

Pharmacy Benefit Manager Agreements in the TDSPA Environment

IMPORTANT NOTE-PLEASE READ

This document, **and the suggested draft provisions [and the draft amending agreement attached hereto (the “Amending Agreement”)]**, was prepared by the Ontario Pharmacists Association (the “OPA”) to assist members (many of whom are small businesses) in assessing their own pharmacy benefit management agreements (“PBM Agreements”) in light of private sector developments in Ontario following the passage of the Transparent Drug System for Patients Act, 2006 (TDSPA, formerly Bill 102).

This document is intended to contribute to the development and utilization of systems, forms, methods, procedures and standards in the pharmacy industry in Ontario. In order to comply with the *Competition Act*, the OPA does not mandate or endorse any particular approach to amending these PBM Agreements, including with regard to mark-ups, professional allowances, professional fees, professional services and the provision of services generally. No suggested mark-ups, professional allowances, or professional fees are provided in this document. While examples of other terms are provided, they are merely examples. Members are free to, and will need to, determine their own approaches to these matters, in their own independent business judgment.

OPA has developed a document entitled **Financial Impact Assessment of the Private Sector in Ontario following the passage of the Transparent Drug System for Patients Act, 2006 (formerly Bill 102)**. This document is available to OPA members to help members understand the overall financial impact, and assess the effect of the TDSPA on their own business.

In order to comply with the *Competition Act*, members must not consult upon, co-ordinate or agree upon their approaches to amending their PBM Agreements with each other. The *Competition Act* sets out severe criminal penalties for agreements or arrangements among competitors which lessen competition. The OPA does not monitor or co-ordinate members’ activities regarding PBM Agreements, nor does it advise or act as an agent for members in commercial negotiations.

Further, this document and the information contained in this document is for educational purposes only and does not, nor is it intended to, provide legal advice or recommendations. This document and the information contained in this document are provided as a resource to facilitate discussions between you and your legal counsel. You will need to review each of your current PBM Agreements carefully with your legal counsel. OPA cannot be responsible for the consequences of any actions taken or not taken in reliance upon this document.

Current PBM Agreements

Undoubtedly all of your current PBM Agreements were entered into with the pharmacy benefit management providers (the “PBMs”) prior to the introduction of the TDSPA. Together with your legal counsel, you will need to review these PBM Agreements very carefully to determine the impact of the current provisions on your business in the TDSPA environment.

The OPA’s third party payor committee (the “Committee”) has identified eight issues that you and your legal counsel may wish to address in your review of the PBM Agreements. These eight issues are listed below:

- 1. Most of the PBM Agreements contain provisions that allow the PBM to change the PBM Agreement, the pharmacy manual, or the payment and reimbursement schedule without the consent of pharmacy by providing notice to pharmacy.**
- 2. Some of the PBM Agreements do not allow pharmacy to charge patients the difference between the usual and customary retail price and the price reimbursed by the PBM.**
- 3. As a result of the changes imposed by the TDSPA, the economics of the relationship entered into with the PBM under the PBM Agreement may need to be reviewed and revised.**
- 4. Pharmacy has experienced some issue with the PBMs changing their systems or system design features such that real time adjudication is negatively impacted.**
- 5. Provisions in the PBM Agreements that allow the PBM to reclaim or “claw back” adjudicated and accepted claims are confusing and unclear and are inequitable where no error was committed by pharmacy.**
- 6. Many of the PBM Agreements do not place limits on the scope of the audit process.**
- 7. The PBM Agreements may try to impose standards which are higher than those imposed by the Ontario College of Pharmacists which can be disruptive to pharmacy practice.**
- 8. The privacy provisions of the PBM Agreements may not be compliant with the requirements of applicable privacy legislation.**

DISCUSSION

1. Most of the PBM Agreements contain provisions that allow the PBM to change the PBM Agreement, the pharmacy manual or the payment and reimbursement schedule without the consent of pharmacy by providing notice to pharmacy.

Notwithstanding that you have entered into an agreement with the PBM for use of their payment systems, the terms and conditions of many of the PBM Agreements may not be fixed. In many of the PBM Agreements there are provisions that allow the PBMs to change the terms and conditions without pharmacy's consent. Provided that the PBM complies with the requirements of these amending provisions, which often involves providing pharmacy with some notice prior to the implementation of the change, changes can be made to the PBM Agreement, the pharmacy manual or other important schedules to the PBM Agreement such as the payment terms or reimbursement schedule. Some examples of provisions that would permit such changes that are similar to the provisions that you may see contained in the PBM Agreements are set out below:

Amendments to the Agreement

Payor has the right to amend this Agreement upon giving the Provider 30 days prior written notice of the amendment.

Or

Payor may amend this Agreement, at any time upon 30 days prior written notice to Provider. A written notice posted on Payor's website shall be deemed to be notice to the Provider.

Or

Payor may amend these provisions at any time and from time to time for any purpose or reason, by giving written notice to Provider of such amendment or by posting the amendment on Payor's website.

Amendments to Pharmacy Manual

The Pharmacy Manual may be modified by Payor from time to time on 30 days written notice to the Provider.

Or

The Pharmacy Manual may be modified or amended by Payor from time-to-time on written notice.

Or

The Pharmacy Manual may be revised from time to time by Payor in its sole discretion, and such amendment shall not require consent of the Provider but shall require notice to Provider of such changes within a reasonable period of time prior to implementation.

Amendments to Payment Schedules

Payor may, at its discretion, determine and set the payment schedules from time to time.

Accordingly, while pharmacy has entered into a PBM Agreement, certain of the important terms and conditions of this agreement may be somewhat fluid. In addition, the PBM Agreements also include provisions that obligate pharmacy to comply with the terms and conditions of the PBM Agreement, including such new terms and conditions as may be imposed by the PBM through these amendments. If new terms and conditions are imposed for which pharmacy cannot comply or for which a pharmacy is unwilling to comply, the only remedy under certain of the PBM Agreements that may be available is for pharmacy to terminate the agreement in accordance with the specific termination provisions set out in the PBM Agreement. Generally, the termination rights in the PBM Agreements are set out in specific enumerated termination provisions. However, in certain cases the amending provisions may also include an express termination right. An example of such a provision which may be similar to the language contained in your current PBM Agreements is set out below:

Any amendment shall be effective 30 days after providing Provider with notice of such amendment or by posting such amendment on the Payor's website unless within such 30 day period Provider gives Payor notice of its non-acceptance of such amendment and includes with such non-acceptance a notice of termination of the Agreement.

Where there is no express termination right included for amendments, if as a result of an amendment that is imposed a pharmacy wishes to terminate the PBM Agreement, the pharmacy may need to rely on the termination for convenience right (i.e., termination other than as a result of breach of the PBM Agreement by the Provider) provided for in the PBM Agreement. If a pharmacy wished to terminate a PBM Agreement, it must ensure that the termination is done in accordance with the provisions of the PBM Agreement, otherwise the pharmacy may be in breach of the PBM agreement in which case pharmacy may be liable to the PBM for damages.

Proposed Clause

To address the foregoing issue, you and your legal counsel may consider adding a restriction on the ability of the PBM to change the PBM Agreement, the pharmacy manual and/or the payment schedule. The Committee has drafted a generic clause, set forth below, which could be considered to be revised and adapted to fit the specific PBM Agreement you wish to amend. The definitions for the capitalized terms used in the clause are included in the attached Appendix A.

Notwithstanding any provisions to the contrary contained in the Original Agreement or the Pharmacy Manual:

- (a) The Original Agreement may not be changed, amended or modified by either Party without the prior written consent of the other Party, such consent not to be unreasonably withheld, delayed or denied.
- (b) The Pharmacy Manual may not be changed, amended or modified by the Payor except as set forth in this clause (b). The Payor shall provide the Provider with not less than **[thirty/sixty/ninety/other]** days prior written notice of any proposed changes, amendments or modifications to the Pharmacy Manual including the reason for, and the proposed text of, such proposed changes, amendments and modifications. If such proposed changes, amendments or modifications:
 - (i) are required to comply with a change in any applicable law or regulation or the application thereof they shall be identified as such in the written notice provided to the Provider and the Payor may implement such changes, amendments or modifications at the end of the **[thirty/sixty/ninety/other]** day notice period unless within such notice period the Provider has provided the Payor with written notice that Provider does not accept such changes, amendments or modifications and that the Provider will be terminating the Original Agreement and this Amending Agreement (the "Termination Notice") in which case the Original Agreement and this Amending Agreement will terminate **[thirty/sixty/ninety/other days]** after the receipt by Payor of the Termination Notice; or
 - (ii) are not required to comply with a change in applicable law or regulation or the application thereof, and the Provider determines, such determination to be exercised in the Provider's sole discretion, that the changes, amendments or modifications would impose a negative economic burden on the Provider or would increase the administrative burden to the Provider without adequate compensation, the Provider may refuse such changes, amendments or modifications by providing written notice to the Payor of such refusal within the **[thirty/sixty/ninety/other]** day notice period in which case, the Parties shall continue to operate under the provisions of the then agreed Pharmacy Manual.
- (c) The Pharmacy Manual shall include all practices, policies, rules and procedures for dispensing Covered Medications and non-prescription medications, supplies and other items and providing Covered Services and there shall be no changes, amendments, modifications or additions to such practices, policies, rules and procedures except as provided in clause (b). To the extent any changes, amendments, modifications or additions to the practices, policies, rules and procedures for dispensing Covered Medications and non-prescription medications, supplies and other items or providing Covered Services are agreed to by the Parties, the Pharmacy Manual shall be revised accordingly. .
- (d) The Payor shall have no ability to change the Payment and Reimbursement Schedule without the prior written consent of the Provider.

The text in clause (a) would permit changes to the Amending Agreement only if such changes were agreed to by both parties. However, as a party cannot act unreasonably in refusing an amendment, a party could not act unilaterally to thwart amendments that were necessary.

The text in clause (b) prescribes the process for changes to the pharmacy manual. Basically, the PBM would be required to provide a pharmacy with notice of the amendment for a prescribed period prior to implementation. If the amendment was necessary to comply with changes in laws or regulations, then the amendment could be imposed after the prescribed notice period. Pharmacy's option in this case would be to either terminate the PBM Agreement or to continue under the PBM Agreement as amended. A specific termination right for changes to the pharmacy manual was included to address a situation where a pharmacy could not comply with the changes that were going to be implemented and an expedient termination right may not otherwise be available in the PBM Agreement. If the amendments to the Pharmacy Manual are proposed for any reason other than compliance with changes or revisions to law and if the proposal had negative economic implications for the pharmacy, a pharmacy could continue to operate under the previous agreed terms and conditions.

The text in clause (c) was added as to restrict amendments to the mechanism agreed in clause (b). This provision was included to address the current situation where amendments to practices, policies, rules and procedures for dispensing of medications were being imposed by informal mechanisms such as e-mail correspondence and pharmacy updates.

The text in clause (d) was added to address situations where the PBM Agreement expressly permitted changes to the agreed payment and reimbursement provisions.

2. Some of the PBM Agreements do not allow pharmacy to charge patients the difference between the usual and customary retail price and the price reimbursed by the PBM.

With the changes imposed by the TDSPA, and the economic consequences of those changes, pharmacy may need to consider a mechanism to allow it to recover from patients the difference between its usual and customary retail price and the amount paid by the insurer and/or plan sponsor through the PBM. Some of the PBM Agreements may currently allow you to collect the difference between your usual and customary retail price and the price paid by the insurers through the PBMs. Other PBM Agreements will not. Some examples of provisions that would prohibit you from charging a patient this difference similar to the provisions you may see in your PBM Agreements are set out below:

Provider will not charge a subscriber for any amounts in addition to the copayment for the Covered Medications and agrees that receipt from Payor of payment in accordance with a current payment schedule will be payment in full for any claims.

Or

Provider agrees not to charge the member for any amount in excess of the co-payment.

Or

Provider accepts Payors adjudicated cost payment and not charge any excess amount to members.

To the extent that insurers are unwilling to pay the full costs of providing the medications and the services, with the uncertainty imposed by the TDSPA you may wish to ensure that all your PBM Agreements allow you to collect the difference between your usual and customary retail price and the amount paid by the insurers.

Proposed Clause

To address the foregoing issue, you and your legal counsel may consider adding an express provision into the PBM Agreement to ensure that you are permitted to collect from patients the difference between your usual and customary retail price and the amount paid by the insurer and/or plan sponsor. The Committee has drafted a generic clause which is set forth below which could be considered to be revised and adapted to fit the specific PBM Agreement you wish to amend. The definitions for the capitalized terms used in the clause are included in the attached Appendix A.

Notwithstanding any provisions to the contrary contained in the Original Agreement or the Pharmacy Manual, the Provider has the right to collect from a Member, and nothing in the Original Agreement or the Pharmacy Manual shall restrict the Provider from collecting from a Member, the difference between the Provider's Usual and Customary Retail Price and the amount paid by the Payor to the Provider for a Covered Medication dispensed to such Member or for a Covered Service provided to such Member, as applicable (including in such difference the amount of the applicable Copayment).

3. As a result of the changes imposed by the TDSPA, the economics of the relationship entered into with the PBM under the PBM agreement may need to be reviewed and revised.

As a result of the changes imposed by the TDSPA and the impact on specific PBM Agreements that cross reference the Ontario formulary pricing and the impact of most favoured nations type clauses contained in the PBM Agreements (i.e., provisions that provide that pharmacy will not charge the PBM more than it would charge another private sector third party payor), you and your legal counsel may need to consider whether the price to be paid for the ingredient cost, the mark-up and the dispensing fee under the PBM Agreement may need to be revised.

Each of the PBM Agreements either within the body of the agreement or in the pharmacy manual) will identify an ingredient cost, a mark-up and a dispensing fee that will be paid. With the new business environment introduced by the TDSPA, pharmacy may need to re-evaluate whether its current PBM Agreements provide an economically sustainable return. Some PBM Agreements may link the ingredient costs, mark-ups and dispensing fees to those paid by the government. Further, certain manufacturers may not be selling the applicable drug product to the private market for the drug benefit price. Accordingly, references in the PBM Agreements linking ingredient costs to the formulary price may be problematic as they may result in losses to pharmacy. In addition, private insurers may be looking to cap the professional fees that they reimburse at the government formulary fees. Finally, a most favoured nations type clause in a

PBM agreement may incorporate into that agreement the lowest pricing agreed to by pharmacy in any other PBM agreement.

Some examples of these provisions that are similar to the type of provisions that you may see in your PBM Agreements is set out below:

Professional Fees

Provider shall pay the lower of (i) the Provider's usual and customary professional fee, (ii) the lowest professional fee charged by Provider for dispensing the Covered Medications other than the one in which the provincial/federal government's of Canada are the payor, or (iii) the insurer's capped fee.

Or

Payor shall pay the lesser of Provider's usual and customary professional fee and the amount payable under the benefit plan under which the relevant medication is to be paid for.

Ingredient costs

The amount reimbursed for the ingredient costs of the Covered Medications will be the lower of (i) the product ingredient costs of the Covered Medications based on the price listed in the provincial formulary; or (ii) the lowest ingredient cost charged by Provider for dispensing the Covered Medications other than the ones in which the provincial/federal government are payors.

Or

Payor will pay Provider a price determined by Payor based upon the provincial formulary pricing.

Or

Payor bases payments on the provincial formulary pricing for ingredient costs.

Mark-Up

The mark-up paid shall not exceed the provincial government level.

Proposed Clause

To address the foregoing issue, you and your legal counsel may consider revising the provisions in the PBM Agreements that address the professional fees, ingredient costs and the mark-up. The Committee has drafted a generic clause which is set forth below which could be considered to be revised and adapted to fit the specific PBM Agreement you wish to amend. The definitions for the capitalized terms used in the clause are included in the attached Appendix A.

- (a) Notwithstanding any provisions to the contrary contained in the Original Agreement or the Pharmacy Manual:
 - (i) the price for any Covered Medications (including those provided as a least cost alternative or as a result of any generic substitution provision in the Original Agreement) shall be the Price for the Covered Medications agreed to under this Agreement;
 - (ii) the mark-up applicable to payments made by the Payor for Members shall be ● percent of the Price of the Covered Medication dispensed (the “Mark-Up”); and
 - (iii) the fee for dispensing of a Covered Medication applicable to payments made by the Payor for Members shall be Provider’s usual and customary dispensing fee filed with the OCP (the “Dispensing Fee”) (the Price for the Covered Medications, the Mark-Up and the Dispensing Fee to be referred to collectively as the “Contracted Price”).

- (b) Notwithstanding any provisions to the contrary contained in the Original Agreement or the Pharmacy Manual, except as set forth below or as otherwise set out in the Payment and Reimbursement Schedule and subject to any Copayment requirement imposed on the Member, the Payor shall pay the Provider:
 - (i) the Contracted Price for each Covered Medicine dispensed by Provider to a Member; and
 - (ii) the Contracted Service Fee for each Covered Service provided by Provider to a Member.

Where the Price for the Covered Medications agreed to under this Agreement is the Wholesaler List Price and the Provider provides a Member with a Covered Medication purchased by the Provider at the drug benefit price (as such term is defined in the *Ontario Drug Benefit Act*) or the drug benefit price plus any applicable wholesaler’s upcharge, the Provider will notify the Payor who shall only be obligated to pay the Actual Acquisition Cost for the supply of such Covered Medications to such Member.

Clause (a) sets forth the pricing that is agreed to by the parties. The Price for the Covered Medications could be the Wholesaler List Price or the Actual Acquisition Cost (see the Definitions in Appendix A for the proposed definitions of these terms) or some other pricing mechanism agreed to with the PBM.

Clause (b) would require the PBM to pay the Contracted Price or Contracted Service Fee for the Covered Medications dispensed or the Covered Services provided subject to any exceptions that were included in the payment and reimbursement schedule. Exceptions to the foregoing rule (such as where there was a discrepancy between what the insurer paid under the member’s plan and the Contracted Price or Contracted Service Fee) would be incorporated as part of the payment and reimbursement schedule.

4. Pharmacy has experienced some issue with the PBMs changing their systems or system design features such that real time adjudication is negatively impacted.

A number of concerns arise regarding PBM's implementing design features or changes to their on-line adjudication systems which, when implemented, did not allow adjudication in real time. There is currently no redress for this issue in the PBM Agreements that were reviewed.

Proposed Clause

To address the foregoing issue, you and your legal counsel may wish to consider including an obligation for the PBMs to work to ensure that system design features or system changes made by the PBMs are able to adjudicate in real time. The Committee has drafted a generic clause which is set forth below which could be considered to be revised and adapted to fit the specific PBM Agreement you wish to amend. The definitions for the capitalized terms used in the clause are included in the attached Appendix A.

Notwithstanding any provisions to the contrary contained in the Original Agreement or the Pharmacy Manual, the Payor shall use its best efforts to ensure that it will be able to adjudicate on-line Claims in real time using the Claims Standard prior to its implementation of any plan design features or any system changes.

5. Provisions in the PBM Agreements that allow the PBM to reclaim or "claw back" adjudicated and accepted claims are confusing and unclear and are inequitable where no error was committed by pharmacy.

Provisions in many of the PBM Agreements concerning repayment by pharmacy to the PBM or "claw backs" are confusing and unclear. Such repayment or claw backs are especially contentious where the claims have been adjudicated and accepted and no error was made by pharmacy in the submission of the claim.

It appears that the PBM's right in the PBM Agreements to receive repayment or compensation from pharmacy for any claims paid in error arises, in part, from the indemnification provisions in the PBM Agreements. In most of the PBM Agreements, pharmacy is obligated by the provisions of the PBM Agreement to indemnify the PBM for any liability the PBM incurs as a result of any breach by pharmacy of the PBM Agreement. Examples of these types of indemnification clauses, which are similar to the indemnification clauses that you may see in your current PBM Agreements, are set out below.

Provider agrees to indemnify Payor from any liability, loss or damage if Payor incurs any such liability or suffers any such loss or damage as a result of any material breach or non-performance of the terms of this Agreement by Provider.

Or

In the event Provider fails to comply with this Agreement or the practice manual or any special instructions provided to it by Payor or improperly uses the adjudication system and as a result Payor suffers any loss, liability or damage, Provider agrees to indemnify and save harmless Payor from such loss, liability or damage.

In many of the PBM Agreements, *any breach* of the PBM Agreement, the pharmacy manual or the special instructions by pharmacy or its employees, may result in pharmacy being liable to the PBM for damages. In other words, the indemnification obligation in many of the PBM Agreements applies whether or not the damages arise without a pharmacy's negligence or misconduct or as a result of pharmacy's negligence or misconduct (a restriction on the indemnity obligation that is often incorporated into commercial agreements is that the indemnified damages must result from a party's negligence of misconduct).

Most of the PBM Agreements include commitments for pharmacy to submit accurate claims. Some examples of these clauses similar to the clauses that you may see in your current PBM Agreements are set out below.

Provider will use its best efforts to ensure that accuracy of the data submitted.

Or

Provider agrees that by the submission of Claims to Payor, all such Claims, when submitted, are authentic and accurate, and are in accordance with the authorized level of benefits.

Or

Where an error has been identified in a Claim, whether or not the Claim has been paid, Provider shall adjust the Claim, and payment based upon such adjustment shall be accepted by the Provider as full and final settlement of such Claim.

If pharmacy breaches these accurate claims type clauses, the PBM may be able to rely on the indemnification provisions to claim repayment or to clawback the amount paid.

Proposed Clause

To address the foregoing issue, you and your legal counsel may consider including provisions in the PBM Agreements that specifically address repayment or "claw backs". The Committee has drafted a generic clause which is set forth below which could be considered to be revised and adapted to fit the specific PBM Agreement you wish to amend. The definitions for the capitalized terms used in the clause are included in the attached Appendix A.

Notwithstanding any provisions to the contrary contained in the Original Agreement or the Pharmacy Manual, once a Claim has been adjudicated and accepted by the Payor, the Payor shall have no right to reverse any such adjudicated and accepted Claim or to deduct an amount from any such adjudicated and accepted Claim unless there has been a technical error (an error in the entry of data by the Provider in the Claim) or negligence on the part of the

Provider in submitting such Claim. To the extent an amount was paid by the Payor for which the Member was not eligible as a result of a technical error or negligence on the part of the Provider, the Payor may reverse the acceptance of such Claim and deduct the portion of the amount for such Claim for which the Member was not eligible from any other amounts owing to the Provider. Notwithstanding the foregoing, any Overpayment shall be reimbursed by the Provider to the Payor.

6. Many of the PBM Agreements do not place limits on the scope of the audit process.

In reviewing the PBM Agreements, it became apparent to the Committee that few of the PBM Agreements limited the scope of the audit to a defined number of prescriptions. In theory, where the scope of the audit was not limited under the PBM Agreement, a PBM could audit a large number or all claims of members which could become disruptive to the business of the pharmacy. The Committee noted that the PBMs, in their agreements with the Association quebecoise des pharmaciens propriétaires in Quebec, had agreed to limit the scope of their audit clause.

Proposed Clause

To address the foregoing issue, you and your legal counsel may consider including provisions in the PBM Agreements that specifically address the scope of audit. The Committee has drafted a generic clause based on the Quebec scope of audit clause which is set forth below which could be considered to be revised and adapted to fit the specific PBM Agreement you wish to amend. The definitions for the capitalized terms used in the clause are included in the attached Appendix A.

- (a) Notwithstanding any provisions to the contrary contained in the Original Agreement or the Pharmacy Manual, the Parties agree that the scope of review of any on-site audit shall be limited as follows:
 - (i) Records maintained by the Provider supporting Claims for Members may not be audited more frequently than once every **[one year/two years]** unless fraud or abuse is reasonably suspected or has been demonstrated in a previous audit.
 - (ii) The Payor may audit prescriptions for Claims for Members paid by the Payor in the **[one/two]** year period prior to the date of the audit up to a maximum number equal to the lesser of: (i) **[two percent (2%) / ● percent]** of the total Claims for Members submitted to the Payor by the Provider within such **[one/two]** year period; or (ii) **one hundred and fifty (150)/ other number ●** prescriptions.
 - (iii) If the audit reveals a percentage of irregularities exceeding **[ten percent (10%) / ● percent]**, the Payor shall be entitled to perform a second audit on prescriptions of Members for the Covered Medications paid within such **[one/two/other period]** year period up to a maximum number equal

to the lesser of: (i) **[two percent (2%) / ● percent]** of the total Claims for Members submitted to the Payor by the Provider within such one/two year period; or (ii) **[one hundred and fifty (150)/ other number ●]** prescriptions.

- (iv) Within **[thirty/sixty/ninety/other]** days following the completion of the audit, the Payor shall forward to the Provider a written audit report containing a list of all alleged irregularities in the Claims reviewed during such audit and, subject to **[the proposed clause set out in 5 above]**, the amount to be deducted by the Provider for such irregularities. The Provider shall have **[thirty/sixty/ninety/other]** days from the receipt of the audit report to provide explanations to the Payor regarding the alleged irregularities. Should the Provider fail to provide satisfactory explanations to the Payor within the **[thirty/sixty/ninety/other]** day period after receipt of the audit report, the Payor shall be entitled to deduct the applicable amount from the Provider as determined by and in accordance with **[the proposed clause set out in 5 above]**. All expenses relating to or arising out of such audits shall be borne by the Payor.
- (v) For the purposes of this Section, an “irregularity” means:
 - (A) a missing prescription;
 - (B) the product, patient’s name, amount of the prescribed product or invoiced service does not correspond to the prescription or service rendered;
 - (C) an inability to identify the prescriber as being an individual authorized to prescribe in accordance with applicable laws; or
 - (D) a systematic absence of a date on prescriptions.
- (b) Notwithstanding any provisions to the contrary contained in the Original Agreement or the Pharmacy Manual, except in the cases where fraud or abuse is reasonably suspected, the Payor’s audit rights are strictly restricted to an inspection and audit of those records maintained by the Provider supporting the Claims for Members and to the scope set forth above in clause (a).

Clause (a) limits the scope of the audit to a defined number of prescriptions. Clause (b) is intended to limit the PBM from using other audit rights that may be included in the PBM Agreement to circumvent the restrictions imposed under clause (a), except in cases where fraud or abuse is reasonably suspected.

7. The PBM Agreements may try to impose standards which are higher than those imposed by the Ontario College of Pharmacists which can be disruptive to pharmacy practice.

The Committee has been made aware of situations where the PBM Agreement has imposed standards of practice that vary from or exceed the Ontario College of Pharmacists’ standards of

practice. Failure to meet these additional standards of practice may be a breach of the PBM Agreement which could lead to the PBM requiring repayment of claims for which these additional standards of practice were not followed. A requirement to follow multiple standards of practice determined by the different PBMs that are different from or add to the Ontario College of Pharmacists' standards of practice may be confusing and disruptive to pharmacy practice.

Proposed Clause

To address the foregoing issue, you and your legal counsel may consider including provisions in the PBM Agreements that specifically address the imposition of additional standards of practice. The Committee has drafted a generic clause which is set forth below which could be considered to be revised and adapted to fit the specific PBM Agreement you wish to amend. The definitions for the capitalized terms used in the clause are included in the attached Appendix A.

Notwithstanding any provisions to the contrary contained in the Original Agreement or the Pharmacy Manual, the Provider shall adhere to the OCP standards of practice and the OCP published Code of Ethics in supplying the Covered Medications and providing the Covered Services and Provider shall not be obligated to adhere to any other standards included in the Original Agreement to the extent such standards are not consistent with or are in addition to the requirements of the OCP standards of practice and the OCP published Code of Ethics.

8. The privacy provisions of the PBM Agreements may not be compliant with the requirements of applicable privacy legislation.

The current PBM Agreements may not adequately address personal information and compliance with privacy legislation. Some of the PBM Agreements seem to place the onus on compliance solely on the pharmacy.

Proposed Clause

To address the foregoing issue, you and your legal counsel may consider including provisions in the PBM Agreements that specifically address applicable privacy laws. The Committee has drafted a generic clause which is set forth below which could be considered to be revised and adapted to fit the specific PBM Agreement you wish to amend. The definitions for the capitalized terms used in the clause are included in the attached Appendix A.

Each Party agrees to be bound by and to comply with its obligations under all applicable privacy legislation including, without limitation, the applicable provisions of the *Personal Health Information Protection Act* and the *Personal Information Protection and Electronic Documents Act*.

OTHER ISSUES

Automatic Renewal

It is likely that most of your PBM Agreements will contain automatic renewal or “evergreening” type clauses. Some examples of automatic renewal clauses similar to those that you may see in your PBM Agreements are set out below.

This Agreement will continue in full force unless terminated by either party on 30 days prior notice in writing.

Or

This Agreement shall be automatically renewed on the anniversary of the effective date for successive one year terms unless terminated by either party upon written notice given by such party to the other not less than 30 days prior to the end of the initial or any subsequent renewal term.

Or

This Agreement shall continue in full force and effect from month to month, unless terminated by either party on 30 days written notice to the other party.

Or

The Agreement continues for an indefinite term until either Payor or Provider gives to the other a notice of termination which notice shall be effective 30 days after the date of such notice.

Accordingly, while the introduction of the TDSPA will impact the provisions of a pharmacy’s PBM Agreements the PBM Agreements will continue. Pharmacy will be subject to the provisions of a PBM Agreement drafted in a pre-TDSPA environment, and will continue to be bound by the terms of these PBM Agreements unless such agreements are amended or terminated.

Standard Form Contracts

You need to carefully review your rights under your current PBM agreement with your legal counsel.

As the PBM Agreements are standard form agreements, and as each PBM will be comfortable with the terms of its current agreement, a PBM will be very reluctant to change or revise many or any of the provisions of its current PBM Agreement. Since the PBMs are the payors, the PBM’s are in a position where they determine the terms on which they are willing to allow pharmacy to participate in their on-line adjudication system. Further, individualized customizations and revisions to their PBM Agreements will create administrative issues for the PBM. Accordingly, it may be unlikely that a PBM will accept or be prepared to negotiate substantial or any revisions or customizations to its current PBM Agreement. A pharmacy must also be cognizant that it is bound by the terms of its current PBM Agreements and that it must not do anything that would breach these terms. Accordingly, a pharmacy cannot impose terms on the PBM. The PBM must

agree to the terms (i.e., the PBM must agree to any amendments that pharmacy and its legal counsel may propose to the PBM Agreement). If the PBM does not agree to accept amendments that you and your legal counsel have determined are necessary for the operation of your business, including amendments that go to the economic viability of the arrangement under the PBM Agreement, you and your legal counsel will need to review options that may be available to you. OPA cannot be responsible for the consequences of any actions taken or not taken in reliance upon this document.

APPENDIX A

DEFINITIONS

- (a) “Actual Acquisition Cost” means the invoice price paid by the Provider for the Covered Medications including the applicable wholesaler’s upcharge if any.
- (b) “Benefit Plan” means a group health insurance plan that is administered by the Payor that provides benefits, products and services to a Member.
- (c) “Business Day” means any day, other than a Saturday or Sunday, on which all major banks in Toronto are open for commercial banking business during normal banking hours.
- (d) “Claim” means a request for payment submitted by Provider to Payor in respect of the supply of the Covered Medications and/or Covered Services.
- (e) “Claims Standard” means the current CPhA Claims Standard (version 3.0) for the transmission of Claims in Canada.
- (f) “Contracted Price” means the Price for the Covered Medications plus the Mark-Up plus the Dispensing Fee.
- (g) “Contracted Service Fee” means the professional fee agreed to by the Provider and the Payor for the Covered Services.
- (h) “Copayment” means that portion of the Contracted Price or Contracted Service Fee that a Member is required to pay to Provider under the terms of the Member’s Benefit Plan including any amount designated as a “copayment” or a “deductible” under the terms of such Benefit Plan.
- (i) “Covered Medications” means those prescription medications for which a Member is eligible under the Member’s Benefit Plan.
- (j) “Covered Services” means those Professional Services for which a Member is eligible under the Member’s Benefit Plan.
- (k) “CPhA” means the Canadian Pharmacists Association.
- (l) “Dispensing Services” means those services offered by pharmacies that are always associated with a dispensing event, that are offered by all pharmacies, and that are required by legislation or OCP then under current standards of practice to dispense a Covered Medication.
- (m) “Manufacturer’s List Price” means the price published by the manufacturer as the manufacturer’s list price for non-governmental payors.
- (n) “Member” means the subscriber entitled to the benefits, products and services under a Benefit Plan and including, if applicable under the Benefit Plan, the dependants of the subscriber.

- (o) “OCP” means the Ontario College of Pharmacists the professional regulatory body governing pharmacists and pharmacy practice in Ontario.
- (p) “Original Agreement” means the current agreement in place between the Parties.
- (q) “Overpayment” means an amount paid by Payor to Provider in excess of the Contracted Price or Contracted Service Fee for the submitted Claim.
- (r) “Payment and Reimbursement Schedule” means the formula for remuneration of the Provider for the supply of the Covered Medications and the provision of the Covered Services to the Members and the agreed timing for payments (i.e., next day payments, twice a month payments and payments 30 days after the transaction date) agreed to by the Parties.
- (s) “Party” means the Provider or the Payor and “Parties” means both the Provider and the Payor.
- (t) “Payor” means the pharmacy benefit manager or other entity that entered into the Original Agreement.
- (u) “Pharmacy Manual” means the written description of practices, policies, rules and procedures provided by Payor to the Provider for pharmacies dispensing Covered Medications and non-prescription medications, supplies and other items and providing Covered Services to Members in effect at the date of this Amending Agreement and attached hereto as Schedule B.
- (v) “Price for the Covered Medications” means the **[Actual Acquisition Cost / Wholesaler List Price / other pricing mechanism] [You would need to choose whether to have ingredient costs paid on an AAC basis or a Wholesaler List Price basis or another agreed pricing mechanism].**
- (w) “Provider” means the pharmacy or other entity that entered into the Original Agreement.
- (x) “Professional Services” means services offered by pharmacies that are not Dispensing Services, including, without limitation, services such as compliance packaging, home infusion services, services that are delivered under a defined process or protocol, and which may or may not be associated with a dispensing event, and that are part of a broader care plan, including, without limitation, drug medication reviews and consultations, chronic disease management services, patient outcome monitoring, and adherence services.
- (y) “Usual and Customary Retail Price” means: (i) in respect of any Covered Medication, the Provider’s retail price for cash paying customers dispensed such Covered Medication by Provider in the quantity dispensed and on the date dispensed including the ingredient cost (the Actual Acquisition Cost or the Wholesalers List Price), the mark-up and the Provider’s Dispensing Fee; and (ii) in respect of any Covered Services the Provider’s professional fee for a cash paying customer having the financial capacity to pay such fee for the provision of

such Covered Services to such customer, given the nature of such Covered Service and the time involved in providing same.

- (z) “Wholesaler” means ● or such other licensed wholesaler as may be agreed to by the Parties.
- (aa) “Wholesaler List Price” means, provided that such price is calculated from the Manufacturer’s List Price plus the applicable Wholesaler’s upcharge, the price listed for a Covered Medication on the Wholesaler’s price list.

The capitalized terms set forth above are only defined for the purposes of the proposed clauses and are not intended to change, amend or modify any defined terms in the Original Agreement for the purposes of the Original Agreement.