

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

Form #7

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2007 APR 24 AM 9:59

OFFICE WEST VIRGINIA
SECRETARY OF STATE

Effective Date

NOTICE OF AN EMERGENCY RULE

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

CITE AUTHORITY: WV Code 5A-3C-15; 29A-3-15(f)(3)

EMERGENCY 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: Series 1

TITLE OF RULE BEING PROPOSED: Prescription Drug Advertising Expense Reporting

THE ABOVE RULE IS BEING FILED AS AN EMERGENCY RULE TO BECOME EFFECTIVE AFTER APPROVAL BY SECRETARY OF STATE OR 42ND DAY AFTER FILING, WHICHEVER OCCURS FIRST.

THE FACTS AND CIRCUMSTANCES CONSTITUTING THE EMERGENCY ARE AS FOLLOWS:

(Please See Attachment A)

Use additional sheets if necessary


Authorized Signature



EMERGENCY RULE QUESTIONNAIRE

DATE: April 20, 2007

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: (Agency Name, Address & Phone No.) Department of Administration/WV Pharmaceutical Cost Management Council

Building 1, Room M-146, 1900 Kanawha Boulevard, East

Charleston, WV 25305

EMERGENCY RULE TITLE: Prescription Drug Advertising Expense Reporting

1. Date of filing April 24, 2007

2. Statutory authority for promulgating emergency rule:
WV Code 5A-3C-15; WV Code 29A-3-15 (f)(3)

3. Date of filing of proposed legislative rule: April 24, 2007

4. Does the emergency rule adopt new language or does it amend or appeal a current legislative rule? No

5. Has the same or similar emergency rule previously been filed and expired?
No

6. State, with particularity, those facts and circumstances which make the emergency rule necessary for the **immediate** preservation of public peace, health, safety or welfare.

Please See Attachment A

7. If the emergency rule was promulgated in order to comply with a time limit established by the Code or federal statute or regulation, cite the Code provision, federal statute or regulation and time limit established therein.

Not Applicable

8. State, with particularity, those facts and circumstances which make the emergency rule necessary to prevent substantial harm to the public interest.

Please See Attachment A

Attachment A

1. The facts and circumstances constituting the emergency are as follows:

The WVU Robert C. Byrd Institute for Health Policy Research has produced statistics showing that on any given day approximately 425,107 West Virginians (40,637 children, 292,599 non-elderly adults, and 91,871 older adults) go without prescription drug coverage. Many of these West Virginians must pay the full retail price for medications out of their own pockets.

Approximately 17% of West Virginians remain uninsured.¹ In 2003, roughly 80% of uninsured adult West Virginians (ages 18 to 64) lived in households with an annual family income below \$30,000, and roughly 56% lived in households with an annual income below \$20,000.² Given the high and increasing costs of healthcare, the uninsured cannot afford full health-care coverage, including prescription drug coverage.

For the sixth year in a row, drug prices continue to outpace inflation. In fact, the largest quarterly drug price increase in the past six years occurred in the first three months of 2006.³ In January-March of 2006, coinciding with the launch of Medicare Part D, AARP reports brand-name prescription drugs increased by 3.9 percent, over three times the general inflation rate for the same period.⁴

In addition to outpacing inflation, increases in drug prices far outpace wage increases. The increase in the average annual wage for West Virginians was 3% from calendar years 2004 (\$30,383) to 2005 (\$31,344).⁵ For that corresponding time period, AARP reported that for a sample of 193 brand name drugs, the price increase from 2004 to 2005 was 7.1%.⁶

In 2004, according to the Kaiser Family Foundation,⁷ West Virginia ranked 3rd in the nation with 15 per capita retail drug prescriptions filled at pharmacies. For retail drug prescriptions per capita for working age adults, West Virginia ranked 4th in the nation with 14 per capita prescriptions for the 14-64 age group.

¹Available online at: <http://www.statehealthfacts.org/cgi-bin/healthfacts.cgi?action=compare&category=Health+Coverage+%26+Uninsured&subcategory=Health+Insurance+Status&topic=Total+Population>

²Available online at: <http://www.wvhealthpolicy.org/reports/Older%20Adults.pdf>

³Available online at: http://www.assets.aarp.org/rgcenter/health/dd140_drugprices.pdf

⁴Ibid.

⁵Covered Employment and Wages Series, Workforce West Virginia

⁶AARP Rx Watchdog Report, A Consumer Newsletter on Prescription Drug Costs, Volume 3, Issue 2, April 2006.

⁷Available online at <http://www.statehealthfacts.org/cgi-bin/healthfacts.cgi>

Turning to state agencies, the State of West Virginia, like all states, is among the pharmaceutical industry's biggest customers. Through Medicaid, public employee insurance programs, retirees, prisons/jails, and other aid programs, the states purchase about 16 percent of all prescription drugs sold in the country. In state fiscal year 2005, West Virginia spent nearly \$310 million on pharmaceuticals for the Medicaid program and \$156 million for the Public Employees Insurance Agency.

Advertising by pharmaceutical companies impacts the price that West Virginians must pay for their drug prescriptions. In the United States, drug companies may spend up to 33% of their sales revenue on advertising.⁸ Drug companies will spend in the range of \$60 billion to 82.5 billion on all sales activities next year, approximately \$200 to \$280 per person in the United States.⁹ Drug companies may be spending over \$300 million dollars per year to increase the sales of their products in West Virginia.¹⁰

The November 2006 Government Accountability Office report entitled Prescription Drugs: Improvements Needed in FDA's Oversight of Direct to Consumer Advertising found that, "from 1997 through 2005 spending on DTC advertising in the United States increased from \$1.1 billion to \$4.2 billion. An average annual increase of almost 20 percent". For that same period, the annual increase in spending on research and development and drug promotion to physicians was 9% each.¹¹

The West Virginia Legislature has found, "That the rising cost of prescription drugs is one of the most critical issues facing the current health care system in the State of West Virginia"¹²

The Legislature passed the Pharmaceutical Availability and Affordability Act (the Act)¹³ in March 2004. The Act requires drug companies to report their advertising expenditures to the Pharmaceutical Cost Management Council for the following purposes:

⁸The Influence of the Pharmaceutical Industry, Vol.1 (House of Commons Health Committee) (22 March 2005) at ¶ 76.

⁹Assuming US total drug sales of \$250 billion and a population of 295 million

¹⁰West Virginia's population in 2002 was 1.815 million. US Census Bureau

¹¹Prescription Drugs: Improvements Needed in FDA's Oversight of Direct-to-Consumer Advertising, GAO-07-54 Government Accountability Office, November 2006, p.12.

¹²WV Code §5A-3C-s

¹³H.B. 4084 (passed March 13, 2004)

The reporting shall assist this state in its role as a purchaser of prescription drugs and an administrator of prescription drug programs, enabling this state to determine the scope of prescription drug advertising costs and their effect on the cost, utilization and delivery of health care services and furthering the role of this state as guardian of the public interest.¹⁴

Executive Order No. 18-04 (2004) directs the Pharmaceutical Advocate “to achieve the lowest feasible cost of prescription drugs for the State of West Virginia and its citizens”, and to “achieve disclosure of the amount spent by prescription drug manufacturers with regard to expenditures for advertising, marketing, and promotion...”.

The West Virginia Pharmaceutical Cost Management Council (the Council) was given statutory authority to recommend and implement legislative enactments,¹⁵ and to issue emergency rules requiring drug companies to report their advertising and marketing expenditures.¹⁶

While the reporting date of this rule is March 2008, the Council is filing this rule as an emergency rule in order to provide drug companies with sufficient time to gather the necessary data for compliance. Should this rule be delayed until the regular legislative session, it is reasonable to believe that companies would not collect data based on what might happen and would not be in a position to be compliant with a rule that passed in March 2008 which required reporting before the July 1, 2008 sunset date for the WV Pharmaceutical Cost Management Council.

This emergency rule is being filed in order “to prevent substantial harm to the public interest”,¹⁷ and pursuant to WV Code §5A-3C-15. Reporting of this information will allow the state to obtain an accurate view of the level and scope of drug advertising and marketing in West Virginia.

This emergency rule implements the requirements of the West Virginia Code by collecting information to ascertain what portion of prescription drug prices are attributable to advertising. The state will be able to use this information in negotiations with manufacturers to lower prescription drug prices for West Virginians, thereby embarking upon steps to protect the health and safety of West Virginians.

¹⁴WV Code § 5A-3C-13(a)

¹⁵Senate Concurrent Resolution No. 301 (2004)

¹⁶WV Code §5A-3C-13

¹⁷WV Code §29A-3-15(f)(3)

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Prescription Drug Advertising Expense Reporting

Type of Rule: Legislative Interpretive Procedural

Agency: Department of Administration/WV Pharmaceutical Cost Management Council

Address: Building 1, Room M-146, 1900 Kanawha Boulevard, East Charleston, WV
25305

Phone Number: 304-558-0079 Email: sphares@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.

There will be no fiscal impact on the 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: 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.

There will be no increase or decrease in fees as noted above.

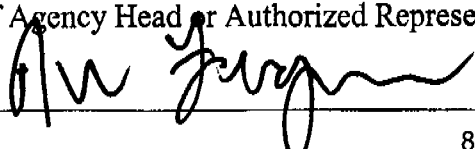
MEMORANDUM

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.

The proposed rule will not have a fiscal impact because the Pharmaceutical Cost Management Council and current staff will review prescription drug advertising expense reports and no additional hiring or expenditures to process these reports will be necessary.

Date: 4/24/07

Signature of Agency Head or Authorized Representative



**TITLE 206
LEGISLATIVE RULE
WEST VIRGINIA PHARMACEUTICAL COST MANAGEMENT COUNCIL**

**SERIES 1
PRESCRIPTION DRUG ADVERTISING EXPENSE REPORTING**

§ 206-1-1. General.

1.1 Scope. -- This rule establishes the reporting requirements for all manufacturers and labelers of prescription drugs dispensed in this state, who employ, direct or utilize marketing representatives, as mandated by W.Va. Code §5A-3C-13.

1.2 Authority. -- W.Va. Code §5A-3C-13.

1.3 Filing Date. --

1.4 Effective Date. --

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FILED

§206-1-2. Definitions.

Terms not defined in this rule have the meanings ascribed to them in W.Va. Code §5A-3C-1 et seq. As used in this rule:

2.1 “Aggregate” or “aggregate data” means information analyzed by the Council which does not disclose personally-identifiable information about specific prescribers or which does not otherwise identify specific individuals or companies.

2.2 “Aggregate list” means the information put into the report by the Council, pursuant to W.Va. Code §5A-3C-13(e) and which contains only aggregate data.

2.3 “Bona-fide clinical trial” (as described in W.Va. Code §5A-3C-13(c)(2)) means a clinical trial approved by an institutional review board [which is in compliance with the statutory (including Title 21 of the U.S. Code) and regulatory requirements (21 CFR, Part 56 and 45 CFR sec. 46.101) set by the federal Food and Drug Administration] and conducted in connection with a research study where the principle purpose is scientific research.

2.4 “Dispensed” or “Dispensing” is 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 or surrogate pursuant to a lawful order of a practitioner for subsequent administration to, or use by, a patient. Dispensing has not occurred until the drug is actually delivered to the patient or patient's representative.

2.5 “Prescription drugs” or “pharmaceutical drugs” means drugs for human use which may be legally dispensed only with a prescription.

2.6 “Prescriber” means a physician or other health care professional licensed to prescribe prescription drugs in the State of West Virginia.

2.7 “Direct to Consumer (DTC)” means the advertising of prescription drugs directly to consumers through radio, television, magazines, newspapers, direct mail and telephone communications as they pertain to residents of this state.

2.8 “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.

§ 206-1-3. Required Reporting.

3.1 After the effective date of these rules, all drug manufacturers, pharmaceutical manufacturers, and/or labelers whose prescription drugs are dispensed in West Virginia or to a West Virginia resident via mail, must complete and file with the Council, on or before March 1, 2008 for reporting period July 1, 2007 to December 31, 2007 and the first of April of each year thereafter, Appendix A listing the advertising expenses incurred by the manufacturer or labeler in the preceding calendar year.

3.2 Every drug manufacturer, pharmaceutical manufacturer, or labeler which engages in business in West Virginia (the “Company”) is required to complete the reporting form in Appendix A. If this form is filed on behalf of a group of entities which file a US federal income tax return as a consolidated group, attach a copy of the organizational chart showing all members of the consolidated group for federal income tax purposes. All references to the “Company” in the form refer to the reporting entity and to all members of its consolidated group for US federal income tax purposes.

3.3. The Company should report all advertising and direct promotion to residents of this state. For national or regional DTC advertising expenses, the Company should report West Virginia’s share in dollars by multiplying the total amount spent on advertising by West Virginia’s most recent population as reported by the U.S. Census Bureau divided by the total population targeted by the DTC advertising using the most recent population statistics reported by the U.S. Census Bureau. Such calculations shall be attached to the reporting form.

3.4 The Company must complete each table in Appendix A. If you are unable to respond to a question as worded in this rule, you must describe what alternative information is available.

1. List, in the corresponding table in Appendix A, the total number of West Virginia prescribers to whom you provided, directly or indirectly, gifts, grants or payments of any kind in the stated amounts for the purpose of advertising prescription drugs. Do not include items exempted in W.Va. Code §5A-3C-13(c).
2. List, in the corresponding table in Appendix A, the name of any prescription drugs advertised using direct-to-consumer (DTC) advertising reaching or targeting West Virginia, the type of advertising used and the total amount expended for advertising each named prescription drug.
3. List, in the corresponding table in Appendix A, the name of any disease-specific patient support or advocacy group, to which you 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.
4. List, in the corresponding table in Appendix A, the name of any pharmacy licensed in West Virginia to which you made, directly or indirectly, gifts, grants or payments of any kind totaling \$10,000 or more, for the purpose of advertising prescription drugs the type of advertising used and the total amount contributed to each named pharmacy.
5. You are permitted, but not required, to furnish the information described in Section 5A-3C-13(c) of the Act. Clinical trials which do not qualify as bona fide clinical trials must be reported.

3.5 The manufacturer or labeler shall file signed originals of completed Appendix A forms with the Council, at the Office of the Pharmaceutical Advocate, Main Building 1, Room M-146, Capitol Complex, Charleston, West Virginia 25305.

**Title 206
Legislative Rule
West Virginia Pharmaceutical Cost Management Council**

**Series 1
Prescription Drug Advertising Expense Reporting**

Name of Reporting Entity	
Reporting Period	

List below the total number of West Virginia prescribers to whom you provided directly or indirectly, gifts, grants or payments of any kind in the stated amounts for the purpose of advertising prescription drugs. Do not include items exempted in W.Va. Code §5A-3C-13(c).

Annual Aggregate Amount of fees, food entertainment, recreational activities, travel expenses, gifts, grants or other payments	Total Number of Prescribers
\$100 - \$2,500	
\$2,501 - \$5,000	
\$5,001 - \$7,500	
\$7,501 - \$10,000	
\$10,001 or over	

List below the name of any prescription drugs advertised using direct-to-consumer (DTC) advertising reaching or targeting West Virginia, the type of advertising used and the total amount expended for advertising each named prescription drug.

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

List below the name of any disease-specific patient support or advocacy group to which you 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 Annual Payments

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

Pharmacy	Type of Advertising	Amount of Payment

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	