MANUFACTURER'S REBATE AGREEMENT

The Agreement, entered into this _____ day of _____, 2006 by and between the Pennsylvania Department of Aging, hereinafter referred to as the "Department" and

_____

(Tax ID _____) and Labeler Code _____, hereinafter referred to as the "Manufacturer."

WITNESSETH:

WHEREAS, pursuant to Act 37 of 2003, as amended by Act 111 of 2006 (collectively, "the Act"), the Department is responsible for the administration of the Pharmaceutical Assistance Contract for the Elderly Program (PACE) and the Pharmaceutical Assistance Contract for the Elderly Needs Enhancement Tier Program (PACENET). PACE and PACENET are sometimes referred to herein as "the Programs"; and

WHEREAS, the Act mandates that the Department coordinate benefits between PACE and PACENET program claimants who are also enrolled in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003(Medicare Part D); and

WHEREAS, the Act mandates that PACE and PACENET receive a flat rebate amount and excessive pharmaceutical price inflation discounts for all covered prescription drugs, and, in the event the claimant is enrolled in a Medicare Part D plan, when PACE or PACENET is the only payor for covered prescription drugs; and

WHEREAS, the Act mandates that PACE and PACENET, General Assistance Program (see 62 P.S. § 402), End Stage Renal Dialysis Program (see 35 P.S. § 6208) and the Special Pharmaceutical Benefits Program (see 35 P.S. § 7601) (hereinafter collectively referred to as "Designated Pharmaceutical Program or Programs") receive rebates and inflation discounts for expenditures made on behalf of recipients of these state-run programs; and

WHEREAS, the Special Pharmaceutical Benefits Program qualifies as a covered entity for purposes of the Federal 340B Drug Pricing Program (see 42 U.S.C. § 256B), which requires Manufacturers to provide outpatient prescription drugs at federally mandated discounts.

WHEREAS, the PACE and PACENET rebate and inflation discount amounts will be deposited in the PACE Fund; the General Assistance Program rebates and inflation discount amounts will be deposited in the Medical Assistance outpatient appropriation of the Department of Public Welfare; the End Stage Renal Dialysis Program rebate and inflation amounts will be refunded by the Department to the Pennsylvania Department of Health End Stage Renal Dialysis Program; and the Special Pharmaceutical Benefits Program will be deposited in the Special Pharmaceutical Benefits Program Appropriations; and

WHEREAS, the PACE, PACENET, and the Designated Pharmaceutical Programs shall not reimburse for any covered prescription drug without a rebate agreement in effect between the Department and the Manufacturer of the covered prescription drug; and

WHEREAS, the Manufacturer agrees to make payments for its prescription drugs utilized by PACE, PACENET, and Designated Pharmaceutical Program enrollees;

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

1. The term of this Agreement shall be from July 1, 2006 to June 30, 2007 and shall be automatically, and on a continuous basis renewed for a period of one year from the date of execution of the Agreement by the parties, unless terminated pursuant to Paragraph 24.

2. The Parties agree to comply with all provisions of the Act, as amended. Copies of Act 111, Act 37 and Act 219 are attached hereto and incorporated herein, and are collectively designated as Attachment "A".

Department's Responsibilities

3. The Department will report to the Manufacturer the total number of dosage units of each of the Manufacturer's covered prescription drugs reimbursed under the PACE, PACENET, and Designated Pharmaceutical Programs during the calendar quarter, not later than sixty (60) days after the end of the calendar quarter. For PACE and PACENET claimants who are also enrolled in the Medicare Part D program, the Department will report only those dosage units for which PACE and PACENET were the sole payors (including required co-payments made by PACE and PACENET claimants) of the covered prescription drugs. The Department's telecommunications format for reporting this information is attached hereto and incorporated herein, and is designated as Attachment "B".

4. The Department will notify providers (pharmacies) of those Manufacturers that have entered into a rebate agreement. All providers will be notified of additional Manufacturers, additions to the list of covered prescription drugs and of Manufacturers' Rebate Agreements terminated by the Department.

5. For purposes of calculating the excessive inflation discount, the Department will provide to the Manufacturer the percentage increase in the Consumer Price Index – Urban ("CPI-U") for the calendar quarter in conformance with paragraph 706(b)(2) of the excessive pharmaceutical inflation discount provision of the Act.

6. The Department will provide to the Manufacturer, upon request, dosage units of each covered prescription drug from prior quarters within the two following calendar quarters for rebate calculation purposes.

7. The Department will maintain electronic claims records for the most recent four quarters in order to assist Manufacturers in verifying information provided by the Department.

8. The Department warrants that it is a State Pharmaceutical Assistance Program (SPAP) as defined by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and as such, is excluded from best price determinations.

Manufacturer's Responsibilities

9. The Manufacturer agrees to provide to the Department:

   (a) the Average Manufacturer Price ("AMP"), the Best Price, the baseline AMP and the baseline CPI-U for single source and innovator multiple source products for the calendar quarter, within thirty (30) days after the last day of each calendar quarter for each covered prescription drug.

   (b) the AMP for non-innovator products for the calendar quarter within thirty (30) days after the last day of each calendar quarter for each covered prescription drug.

   The Manufacturer represents that the AMP, the Best Price, and the baseline AMP to the Department is 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. The Manufacturer agrees that continued reimbursement for covered prescription drugs by the PACE and PACENET Programs is conditioned upon the submission of accurate data and rebate payments to the Department that comply with all laws, regulations, and program instructions. The Manufacturer also understands and agrees that the knowing submission of false information to the Department will subject the Manufacturer to substantial criminal, civil and/or administrative penalties.

10. The Manufacturer agrees to identify all of the Manufacturer's covered prescription drugs to the Department. The name of the drug and the national drug code ("NDC") number, i.e., the complete eleven digit number including the labeler code, product code and package size code will be provided to the Department within sixty (60) days of Manufacturer's execution

of this Agreement. Notice of any new drug marketed by the Manufacturer shall be given to the Department within ten (10) days of market introduction in order for Manufacturer to receive reimbursement from PACE, PACENET and Designated Pharmaceutical Programs.

11. The Manufacturer may review and verify the information provided in Paragraph 3. Adjustments to the rebate amount will be made to the extent that information indicates that utilization was greater than the amount previously specified. Prior quarter adjustments will not be accepted for more than two (2) years prior to the current quarter.

12. The Manufacturer shall calculate and, except as provided in Paragraph 22 of this Agreement, make a rebate payment and discount payment, if applicable, to the Department each calendar quarter for the Manufacturer's covered prescription drugs based on the data submitted to the Manufacturer by the Department. This rebate and discount payment shall be made within thirty (30) days of receipt of the information set forth in Paragraph 3. The Manufacturer agrees that it shall be liable for interest for failure to pay the rebate and/or discount within this timeframe. The Manufacturer also agrees to identify for the Department monies applied to the flat rebates and monies applied to inflation rebates. Two successive failures on the part of the Manufacturer to pay the rebate and/or discount amount on time constitutes a material breach of this Agreement and is cause for termination.

13. The calculation of the rebate for PACE, PACENET, General Assistance and End Stage Renal Dialysis Program is as follows:

    (a) For each calendar quarter beginning after December 31, 2002, with respect to each dosage form and strength of a single-source and innovator multiple-source drug determination of the rebate shall be established by Section 1927 (c)(1) of the Social Security Act (49 Stat. 620, 42 U.S.C. § 1396r-8(c)(1)).

    (b) For each calendar quarter beginning after December 31, 2003, with respect to covered prescription drugs which are noninnovator multiple-source drugs, a rebate shall be based on

the total number of units of each dosage form and strength reimbursed by PACE, PACENET and Designated Pharmaceutical Programs in the quarter, pursuant to the determination established by Section 1927(c)(3) of the Social Security Act (49 Stat. 620, 42 U.S.C. § 1396r-8(c)(3).

(c) In the event that any covered prescription is not sold, marketed or distributed by the Manufacturer during the calendar quarter, the AMP last reported or, the last calendar quarter in which the drug was sold, marketed or distributed, shall be used in calculating rebates.

14. The calculation for the Special Pharmaceutical Benefits Program is as follows:

For each calendar quarter beginning after January 1, 2003, the Manufacturer will pay the Department the difference between the amount paid for each drug by the Program and the 340B ceiling price 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.

15. The calculation of the excessive pharmaceutical inflation discount for single-source drugs, innovator multiple-source drugs and non-innovator multiple-source drugs shall be in accordance with Section 706 of the Act (Attachment "A").

(a) In the event the amount due under this Paragraph 15 exceeds the Program amount paid for non-innovator multiple-source drugs, payment of the Program amount less the dispensing fee satisfies the excessive pharmaceutical inflation discount.

(b) The excessive pharmaceutical inflation discount calculated under this Paragraph 15 shall not apply to non-innovator multiple-source drugs dispensed after December 31, 2006.

16. The Manufacturer agrees that the Department may, at its option, compute the total amount owed by the Manufacturer (flat rebate and inflation discount) based on the Department's own records, but it shall remain the responsibility and obligation of the Manufacturer to correctly calculate these amounts. The Department or its designee shall have the right to review the AMP unit value as computed by the Manufacturer and the source data for all of those calculations. Upon request by the Department, the Manufacturer agrees to provide a reasonable explanation of these calculations to the Department or its designee, including the methodologies used in calculating the AMP, the baseline AMP and the Best Price.

17. The Manufacturer agrees to continue to make rebate and discount payments to the PACE, PACENET, and Designated Pharmaceutical Programs for all of its covered prescription drugs for the duration of this Agreement so long as the covered prescription drugs are dispensed under the Manufacturer's NDC number, regardless of whether the Manufacturer continues to market or distribute the drug.

18. The Manufacturer agrees to pay the Department an amount sufficient to cover all costs associated with providing electronic claims data to the Manufacturer for verification purposes.

19. The Manufacturer agrees to comply with all provisions of the Health Insurance Portability and Accountability Act of 1996 and its regulations.

20. The Manufacturer agrees to provide all information required pursuant to this Agreement to: The PACE Program, Pennsylvania Department of Aging, Forum Place Building, 5th Floor, 555 Walnut Street, Harrisburg, PA 17101-1919.

21. The parties agree that the provisions in this section are not intended nor should be interpreted as precluding supplemental rebates by the Manufacturer.

Dispute Resolution

22. The Department and Manufacturer agree to abide by the provisions set forth in Section 704(b)(3) of the Act for purposes of resolving material discrepancies in the Department's information.

23. The Manufacturer agrees to provide, in writing, the basis for and specific proof of any material discrepancy in the Department's information at the time of certification of such discrepancy. Monies owed to the Manufacturer as a result of dispute resolution on prior period adjustments will be refunded via the Department's Comptroller. Monies shall not be withheld from quarterly payments by the Manufacturer.

Termination

24. The parties agree that termination may occur as follows:

    (a) The Department may terminate this Agreement for any reason. Termination shall not be effective earlier than sixty (60) days after the date of receipt of notice of termination by the Manufacturer.

    (b) The Manufacturer may terminate this Agreement for any reason. Termination shall not be effective earlier than sixty (60) days after the date of receipt of notice of termination by the Department.

    (c) Upon written mutual agreement of both parties, termination of this Agreement may be effected immediately.

    (d) Termination of this Agreement shall not affect rebates due under this Agreement before the effective date of termination.

25. In the event of termination of this Agreement for any reason, the PACE, PACENET, and Designated Pharmaceutical Program will reimburse for the Manufacturer's covered prescription drugs after the termination date only if the

Department determines that the availability of a drug is essential to the health of eligible claimants enrolled in the Programs referenced in this paragraph.

26. If this Agreement is terminated for cause by the Department, another rebate agreement with the Manufacturer or a successor manufacturer may not be entered into until a period of one (1) year has elapsed from the date of the termination unless the Department finds good cause to enter into an earlier agreement.

27. Objections to termination of this Agreement shall be governed by the provisions of Section 704(g) of the Act. Commencement of an action shall not delay the effective date of termination.

Confidentiality

28. The parties agree that information provided under this Agreement is confidential and will not be disclosed by the Department in any form which identifies the Manufacturer or the specific prices charged by the Manufacturer, except as the Department determines to be necessary to carry out the Act or as otherwise required by Law. The Department of the Auditor General and the Office of State Inspector General may review information provided under this Agreement when warranted.

29. The Manufacturer agrees to maintain the confidentiality of all PACE, PACENET, and Designated Pharmaceutical Programs' information and use such information only for purposes of carrying out this Agreement or as approved in writing by the Department.

30. The parties agree that their respective employees, agents, advisors, consultants and officials shall be aware of the confidential nature of the information and data supplied by both parties.

Drug Formulary

31. Except as provided in Section 512 of the Act, the parties agree that until December 31, 2007, there will be no drug formulary, prior or retroactive approval system or any similar restriction

imposed on the coverage of outpatient drugs made by Manufacturers who have agreements in effect with the Commonwealth to pay rebates for drugs utilized in the PACE or PACENET Program, provided that such outpatient drugs were approved for marketing by the Food and Drug Administration. This paragraph shall not apply to any act taken by the Department pursuant to its therapeutic drug utilization review program under Section 505 of the Act.

32. The parties agree that drug formularies will be utilized as appropriate in the Designated Pharmaceutical Program.

33. The Manufacturer agrees that for the PACE and PACENET Programs the Department is prohibited from reimbursing for experimental drugs or drugs prescribed for wrinkles or hair growth; nor may the Department reimburse for any drug appearing on the Drug Efficacy Study Implementation List unless the treating physician or certified registered nurse practitioner declares its' necessity on the prescription and no Notice for Opportunity Hearing (NOOH) for the purpose of withdrawing the New Drug Application approved for that drug has been issued by the Food and Drug Administration (FDA). The Manufacturer also agrees that the Department may deny reimbursement for off-label uses of medications, unless documentation of their efficacy can be found by two or more drug compendia, i.e., U.S. Pharmacopoeia Drug Information, American Hospital Formulary Services Drug Information and American Medical Association Drug Information.

General Provisions

34. The Manufacturer understands and agrees that the Department will strictly enforce penalties for failure to supply information or provision of false information as mandated by the Act and for failure to make prompt payments of the rebate and discount amounts. These civil monetary penalties are in addition to other civil or criminal penalties, as appropriate.

35. In the event of a transfer in ownership of the Manufacturer, the Manufacturer shall assign its rights and responsibilities under this Agreement, to the new owner, subject to the conditions

specified in Section 20 of the Commonwealth's General Terms and Conditions attached hereto and made a part hereof, and is designated as Attachment "C".

36. The parties, with the exception of information provided by the Manufacturer for the verification and calculation of rebates, recognize that any notice required by the terms of this Agreement or by law shall be sent in writing and by certified mail, return receipt requested.

Notice to the Department:

PACE
Pennsylvania Dept. of Aging
555 Walnut Street, 5th Floor
Harrisburg, PA 17101-1919

Notice to the Manufacturer: _____
Company Name

_____
Address

_____

37. Nothing in this Agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of this Agreement is found to be invalid by a court of law, this Agreement will be construed in all respects as if any invalid or unenforceable provision were eliminated, and without any effect on any other provision.

38. Nothing in this Agreement shall be construed as a waiver of any legal rights of the Manufacturer or the Department under state or federal law.

39. To the extent applicable, in performing its obligation under this Agreement, the Manufacturer agrees to comply with the Commonwealth's General Terms and Conditions (Attachment "C"). If there is a conflict between Attachment "C" and any terms and conditions in the Agreement, Attachment "C" will supersede these provisions, unless the provision in conflict is based on statutory authority.

40. This Agreement shall be interpreted consistent with the law of the Commonwealth of Pennsylvania.

IN WITNESS WHEREOF, the parties have caused this Agreement consisting of thirteen (13) pages and Attachments A – C to be executed by their duly authorized officials.

APPROVED:_____

(Manufacturer)

BY:_____ BY:_____

Print Name: _____ Print Name: _____

Title: _____ Title: _____

Date: _____ Date: _____

BY: _____ BY: _____

Print Name: _____ Print Name: _____

Title: _____ Title:_____

Date: _____ Date: _____

COMMONWEALTH OF PENNSYLVANIA, DEPARTMENT OF AGING

BY: _____

Secretary, Department of Aging

BY: _____

Director, PACE

APPROVED AS TO LEGALITY AND FORM:

BY:_____

Chief Counsel, Department of Aging (Date)

BY: _____

Office of General Counsel

BY:_____

Office of Attorney General