugs to consumers in this state for the previous calendar year in full. Beginning on or before April 1, 2010, and by the first of April thereafter, the reporting entity shall annually complete and file with GOHELP the form contained in Appendix A of this rule, disclosing advertising expenses for the previous calendar year in full.

3.2. The reporting entity shall disclose all expenditures for advertising and direct promotion of prescription drugs dispensed in this state, including:

3.2.a. The total amount the reporting entity spent for advertising and direct promotion of prescription drugs to consumers, prescribers, pharmacies and patient support or advocacy groups within the State of West Virginia;

3.2.b. The total number of West Virginia prescribers to whom the reporting entity provided, directly or indirectly, gifts, grants or payments of any kind in excess of one hundred dollars (\$100.00) for the purpose of advertising prescription drugs. Annual payments which cumulatively total more than the amount shown on the reporting form shall be reported in increments of two thousand five hundred dollars (\$2,500.00) until all payments of any kind to prescribers have been reported; and

3.2.c. Direct-to-consumer advertising which is directed at, received by or intended to be received by consumers in this state, the form of the advertising and the total amount expended for such advertising.

3.3. If the reporting entity represents a number of entities which file a federal income tax return as a consolidated group, the reporting entity shall attach to the disclosure form a copy of the organizational chart showing all members of the consolidated group and their interrelationship.

3.4. If the reporting entity does not maintain separate records of expenditures for advertising of prescription drugs within West Virginia, it may calculate the advertising expenditures directed at this state by:

3.4.a. Dividing the West Virginia population receiving the DTC advertising by the population of the nation or region for which the reporting entity does maintain records; and

3.4.b. Multiplying the quotient determined pursuant to subdivision a of this subsection by the total amount the reporting entity spent on advertising in the nation or the named region.

3.5. For the purposes of subsection 3.4 of this rule, the following applies:

3.5.a. The populations of this state and of the nation or region for which the reporting entity maintains records are to be determined by the most recent population data available from the United States Census Bureau.

3.5.b. The reporting entity must attach the calculations to the disclosure form contained in Appendix A.

3.6. The reporting entity shall file signed and verified originals of completed Appendix A forms with GOHELP.

§210-1-4. Discretionary Disclosures.

The reporting entity may, but is not required to, disclose:

4.1. Free samples of prescription drugs distributed to patients;

4.2. Payments of reasonable compensation and reimbursement of expenses in connection with a bona-fide clinical trial; and

4.3. Scholarships or other support for medical students, residents and fellows selected by a national, regional or specialty medical or other professional association to attend significant educational, scientific or policy-making conferences sponsored by such association.

Appendix A

Prescription Drug Advertising Expenses Reporting Form

Please file your completed Appendix A with:
 Governor's Office of Health Enhancement and Lifestyle Planning
 Greenbrooke Building, 1124 Smith Street, Room 105
 Charleston, West Virginia 25301

| | |
|---------------------------------|--|
| Name of Reporting Entity | |
| Reporting Period | |

3.2.a. List below the total amount the reporting entity spent for advertising and direct promotion of prescription drugs to consumers, prescribers, pharmacies and patient support or advocacy groups within the State of West Virginia.

| Name of Reporting Entity | Amount Spent |
|---------------------------------|---------------------|
| | |
| | |
| | |
| | |
| | |
| | |

3.2.b. List below the total number of West Virginia prescribers to whom the reporting entity provided directly or indirectly, gifts, grants or payments of any kind in excess of one hundred dollars (\$100.00) for the purpose of advertising prescription drugs.

| Annual Aggregate Amount of fees, food entertainment, recreational activities, travel expenses, gifts, grants or other payments | Total Number of Prescribers |
|---|------------------------------------|
| \$100.00 - \$2,500.00 | |
| \$2,501.00 - \$5,000.00 | |
| \$5,001.00 - \$7,500.00 | |
| \$7,501.00 - \$10,000.00 | |

210CSR1

3.2.c. List below the direct-to-consumer advertising which is directed at, received by or intended to be received by consumers in this state, the form of the advertising and the total amount expended for advertising.

| Form of Advertising | Total Expenditure on Advertising |
|---------------------|----------------------------------|
| | |
| | |
| | |
| | |
| | |

I certify upon information and belief that the information contained on this form is true, correct and complete.

| | |
|----------------------|--|
| Signature: | |
| Printed Name: | |
| Title: | |
| Date: | |

Taken, sworn and subscribed before me, this _____ day of _____, 20____,
by _____.

| | |
|---------------------------|--|
| Notary signature | |
| Commission expires | |

Seal: