MEDI-CAL NET COST SUPPLEMENTAL DRUG REBATE AGREEMENT

This Agreement is made and entered into this _____ day of _____ 20___, by and between the State of California (State), represented by the Department of Health Care Services (Department), and **(ENTER FULL, LEGAL NAME OF COMPANY)** (Contractor), Labeler Code **00000**. The parties, in consideration of the covenants, conditions, agreements, and stipulations expressed in this Agreement, do agree as follows:

ARTICLE I - PREAMBLE

1.1 It is the intent of this Agreement that, pursuant to Welfare and Institutions Code Sections 14105.31 and 14105.33, the Department will receive a Rebate for Contractor's Covered Product(s), including a State Supplemental Rebate, and that the Department will **(add/retain)** Contractor's Covered Product(s) **(to/on)** the Medi-Cal List of Contract Drugs. The parties also intend for this Agreement to meet the requirements of federal law at Title 42 United States Code Section 1396r-8.

ARTICLE II - DEFINITIONS

2.1 'Actual Acquisition Cost' (AAC) means the highest cost of the drug, pursuant to Welfare and Institutions Code, Section 14105.45, during the calendar quarter that corresponds to the calendar quarter for which the Medi-Cal Utilization Data for the Covered Product(s) is reported to Contractor by the Department in the applicable Rebate Summary.

2.2 'Covered Product(s)' means the pharmaceutical product(s) **[CHEMICAL NAME (REGISTERED TRADEMARK NAME), DOSAGE FORM, STRENGTH]**.

2.3 'CMS Agreement' means the Contractor's drug rebate contract with the Centers for Medicare and Medicaid Services (CMS), entered pursuant to Section 1927 of the Social Security Act (42 USC 1396r-8).

2.4 'CMS Basic Rebate' means, with respect to the Covered Product(s), the quarterly payment by Contractor pursuant to Contractor's CMS Agreement, made in accordance with Section 1927(c)(1) or Section 1927(c)(3) of the Social Security Act (42 USC 1396r-8(c)(1) and 42 USC 1396r-8(c)(3)).

2.5 'CMS CPI Rebate' means, with respect to the Covered Product(s), the quarterly payment by Contractor pursuant to Contractor's CMS Agreement, made in accordance with Section 1927(c)(2) of the Social Security Act (42 USC 1396r-8(c)(2)).

2.6 'Medi-Cal Net Cost' means the prescription drug ingredient reimbursement by NDC for the Covered Product(s) paid by the Department to Medi-Cal providers during a calendar quarter calculated as the AAC of the drug, minus the sum of all Rebates paid by Contractor to the Department for the Covered Product(s) for the same calendar quarter pursuant to Article III, Section 3.1 and 3.2 of this Agreement. In the event of any change to the calculation used by the Department to determine drug ingredient reimbursement paid by the Department to Medi-Cal providers, the parties may elect to renegotiate the terms of this Agreement pursuant to Section 5.8.

2.7 'Medi-Cal Utilization Data' has the same meaning as 'utilization data' as described in Welfare and Institutions Code section 14105.33.

2.8 'Rebate' means, with respect to the Covered Product(s), the quarterly payment by Contractor pursuant to Article III, Sections 3.1 and 3.2 of this Agreement. It also means equalization payment as used in Welfare and Institutions Code Section 14105.31(c).

2.9 'Rebate Summary' means the report itemizing the Medi-Cal Utilization Data supporting the Department's invoice for Rebates. The Rebate Summary will comply in all respects with requirements for Medicaid Utilization Information in the CMS Agreement.

2.10 'State Supplemental Rebate' means, with respect to the Covered Product(s), the quarterly payment by Contractor pursuant to Article III, Section 3.2 of this Agreement.

ARTICLE III - CONTRACTOR'S RESPONSIBILITIES

3.1 Contractor will provide the Department a Rebate for the Covered Product(s), which includes the CMS Basic Rebate and CMS CPI Rebate, as appropriate. The CMS rebates represent the discount obtained by multiplying the units of the Covered Product(s) reimbursed by the Department in the preceding quarter by the per unit rebate amount provided to the Department by CMS. CMS will calculate the rebate amount in accordance with Contractor's CMS Agreement. Contractor's obligation for Rebates will continue for the duration of the Contractor's CMS Agreement.

3.2 In addition to the Rebates described in Section 3.1 of this Agreement, Contractor will remit to the Department a State Supplemental Rebate for the Covered Product(s) such that the Medi-Cal Net Cost of the Covered Product(s) will be **($x.xx)** per **(specify unit – gm, ml, tablet, etc)** or a lower Medi-Cal Net Cost which may be generated by Contractor's CMS Agreement. Contractor's obligation for State Supplemental Rebates will begin with the rebate billing period for **first, second, third, fourth** quarter **year** which begins **DATE GENERALLY SHOULD BE THE START OF A CALENDAR QUARTER**, and will continue through the quarter that ends **DATE GENERALLY COINCIDES WITH THE END DATE OF THE CONTRACT IN SECTION 5.9**. If CMS establishes and the Department implements Federal Upper Limit prices, or if the Department establishes and implements Maximum Allowable Ingredient Cost prices on any strengths of the Covered Product(s), Contractor shall pay no State Supplemental Rebate for those strengths of the Covered Product(s) commencing with the beginning of the quarter in which the Federal Upper Limit price or Maximum Allowable Ingredient Cost price is implemented.

3.3 The quarters to be used for calculating the Rebates in Section 3.1 and 3.2 of this Agreement will be those ending on March 31, June 30, September 30, and December 31 of each calendar year during the term of this Agreement.

3.4 Contractor will assist the Department in developing annual estimates of aggregate Rebates for the Department's budgetary purposes.

3.5 Contractor will pay the Rebates, including any applicable interest on late Rebate payments, in accordance with Welfare and Institutions Code Sections 14105.31 and 14105.33(k) - (u), and federal laws, regulations, and/or guidelines. Interest on Rebates payable under Section 3.1 of this Agreement begins accruing 38 calendar days from the postmark date of the Department's invoice and supporting utilization data sent to the Contractor, and interest will continue to accrue until the postmark date of the Contractor's payment. For State Supplemental Rebates payable under Section 3.2 of this Agreement, interest is only applicable to invoices for **first, second, third, fourth** calendar quarter **year**, and thereafter, and if the date of mailing of the Rebate payable under Section 3.2 of this Agreement is 69 days or more from the date of mailing of the invoice, the interest rate will be calculated as required under federal guidelines, but will be increased by ten percentage points. For Rebates invoiced for **first, second, third, fourth** calendar quarter **year**, and thereafter, if the Department has not received the Rebates payable under Section 3.1 or 3.2 of this Agreement, including interest, within 180 days of the postmark date of the Department's invoice and supporting utilization data sent to the Contractor, this Agreement will be deemed to be in default and will be terminated in accordance with Section 5.11 of this Agreement.

3.6 With each quarterly remittance, Contractor will submit a Form CMS-304 (Reconciliation of State Invoice), consistent with federal requirements, and a separate Form CMS-304 for the State Supplemental Rebate. In the event that in any quarter any material discrepancy is discovered by Contractor, which Contractor in good faith is unable to resolve, Contractor will provide written notice of the discrepancy to the Department. The Department and Contractor will use their best efforts to resolve the discrepancy within 90 days of receipt by the Department of the notification.

3.7 If Contractor in good faith believes the amount claimed in the Rebate Summary is erroneous, Contractor may pay the Department only that portion of the amount claimed which is not disputed. Upon resolution of the dispute, any balance will be paid by Contractor promptly; any overpayment will be credited against the next payment due, if any.

3.8 Contractor agrees to continue to pay a Rebate on the Covered Product(s) for as long as this Agreement is in force, and Medi-Cal Utilization Data shows that payment was made for that drug, regardless of whether the Contractor continues to market that drug.

3.9 Unless notified otherwise, Contractor will send Rebate payments to the following address:

Department of Health Care Services
Accounting Section
1501 Capitol Avenue, Suite 2048, MS 1101
Sacramento, CA 95814

ARTICLE IV - DEPARTMENT RESPONSIBILITIES

4.1 The Department will **(add/retain)** the Covered Product(s) **(to/on)** the Medi-Cal List of Contract Drugs. **(ENTER HERE A STATEMENT REGARDING EXCLUSIVITY OR CODE I RESTRICTIONS, IF APPLICABLE).**

4.2 The Department will provide Medi-Cal Utilization Data to Contractor on a quarterly basis. This data will be based on paid claims data (data used to reimburse providers) under the Medi-Cal program, will be consistent with any applicable Federal or State guidelines, regulations and standards for such data, and will be the basis for the Department's calculation of the Rebate.

4.3 The Department will maintain those data systems and audits as are necessary to ensure the accuracy of the data used to calculate the Rebate. In the event material discrepancies are discovered, the Department will promptly justify its data or make an appropriate adjustment which may include a credit as to the amount of the Rebate or a refund to Contractor as the parties may agree.

4.4 Upon implementation of this Agreement, and from time to time thereafter, the Department and Contractor will meet to discuss any data or data system improvements which are necessary or desirable to ensure that the data and any information provided by the Department to Contractor are adequate for the purposes of this Agreement.

4.5 The Department will provide Contractor with a copy of the independent auditor's report of the Electronic Data Processing Application Systems Audit of the Department's fiscal intermediary for Medi-Cal Utilization Data. In the event material discrepancies are discovered by the auditor, the Department will promptly justify its data or make an appropriate adjustment.

ARTICLE V - GENERAL PROVISIONS

5.1 This Agreement will be governed and construed in accordance with: (a) Part 3, Division 9 of the Welfare and Institutions Code; Division 3 of Title 22 of the California Code of Regulations; and all other applicable State law and regulations; and (b) Title 42 United States Code Section 1396; Title 42 of the Code of Federal Regulations; and all other applicable federal law and regulations.

5.2 Any notice required to be given pursuant to the terms and provisions of this Agreement will be in writing and will be sent by certified mail, return receipt requested. Notice to the Department will be sent to:

California Department of Health Care Services
Pharmacy Benefits Division
1501 Capitol Avenue, Suite 71.6089, MS 4604
Sacramento, CA 95814

Notice to Contractor will be sent to:

_____(NAME)
_____(TITLE)
_____(COMPANY NAME)
_____(ADDRESS)

5.3 Pursuant to 42 USC 1396r-8(b)(3)(D), the parties agree that confidential information will not be disclosed. Pursuant to Welfare and Institutions Code Section 14105.33(h) and Evidence Code Section 1060, the parties agree that the terms of this Agreement are confidential and exempt from disclosure under the California Public Records Act at Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code. Each party will treat trade secrets and other confidential information as confidential, will preserve the confidentiality and will not duplicate, disclose or use the information, except in connection with this Agreement or as may be required by judicial order. Notwithstanding the termination of this Agreement for any reason, these confidentiality provisions will remain in full force and effect.

5.4 Contractor and the agents and employees of Contractor in the performance of this Agreement, will act in an independent capacity and not as officers or employees or agents of the State of California.

5.5 This Agreement is not assignable either in whole or in part without the written consent of the Department, which will not unreasonably be withheld.

5.6 Nothing in this Agreement will be construed so as to require the commission of any act contrary to law. If any provision of this Agreement is found to be invalid or illegal by a court of law, or inconsistent with federal requirements, this Agreement will be construed in all respects as if any invalid, unenforceable, or inconsistent provision were eliminated, and without any effect on any other provision. The parties agree to negotiate replacement provisions, to afford the parties as much of the benefit of their original bargain as is possible.

5.7 The Department and Contractor declare that this Agreement, including attachments, contains a total integration of all rights and obligations of both parties. There are no extrinsic conditions or collateral agreements or undertakings of any kind. In regarding this Agreement as the full and final expression of their contract, it is the express intention of both parties that any and all prior or contemporaneous agreements, promises, negotiations or representations, either oral or written, relating to the subject matter and

period of time governed by this Agreement which are not expressly set forth herein are to have no force, effect, or legal consequences of any kind.

5.8 The introductory paragraph and sections 1.1, 2.2, 3.2, 3.5, 4.1, 5.2, and 5.9 of this Agreement will not be altered except by an amendment in writing signed by both parties and approved by the appropriate State control agencies. All other numbered sections of this Agreement will not be altered except by an amendment in writing signed by both parties and approved by the appropriate State control agencies and authorized by the Centers for Medicare and Medicaid Services. No person is authorized to alter or vary the terms or make any representation or inducement relative to it, unless the alteration appears by way of a written amendment, signed by duly appointed representatives of the State and Contractor and approved by the appropriate State control agencies.

5.9 This Agreement will be in effect from date of execution through **(Insert Date)**.

5.10 The Department intends to implement this contract through a single administrator, called the "Contracting Officer". The Contracting Officer will be appointed by the Director of the Department. The Contracting Officer will make all determinations and take all actions as are appropriate under this contract on behalf of the Department, subject to the limitations of California law.

5.11 This Agreement may be terminated by either party by giving written notice to the other party at least 90 days prior to the effective date of the termination. Termination of this Agreement will result in Contractor's Covered Product(s) being available to Medi-Cal beneficiaries only through prior authorization.

5.12 Neither party contemplates any circumstances under which indemnification of the other party would arise. Nevertheless, should such circumstances arise, Contractor agrees to indemnify, defend and hold harmless the State, its officers, agents and employees from any and all claims and losses accruing or resulting to any person, firm or corporation who may be injured or damaged by the Contractor in the performance of this Agreement.

5.13 Inasmuch as the State Supplemental Rebate required by this Agreement is only for Medi-Cal beneficiaries, the State Supplemental Rebate does not establish a new 'Best Price' for purposes of Contractor's CMS Agreement.

5.14 In the event that the Department determines, as a result of a therapeutic category review, that a Covered Product of the Contractor included on the Medi-Cal list of contract drugs as a consequence of this Agreement should be removed from the list of contract drugs and require prior approval, the parties agree that the terms of Section 5.11 shall apply.

As evidence of their Agreement to the foregoing terms and conditions the parties have signed below.

_____	_____
Harry Hendrix Jr., Chief	_____(NAME)
Pharmacy Benefits Division	_____(TITLE)
Department of Health Care Services,	_____(COMPANY NAME)
for the State of California	
Dated:_____	Dated:_____

Prepared by: ____