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

Form #2

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OFFICE OF 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

AMENDMENT TO AN EXISTING RULE: YES X NO ____

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 1

TITLE OF RULE BEING AMENDED: Prescription Drug Advertising Expense Reporting

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: ____

TITLE OF RULE BEING PROPOSED: ____

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 July 5, 2011 AT 5:00 PM ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS:

GOHELP
1124 Smith Street, Suite 105
Charleston, WV 25301

GOHELP@wv.gov

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

Martha Y. Walker
Authorized Signature

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

Governor's Office of Health Enhancement and Lifestyle Planning
Title 210, Series 1

Prescription Drug Advertising Expense Reporting
Title 210, Series 1

Brief Summary

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. To prevent having a period of time in which pharmaceutical advertising reporting was not required by the state, GOHELP filed an emergency and a legislative rule in October 2009. This amendment to 210CSR1 clarifies the rule and permits pharmaceutical companies to file the rule electronically.

Governor's Office of Health Enhancement and Lifestyle Planning
Title 210, Series 1

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. To prevent having a period of time in which pharmaceutical advertising reporting was not required by the state, GOHELP filed an emergency and a legislative rule in October 2009. This amendment to 210CSR1 clarifies the rule and permits pharmaceutical companies to file the rule electronically

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Prescription Drug Advertising Expense Reporting

Type of Rule: [X] Legislative [ ] Interpretive [ ] Procedural

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

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: June 3, 2011

Signature of Agency Head or Authorized Representative

Martha Y. Walker

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period; Proposed Rule, and if needed, Emergency and Modified Rule.)

DATE: June 3, 2011

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM:(*Agency Name, Address & Phone No.*) Governor's Office of Health Enhancement and Lifestyle Planning
1124 Smith Street, Suite 105
Charleston, WV 25301
(204)558-0079

LEGISLATIVE RULE TITLE: Prescription Drug Advertising Expense Reporting

1. Authorizing statute(s) citation §16-29H-8

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:

   June 3, 2011

   b. What other notice, including advertising, did you give of the hearing?

   No hearing.

   c. Date of Public Hearing(s) ***or*** Public Comment Period ended:

   Comment Period will end July 5, 2011

   d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

   Attached _____ No comments received _____

e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)

f. **Name, title, address and <u>phone/fax/e-mail numbers</u>** of agency person(s) to receive all *written correspondence* regarding this rule: (Please type)

Shannon Landrum, Research and Policy Coordinator
1124 Smith Street, Suite 105
Charleston, WV 25301
(304)558-0079
(304)558-8158
Shannon.L.Landrum@wv.gov

g. **<u>IF DIFFERENT</u> FROM ITEM 'f'**, please give **Name, title, address and phone number(s)** of agency person(s) who wrote and/or has responsibility for the contents of this rule: (Please type)

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

   a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.

b. Date of hearing or comment period:

_____

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

_____

d. Attach findings and determinations and reasons:

Attached _____

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

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. -- ~~April 27, 2010~~.

1.4. Effective Date. -- ~~April 30, 2010~~.

§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.~~ "Drug manufacturer" or "pharmaceutical manufacturer" means any entity, except a wholesale distributor of drugs or a retail pharmacy licensed under state law, which is engaged in:

2.1.a. The production, preparation, propagation, compounding, conversion or processing of prescription drugs, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis; or

2.1.b. The packaging, repackaging, labeling, relabeling or distribution of prescription drugs.

~~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~~ 2.2. "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~~ 2.3. "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~~ prescriber 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.~~

2.4. "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. "Labeler" means an entity that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the United States Food and Drug Administration pursuant to 21 C. F. R. §207.20.

~~2.8~~ 2.6. "Prescription drugs" ~~or "pharmaceutical drugs"~~ means drugs for human use which may be legally dispensed only with a prescription.

~~2.9~~ 2.7. "Prescriber" means a physician or other health care professional licensed to prescribe drugs in the State of West Virginia.

~~2.10~~ 2.8. "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~~ that 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~~ must annually submit to GOHELP certain data described in subsection 3.4 of this section on a form provided by GOHELP. ~~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 form described in subsection 3.1 of this section shall be filed with GOHELP on or before May 1 of each year with respect to data for the previous calendar year, ending December 31.

3.3. The form described in subsection 3.1 of this section shall be filed electronically by means to be established by GOHELP. The requirement to file the form electronically may be waived at the discretion of GOHELP upon a showing of good cause by the reporting entity

~~3.2.~~ 3.4. The reporting entity shall disclose ~~all~~ the following with respect to expenditures for advertising and direct promotion of prescription drugs dispensed in this state~~, including~~:

~~3.2.a.~~ 3.4.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.~~ 3.4.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)~~ $99.99 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.~~ 3.4.c. ~~Direct to consumer advertising which is directed at, received by or intended to be received by consumers in this state,~~ With respect to DTC advertising, the form of the advertising and the total amount expended for ~~such~~ each category of 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.~~ 3.5. 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.~~ 3.5.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.~~ 3.5.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.~~ 3.6. For the purposes of subsection ~~3.4~~ 3.5 of this ~~rule~~section, the ~~following applies~~ 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.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~~	

~~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:~~

21 CFR 207.20

TITLE 21 -- FOOD AND DRUGS
CHAPTER I -- FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER C -- DRUGS: GENERAL
PART 207 -- REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL DISTRIBUTION
SUBPART C -- PROCEDURES FOR DOMESTIC DRUG ESTABLISHMENTS

Go to the CFR Archive Directory

21 CFR 207.20

§ 207.20 Who must register and submit a drug list?

(a) Owners or operators of all drug establishments, not exempt under section 510(g) of the act or subpart B of this part 207, that engage in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs shall register and submit a list of every drug in commercial distribution (except that registration and listing information may be submitted by the parent, subsidiary, and/or affiliate company for all establishments when operations are conducted at more than one establishment and there exists joint ownership and control among all the establishments). Drug listing is not required for the manufacturing, preparation, propagation, compounding, or processing of an animal feed bearing or containing an animal drug (i.e., a Type B or Type C medicated feed), nor is drug listing required for establishments engaged in drug product salvaging. Drug products manufactured, prepared, propagated, compounded, or processed in any State as defined in section 201(a)(1) of the act must be listed whether or not the output of such establishments or any particular drug so listed enters interstate commerce. No owner or operator may register an establishment if any part of the establishment is registered by any other owner or operator.

(b) Owners or operators of establishments not otherwise required to register under section 510 of the act that distribute under their own label or trade name a drug manufactured or processed by a registered establishment may elect to submit listing information directly to FDA and to obtain a Labeler Code. A distributor who submits drug listing information shall include the registration number of the drug establishment that manufactured, prepared, propagated, compounded, or processed each drug listed. All distributors who submit drug listing information to FDA assume full responsibility for compliance with all of the requirements of this part. Each such distributor at the time of submitting or updating drug listing information as required under § 207.30 shall certify to the registered establishment that the submission has been made by providing a signed copy of Form FDA-2656 (Registration of Drug Establishment) to the registered establishment that manufactures or processes the drug. Each such distributor shall submit the original of Form FDA-2656 showing this certification to FDA, and shall accompany the certification with a list showing the National Drug Code number that the distributor has assigned to each drug product. If a distributor does not elect to submit drug listing information directly to FDA and to obtain a Labeler Code, the registered establishment shall submit the drug listing information. Distributors or registered establishments shall use Form FDA-2658

(Registered Establishments' Report of Private Label Distributors) to submit drug listing information or to request a Labeler Code, or both.

(c) Before beginning manufacture or processing of a drug subject to one of the following applications, an owner or operator of an establishment is required to register before the agency approves or grants it: A new drug application, an abbreviated new drug application, a new animal drug application, an abbreviated new animal drug application, a medicated feed mill license application, a biologics license application, or a request for addition to the index.

(d) No registration fee is required.

(e) Registration and listing do not constitute an admission, or agreement, or determination that a product is a drug as defined in section 201(g) of the act.

(f) Owners and operators of establishments or persons engaged in the recovery, screening, testing, processing, storage, or distribution of human cells, tissues, and cellular and tissue-based products, as defined in § 1271.3(d) of this chapter, that are regulated under section 351 of the Public Health Service Act and/or the Federal Food, Drug, and Cosmetic Act must register and list those human cells, tissues, and cellular and tissue-based products with the Center for Biologics Evaluation and Research on Form FDA 3356 following the procedures set out in subpart B of part 1271 of this chapter, instead of the procedures for registration and listing contained in this part, except that the additional listing information requirements in § 207.31 remain applicable.

HISTORY:
[45 FR 38043, June 6, 1980, as amended at 45 FR 32293, May 16, 1980; 52 FR 2682, Jan. 26, 1987; 55 FR 11576, March 29, 1990; 64 FR 396, 400, Jan. 5, 1999, as confirmed at 64 FR 26657, May 17, 1999; 64 FR 56441, 56448, Oct. 20, 1999; 64 FR 63195, 63203, Nov. 19, 1999; 66 FR 5447, 5466, Jan. 19, 2001; 66 FR 59138, 59157, Nov. 27, 2001; 68 FR 2689, Jan. 21, 2003; 72 FR 69108, 69120, Dec. 6, 2007]

AUTHORITY:
AUTHORITY NOTE APPLICABLE TO ENTIRE PART:
21 U.S.C. 321, 331, 351, 352, 355, 360, 360b, 371, 374, 381, 393; 42 U.S.C. 262, 264, 271.