#### MANUFACTURER'S REBATE AGREEMENT

#### **Contract Amendment Number 1**

WHEREAS, the Pennsylvania Department of Aging forwarded a new Manufacturer's Rebate Agreement to all pharmaceutical manufacturers on or about October 3, 2006 (hereinafter the Original Agreement');

WHEREAS, the Parties seek to amend and to clarify several provisions of the Original Agreement;

NOW THEREFORE, the Parties mutually agree, with the intent to be legally bound, to the following provisions:

1. Paragraph 1, in its entirety, is amended to read, as follows:

The term of this Agreement shall be from September 1, 2006 to August 31, 2007, and shall be automatically, and on a continuous basis, renewed for a period of one year, unless terminated pursuant to paragraph 24. The prior Manufacturer's Rebate Agreement, executed in 2005, shall remain in effect until full execution of this Agreement by the Parties. Upon full execution of this Agreement by the Parties, all prior Rebate Agreements shall be terminated as of August 31, 2006.

# 2. Paragraph 3, line 2 is amended as follows:

For PACE, PACENET and claimants covered by Designated Pharmaceutical Programs who are also enrolled in the Medicare Part D program, the Department will report only those dosage units for which PACE, PACENET and the Designated Pharmaceutical Programs were the sole payors (including required co-payments made by the Programs' and Designated Pharmaceutical Programs' claimants) for the covered prescription drugs.

#### 3. Paragraph 7 is amended to read as follows:

The Department will maintain electronic claims records for three (3) years from the date of final payment in order to assist Manufacturers in verifying information provided by the Department.

## 4. Paragraph 8, line 2 is added as follows:

In the event that the Department or a Manufacturer receives a final determination from the Centers for Medicare and Medicaid Services (CMS) that any pharmaceutical program administered by the Department fails to qualify as a state pharmaceutical program, or that the Special Pharmaceutical Benefits Program is no longer a qualifying 340B covered entity, the Parties agree to the following procedure:

- (a) Notice shall be provided by the Department to the Manufacturer or to the Department by the Manufacturer within thirty (30) days of receipt of the final CMS determination:
- (b) Within forty-five (45) days from the date of notification of the final CMS determination and upon submission of sufficient proof by the Manufacturer as verified by the Department in accordance with Section 707(b) of the Act, for quarter(s) for which any program administered by the Department was not a "State Pharmaceutical Assistance Program," or in the case of the Special Pharmaceutical Benefits Program, a 340B covered entity, the Manufacturer may recoup by check or by offset against future rebate payments, that portion of any rebate(s) paid under the Agreement which reduced the best price to establish a new best price;
- (c) If, after providing sufficient proof to the Department that the calculated rebate amount would establish a new Medicaid Best Price, the unit rebate amount will be capped at the current Medicaid Best Price.

# 5. Paragraph 9 is amended, in part, as follows:

The Manufacturer represents that at the time of submission, the AMP, the Best Price, and the baseline AMP are true, correct and accurate and that all calculations were performed in accordance with applicable state and federal laws and regulations, including, but not limited to, regulations promulgated by the Centers for Medicare and Medicaid Services pursuant to the Deficit Reduction Act of 2005.

## 6. Paragraph 10, line 3 is amended to read as follows:

Notice of any new drug marketed by the Manufacturer shall be given to the Department within thirty (30) days of market introduction in order for Manufacturer to receive reimbursement from PACE, PACENET and Designated Pharmaceutical Programs.

#### 7. Paragraph 11, lines 2 and 3 are amended to read as follows:

Adjustments to the rebate amount will be made to the extent that information evidences that utilization was greater or lesser than the amount previously specified. Prior quarter adjustments will not be accepted for more than three (3) years prior to the current quarter, or such time frame as required by federal law or regulation governing the time frame for reporting revised average manufacturer price or best price, whichever is less.

### 8. Paragraph 12, line 4 is amended as follows:

To the extent possible, the Manufacturer also agrees to identify for the Department monies applied to the flat rebates and monies applied to inflation rebates.

#### 9. Paragraph 14, in its entirety, is amended as follows:

The calculations for Manufacturers that participate in the Special Pharmaceutical Benefits Program are as follows:

The Manufacturer agrees to pay the rebate discount for each drug as provided in Section 340B of the Public Health Service Act, 42 U.S.C. § 256B. To the extent that the 340B pricing and related supplemental rebate agreements with the Pennsylvania Department of Public Welfare yield a larger rebate amount to the Special Pharmaceutical Benefits Program than the calculation under this paragraph, the larger rebate calculation shall control.

# 10. Paragraph 28, line 2:

Nothing in this Agreement shall prohibit disclosure of Confidential Information as required by state or federal law or by judicial process or order. The Department may give written notice to the Manufacturer, by facsimile, five (5) business days prior to its disclosure of Confidential Information pursuant to a lawful request for Confidential Information. After termination of the Agreement, the Department may provide five (5) business days' advance notice of its intent to release Confidential Information.

# 11. New paragraph 38:

Neither party shall have any liability to the other if its performance of any major obligation under this Agreement is prevented or delayed by causes beyond its control or without the fault or negligence of either party. Causes beyond a party's control may include, but are not limited to, acts of God or war, changes in controlling law, regulations, orders or the requirements of any governmental entity, severe weather conditions, civil disorders, natural disasters, fire, epidemics and quarantines and freight embargoes.

The Manufacturer shall notify the Department orally within five (5) days and in writing within ten (10) days of the date of which the Manufacturer becomes aware, or should have reasonably become aware, that such cause would prevent or delay its performance. Such notification shall (i) describe fully such cause(s) and its effect on performance, (ii) state whether performance under the contract is prevented or delayed and (iii) if performance is delayed, state a reasonable estimate of the duration of the delay. The Manufacturer shall have the burden of proving that such cause(s) delayed or prevented its performance despite its diligent efforts to perform and shall produce such supporting documentation as the Department may reasonably request. After receipt of such notification, the Department may elect either to terminate the Agreement or to extend the time for performance as reasonably necessary to compensate for the Manufacturer's delay.

In the event of a declared emergency by competent governmental authorities, the Department, by notice to the Manufacturer, may suspend all or a portion of this Agreement.

- 12. Paragraph 38 is renumbered 39.
- 13. Paragraph 39 is renumbered 40.
- 14. Paragraph 40 is renumbered 41.
- 15. All provisions of the Original Agreement not amended by this Amendment shall remain in full force and effect. The terms of the Original Agreement and this Amendment supercede any and all prior agreements and understandings between the Parties.

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be executed by their duly authorized officials.

Authorized Signature	Date	Authorized Signature	Date
Print Name:		Print Name:	
Title:		Title:	
Authorized Signature	Date	Authorized Signature	Date
Print Name:		Print Name:	
Title:		Title:	

In accordance with 15 PA. C.S. § 1506, all corporations, both for-profit and not-for-profit, must execute this contract with original signatures from: (1) the president or vice president; and (2) the secretary or assistant secretary or treasurer or assistant treasurer. The execution of the contract will not be effective unless there are signatures from one officer in each group. For example, a corporation's president and vice president may not sign the contract; a president and secretary may sign the contract.

# COMMONWEALTH OF PENNSYLVANIA, DEPARTMENT OF AGING

BY:			
	Secretary, Department of Aging		
BY:			
	Director, PACE		
APPROV	ED AS TO LEGALITY AND FORM:		
BY:			
	Chief Counsel, Department of Aging	(Date)	
BY:			
	Office of General Counsel		
BY:			
<i>-</i>	Office of Attorney General		