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Departmental Review

Department of Administration Pharmaceutical Cost Management Council

AUDIT OVERVIEW

The Legislature Should Consider Several Options Pertaining
to the Future of the West Virginia Pharmaceutical Cost
Management Council



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August 26, 2008

The Honorable Edwin J. Bowman
State Senate
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The Honorable Jim Morgan
House of Delegates
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Dear Chairs:

Pursuant to the West Virginia Performance Review Act, we are transmitting a Departmental Review of the *West Virginia Department of Administration-Pharmaceutical Cost Management Council*, which will be presented to the Joint Committee on Government Operations and Joint Committee on Government Organization on Tuesday, August 26, 2008. The issue covered herein is "*The Legislature Should Consider Several Options Pertaining to the Future of the West Virginia Pharmaceutical Cost Management Council.*"

We transmitted a draft copy of the report to the West Virginia Department of Administration and to the West Virginia Governor's Pharmaceutical Advocate Council on August 12, 2008. We held an exit conference with the West Virginia Governor's Pharmaceutical Advocate Council on August 19, 2008. We received the agency responses from the Department of Administration on August 18, 2008 and the West Virginia Governor's Pharmaceutical Advocate Council on August 21, 2008.

Let me know if you have any questions.

Sincerely,

Handwritten signature of John Sylvia in cursive script.
John Sylvia

JS/tlc

Joint Committee on Government and Finance

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EXECUTIVE SUMMARY

The Legislature Should Consider Several Options Pertaining to the Future of the West Virginia Pharmaceutical Cost Management Council

The Pharmaceutical Cost Management Council was created in 2004 as part of the Pharmaceutical Availability and Affordability Act. The Council was charged with 10 statutory mandates, 8 of which have been completed.

Upon reviewing the Pharmaceutical Cost Management Council, the Legislative Auditor questions whether the Council needs to be continued. The Legislative Auditor has several reasons for questioning the continued need for the Council which are listed below.

Upon reviewing the Pharmaceutical Cost Management Council, the Legislative Auditor questions whether the Council needs to be continued.

- The Council has completed the majority of its statutory mandates. Eight of the 10 have been completed, and the Council determined that one was not necessary.
- The Council has an indistinguishable mission from the Office of 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 Legislative Auditor questions whether the savings were a result of the efforts of the Council or the efforts mainly of the Office of the Pharmaceutical Advocate.
- The Council has mixed interest among its membership.

The Council was mandated by West Virginia Code §5A-3C-8(d)-(12) to “determine the ability to establish a savings of 42 percent of the retail cost” on pharmaceutical drugs. According to the Pharmaceutical Advocate, the Council has worked in promoting the Federal 340b program. Furthermore, in a letter to the Joint Committee on Government and Finance, and to the Legislative Auditor, the Pharmaceutical Advocate described in detail the costs savings attained by the Council. The Pharmaceutical Advocate primarily credited the Council with the savings

but the Legislative Auditor can not determine whether the savings are actually a result of the Council's efforts or the Office of the Pharmaceutical Advocate.

The Legislature has several options regarding the future of the Council. The following options are provided by the Legislative Auditor:

- Terminate the Council.
- Re-establish the Council as an advisory board for the Office of the Pharmaceutical Advocate.
- Restructure the Council's membership to be more consumer oriented.

The Pharmaceutical Advocate provides some caveats for terminating the Pharmaceutical Cost Management Council. Specifically, the Pharmaceutical Advocate believes if the Council is terminated, the advertising reporting rule would be lost. The Legislative Auditor understands the importance of this rule, and recommends maintaining it by transferring it to another agency. The Legislative Auditor considers the most appropriate state agency would be the Health Care Authority.

The Legislative Auditor also questions whether the Pharmaceutical Advocate can legally chair the Council. West Virginia Code states the Secretary of the Department of Administration shall serve as chair of the Council. West Virginia Code also lists the Secretary or his designee as a statutory member. Currently, the Pharmaceutical Advocate serves as chair of the Council. Legislative Services legal counsel concludes that it is not an acceptable practice for the Pharmaceutical Advocate to serve as chair of the Council. Furthermore, the Legislative Auditor recommends the Governor re-evaluate the need for the Office of the Pharmaceutical Advocate because the savings attained by the Council and the Advocate are less than the total budget for the Office of the Pharmaceutical Advocate.

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.*
2. *If the Legislature decides to terminate the Pharmaceutical Cost Management Council, then the Legislative Auditor recommends that oversight of the advertising reporting rule for pharmaceutical companies be transferred to the Health Care Authority.*
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.*
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.*
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.*
6. *If the Legislature decides to allow the Pharmaceutical Cost Management Council to continue, then the Legislative Auditor recommends that the Secretary of Administration or a designee under his authority be selected as chair of the Council.*

- 7. The Legislative Auditor recommends that the Governor evaluate the effectiveness and necessity of the Office of the Pharmaceutical Advocate.*

OBJECTIVE, SCOPE & METHODOLOGY

This is a Performance Review of the West Virginia Pharmaceutical Cost Management Council conducted as part of the Departmental Review of the Department of Administration.

Objective

The objective of this report was to determine the Council's effect on the cost of pharmaceutical drugs and the Council's compliance with West Virginia State Code §5A-3C.

Scope

The scope of this report focused on the period beginning with the creation of the Council in 2004 through July 2008.

Methodology

The Legislative Auditor utilized information received from the West Virginia Pharmaceutical Cost Management Council, information received from the office of the Pharmaceutical Advocate, meeting minutes for the Council, a survey of Council members, legal opinions provided by Legislative Services legal counsel, Council expenditure schedules, and West Virginia State Code. Every aspect of this review complied with the Generally Accepted Governmental Auditing Standards (GAGAS) as set forth by the Comptroller General of the United States of America.

ISSUE 1

The Legislature Should Consider Several Options Pertaining to the Future of the West Virginia Pharmaceutical Cost Management Council

Issue Summary

The West Virginia Pharmaceutical Cost Management Council was created by the Pharmaceutical Availability and Affordability Act in an effort to provide low-cost pharmaceuticals to uninsured and underinsured West Virginians. The Pharmaceutical Cost Management Council has completed 8 of its 10 mandates. The Council created rules which require reporting of drug advertising expenses by pharmaceutical labelers and manufacturers. The effectiveness of the Council is questionable because there has been little discretion between the efforts of the Council and the efforts of the Pharmaceutical Advocate. The Pharmaceutical Cost Management Council has mixed interest among its membership. The majority of Council members which responded to the Legislative Auditor's survey believe the Council should be terminated in its current capacity. The Legislative Auditor has questions of whether the Pharmaceutical Cost Management Council should be continued and has several options in regards to the Council's future.

The West Virginia Pharmaceutical Cost Management Council was created by the Pharmaceutical Availability and Affordability Act in an effort to provide low-cost pharmaceuticals to uninsured and underinsured West Virginians.

The West Virginia Pharmaceutical Cost Management Council Has Completed 8 of Its 10 Mandates

The West Virginia Pharmaceutical Cost Management Council (Council) was created in 2004 as part of the Pharmaceutical Availability and Affordability Act. The Act was created as an effort to provide low cost pharmaceuticals to uninsured and low income West Virginians. The Pharmaceutical Availability and Affordability Act charged the Council with 10 statutory mandates. The Council consists of 11 members, 6 of which are state agency heads or their designee and 5 are gubernatorial appointed lay members.

The Pharmaceutical Availability and Affordability Act charged the Council with 10 statutory mandates.

The Council is statutorily chaired by the Secretary of the Department of Administration or his or her designee. Currently, the Pharmaceutical Advocate, appointed by the Governor, serves as the designee for the Secretary of Administration and chairs the Council. The Council meets at the discretion of the Chair or upon the request of two members.

The Council has completed 8 of its 10 statutory mandates. The Legislative Auditor commends the council for completing these mandates. The mandates that have been completed are as follows:

- (§5A-3C-4(a)) - **Recommend the state agency to own, control and operate the state prescription drug assistance clearinghouse program.** The recommended agency was the Department of Administration in its Clearing House report in September 2004.
- (§5A-3C-5) - **Establish a pharmaceutical discount program with eligible individuals.** The Council reported in September 2004 that it would be better practice to have a central fill pharmacy instead of a discount card program. The Office of the Pharmaceutical Advocate, West Virginia Health Right and the Governor worked in cooperation to create WVRx, a central fill pharmacy, in March 2008.
- (§5A-3C-8(11)) - **Evaluate the discount program and the clearing house program created by the Council.** The Council delivered this report to the Joint Committee on Government and Finance in September 2004.
- (§5A-3C-6(e)) – **Develop a pricing schedule and report it to the Legislature.** The West Virginia Pharmaceutical Cost Management Council reported the Reference Pricing Report to the Joint Committee on Government and Finance in September 2004. The pricing schedule chosen by the Council was the Federal Supply Schedule (FSS).
- (§5A-3C-8(d)(8)) - **Report to the Legislature annually and provide recommendations on needed legislative action and other functions established in the article or requested by the Legislature.** The Council reports to the Joint Committee on Government and Finance every month. The Council submits annual reports in December of each year. Thus far, the Council has made two recommendations to the Legislature. The first recommendation was to consider making remote dispensing legal. The second recommendation was to make electronic dispensing legal.

- (§5A-3C-8(d)(9)) - **Study the fiscal impact of the “Medicare Prescription Drug Improvement and Modernization Act of 2003” and report its findings to the Legislature.** The Council reported on the Medicare Prescription Drug Improvement and Modernization Act on October 15, 2004.
- (§5A-3C-13) - **Establish reporting requirements by labelers and manufacturers of all expenses associated with advertising and direct promotion of pharmaceutical drugs.** The Emergency Rule went into effect in August 2007. Reports from pharmaceutical companies were due March 1, 2008. At the time of this writing 111 companies have submitted reports to the Council. (The following section includes more detailed information on this rule.)
- (§5A-3C-17) - **Savings by the Council will be directed towards maintenance of existing health programs and expansion of insurance programs for the uninsured and under insured.** The savings attained by the Council have allowed it not to require additional Legislative funding.

Establish reporting requirements by labelers and manufacturers of all expenses associated with advertising and direct promotion of pharmaceutical drugs.

The two mandates the Council has not completed are as follows:

- §5A-3C-8(d)-(12) - **The Council shall: (1) review and determine the implementations of programs that will not jeopardize the benefits of veterans or other recipients of FSS drug prices; (2) commence negotiations to obtain independent agreements with as many as 10 states to use or reference pricing schedules; (3) and determine the ability to establish a savings of 42 percent of the retail cost.** The Council found to date there has been no explicit use of a Federal Supply Schedule (FSS) and there was no reason to evaluate the effects on veterans, thus this mandate has not been completed by the Council.
- (§5A-3C-6(e)) – **Develop a strategic plan for implementation.** The West Virginia Pharmaceutical Cost Management Council reported the Reference Pricing Report to the Joint Committee on Government and

Finance in September 2004. According to the Council, the strategic plan has not been completed by the Council because the Advertising Reporting Rule took the Council longer than expected.

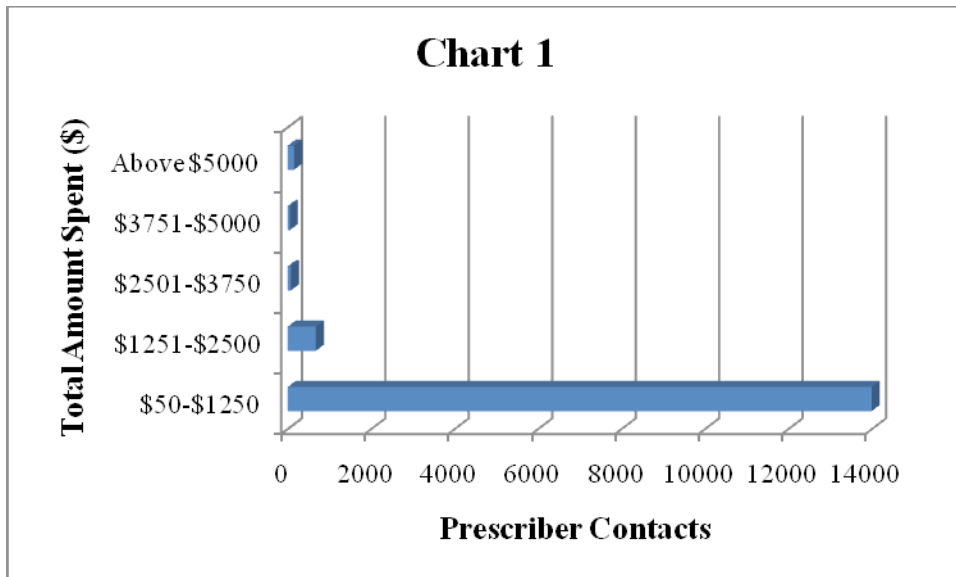
The Council Promulgated Legislative Rules Requiring the Reporting of Drug Advertising Expenses by Pharmaceutical Companies

As stated previously, the Council was mandated by West Virginia Code §5A-3C-13 to establish reporting requirements by labelers and manufacturers of all expenses associated with the advertising and direct promotion of pharmaceutical drugs. Specifically, the rule requires all pharmaceutical manufacturers, drug manufacturers and labelers of prescription drugs dispensed in West Virginia to report advertising expenses. Pharmaceutical manufacturers and labelers are not required to report the following: free samples of prescription drugs; compensation and reimbursement of expenses in connection with a bona fide clinical trial; and scholarships or other support for medical students, residents and fellows.

As of July 2008, 111 companies reported their advertising expenses to the West Virginia Pharmaceutical Cost Management Council. The report released by the Council shows there were 13,998 prescriber contacts that resulted in reported expenses from \$50 to \$1,250. The total amount spent on advertising in West Virginia was \$16,019,155. The Council also reported that a total 14,933 gifts, grants or payments were made to pharmaceutical prescribers in that same time frame. Chart 1 below shows the total expenses pharmaceutical manufacturers and labelers on advertising from July 2007 to December 2007.

The rule requires all pharmaceutical manufacturers, drug manufacturers and labelers of prescription drugs dispensed in West Virginia to report advertising expenses.

As of July 2008, 111 companies reported their advertising expenses to the West Virginia Pharmaceutical Cost Management Council.



Furthermore, the total reported expenses to patient advocacy groups in West Virginia by pharmaceutical manufacturers and labelers were \$31,675. The total reported expenses to licensed West Virginia pharmacies by pharmaceutical manufacturers and labelers were \$13,469. Only three manufacturers or labelers reported contributing to advocacy groups, and one manufacturer or labeler reported payments to licensed West Virginia pharmacies.

The report released by the Council shows there were 13,998 prescriber contacts that resulted in reported expenses from \$50 to \$1,250. The total amount spent on advertising in West Virginia was \$16,019,155.

The Legislative Auditor Questions Whether the Pharmaceutical Cost Management Council Should Be Continued

Upon reviewing the Pharmaceutical Cost Management Council, the Legislative Auditor questions whether the Council needs to be continued. The Legislative Auditor has several reasons for questioning the continued need for the Council which are listed below. With the exception of the first item, each item will be discussed in further detail in the following paragraphs.

Upon reviewing the Pharmaceutical Cost Management Council, the Legislative Auditor questions whether the Council needs to be continued.

- As discussed previously, the Council has completed the majority of its statutory mandates. Eight of the 10 have been completed, and the Council determined that one was not necessary.

- The Council has an indistinguishable mission from the Office of 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 amongst its membership.

The Office of the Pharmaceutical Advocate and the West Virginia Pharmaceutical Cost Management Council Have Similar, Indistinguishable Missions

The Office of the Pharmaceutical Advocate was created in 2004 per a recommendation of the Council and signed as an Executive Mandate. The missions of the Pharmaceutical Advocate and the Council are similar. Both the Pharmaceutical Advocate and the Council's primary missions are to provide low cost pharmaceutical drugs to West Virginians. The mandate given to the Pharmaceutical Advocate reads as follows:

The Pharmaceutical Advocate shall develop a comprehensive plan and exercise his or her authority to achieve the lowest feasible cost of prescription drugs for the State of West Virginia and its citizens.

The Pharmaceutical Availability and Affordability Act, the statute which created the Council, states the following mission:

...to promote healthy communities and to protect the public health and welfare of West Virginia residents, the Legislature finds that it is its responsibility to make every effort to provide affordable prescription drugs for all residents of West Virginia.

Table 1 below shows the similarities in missions between the Office of the Pharmaceutical Advocate and the Pharmaceutical Cost Management Council.

The Council has an indistinguishable mission from the Office of the Pharmaceutical Advocate, and at times appears to operate as an extension of the Pharmaceutical Advocate.

Table 1	
Similar Roles of the Pharmaceutical Advocate and the Pharmaceutical Cost Management Council	
Pharmaceutical Advocate	Pharmaceutical Cost Management Council
Provide discount prices or rebate programs as prudent for seniors and persons without adequate prescription insurance.	Explore discount prices or rebate programs for seniors and persons without prescription drug coverage.
Work to achieve disclosure of the amount spent by prescription manufacturers with regard to expenditure for advertising, marketing, and promotion as well as for provider incentives and research and development efforts.	The Council shall establish, by legislative rule, the report 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 communication as they pertain to state residents.
Establish programs aimed at education health care practitioners authorized to prescribe prescription drugs about the relative costs and benefits of various prescription drugs, with emphasis on generic substitutions for brand name drugs when available and appropriate; prescribing established, less-costly drugs instead of newer more expensive drugs when appropriate; and prescribing lower dosages of prescription drugs when appropriate.	Explore establishment to educate practitioners whom prescribe prescriptions. Explore policies which promote the use of generic drugs.
Develop and implement a program to maximize savings to the State and its citizens from Sec. 340b of the Federal Public Health Service Act and 42 USC 256, as applicable.	Determine the ability to establish a savings of 42 percent the retail cost to be reported to the Joint Committee.*
Facilitate the establishment of voluntary private buying clubs, cooperatives of purchasing alliances comprised of small businesses and/or individuals for the purpose of purchasing prescription drugs at optimal prices.	Explore current drug purchasing agreements in the private sector.
*The West Virginia Pharmaceutical Cost Management Council currently promotes the Federal 340b plan to lower cost of pharmaceutical drugs by 51 percent.	

The Council's Effect on Lowering Pharmaceutical Drug Costs in West Virginia Has Been Minimal

The Council was mandated by West Virginia Code §5A-3C-8(d)-(12) to “determine the ability to establish a savings of 42 percent of the retail cost” on pharmaceutical drugs. According to the Pharmaceutical Advocate, the Council has worked in promoting the Federal 340b program. This federal program offers savings of up to 51 percent on prescription drugs.¹

Furthermore, the following cost savings were recently attributed to the Council by the Pharmaceutical Advocate, who serves as Chair of the Council. These cost savings were indicated by letter to the Joint Committee on Government and Finance, and to the Legislative Auditor (see Appendix B).

- Through contract negotiations and joining group purchasing organizations, the Pharmaceutical Cost Management Council, with assistance from the Office of the Pharmaceutical Advocate saved West Virginia hospitals \$118,096.45.
- With the assistance of the Office of the Pharmaceutical Advocate, the Bureau of Public Health found optimum pricing for antibiotics which led to a 33 percent increase in the amount of antibiotics the Bureau of Public Health was able to purchase.
- The Pharmaceutical Cost Management Council used its purchasing exemptions to enter the 340b Prime Vendor Program on behalf of the Family Planning Program. The Council attained savings on contraceptive products used by the Family Planning Program. The total savings by the Council is not available yet.
- Through the use of the 340b program, the Bureau of Medical Services projected a savings of \$181,352.40 and avoided costs of \$725,000.

The Legislative Auditor requested a response from the Secretary of the Department of Health and Human Resources regarding the attributed savings (see Appendix C). It must be noted that the Secretary is statutorily a member of the Council. The Secretary stated in part:

¹ In 2004, the Legislative Auditor recommended that the Council continue its efforts with the Division of Corrections to contract with 340b providers. As of this writing, the Division of Corrections is still not contracting with 340b providers.

*I would note that in a department where the Medicaid budget alone for pharmaceuticals is approximately \$181 million after rebates and the Department of Health and Human Resources' (DHHR) total expenditure is about \$192 million, **the total savings listed – less than \$300,000 in actual dollars – is less than two tenths of one percent of our budget.** (emphasis added)*

While the Legislative Auditor had noticed the minimal savings as a result of the attributed efforts of the Council, the Legislative Auditor also questioned whether the savings were a result of the efforts of the Council or the efforts mainly of the Office of the Pharmaceutical Advocate. As stated previously, the Council and the Office of the Pharmaceutical Advocate have similar missions, and there does not seem to be a distinction between the efforts of the Council and the efforts of the Pharmaceutical Advocate. The Pharmaceutical Advocate primarily credited the Council with the savings but the Legislative Auditor can not determine whether the savings are actually a result of the Council. The Secretary of DHHR appeared to credit the savings to the Pharmaceutical Advocate, which is as follows:

The Pharmaceutical Advocate primarily credited the Council with the savings but the Legislative Auditor can not determine whether the savings are actually a result of the Council.

I applaud the Pharmaceutical Advocate for her efforts. Any savings stated in (the letter to the Joint Committee on Government and Finance and the Legislative Auditor) have been a result of her work. I, as a member, do not see a positive role for the Pharmaceutical Cost Management Council. Because of its purchasing power and continued attention to national trends, the DHHR has and will continue to use every means available to reduce the cost of prescription drugs on its own initiative.

The Legislative Auditor also commends the efforts of whichever entity - the Pharmaceutical Advocate or the Council – is responsible for the attributed savings. But, these savings are minimal at best.

The Council Has Mixed Interest Among Its Membership

The Legislative Auditor surveyed members of the Council and asked their opinions of the Council. Eight of the 10 members responded to the Legislative Auditor's request. Five of the eight respondents

believe that the Council was worthwhile and important to facilitating the Pharmaceutical Availability and Affordability Act. Five of the eight respondents believed that there would be discernable effects if the Council was terminated. When asked if the Pharmaceutical Availability and Affordability Act could be carried out without the Council the results were inconclusive. Half of the respondents believed it could and half of the respondents believe it could not. **Five of the eight Council members who responded believe the Council should be terminated in its current capacity.**

Five of the eight Council members who responded believe the Council should be terminated in its current capacity.

Table 2 shows in detail how Council members responded to the Legislative Auditor’s survey.

Table 2		
West Virginia Pharmaceutical Cost Management Council Survey Results*		
		Percentage (Based on Responses)
<i>Question 1: Do you find the Council meetings worthwhile and important to facilitate the West Virginia Pharmaceutical Availability and Affordability Act?</i>		
A. Yes	5	62.5%
B. No	3	37.5%
<i>Question 2: Do you feel there would be any discernable effects if the Council was terminated?</i>		
A. Yes	5	62.5%
B. No	3	37.5%
<i>Question 3: In your opinion, could the West Virginia Pharmaceutical Availability and Affordability Act be adequately and completely carried out if the West Virginia Pharmaceutical Cost Management Council were to be terminated?</i>		
A. Yes	4	50%
B. No	4	50%
<i>Question 4: In your opinion, should the council be continued?</i>		
A. Yes	3	37.5%
B. No, terminated	3	37.5%
C. No, but should be re-established as an Advisory Board	2	25%
*Survey was sent to all 10 Council members, with 8 responding.		
Source: Survey conducted by the Legislative Auditor.		

In addition to the survey questions, Council members were invited to provide additional comments, which are as follows:

I believe the Council has completed its mission.

It was hard for the Council to be productive because of special interest and personal agendas.

I believe the effectiveness of the Council would be enhanced if more consumer interests were involved and if interested Legislators had more input.

The Council focuses attention, but it also delays issues through long discussion.

The Pharmaceutical Advocate chairs the Council instead of reporting TO the Council, so there is a blurring of responsibilities.

We have no operating rules.

Too many people participate by phone most of the time so there is no personal interaction.

The comments and survey results from the Council members show a mixed interest in the effectiveness of the Council.

The comments and survey results from the Council members show a mixed interest in the effectiveness of the Council. According to the survey results, the greatest lack of interest in the future of the Council was among the state agency representatives. **State agency representatives are the majority of those who thought the Council should be terminated in its present capacity.**

The Legislature Has Several Options in Considering the Future of the Council

As stated previously, the Legislative Auditor questions whether the Pharmaceutical Cost Management Council should be continued, but must acknowledge that additional time or making modifications to the

Council could allow it to become more effective. Thus, the Legislative Auditor provides the West Virginia Legislature with several options:

- Terminate the Council. This option is discussed in more detail below.
- Re-establish the Council as an advisory board for the Office of the Pharmaceutical Advocate. Two of the current Council members recommended this in the Legislative Auditor's survey results.
- Restructure the Council's membership to be more consumer oriented. Survey responses show some disinterest by state agency representatives. Replacing these members with members from a consumer background could spark some renewed interest in the Council.

Caveats for Terminating the Pharmaceutical Cost Management Council

If the Legislature chooses to terminate the Council, there would potentially be three main losses, according to the Pharmaceutical Advocate. First, the statutory authority for the advertising reporting rule would be lost. The Pharmaceutical Advocate does not have rule making authority, unlike the Council, and this authority would be lost completely if the Council were completely terminated. Secondly, without the Council there would be a loss of the exemption from state purchasing rules. The State would be able to enter into purchasing agreements through the Department of Administration, but there would not be a purchasing exemption. Lastly, the Pharmaceutical Advocate believes if the Council is terminated there would be a lack of professional, private-sector expertise, which is represented by Council members.

If the Legislature Terminates the Council, Oversight of the Advertising Rule Could Be Transferred to the Health Care Authority

The Legislative Auditor acknowledges that the oversight of the advertising reporting rule by pharmaceutical companies would be lost.

If the Legislature chooses to terminate the Council, the statutory authority for the advertising reporting rule would be lost. However, the Legislative Auditor contends that the authority for the reporting rule can be transferred to another agency.

But, this authority could be transferred to another state agency. The Legislative Auditor suggests that the oversight of the advertising reporting rule should be transferred to the Health Care Authority if the Council is terminated. The Health Care Authority has access to data regarding health care, and should be able to accept this mandate. The Legislative Auditor contacted the Chair of the Health Care Authority for her opinion on this suggestion. She responded by stating in part that the Health Care Authority does not have “any experience with pharmaceutical data or data related specifically to advertising”. Although the Chair does not feel as though the Health Care Authority is the correct entity to accept this mandate, the Legislative Auditor feels that it is fully capable. This data is submitted to the Council by pharmaceutical manufacturers and labelers; it requires no active collection process. Also the Health Care Authority would simply be receiving, compiling, and reporting the data with no analysis needed. Thus the Legislative Auditor maintains the opinion that the Health Care Authority is the proper entity for this mandate. The Chair’s response can be seen in its entirety in Appendix D.

Legal counsel from Legislative Services stated that if the Legislature terminated the Council, the associated bill could amend §5A-3C-13 to report data to the Health Care Authority rather than the Council. In addition, the bill could include language transferring the enacting rule to the Health Care Authority. Furthermore, the Legislature could require the Health Care Authority to re-file rules under its authority at a later date.

If the Council Continues, Several Modifications Should Be Made

If the Legislature chooses the option to keep the Council, the Legislative Auditor recommends that several modifications be made. When the Council was created in 2004 there was a statutory position for the Executive Director of the Workers’ Compensation Commission or his or her designee. Since there is no longer a state Workers’ Compensation Commission there should not be a place on the Council for this position. **If the Council continues, 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 Legislative Auditor suggests that the oversight of the advertising reporting rule should be transferred to the Health Care Authority if the Council is terminated.

Legal counsel from Legislative Services stated that if the Legislature terminated the Council, the associated bill could amend §5A-3C-13 to report data to the Health Care Authority rather than the Council.

The Council currently has a member living in Massachusetts. West Virginia Code §5A-3C-8 requires that this particular position to:

...represent those who will receive benefit from the establishment of (the Council)...

Since this member lives outside West Virginia, the Legislative Auditor questions how this person represents those who will benefit from the Council's activities or serves the interest of West Virginians. **If the Council continues, the Legislative Auditor recommends that this member living in Massachusetts be replaced with an individual who represents the conditions of the statute, and who represents those who receive benefits from the Council.**

Some members of the Council attend meetings by teleconference, as documented by meeting minutes and survey results from Council members. State Code allows for meetings to be held via teleconference. The most recent meeting held on July 7, 2008 was conducted by Microsoft WebEx which was an internet teleconference. There was no physical meeting place, and members and those wishing to "listen" to the meeting had to log in online. The Legislative Auditor attempted to log into the meeting, but technical difficulties would not allow access. This could have posed problems for other individuals as well. The lack of interest by some Council members may be attributed to the absence of personal interaction at Council meetings because meetings are being held by these means.

The lack of interest by some Council members may be attributed to the absence of personal interaction at Council meetings.

Finally, the Council was scheduled to sunset on July 1, 2008. The Sunset Law no longer exists and has been amended as the Performance Review Act. **Since the Sunset Law no longer exists, the Legislative Auditor recommends that the sunset language be removed from the Council's Code if the Council continues.**

The Legislative Auditor Questions Whether the Pharmaceutical Advocate Can Legally Chair the Pharmaceutical Cost Management Council

Legislative Services legal counsel is of the opinion that the Pharmaceutical Advocate chairing the Council is improper. West Virginia Code §5A-3C-8(b) states that the Secretary of Administration shall

serve as chair of the Council. The previous section lists the Secretary or his designee as a statutory member. The Pharmaceutical Advocate currently is serving as chair, but that position is located in the Governor's Office. Legislative Services legal counsel states that the Secretary of Administration does not have authority to appoint a designee outside of his authority. Thus, if the Legislature chooses to continue the Council, the Pharmaceutical Advocate should no longer be designated as a member by the Secretary of Administration, thus should not serve as its chair.

In a letter to the Legislative Auditor regarding the matter of the Pharmaceutical Advocate serving as the chair of the Council, the Legislative Services legal counsel stated the following:

Based on the information you provided me, the Pharmaceutical Advocate is not an officer or employee of the Department of Administration.

W. Va. Code §5A-3C-8 provides, in part:

(a) There is hereby created the West Virginia pharmaceutical cost management

council which consist of the secretary of the department of administration or his or her designee,...

(b) The secretary of the department of administration shall serve as the chairperson of the council, which shall meet at times and places specified by the chairperson or upon the request of two members of the council.

...

Although this code section does not elaborate on who the Secretary may name as his designee, several other code sections provide guidance on this issue.

W. Va. Code §5A-1-7 provides:

*The powers and duties vested in the secretary may be delegated to him to **his assistants and employees**, but the secretary shall be responsible for all official acts of the department. (Emphasis added.)*

W.Va. Code §5F-2-2, in outlining the powers of the department secretaries, provides that the secretary may:

...

Legislative Services legal counsel states that the Secretary of Administration does not have authority to appoint a designee outside of his authority.

(14) Delegate to administrators the duties of the secretary as the secretary may deem appropriate, from time to time, to facilitate execution of the powers, authority and duties delegated to the secretary;

...

§5F-1-4 defines an “administrator” as:

...any person who fills a statutorily created position within or related to an agency or board (other than a board member) and who is designated by statute as commissioner, deputy commissioner, assistant commissioner, director, chancellor, chief, executive director, executive secretary, superintendent, deputy superintendent, or any other administrative title however designated.

If the Secretary is to designate another to serve in his place he must do so in a manner consistent with these statutes. Designating someone who is not employed within the Department of Administration is not consistent with these statutes.

Consequently, it is my opinion that it is not acceptable practice for the Pharmaceutical Advocate to chair the West Virginia Pharmaceutical Cost Management Council as the Secretary of the Department of Administrations designee.

As stated previously, the Advocate or the Council has assisted the state in saving less than \$300,000. This savings is less than the annual budget of the Office of the Pharmaceutical Advocate.

The Legislative Auditor Recommends that the Governor Re-evaluate the Need for the Office of the Pharmaceutical Advocate

The Office of the Pharmaceutical Advocate was created by Executive Order 18-04 in 2004 under the previous administration. As stated previously, the Advocate or the Council has assisted the state in saving less than \$300,000. This savings is less than the annual budget of the Office of the Pharmaceutical Advocate. The FY 2008 budget for the Office is \$503,138, and the budgets for FY 2006 and FY 2007 were \$501,200 respectively \$501,800. Actual expenditures for FY 2008 were

\$469,806. The total actual expenses for the Office of the Pharmaceutical Advocate from FY 2006 to FY 2008 were \$1,105,191, which far exceeds the \$299,449 attributed savings to the State. **As a result, the Legislative Auditor recommends that the Governor re-evaluate the necessity of the Office of the Pharmaceutical Advocate.**

Conclusion

The West Virginia Pharmaceutical Cost Management Council was created by the Pharmaceutical Availability and Affordability Act in an effort to provide low-cost pharmaceuticals to uninsured and underinsured West Virginians. The Council was charged with 10 statutory mandates and has completed 8. Although it has completed the majority of its mandates, it is questionable how effective the Council has been. There is no distinction between the efforts of the Council and the efforts of the Pharmaceutical Advocate, since the Council is currently chaired by the Pharmaceutical Advocate. The Legislative Auditor can not determine whether the savings attributed by the Advocate were a result of the Council. This cost savings was less than \$300,000, which is minimal compared to the pharmaceutical budget of the Department of Health and Human Resources. The Legislative Auditor recommends several options for the Legislature to consider in respect to the Council's future. These options include termination of the Council or continuation with modifications to the entity that it reports and to its membership. If the Council is terminated, the Legislature could consider transferring the oversight of the advertising reporting rule for pharmaceutical companies to the Health Care Authority. In addition, if the Council is continued, the Legislative Auditor is of the opinion that the Council can not be chaired by the Pharmaceutical Advocate. This position does not lie within the purview of the Secretary of Administration, thus should not serve as his designee to the Council.

The total actual expenses for the Office of the Pharmaceutical Advocate from FY 2006 to FY 2008 were \$1,105,191, which far exceeds the \$299,449 attributed savings to the State.

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.*
2. *If the Legislature decides to terminate the Pharmaceutical Cost Management Council, then the Legislative Auditor recommends that oversight of the advertising reporting rule for pharmaceutical companies be transferred to the Health Care Authority.*
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.*
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.*
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.*
6. *If the Legislature decides to allow the Pharmaceutical Cost Management Council to continue, then the Legislative Auditor recommends that the Secretary of Administration or a designee under his authority be selected as chair of the Council.*
7. *The Legislative Auditor recommends that the Governor evaluate the effectiveness and necessity of the Office of the Pharmaceutical Advocate.*

Appendix A: Transmittal Letters

WEST VIRGINIA LEGISLATURE *Performance Evaluation and Research Division*

Building 1, Room W-314
1900 Kanawha Boulevard, East
Charleston, West Virginia 25305-0610
(304) 347-4890
(304) 347-4939 FAX



John Sylvia
Director

August 12, 2008

Robert W. Ferguson, Jr.
Cabinet Secretary
Department of Administration
State Capitol Complex, Room E-119
1900 Kanawha Blvd., East
Charleston, West Virginia 25305

Dear Secretary Ferguson:

This is to transmit a draft copy of the Performance Review of the West Virginia Pharmaceutical Cost Management Council conducted as part of the Departmental Review of the Department of Administration. This report is scheduled to be presented during an August 24-26, 2008 interim meeting of the Joint Committee on Government Operations and the Joint Committee on Government Organization. We will inform you of the exact time and location once the information becomes available. It is expected that a representative from your agency be present at the meeting to orally respond to the report and answer any questions the committees may have.

If you would like to schedule an exit conference to discuss the findings of the report please notify us to schedule an exact time before Friday, August 15, 2008. In addition, we need your written response by noon on August 18, 2008 in order for it to be included in the final report. If your agency intends to distribute additional material to committee members at the meeting, please contact the House Government Organization staff at (304) 340-3192 by Thursday, August 21, 2008 to make arrangements.

We request that your personnel not disclose the report to anyone not affiliated with your agency. Thank you for your cooperation.

Sincerely,

A handwritten signature in black ink that reads "Denny Rhodes".

Denny Rhodes
Research Manager

Enclosure

Joint Committee on Government and Finance

WEST VIRGINIA LEGISLATURE
Performance Evaluation and Research Division

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John Sylvia
Director

August 12, 2008

Shana Phares
West Virginia Governor's
Pharmaceutical Advocate Office
Building 1, Room M-146
1900 Kanawha Blvd., East
Charleston, West Virginia 25305

Dear Ms. Phares:

This is to transmit a draft copy of the Performance Review of the West Virginia Pharmaceutical Cost Management Council conducted as part of the Departmental Review of the Department of Administration. This report is scheduled to be presented during an August 24-26, 2008 interim meeting of the Joint Committee on Government Operations and the Joint Committee on Government Organization. We will inform you of the exact time and location once the information becomes available. It is expected that a representative from your agency be present at the meeting to orally respond to the report and answer any questions the committees may have.

We need to schedule an exit conference to discuss any concerns you may have with the report. We would like to have the meeting before Friday, August 15, 2008. Please notify us to schedule an exact time. In addition, we need your written response by noon on August 18, 2008 in order for it to be included in the final report. If your agency intends to distribute additional material to committee members at the meeting, please contact the House Government Organization staff at (304) 340-3192 by Thursday, August 21, 2008 to make arrangements.

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Denny Rhodes
Research Manager

Enclosure

_____ *Joint Committee on Government and Finance* _____

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Performance Evaluation and Research Division

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(304) 347-4890
(304) 347-4939 FAX



John Sylvia
Director

August 12, 2008

Larry Puccio
Governor's Office
State Capitol Complex
1900 Kanawha Blvd., East
Charleston, West Virginia 25305

Dear Mr. Puccio:

This is to transmit a draft copy of the Performance Review of the West Virginia Pharmaceutical Cost Management Council conducted as part of the Departmental Review of the Department of Administration. This report is scheduled to be presented during an August 24-26, 2008 interim meeting of the Joint Committee on Government Operations and the Joint Committee on Government Organization. We will inform you of the exact time and location once the information becomes available.

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We request that your personnel not disclose the report to anyone not affiliated with your agency. Thank you for your cooperation.

Sincerely,

Handwritten signature of Denny Rhodes in cursive script.
Denny Rhodes
Research Manager

Enclosure

Joint Committee on Government and Finance

WEST VIRGINIA LEGISLATURE
Performance Evaluation and Research Division

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(304) 347-4939 FAX



John Sylvia
Director

August 12, 2008

J.J. Bernabei
Tri-State Medical Group
4009 Palisades Drive
Weirton, West Virginia 26062

Dear Mr. Bernabei:

This is to transmit a draft copy of the Performance Review of the West Virginia Pharmaceutical Cost Management Council conducted as part of the Departmental Review of the Department of Administration. The report is scheduled to be presented during an August 24-26, 2008 interim meeting of the Joint Committee on Government Operations and the Joint Committee on Government Organization. We will inform you of the exact time and location once the information becomes available.

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We request that you not disclose the report to anyone not affiliated with the Council. If you have any questions, please feel free to contact Ms. Kueck. Thank you for your cooperation.

Sincerely,

A handwritten signature in cursive script that reads "Denny Rhodes".

Denny Rhodes
Research Manager

Joint Committee on Government and Finance

WEST VIRGINIA LEGISLATURE
Performance Evaluation and Research Division

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1900 Kanawha Boulevard, East
Charleston, West Virginia 25305-0610
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(304) 347-4939 FAX



John Sylvia
Director

August 12, 2008

Felice Joseph, Pharmacy Benefits Administrator
Public Employees Insurance Agency
State Capitol Complex
Building 5, Room 1001
Charleston, West Virginia 25305


Dear Ms. Joseph:

This is to transmit a draft copy of the Performance Review of the West Virginia Pharmaceutical Cost Management Council conducted as part of the Departmental Review of the Department of Administration. The report is scheduled to be presented during an August 24-26, 2008 interim meeting of the Joint Committee on Government Operations and the Joint Committee on Government Organization. We will inform you of the exact time and location once the information becomes available.

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Sincerely,


Denny Rhodes
Research Manager

Joint Committee on Government and Finance

WEST VIRGINIA LEGISLATURE
Performance Evaluation and Research Division

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1900 Kanawha Boulevard, East
Charleston, West Virginia 25305-0610
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John Sylvia
Director

August 12, 2008

Marsha Morris, Commissioner
Bureau of Medical Services
350 Capitol Street, Room 251
Charleston, West Virginia 25301


Dear Ms. Morris:

This is to transmit a draft copy of the Performance Review of the West Virginia Pharmaceutical Cost Management Council conducted as part of the Departmental Review of the Department of Administration. The report is scheduled to be presented during an August 24-26, 2008 interim meeting of the Joint Committee on Government Operations and the Joint Committee on Government Organization. We will inform you of the exact time and location once the information becomes available.

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Sincerely,


Denny Rhodes
Research Manager

_____ *Joint Committee on Government and Finance* _____

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(304) 347-4890
(304) 347-4939 FAX



John Sylvia
Director

August 12, 2008

Stephen Neal, RPh
The Health Plan
52160 National Road East
St. Clairsville, Ohio 43950-9365

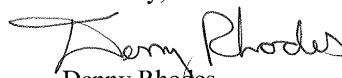
Dear Mr. Outterson-:

This is to transmit a draft copy of the Performance Review of the West Virginia Pharmaceutical Cost Management Council conducted as part of the Departmental Review of the Department of Administration. The report is scheduled to be presented during an August 24-26, 2008 interim meeting of the Joint Committee on Government Operations and the Joint Committee on Government Organization. We will inform you of the exact time and location once the information becomes available.

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Denny Rhodes
Research Manager

Joint Committee on Government and Finance

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John Sylvia
Director

August 12, 2008

Kevin Outterson
Boston University School of Law
765 Commonwealth Avenue
Boston, Massachusetts 02215

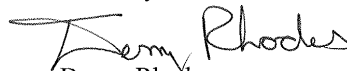
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Sincerely,


Denny Rhodes
Research Manager

————— *Joint Committee on Government and Finance* —————

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John Sylvia
Director

August 12, 2008

Wayne C. Spiggle, M.D.
Route 2, Box 97
Keyser, West Virginia 26726

Dear Dr. Spiggle:

This is to transmit a draft copy of the Performance Review of the West Virginia Pharmaceutical Cost Management Council conducted as part of the Departmental Review of the Department of Administration. The report is scheduled to be presented during an August 24-26, 2008 interim meeting of the Joint Committee on Government Operations and the Joint Committee on Government Organization. We will inform you of the exact time and location once the information becomes available.

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Handwritten signature of Denny Rhodes in black ink.
Denny Rhodes
Research Manager

Joint Committee on Government and Finance

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1900 Kanawha Boulevard, East
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John Sylvia
Director

August 12, 2008

Leah Summers
Government and Public Relations
Mylan Laboratories, Inc.
1500 Corporate Drive, Suite 400
Canonsburg, Pennsylvania 15317

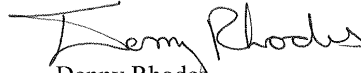
Dear Ms. Summers:

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Sincerely,


Denny Rhodes
Research Manager

_____ *Joint Committee on Government and Finance* _____

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1900 Kanawha Boulevard, East
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(304) 347-4939 FAX



John Sylvia
Director

August 12, 2008

Sandra Vanin, Commissioner
Bureau of Senior Services
1900 Kanawha Blvd., East
Charleston, West Virginia 25305

Dear Ms. Vanin:

This is to transmit a draft copy of the Performance Review of the West Virginia Pharmaceutical Cost Management Council conducted as part of the Departmental Review of the Department of Administration. The report is scheduled to be presented during an August 24-26, 2008 interim meeting of the Joint Committee on Government Operations and the Joint Committee on Government Organization. We will inform you of the exact time and location once the information becomes available.

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Denny Rhodes
Research Manager

Joint Committee on Government and Finance

WEST VIRGINIA LEGISLATURE
Performance Evaluation and Research Division

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1900 Kanawha Boulevard, East
Charleston, West Virginia 25305-0610
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John Sylvia
Director

August 12, 2008

Martha Yeager Walker, Secretary
Department of Health & Human Resources
State Capitol Complex
Building 3, Room 206
Charleston, West Virginia 25305


Dear Secretary Walker:

This is to transmit a draft copy of the Performance Review of the West Virginia Pharmaceutical Cost Management Council conducted as part of the Departmental Review of the Department of Administration. The report is scheduled to be presented during an August 24-26, 2008 interim meeting of the Joint Committee on Government Operations and the Joint Committee on Government Organization. We will inform you of the exact time and location once the information becomes available.

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Sincerely,


Denny Rhodes
Research Manager

Joint Committee on Government and Finance

Appendix B: The Pharmaceutical Advocate's letter to the President and Speaker



West Virginia Pharmaceutical Cost Management Council

June 13, 2008

President Earl Ray Tomblin
Speaker Richard Thompson
Joint Committee on Government and Finance
Capitol Complex, Main Building
Charleston, West Virginia 25305

Dear Mr. President and Mr. Speaker:

During the May 22, 2008, Joint Committee on Government and Finance meeting, President Tomblin asked for clarification as to why the amount that Medicaid spent on pharmaceuticals in state fiscal year 2007 was shown as \$305,342,895 on the Medicaid report and \$180,711,842 on the report compiled by the Pharmaceutical Advocate Office. The email used as the source for the data used by the Pharmaceutical Advocate is attached at **Appendix A**. As the President surmised, the amount shown on the chart prepared by the Pharmaceutical Advocate's Office was net of any manufacturer rebates and the amount shown on the Medicaid report was a gross amount not including the rebates.

President Tomblin also inquired as to any savings realized by the Department of Health and Human Resources as a result of the activities of the West Virginia Pharmaceutical Cost Management Council. General information on several initiatives was shared. Following is a full description of those efforts with the source data.

Savings to the Bureau for Medical Services (the Medicaid agency) through the use and state expansion of the federal 340b program.

As you know, 340b is a federal public health pricing program. Drugs available through 340b are approximately **51% off the average wholesale price** which is **18% lower than Canadian prices**. **All patients** of participating clinics are eligible to buy drugs at the 340b price.

Each 340b entity is required to provide pharmaceuticals dispensed from its 340b inventory to the Medicaid program at the 340b price plus a reasonable dispensing fee. To encourage 340b-eligible entities to offer pharmaceutical services and dispense 340b drugs to Medicaid members, the Pharmaceutical Advocate facilitated negotiations between the Medicaid program and the West Virginia Primary Care Association in January 2006. Following those successful negotiations, the Medicaid program submitted a 340b state plan amendment with the agreed upon dispensing fee which became effective on May 19, 2006.

Page 1 of 3

Building 1, Room M-146 | 1900 Kanawha Blvd, East | Charleston, WV 25305
Phone (304) 558-0079 | Fax (304) 558-8158
www.pharmacycouncil.wv.gov

In May 2006, the Pharmaceutical Advocate in consultation with the Pharmaceutical Cost Management Council provided one-time start-up funds to two primary care centers to develop in-house pharmacies. Three other clinics subsequently received start-up funds for in-house pharmacies. (**Appendix B**).

Tina Bailes, the Chief Financial Officer for Medicaid, stated in a report from July 2007, "Annualizing these results produced avoided costs of approximately **\$725,000.**" Her report further stated a projected the net savings of **\$181,352.40.** (**Appendix C - email from Ms. Bailes, spreadsheet showing cost-avoidance and savings and bar-chart showing savings**). Ravenswood, one of the first clinics to receive a start-up grant to develop in-house pharmacy services, shows a first-year savings of \$17,010.17 to the Medicaid program. Not including growth in patients using the pharmacy, Ravenswood is projected to recoup all the state's initial \$60,000 investment in just over 3 years with ongoing annual savings after that. An updated 340b report has been requested from the Medicaid program.

Savings to the state facilities of the Bureau for Behavioral Health and Health Facilities through contract negotiations and joining a group purchasing organization

At the request of the then-Chief Financial Officer for State Facilities, Doug Price, the Pharmaceutical Advocate assisted with contract negotiations for the state hospitals in January 2006. The Request for Proposals had yielded only one bid which was the current vendor. The current contract terms were "**cost of the product + 6%**" (**Appendix D - page 9 of the initial contract**). Through aggressive negotiations and the addition of the Department of Education and the Arts, and the Division of Rehabilitation Services pharmacy, the new contract terms were "**cost less .175%.**" (**Appendix D - page 10 of the contract - Contract signed by Pharmaceutical Advocate, DHHR and the vendor**) Pharmaceutical spending at the DHHR hospitals decreased from \$3,023,353.76 in SFY '06 to \$2,905,257.31 in SFY '07, a difference of **\$118,096.45** (Source data for drug spending in **Appendix A**).

Subsequently, the West Virginia Pharmaceutical Cost Management Council used its purchasing exemption to enter into a group purchasing organization known as the Minnesota Multi-State Contracting Alliance for Pharmacy (MMCAP - 45 states, the City of Chicago and the City of Los Angeles) on behalf of the state hospitals in September 2006. (**Appendix E - Contract signed by the Pharmaceutical Council Designated Chair, DHHR, the Attorney General and the Vendor**). The hospitals began using MMCAP in April 2007. The MMCAP contract provides pharmaceuticals at **cost less .63% and a year-end administrative credit** based on the volume of pharmaceuticals purchased from the MMCAP contract (**Appendix E**). The Office of the Pharmaceutical Advocate is currently soliciting verbal bids for an audit of the agency use of the contract to determine cost savings and any procurement or inventory practices that can be modified to maximize the savings.

Savings to the Division of Threat Preparedness, Bureau for Public Health

In Summer 2006, the Acting State Health Officer, Dr. Cathy Slemp, requested assistance from the Pharmaceutical Advocate in finding optimum pricing for antibiotics.

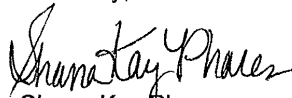
The Bureau for Public Health had received funding from the federal government to create an antibiotic cache to prepare for biologic events. Two requests for proposals resulted in no bidders that met the requirements of the Bureau for Public Health. The federal funds needed to be expended by August 31, 2006 or returned. The Pharmaceutical Advocate, through contact with MMCAP, learned that the Veterans' Administration was permitting limited access to its pricing schedule (the best of any commercial or government pricing available) for the purchase of antibiotics with federal funds. By using this avenue, the Bureau for Public Health was able to purchase **33% more antibiotics**. The only exception was Cipro where the Bureau was able to purchase **39% more** than originally budgeted. (**Appendix F** - email from Mr. Schorr with percentages, email from Dr. Slemp showing comparisons of wholesaler prices and VA prices and associated correspondence).

Savings to the Family Planning Program, Office of Maternal Child and Family Health, Department of Health and Human Resources

In July 2006, Johnson and Johnson subsidiary Ortho-McNeil announced that it would raise prices of a number of its contraceptive products provided to Family Planning Programs from pennies a monthly cycle to more than \$15.00 per cycle. Following press reports and inquiries by Congress, Ortho-McNeil lowered its prices to \$3.20 per monthly cycle through the end of 2007 (**Appendix G**). The Pharmaceutical Cost Management Council used its purchasing exemption to enter the 340b Prime Vendor Program, a federal group purchasing organization, on behalf of the state Family Planning Program. Denise Smith, Director of the West Virginia Family Planning Program reported to the Council at its February 4, 2008 meeting that the program is saving money with the Prime Vendor Program; an annualized number is not yet available.

Should you have any questions or need more information, please call me at 558-0079.

Sincerely,



Shana Kay Phares
Governor's Pharmaceutical Advocate and Designated
Chair of the West Virginia Pharmaceutical Cost
Management Council

Attachments

cc: Members of the Joint Committee on Government and Finance
Aaron Allred, Legislative Auditor, Legislative Manager
Denny Rhodes, Research Manager, Performance Evaluation and Research Division
Meghan Kueck, Research Analyst Performance Evaluation and Research Division
Members of the WVPCMC

Appendix C: Letter from the Secretary of DHHR



**STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES**

Office of the Secretary
State Capitol Complex, Building 3, Room 206
Charleston, West Virginia 25305
Telephone: (304) 558-0684 Fax: (304) 558-1130

Joe Manchin III
Governor

Martha Yeager Walker
Secretary

July 2, 2008

Mr. Denny Rhodes
Research Manager
Performance Evaluation and Research Division
State Capitol Building, Room W-314
Charleston, West Virginia 25305-0610

Re: Pharmaceutical Cost Management Council

Dear Mr. Rhodes:

Thank you for the opportunity to respond to your letter dated June 25, 2008. I do not dispute or confirm any of the savings noted in the Pharmaceutical Advocate's letter to PERD. I would note that in a department where the Medicaid budget alone for pharmaceuticals is approximately \$181 million after rebates and the Department of Health and Human Resources' (DHHR) total expenditure is about \$192 million, the total savings listed —less than \$300,000 in actual dollars — is less than two tenths of one percent of our budget.

I applaud the Pharmaceutical Advocate for her efforts. Any savings stated in the letter have been a result of her work. I, as a member, do not see a positive role for the Pharmaceutical Cost Management Council. Because of its purchasing power and continued attention to national trends, the DHHR has and will continue to use every means available to reduce the cost of prescription drugs on its own initiative.

I hope this answers your questions. If you need any additional information, please let me know.

Sincerely,

A handwritten signature in cursive script that reads "Martha Yeager Walker".

Martha Yeager Walker
Secretary

Appendix D: Letter from the Health Care Authority

08/06/2008

02:27

WV HEALTH CARE AUTHORITY → 93474939

NO. 368

P02

Joe Manchin III
Governor



Sonia D. Chambers
Chair

Martha Yeager Walker, Secretary
West Virginia Department of
Health and Human Resources

Board Members
Sam G. Kapourales
Marilyn G. White

August 6, 2008

Denny Rhodes, Research Manager
West Virginia Legislature
Performance Evaluation and Research Division
Building 1, Room W-314
1900 Kanawha Boulevard, East
Charleston, West Virginia 25305-0610

Dear Mr. Rhodes:

I have received your letter of July 25th asking for the Health Care Authority's opinion on assuming responsibility for the pharmaceutical advertising reporting rule. I appreciate the opportunity to respond.

The Health Care Authority has a great deal of experience with health care data collection and analysis. However, we do not have any experience with pharmaceutical data or data related specifically to advertising.

I would respectfully suggest instead that the function be moved to the Pharmaceutical Advocate. The Advocate has much more knowledge and experience in the area.

Sincerely,

Sonia D. Chambers
Chair

SDC:lh

Appendix E: Agency Responses



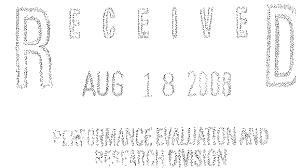
JOE MANCHIN III
GOVERNOR

STATE OF WEST VIRGINIA
DEPARTMENT OF ADMINISTRATION
OFFICE OF THE CABINET SECRETARY

ROBERT W. FERGUSON, JR.
CABINET SECRETARY

August 18, 2008

Mr. Denny Rhodes
West Virginia Legislature
Performance Evaluation and Research Division
Building 1, Room W-314
1900 Kanawha Boulevard, East
Charleston, WV 25305



Re: Department of Administration

Dear Mr. Rhodes,

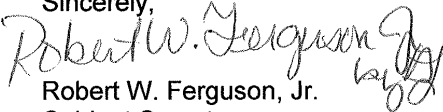
I am in receipt of your letter and report dated August 12, 2008, regarding the West Virginia Pharmaceutical Cost Management Council wherein you make the determination that the Secretary of Administration does not have the authority to designate the Pharmaceutical Advocate as chairperson of the council. First, as you note, there is no statutory prohibition in West Virginia Code § 5A-3C-8. What you do not point out is that the statute is no way ambiguous. Thus, the *in pari materia* approach to statutory interpretation your counsel employs is misplaced.¹ In the event you insist on reading the statutes together, you must reach the opposite conclusion. That is, had the Legislature desired to limit the Secretary's delegation authority, it could have easily done so as it did in West Virginia Code §§ 5A-1-7 and 5F-2-2.

Since not prohibited by statute, I designated the Pharmaceutical Advocate to serve as my designee in chairing the council as she has the requisite knowledge and experience and is able to commit the time necessary to effect the council's mission.

¹Furthermore, these statutes should not be read together because West Virginia Code §§ 5A-1-7 and 5F-2-2 are general provisions which simply acknowledge that the Secretary of Administration can not, by himself/herself, perform all duties prescribed by statute and sets forth, where not otherwise expressly authorized, the extent of his powers of delegation. On the other hand, West Virginia Code § 5A-3C-8 is an express provision permitting the Secretary to delegate a specific duty.

DEPARTMENT OF ADMINISTRATION
OFFICE OF THE CABINET SECRETARY

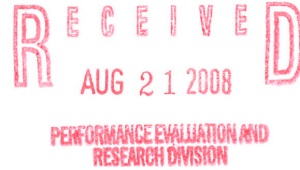
For the above stated reasons, I disagree with your aforementioned finding. As to the other issues in your report, I defer to the Pharmaceutical Advocate for a response. If you have any questions, or need any additional information, please do not hesitate to contact me.

Sincerely,

Robert W. Ferguson, Jr.
Cabinet Secretary



West Virginia Pharmaceutical Cost Management Council

August 21, 2008



By hand delivery

Denny Rhodes
Research Manager
Megan Kueck
Research Analyst
Performance Evaluation and Research Division
West Virginia Legislature
Building 1, Room W-314
Charleston, West Virginia 25305-0610

Dear Mr. Rhodes and Ms. Kueck:

Thank you for the opportunity to respond to the PERD Audit Review of the West Virginia Pharmaceutical Cost Management Council. This correspondence offers additional background on the PERD findings and addresses the PERD recommendations. Unfortunately, as discussed during the exit interview on August 19, 2008, because I was out of town for medical treatment the week of August 11, 2008, there was not an opportunity to discuss and resolve some of these issues before PERD staff had to finalize the report. If that opportunity had been available, it is likely that the agency and PERD staff would have presented report and response in near total agreement.

The Council's Effect on Lowering Pharmaceutical Drug Costs in West Virginia Has Been Minimal

Response: This finding omits savings to the general public. In this finding savings to the Executive Branch rely on old data and need additional background.

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**

Page 1 of 5 PCMC response to PERD report

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.

In terms of savings to the Medicaid program, the Bureau of Medical Services projected annual savings of \$181,352.40 and avoided costs of \$725,000 is based on data from January to March 2007 and was completed in July 2007. The data is 18-months old. An updated report was requested from the Secretary of the Department of Health and Human Resources on June 13, 2008. As additional sites were added over the 18-month period, it is anticipated that the report will show additional savings and cost avoidance.

The savings reported to the West Virginia state hospitals from state fiscal year 2006 to state fiscal year 2007 are a net of \$118,096.45. However, there are a number of mitigating factors including increase number of patients, prescribing practices and contract compliance that are suspected to have significantly diminished the potential savings. The Office of the Pharmaceutical Advocate is working with the Department of Health and Human Resources to design and complete an audit that will review the number of patients, prescribing practices and contract compliance.

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.

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.

6. If the Legislature decides to allow the Pharmaceutical Cost Management Council to continue, then the Legislative Auditor recommends that the Secretary of Administration or a designee under his authority be selected as chair of the Council.

The Secretary of Administration responded under separate cover to this recommendation.

7. The Legislative Auditor recommends that the Governor evaluate the effectiveness and necessity of the Office of the Pharmaceutical Advocate.

Although this recommendation is beyond the purview and scope of this audit, it will be taken under consideration. For the benefit of the members of the PERD committee and PERD staff, it must be clarified that while the Legislature has approved an annual appropriation of \$500,000 for the Pharmaceutical Advocate line-item in the Governor's Budget, the office has operated in a fiscally conservative manner. As of January 9, 2008, the Office had unencumbered balances for SFY '06 of \$218,878 and SFY '07 of \$311,229. These balances are used to fund one-time investments in pharmacy projects that reap a positive return on investment for the state and its citizens.

Again, the Council appreciates the opportunity to respond to this report and is appreciative of the professional staff of PERD. If you need additional information or have any questions, please call me at 541-3324.

Sincerely,



Shana Kay Phares
Designated Chair, Pharmaceutical Cost Management
Council and Acting Pharmaceutical Advocate

cc: PERD Committee Members
WVPCMC Members via email and hard copy



STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

Joe Manchin III
Governor

Office of the Secretary
State Capitol Complex, Building 3, Room 206
Charleston, West Virginia 25305
Telephone: (304) 558-0684 Fax: (304) 558-1130

Martha Yeager Walker
Secretary

August 25, 2008

Hand Delivered



PERFORMANCE EVALUATION AND
RESEARCH DIVISION

Mr. Aaron Allred
Legislative Manager
West Virginia Legislature
State Capitol Building, Room W-314
Charleston, West Virginia 25305

Re: PERD audit review of West Virginia Pharmaceutical Cost Management Council

Dear Aaron:

I have reviewed the final report and the response of the Pharmaceutical Advocate. I will note that the Department of Health and Human Resources has provided all information requested by the Advocate and that I stand by the assertion that the Pharmaceutical Cost Management Council has been unable to provide any substantial, substantiated savings to the Medicaid Pharmacy Program or to the Bureau for Behavioral Health and Health Facilities.

If the Council is continued, I would urge it expand its interest in pharmaceuticals to all state payors and not limit itself to the Department of Health and Human Resources.

Sincerely,

A handwritten signature in cursive script that reads "Martha Yeager Walker".

Martha Yeager Walker
Secretary

cc: Jim Pitrolo, Office of the Governor
Shana Phares, Office of the Governor
Marsha Morris, Commissioner, Bureau for Medical Services
John Bianconi, Commissioner, Bureau for Behavioral Health and Health Facilities

Megan B. Kueck

From: Steve Neal [sneal@healthplan.org]
Sent: Tuesday, August 19, 2008 9:12 AM
To: mkueck@mail.wvnet.edu
Cc: jjrphrx@prodigy.net; sphares@wv.gov.org
Subject: Pharm Cost Management Council.

Sorry for my tardy response, I was out of the office till this morning. I only have small comment.

The council initially was involved in an attempt to consolidate the purchasing of drugs by various state agencies into one collaborative purchasing group. Things quickly changed. Worker's comp went private; Medicaid was faced with other problems of claw back of Medicare payments with the advent of Medicare Part D etc.

The focus changed to high level efforts to contain costs. Some were very successful. Advertising rule is not something to hang your hat on. 340B efforts and central fill concepts are note worthy.

I am one of the over the phone folks. To attend in person would require a six hour round trip. It could be accomplished but the council usually set the meeting in odd times for private working folks, especially Mondays and Friday meeting in the afternoon. The pharmacists on the council have their greatest patient loads at those times.

I speak on this because I am recommending the council dissolve into an advisory group to the pharmacy advocate. I realize legal work would be needed for this to happen. Yet, timeliness and efficiencies would increase from the office of the advocate. Shana has done a great job and I believe your office has captured that assumption in your report. Yet, she is not a healthcare professional, and more importantly not a pharmaceutical care provider. Therefore is an advisory board develops it should include pharmacists that deal with purchasing, (institutional practice) payers (formulary managers from insurance carriers) and practicing pharmacists in the community. I am afraid if the advisory board gets too polarized with consumers, the theme of the board will be what patients want for pharmacy care instead of what they need to deal with the diseases affecting our fellow West Virginians.

Thanks

Steve

Megan B. Kueck

From: Outterson, Michael Kevin [mko@bu.edu]
Sent: Wednesday, August 13, 2008 6:01 AM
To: Megan B. Kueck
Subject: RE: West Virginia Pharmaceutical Cost Management Council Performance Evaluation

My responses:

The central fill pharmacy was a major initiative of the Council and a major success.

Likewise, the advertising rule is one of only a few states that have pulled this off. It will take some time for this data to collect and be useful. If the Council terminates, the Rule should be administered by the Pharmaceutical Advocate.

The ad rule took so long because we negotiated for a long time to reconcile consumer and drug company interests. We were successful in the end - all of the companies complied and no one sued. This is a major accomplishment.

The problem with the structure of the Council are voting agency heads - as time went on, they became less interested and worried about the politics of their votes. It is good to have them at Council meetings (expertise in how the government works) but they shouldn't vote. Add consumer and academic and business people instead as voting members, with a strong outside chair.

I attended more meetings in person than anyone on the Council over the past 4 years. Why exactly are Massachusetts residents not good for the Council? Are we being insular on purpose?

Kevin Outterson

-----Original Message-----

From: Megan B. Kueck [mailto:mkueck@wvnet.edu]
Sent: Tue 8/12/2008 5:37 PM
To: Outterson, Michael Kevin
Subject: West Virginia Pharmaceutical Cost Management Council Performance Evaluation

Dear Mr. Outterson:

This is to transmit a draft copy of the Performance Review of the West Virginia Pharmaceutical Cost Management Council conducted as part of the Departmental Review of the Department of Administration. The report is scheduled to be presented during an August 24-26, 2008 interim meeting of the Joint Committee on Government Operations and the Joint Committee on Government Organization. We will inform you of the exact time and location once the information becomes available.

Transmittal of this report also provides you the opportunity to provide a written response to the report. If you would like to provide a response to the report, please do so by noon on August 18, 2008 in order for it to be included in the final version of the report. If you do not plan to provide a response, please contact Megan Kueck, Research Analyst at 304-347-4890 or at mkueck@mail.wvnet.edu.

We request that you not disclose the report to anyone not affiliated with the Council. If you have any questions, please feel free to contact Ms. Kueck. Thank you for your cooperation.

Megan Kueck

Research Analyst

West Virginia Legislative Auditor's Office

Performance Evaluation and Research Division

Building 1, Room W-314, State Capitol

Charleston, WV 25305-0610

Telephone (304)347-4890

Direct Line (304) 347-4900

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<mailto:mkueck@mail.wvnet.edu> mkueck@mail.wvnet.edu



WEST VIRGINIA LEGISLATIVE AUDITOR

PERFORMANCE EVALUATION & RESEARCH DIVISION

Building 1, Room W-314, State Capitol Complex, Charleston, West Virginia 25305

telephone: 1-304-347-4890 | www.legis.state.wv.us/Joint/PERD/perd.cfm | fax: 1-304-347-4939