

2008 Annual Report of the West Virginia Pharmaceutical Cost Management Council

Authority to Act

§5A-3C-8 (8) The Council shall report to the Legislature's joint committee on government and finance on or before the first day of September, two thousand four and on or before the thirty-first day of December, two thousand four and annually thereafter to the Legislature and provide recommendations to the Legislature on needed legislative action and other functions established by the article or requested by the joint committee on government and finance of the Legislature;

Executive Summary

This annual report details activity resulting from actions taken by the West Virginia Pharmaceutical Cost Management Council (the Council) for calendar year 2008. The topics include the first report from the Advertising Reporting Rule; the launch of the central fill pharmacy, WVRx; the completion of the Performance Evaluation and Review Division audit; the launch of a new website with prescription drug assistance information for the general public and continued review of purchasing options for state agencies.

The Council met two times during calendar year 2008. Minutes of each meeting are attached in **Appendix A**.

Advertising Reporting Rule

Authority to Act

§5A-3C-13 (b) The Council shall establish, by legislative rule, the reporting requirements of information by labelers and manufacturers which shall include all national aggregate expenses associated with advertising and direct promotion of prescription drugs through radio, television, magazines, newspapers, direct mail and telephone communications as they pertain to residents of this state.

The Secretary of State approved the Council's amended Emergency Advertising Reporting Rule on August 22, 2007. Manufacturers and labelers were required to

submit reports in compliance with the emergency rule for the first reporting period of July 1, 2007 to December 31, 2007 by March 1, 2008. (**Appendix B - Emergency Prescription Drug Advertising Expense Reporting Rule**).

In an effort to ensure that all affected manufacturers and labelers were aware of the reporting requirement, the Council mailed letters to approximately 1,000 manufacturers listed in the 2007 Red Book. While a number of those listed as manufacturers produce only over-the-counter drugs or operate in a wholesale capacity, this mailing ensured the broadest spectrum of compliance possible.

Highlights of the Advertising Report include:

- 111 pharmaceutical manufacturers and labelers filed reports with **57** reports indicating spending activities.
- Companies reported making **14,933** gifts, grants, or payments to West Virginia prescribers from July – December 2007. Companies reported a cumulative gift, grant and payment amount for the six-month time period so a prescriber may have received several payments from the individual company that result in the amount reported. Payments, as discussed below, mean the total amount of money from an individual company to a prescriber during the reporting period.
- There are **4,604** doctors and **583** nurse practitioners with prescribing authority and **14,933** payments were made; therefore some prescribers received payments from multiple companies and some prescribers may have not received any payments.
- Highest amount paid to an individual prescriber by a single company in the 6-month reporting period fell in the **\$51,250 - \$52,000** payment category.
- **16** payments of **\$20,000 or more** were made to prescribers from individual companies.
- **678** payments of **\$2,500 or more** were made to prescribers from individual companies.
- **5,500** payments were made from individual companies to prescribers in the lowest payment category of **\$50 - \$1,250**.
- Total reported payments to pharmacies: **\$13,469.10** (payments from **1** company).
- Total reported payments to patient advocacy groups operating in West Virginia: **\$31,675** (payments from **3** companies).

- Total direct to consumer (DTC) advertising **\$16,019,154.58** (spending by **46** companies - **41.1%** of respondents).

The full report is included at **Appendix C - 2008 Prescription Drug Advertising Expense Reporting Report.**

At the request of the Governor, in 2009, the Council will revisit the reporting rule, specifically in regard to payments to prescribers.

On April 14, 2008, the Prescription Drug Advertising Expense Reporting rule, WV CSR 206-1, became a permanent rule following passage by the legislature during the regular 2008 Legislative Session, signature by the Governor and final filing by the agency. This rule replaced the Emergency Advertising Reporting Rule. **(Appendix D - Prescription Drug Advertising Expense Reporting Rule)**

Central Fill Pharmacy

The Council recommended the formation of a Central Fill Pharmacy in its report to the Legislature on September 1, 2004. Following the completion of a Business Plan in December 2006, a Central Fill Pharmacy Board formed and met through throughout 2007. Those meetings reviewed other central fill pharmacies and forwarded the structural outline of the program. In October 2007, the request of Governor Manchin, West Virginia Healthright and the Governor's Pharmaceutical Advocate Office worked together to chart a course to bring the Central Fill Pharmacy into fruition. The Governor announced the formation of WVRx, a statewide, web-based central fill pharmacy in his 2008 State of the State Address.

WVRx held its grand opening on March 28, 2008. Two Council members continue to serve on the WVRx Advisory Board. Brenda Dane, WVRx Executive Director, reported to the Council at the July 2008 meeting **(Appendix E - WVRx presentation)**. In mid-September after 5½ months of operation WVRx reported having 303 patients enrolled, 339 prescriptions filled with a value of \$147,072.23. The Council will continue through its members on the WVRx Advisory Board to monitor and support this organization.

Performance Evaluation and Research Division (PERD) Audit

From February 27, 2008 to August 26, 2008, the Council was audited by the West Virginia Legislature's Performance Evaluation and Research Division. Audit inquiries and the responses to those inquiries were shared by the Designated Chair with the Council via email to ensure that the members remained informed of the audit process. This routine PERD audit resulting in the following findings:

- The Council has completed 8 of its 10 statutory mandates, and the Council determined that one was not necessary.
- The Council has an indistinguishable mission from the Pharmaceutical Advocate and at times appears to operate as an extension of the Pharmaceutical Advocate.
- The Council's effect on lowering pharmaceutical prices has been minimal.
- The Council has mixed interest among its membership.

In regard to the findings, the Council agreed that 8 of the 10 statutory mandates were completed. In addition, as with any large working group of 10 members or more the level of interest and engagement varies among individuals.

In terms of the mission of the Council and the mission of the Pharmaceutical Advocate, an extensive explanation of the origins of the Pharmaceutical Advocate and the statutory responsibilities of the Council were outlined in the July 3, 2008 letter to the auditors (included at **Appendix F - PERD Audit - Correspondence and Final Report**).

Structural and authoritative divisions require the Council and the Advocate to work hand-in-hand to maximize cost-savings. Specifically, the following three point illustrate that necessity:

- 1) the statute, W.Va. Code 5A-3C-4, et seq. (Check citation) exempts the Council from state purchasing requirements, this is not available to the Advocate;
- 2) Governor Manchin issued Executive Order 4-06 on May 30, 2006 to expand the authority of the Office of the Pharmaceutical Advocate to include grant-making authority, grant-making authority is not available to the Council; and
- 3) the two persons who served as the Advocate also served as Designated Chair of the Council.

In terms of the savings achieved by the Council, the auditors received this information:

“This finding is confined to savings to state government and omits savings to working West Virginia citizens not covered by public programs. On page 3 of the May 12, 2008 response to PERD the following information was provided,

“the Council worked to expand access to federal pricing programs, group purchasing programs organizations and the use of lower-cost prescription drugs. As noted in the April 16, 2008 response page 6 of 8, “The Council has actively

promoted the use of the federal 340b public health pricing program available to Federally Qualified Health Centers (FQHCs) and other designated entities. **The 340b program offers brand name pharmaceuticals to patients of eligible facilities at a maximum of 51% off the average wholesale price. This pricing is well beyond the 42% off the retail cost set by statute.** The Council began reviewing and promoting the 340b program during its May 6, 2004 meeting. At that time there were pharmacies at 15 FQHC sites. **As of March 24, 2008, there were 39 FQHC pharmacies - an increase of 260%.”** *(Emphasis added.)*

Just one of these Federal Qualified Health Centers, FamilyCare Health Center stated in its 2007 Annual Report release on March 24, 2008 that it, “Helped our Patients obtain 12,000 prescription medications at an average of 40% off the usual price through our 340b Pharmacy Program at Fruth Pharmacy in Scott Depot and Drug Emporium on the West Side of Charleston.” *(Note: The 51% off the average wholesale price citation does not include the cost of the professional services of dispensing and cognitive counseling.)*”

The savings to public citizens are not easily or neatly quantified. More specific data would involve individual analysis from each of the health center sites. However a very, very conservative estimate of 2,000 patients per clinic site means that more than **78,000** West Virginians of all income levels now have access to drugs at below the price threshold set by the Legislature in the statute. Based on that estimate and the FamilyCare report it can safely be said that **hundreds of thousands of prescriptions** are eligible for this pricing. The Council will work with the West Virginia Primary Care Association to better quantify the number of West Virginians receiving this pricing and how many prescriptions are being filled under the 340b program. The increase of the number of sites by **260%** since the Council’s inception is significant and consistent with the direction given by PERD to the Executive Branch in September 2004.”

The PERD auditors also made 5 recommendations specifically directed at the Council. Following are those recommendations and the responses to those recommendations:

1. *The Legislative Auditor recommends that the Legislature consider several options pertaining to the future of the Pharmaceutical Cost Management Council:*
 - a. Terminate the Council,
 - b. re-establish the Council as an advisory board for the Office of the Pharmaceutical Advocate, or
 - c. re-structure the Council’s membership to be more consumer oriented.

The Council notes that recommendations b and c correspond to legislation proposed by the Governor during the 2007 Legislative session. The restructuring of the Council's membership to be more consumer oriented was included in the Governor's proposed committee substitute. This modification was made in response to input from House members.

2. *If the Legislature decides to terminate the Pharmaceutical Cost Management Council, then the Legislative Auditor recommends that the oversight of the advertising reporting rule for pharmaceutical companies be transferred to the Health Care Authority.*

As Sonia Chambers, Chair of the Health Care Authority, expressed in her August 6, 2008 letter to Mr. Rhodes the HCA does not have experience with pharmaceutical data or data related specifically to advertising. If the Council is reconstituted as an advisory council to the Pharmaceutical Advocate it would seem logical to keep the advertising rule with bodies that have the expertise to administer it.

3. *If the Legislature decides to allow the Pharmaceutical Cost Management Council to continue, then the Legislative Auditor recommends that the legislature amend §5A-3C-8 of the Code to remove the provision requiring that the Executive Director of the Workers' Compensation Commission serve on the Pharmaceutical Cost Management Council.*

The Council agrees with this recommendation for technical cleanup of the Code.

4. *If the Legislature decides to allow the Pharmaceutical Cost Management Council to continue, then the Legislative Auditor recommends that the Legislature remove the sunset provision in §5A-3C-16.*

The Council agrees with this recommendation for technical cleanup of the Code.

5. *If the Legislature decides to allow the Pharmaceutical Cost Management Council to continue, the Legislative Auditor recommends that the Council member who no longer resides in West Virginia be replaced by a resident of the state of West Virginia or surrounding area.*

The Council suggests that the language for the public seat currently held by the Council member who no longer resides in West Virginia be revised. That language currently reads, "one member shall represent those who will receive benefit from the establishment of this program." Modification of this language to include member residency, member benefit from the

program or direct connection of the member to a West Virginia program may be alternatives.

Given the volume, groundbreaking nature and the scope of the work performed by the Council it is remarkable that 80% of the statutory mandates were completed in the first 4½ years of existence with merely \$23,351.03 in expenses.

All PERD correspondence, including the final report and supplementary correspondence from the Pharmaceutical Advocate Office included at **Appendix F - PERD Audit - Correspondence and Final Report.**

New website launched - www.pharmacycouncil.wv.gov

The Council launched of a new health care information resource on the West Virginia Pharmaceutical Cost Management Council website. The website includes two resource pages, one for free and low-cost healthcare services and one for free and low-cost prescription drugs. This website helps streamline the search for consumers, providers and patient advocates in searching for affordable health services.

At one convenient location, the public can find short descriptions and links to the following health care services:

Pre-paid clinic services plans at three pilot sites across the state;

The West Virginia Small Business Plan;

Access West Virginia for people with existing medical conditions;

West Virginia Children's Health Insurance Program (CHIP);

M-WIN, the Medicaid Buy-In program for people with disabilities;

The Tiger Morton Catastrophic Illness Fund for people with medical bills;

The West Virginia Oral Health Task Force for low-cost oral health care;

West Virginia Primary Care Clinics for comprehensive primary care; and

West Virginia Free Clinics.

Also at this location description and links of a variety of discount prescription drug programs are available. For working West Virginians searching for the best prices for prescription drugs this is the place to start to look at a number of retail generic programs. These programs are monitored and updated on a regular basis as the

discount generic market continues to expand and change. The programs inventoried on the website include:

- WVRx, a centralized pharmacy distributing medications donated by drug companies;
- 340b, a federal-pricing program available to patients of participating primary care centers;
- CVS (check name of program);
- Fruth Pharmacy Generic SaveRx Plan, \$4 Generic Prescription Program;
- Kroger \$4 Generic Prescription Program;
- K-Mart's 90-day Generic Prescription Drug Program for \$15;
- Rite-Aid (check name of program);
- Targets' \$4 Generic Prescription Program;
- Walgreen's (check name of program);
- Wal-Mart's \$4 Generic Prescription Program; and
- RxOutreach, a mail order generic prescription program.

Especially for medical providers and their staff, the Council website also includes links to the current preferred drug lists for all state insurance programs, including PEIA, CHIP and Medicaid. (**Appendix G - Website highlights - Discount health care services page, Discount prescription drug page**).

Conclusion

During calendar year 2008, the Council fulfilled the statutory requirement to promulgate an advertising reporting rule, advanced the Central Fill Pharmacy, launched a new website with prescription drug assistance pages and underwent a PERD audit.

In 2008, the Council will:

- assess the effectiveness of the group-buying agreements it entered on behalf of the state;

- examine how it can use its purchasing exemption to assist other state agencies, how to make available the 340b and other low-cost drug programs to a greater number of West Virginians;
- redouble its efforts to communicate with other states to explore new and innovative ways to lower drug costs;
- interact more closely with consumers around the state to assess pharmaceutical issues; and
- work to further fulfill the remaining provisions of its statutory mandate.

Appendices

Appendix A	Minutes of all Council meetings for calendar year 2008
Appendix B	Emergency Prescription Drug Advertising Expense Reporting Rule
Appendix C	2008 Prescription Drug Advertising Expense Reporting Report
Appendix D	Prescription Drug Advertising Expense Reporting Rule
Appendix E	WVRx presentation
Appendix F	PERD Audit - Correspondence and Final Report
Appendix G	Website highlights - Discount health care services page, Discount prescription drug page