

**WEST VIRGINIA
SECRETARY OF STATE
BETTY IRELAND
ADMINISTRATIVE LAW DIVISION**

Do Not Mark In This Box

FILED
2008 APR 11 AM 10:16

OFFICE OF THE
SECRETARY OF STATE

Form #6

**NOTICE OF FINAL FILING AND ADOPTION OF A LEGISLATIVE RULE AUTHORIZED
BY THE WEST VIRGINIA LEGISLATURE**

WV Department of Administration/
AGENCY: WV Pharmaceutical Cost Management Council TITLE NUMBER: 206

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

THE ABOVE RULE HAS BEEN AUTHORIZED BY THE WEST VIRGINIA LEGISLATURE.

AUTHORIZATION IS CITED IN (house or senate bill number) Senate Bill 349

SECTION 64-9-12, PASSED ON March 8, 2008

THIS RULE IS FILED WITH THE SECRETARY OF STATE. THIS RULE BECOMES EFFECTIVE ON THE
FOLLOWING DATE: April 14, 2008


Authorized Signature

Revised 1-11-08

**TITLE 206
LEGISLATIVE RULE
DEPARTMENT OF ADMINISTRATION
WEST VIRGINIA PHARMACEUTICAL COST MANAGEMENT COUNCIL**

FILED
2008 APR 11 AM 10:16
DEPARTMENT OF ADMINISTRATION
WEST VIRGINIA
OFFICE OF THE REGISTER OF STATE

**SERIES 1
PRESCRIPTION DRUG ADVERTISING EXPENSE REPORTING**

§ 206-1-1. 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 §5A-3C-13.

1.3 Filing Date. --

1.4 Effective Date. --

§206-1-2. Definitions.

Terms not defined in this rule have the meanings ascribed to them in West Virginia Code §5A-3C-3. As used in this rule:

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 Council's report to the Joint Committee on Government and Finance, pursuant to West Virginia Code §5A-3C-13(e).

2.3. As used in West Virginia Code §5A-3C-13(c)(2), "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 and 21 CFR, 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. "Council" means the West Virginia Pharmaceutical Cost Management Council established under the authority of West Virginia Code § 5A-3C-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.

§ 206-1-3. Required Disclosure.

3.1. On or before March 1, 2008, 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 the Council, the form contained in Appendix A of this rule, disclosing the reporting entity's expenditures for advertising prescription drugs to consumers in this state during the period from July 1, 2008 to December 31, 2007. Any amount required to be reported shall be prorated to reflect the six (6) month reporting period, and every reporting threshold contained in this rule shall be halved. On or before April 1, 2009, and every first of April thereafter, the reporting entity shall complete and file with the Council the form containing 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:

3.2.1. 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;

3.2.2. 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 \$2,500.00 increments until all payments of any kind to prescribers have been reported.

3.2.3. The name of each prescription drug advertised by 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 each named prescription drug;

3.2.4. The name of any disease-specific patient support or advocacy group operating in this state to which the reporting entity made, directly or indirectly, gifts, grants or payments of any kind totaling \$10,000 or more for the purpose of advertising prescription drugs and the total amount contributed to each named support group; and

3.2.5. The name of any pharmacy licensed in this state to which the reporting entity made, directly or indirectly, gifts, grants or payments of any kind totaling \$10,000 or more, for the purpose of advertising prescription drugs, the form of the advertising and the total amount contributed to each named pharmacy.

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.

3.4.1. 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:

3.4.1.a. Dividing the West Virginia population receiving the DTC communication by the population of the national or region for which the reporting entity does maintain records; and

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

3.4.2. 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.

3.4.3. A reporting entity which elects to disclose advertising expenditures according to this subsection, must attach the calculations to the disclosure form .

3.5. The reporting entity shall file signed and verified originals of completed Appendix A forms with the West Virginia Pharmaceutical Cost Management Council and the West Virginia Department of Administration.

§ 206-1-4. Discretionary Disclosure.

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; or

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.

3.2.2. 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	

3.2.3. List below the name of each prescription drug advertised by 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 each named prescription drug.

Name of Drug (chemical name and brand name)	Form of Advertising	Total Expenditure on Advertising

3.2.4. List below the name of any disease-specific patient support or advocacy group operating in this state to which the reporting entity made, directly or indirectly, gifts, grants or payments of any kind totaling \$10,000 or more for the purpose of advertising prescription drugs and the total amount contributed to each named support group.

Name of Advocacy Group	Amount of Payments

3.2.5. List below the name of any pharmacy licensed in West Virginia to which the reporting entity made, directly or indirectly, gifts, grants or payments of any kind totaling \$10,000 or more, for the purpose of advertising prescription drugs, the form of the advertising and the total amount contributed to each named pharmacy.

Pharmacy	Type of Advertising	Amount of Payment

Revised 1-11-08

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

by

Notary signature	
Commission expires	