EPIC Pharmacies, Inc.

July 23, 2010

Dear Virginia member:

After more than a year of effort, we've made significant progress on addressing your concerns about PBM audits. I explain a little more about this below, but I want to stress that **THIS PROGRESS WON'T BE MEANINGFUL UNLESS YOU LET US KNOW WHEN YOU HAVE AUDIT PROBLEMS**.

For a number of years, EPIC Pharmacies has heard its members express concerns about how the PBM industry handled pharmacy audits, whether "on site" or in the form of a "desk audit." In 2009 EPIC Pharmacies requested legislation in Virginia to regulate pharmacy audit procedures. The legislation, patroned by Del. Lee Ware, focused on due process and business courtesy.

The PBM industry, represented by the Virginia Association of Health Plans, Medco, Express Scripts, and CVS Caremark, participated in a series of meetings with the pharmacy community to discuss alternatives to legislation. These discussions were very positive, and the parties were able to reach a general consensus on Recommended Best Practices for pharmacy audits. Those recommendations have now been incorporated into a document that we will be providing to you shortly. A few examples of the Recommended Best Practices are:

- Notice of an audit should be in writing and given at least 14 days in advance
- PBM should provide a contact person with authority to resolve audit issues
- On site audits should be conducted during the pharmacy's regular business hours
- Audits should not be scheduled to begin during the first week of the month or on a Monday
- Audits should go back no more than 2 years
- Chargebacks should not occur until the pharmacy has had ample time to correct the records

Naturally, not all of the PBMs agree with all of the Recommended Best Practices. At this point, the Recommended Best Practices are simply recommendations and are not binding on the PBMs. However, the PBMs have stated that the recommendations are reasonable and a good basis for continuing dialogue. Accordingly, EPIC Pharmacies, along with other Virginia pharmacists, will continue discussions with the PBMs in order to solidify the industry's commitment to due process and business courtesy. It is our hope that at the end of this process the Recommended Best Practices, as amended, will be adopted by all of the PBMs.

The complete list of Recommended Best Practices will be posted in the Members Only section of the EPIC website (**Select**: Buying Group – Documents – News). The website will also include this letter, a letter from the Virginia Association of Health Plans which describes the efforts of both sides to reach this interim agreement.

This is a good opportunity to remind each of you to make sure that EPIC has your current e-mail address, and to make sure that you update your information whenever your e-mail or store address or telephone or FAX numbers change.

As I said above, we are very proud of the progress that has been made, and we want the Recommended Best Practices to be adopted as broadly as possible. But we also need to make sure that they are ***working***, and this means that you have to **LET US KNOW IF THEY ARE NOT**. That's the only way we can make improvements and clear up confusion.

Thanks, and please let us know if we can be of assistance.

Cordially,

M. Keith Hodges RPh

VIRGINIA ASSOCIATION
OF HEALTH PLANS

804-648-8466 phone · 804-648-8036 fax · 1111 East Main Street, Suite 910 · Richmond, VA 23219
Email: info@vahp.org · Website: www.vahp.org

May 28, 2010

Mr. Alexander Macaulay
Macaulay and Burtch, P.C.
Attorneys at Law
The Branch Building
1015 East Main Street
Richmond, Virginia 23219-3527

Dear Alexander:

This letter describes the progress made by you and your staff in working with affected parties to address concerns brought forth by EPIC Pharmacies (and other pharmacy groups) regarding pharmacy audits conducted by pharmacy benefit managers, health plans and their contractors. We appreciate the constructive efforts of your clients, and particularly Gerry Milsky in your office, as we all worked to better understand these issues over the last year.

House Bill 1650, which was introduced on behalf of EPIC Pharmacies (and other pharmacy groups) by Delegate Lee Ware during the 2009 General Assembly Session, raised a lengthy list of concerns about the administrative conduct of pharmacy audits. Requirements included addressing notice of audits, nondiscrimination, use of a licensed pharmacist to assist the auditor, provision of preliminary audit reports, use of extrapolations, charging interest, recovery or setoff for any overpayment or denial of claims, and issues of scheduling and timing.

In an effort to get more information about the concerns and the parties involved, representatives of EPIC Pharmacies, other pharmacy groups, the Virginia Association of Health Plans and three of the pharmacy benefit managers (Medco Health Solutions, Express-Scripts, and CVS Caremark) agreed to engage in a series of meetings to discuss non-legislative solutions to address many of the identified issues.

Shortly after the introduction of House Bill 1650 (12/18/08) representatives of the interested parties had a meeting to discuss the legislation and agreed to convene representatives of the principals together so that both groups could understand the issues.

At the first large group meeting (12/22/08) representatives of the Virginia Pharmacists Association, Virginia Association of Chain Drug Stores, EPIC Pharmacies, Virginia Association of Health Plans, CVS Caremark, Medco and Express Scripts were present. Pharmacists and their representatives

described a series of administrative, communication and policy concerns that were represented in the legislation and attempted to describe the sources of their frustration.

After a healthy discussion and exchange of ideas, the group identified key policy concerns, divided up the research workload to review the issues and agreed to put aside the legislation and work together during the off session. Of particular concern were policies regarding extrapolations, hiring of subcontractor auditors paid on a contingency basis, notification of audits, standards for accepting a prescription and recouping of days supplies.

After the legislative session, the second large group meeting (5/5/09) took place at the offices of Williams Mullen. Representatives of health plans (many of which operate their own PBMs), Medco, CVS Caremark, and Express Scripts reported on some of the major issues that had been identified at their previous meeting.

It was acknowledged by the parties that the health plans and PBMs participating in the discussions were not representative of all the entities interacting with pharmacists in regard to auditing issues. The Department of Medical Assistance Services (Medicaid) and smaller PBMs were recognized as opportunities for pharmacists to engage individually in addition to the current process. Although there was explicit recognition that the health plans and PBMs were not necessarily the source of all of the pharmacists' major concerns, specific practices by specific entities were identified as a result of the meeting, as well as a desire for recognition of the need for some form of "industry best practices" that could be utilized as a model for pharmacy audits by the participants at the meeting and other entities as well.

Before adjourning the May 5th meeting, the principal representatives asked (on behalf of pharmacists) Alexander Macaulay and Gerald Milsky, and (on behalf of health plans and PBMs) Reggie Jones, Doug Gray, and representatives of the Medco, Express-Scripts and CVS Caremark, to collect provider manuals for pharmacy audits and to attempt to describe a general non-binding best practices document by assimilating the data.

After some discussion during the remainder of May and June 2009, the designated representatives agreed that it would be most appropriate to proceed by having each entity meet individually with Messrs. Macaulay and Milsky as well as pharmacist representatives to discuss and respond to a forty question pharmacy audit questionnaire drafted by Mr. Milsky. (attached)

Mr. Milsky collected the provider manuals of the major plans and PBMs, combed through their many pages to identify the answers to various questions or to determine whether the manual was silent on the issue at hand. PBMs and plans expressed some anti-trust concerns regarding meeting collectively about the questionnaire. All agreed to bring in appropriate regulatory and pharmacy staff (many from out of town) from the PBMs/plans and to meet individually with Mr. Macaulay, Mr. Milsky and pharmacy representatives. The meetings took place on the following dates:

- July 10, 2009: Medco Meeting at Macaulay & Burtch
- July 14, 2009: Virginia Association of Health Plans Meeting at Macaulay&Burtch
- Sept 23, 2009: CVS Caremark Meeting at Macaulay & Burtch
- Oct. 6, 2009: Express Scripts Meeting at Macaulay & Burtch

Mr. Milsky assimilated the results of each meeting to keep a running tally of the responses to the questions in the Pharmacy Audit Questionnaire. He then designed a suggested best practice standard based on the response to each question and created a new document entitled PBM Pharmacy Audit Suggested Best Practices that is attached to this letter.

The PBM Pharmacy Audit Suggested Best Practices document is designed for (a) pharmacists to assist them and their office staff in knowing what to expect when dealing with a pharmacy audit, and (b) entities conducting pharmacy audits to assist them in identifying practices that will improve both the actual and perceived audit process problems for pharmacies. EPIC Pharmacies representatives (and other pharmacy groups) have agreed to share the PBM Pharmacy Audit Suggested Best Practices document as an internal educational effort with a disclaimer that the practices described are not endorsed by any single entity as a binding standard. They are an educated approximation of (a) current practices in the marketplace according to Mr. Milsky's research and information collected during meetings with the parties, or (b) practices that pharmacists, health plans, and PBMs feel are reasonable and subject to implementation without undue cost or effort.

The PBM Pharmacy Audit Suggested Best Practices document is intended by all parties to be a "living" document, and it is fully expected that the document will evolve as pharmacists, health plans, and PBMs initiate their efforts to implement the suggested best practices.

The health plans and PBMs that have participated in this cooperative effort have promised their cooperation by individually identifying staff to work with Mr. Macaulay, Mr. Milsky and other pharmacy representatives to identify and resolve pharmacy audit policy concerns on an ongoing basis.

Thanks again for your hard work on this cooperative project.

Best regards,

Doug Gray
Executive Director
Virginia Association of Health Plans

Attachments (2)

PBM Pharmacy Audit Suggested Best Practices

	SUGGESTED BEST PRACTICE
NOTIFICATION (assuming no documented evidence of fraud)	
1. How much written notice do you provide prior to the beginning of a regular on-site audit?	Notice should be provided to the pharmacy no less than 14 days prior to the beginning of an on-site audit. Notice should be in writing, and should include a handbook explaining all aspects of the audit process.
2. How many days prior notice do you provide of a desk audit?	No prior notice required. However, the desk audit notification should include access to a handbook explaining all aspects of the desk audit process.
3. What is your deadline for a pharmacy to respond to a desk audit? **An on-site autit?**	The pharmacy's response should be provided within 10 days for a desk audit. 30 days
4. How many days notice do you give for a compliance audit?	If a compliance audit is to be conducted, the pharmacy should be given the same notice as is given for an on-site audit.

SUBCONTRACTING & CONTINGENCY PAYMENTS	
5. Who are your sub-contractors?	If subcontractors are to be utilized, the pharmacy should be informed of this.
6. Is compensation of sub-contractors or direct employees subject to any form of contingency or bonus formula? **If yes, please explain.**	Compensation of subcontractors should never be subject to any form of contingency or bonus formula.

PBM Pharmacy Audit Suggested Best Practices

	SUGGESTED BEST PRACTICE
SCHEDULING	
7. Do you restrict on-site audits to normal business hours (i.e. 9:00 a.m. until 5:00 p.m.)?	On site audits should be conducted during the pharmacy's regular business hours, and auditors should attempt to avoid the pharmacists' busiest hours.
8. Do you begin audits during the first week of the month?	Regular audits should not be scheduled during the first week of the month.
9. Do you begin audits on Mondays?	Regular audits should not be scheduled to begin on Monday.
10. Will you re-schedule an on-site audit if requested by the pharmacy? What factors are considered in granting such requests?	Reasonable efforts should be made both by the auditor and the pharmacy to find a date for the audit that works for both sides.
11. Do you notify pharmacies if an audit is postponed or rescheduled? How many days notice of such change is provided? How is this notice delivered?	Except in emergencies, the pharmacy should be given at least 7 days' notice if an audit is to be postponed or rescheduled. Notice should be both in writing (or e-mail) and by telephone to work out the rescheduled date.
12. How and when do you notify the pharmacy if the auditor's schedule changes for a particular day?	The pharmacy should be notified the prior day, if possible, or first thing in the morning. Either the PBM or the auditor may be responsible for notification.

RECORDS REQUESTS	
13. Do you provide the pharmacy with a specific list of claims/scripts/files/ records, etc. to be audited in advance of the beginning of the audit?	Pharmacy should be provided with the range of scripts by #s.

PBM Pharmacy Audit Suggested Best Practices

	SUGGESTED BEST PRACTICE
14. How many days in advance do you inform the pharmacy of the specific information to be audited?	Pharmacy should be provided at least 10 working days prior notice to allow time to pull the files.
15. How many years back do you audit?	No more than 2 years

AUDIT STANDARDS	
16, Do you apply the same rules as the Board of Pharmacy to determine the validity of prescriptions, refills, changes in prescriptions, etc. such as written, telephonic, FAX, electronic, etc.?	Any prescription that is issued in compliance with Virginia law and regulations should be accepted.
17. Do you identify and reimburse underpayments to the pharmacy as part of the audit?	Yes, if the pharmacy brings it to their attention or if is discovered during the audit. Adjustments are also made on an ongoing basis during random daily audits.
18. Days' supply issues – do you recoup all monies as opposed to just the overage when there is a days' supply discrepancy?	Only the overage should be recouped, and only subsequent to expiration of appeal period.
19. Provider identification discrepancies – do you charge back all monies paid on a claim if the provider's prescriber number (such as DEA # or NPI #) is incorrect?	Chargebacks should not be made until the pharmacy has had ample time to perfect the claim by providing the correct information.
20. Are there any circumstances under which you will utilize extrapolation in determining amounts subject to recoupment? If so, please explain.	Extrapolation should not be permitted under any circumstances.

PBM Pharmacy Audit Suggested Best Practices

	SUGGESTED BEST PRACTICE
21. Do you extrapolate on % of drugs dispensed compared with purchasing invoices? (i.e. X% of scripts were a certain drug but a different percent of total purchases were for that drug)	Extrapolation should not be permitted. Audit may include purchase invoice verification – i.e. did the pharmacy purchase enough units to cover the amounts dispensed and paid by the PBM.
22. Do you require a pharmacy to request a re-signed prescription where the documentation is alleged to be unclear, illegible or needs clarification for any other reason? **If yes, do you charge the amount back to the pharmacy if the prescriber does not respond to the request?**	Auditor should require either a re-signed script or a letter from the physician, and the pharmacy should not be charged back for the script until the appeal process has been completed.
23. Under what circumstances do you contact a prescriber directly in connection with an audit? **If such contact occurs, is the pharmacy given notice of such contact?**	Prescriber may be contacted directly, but pharmacy should be informed of this simultaneously.
24. Do you limit the duration of an audit? Please explain, including differences for on-site and desk audits?	General goal for audit completion should be included in notification materials, with the understanding that circumstances may require a longer (or shorter) period of time.
25. Do you notify the pharmacy of the expected duration of an audit?	General goal for audit completion should be included in notification materials, with the understanding that circumstances may require a longer (or shorter) period of time.

PBM Pharmacy Audit Suggested Best Practices

	SUGGESTED BEST PRACTICE
POST-AUDIT	
26. Do you accept post-audit prescriber authorizations?	Yes, including black & white scans.
27. What is your deadline for delivery of discrepancy reports to the pharmacy?	Discrepancy reports should be provided to the pharmacy within 30 days following conclusion of the audit.
28. Who reviews the auditors' discrepancy reports, preliminary reports, and final reports?	All discrepancy reports, preliminary reports, and final reports should be reviewed by a managerial level representative of the PBM who is a licensed pharmacist.
29. Do you give the pharmacy a direct contact person who is knowledgeable of pharmacy audits and authorized to resolve audit issues?	At the beginning of the audit, the pharmacist should be provided with the name, title and contact information for a licensed pharmacist at the PBM with management authority to resolve audit issues.
30. What is your deadline for responding to audit inquiries from pharmacies?	The licensed pharmacist with management authority at the PBM should be required to respond to audit inquiries within 14 days.
31. What is your deadline for issuing preliminary audit reports?	Preliminary reports, subsequent to internal review by the PBM, should be issued within 21 days after conclusion of the audit.
32. What is your procedure for appeals of discrepancy reports or preliminary audit reports?	Appeals by the pharmacy of discrepancy reports and preliminary reports should be required to be filed within 30 days of receipt of the discrepancy report or preliminary report. Specific response times for the PBM to respond to the appeal should be clearly stated, including additional levels of appeal to higher PBM management where appropriate.
33. Do you have a clear written explanation of your appeal process, and do you provide this written explanation to a pharmacy prior to or during the audit?	Each PBM should have a clear and understandable appeal process, through the licensed pharmacist contact, that is provided in writing to the pharmacy at the beginning of the audit. This appeal process should include appeals of discrepancy reports, preliminary reports, and final reports.

PBM Pharmacy Audit Suggested Best Practices

	SUGGESTED BEST PRACTICE
34. What is your deadline for responding to pharmacy appeals?	Deadline for responding should be the same amount of time granted to the pharmacy to submit an appeal.
35. What is your deadline for the pharmacy to respond to the appeal determination?	Deadline for pharmacy to respond to appeal determination should be the same amount of time granted to the PBM to respond to the original appeal.
36. What is your deadline for issuance of the final audit report?	Subsequent to completion of all appeals, the final report should be issued within 30 days.
37. Do you implement charge backs, recoupment, or any other penalties upon the pharmacy prior to resolution of appeals?	No chargebacks, recoupment or other penalties should be assessed until the appeal process has been exhausted and the final report issued.

ADMINISTRATION	
38. Do you have a written audit policy and procedure manual covering desk audits, on-site audits, and compliance audits? **If so, do you provide it to the pharmacy prior to or as a part of the audit process?** **If you have a manual, please provide a copy along with your responses to this questionnaire.**	Each PBM should, separate and apart from the standard contract and/or manual, create a set of audit procedures, including all notice, timing, appeal and other related information so that the pharmacy has a singe source of reference for audits. It is recommended that the audit guide be provided in printed form along with the initial notification of the audit, and also be made available on line.
39. Do you provide pharmacies with a chargeback guide? If so, please provide a copy along with your responses to this questionnaire.	The chargeback guide, along with any other specific audit-related material, should be included in the separate audit procedures guide.

PBM Pharmacy Audit Suggested Best Practices

	SUGGESTED BEST PRACTICE
40. Do you or your subcontracted auditors share audit information about an audited pharmacy with other pharmacy administrators or auditors?	Where not otherwise superseded by state or federal law, audit information should not be shared. PBM auditors should have access to previous audit reports on the pharmacy that were conducted by the same PBM.