STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT STATE: California

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES -PRESCRIBED DRUGS

PAYMENT METHODOLOGY FOR PRESCRIPTION DRUGS

The policy of the State Agency is that reimbursement for Pharmaceutical Services and Prescribed Drugs, as one category of health care or service from among those listed in Section 1905(a) of the Social Security Act that are included in the program under the plan, will be at the provider pharmacy's current charges to the general public, up to the State Agency's limits. The price providers charge to the program shall not exceed that charged to the general public. The pharmacist, to the extent permitted by law, shall dispense the lowest cost, therapeutically equivalent drug product that the pharmacy has in stock, which meets the medical needs of the beneficiary.

The methodology utilized by the State Agency, in compliance with 42 C.F.R. §§ 447.331 and 447.332, in establishing payment rates for Pharmaceutical Services (pharmacy dispensing fees) and Prescribed Drugs (dispensed drug products) to implement the policy is as follows:

A. The method used to establish maximum drug product payments is that payments for drugs dispensed by pharmacists shall consist of the state's Estimated Acquisition Cost (EAC) of the drug product dispensed plus a dispensing fee that is added to the drug product payment (see paragraph B below). The EAC is the lowest of the Average Wholesale Price (AWP) minus 17 percent, the Maximum Allowable Ingredient Cost (MAIC); the federal upper limit of reimbursement for listed multiple source drugs (called "Federal Upper Limit," or FUL), or the charges to the general public.

B. The professional fee for dispensing is seven dollars and 25 cents ($7.25) per dispensed prescription. The professional fee for legend drugs dispensed to a beneficiary residing in a skilled nursing facility or intermediate care facility is eight dollars ($8.00) per dispensed prescription. For the purposes of this paragraph B, "skilled nursing facility" and "intermediate care facility" mean as defined in Division 5 (commencing with Section 70001) of Title 22 of the California Code of Regulations.

C. For purposes of this Supplement 2, the following definitions apply:

- "Average wholesale price" means the price for a drug product listed in the department's primary price reference source.

- "Direct price" means the price for a drug product purchased by a pharmacy directly from a drug manufacturer listed in the department's primary reference source.

- "Federal upper limit" means the maximum per unit reimbursement when established by the Centers for Medicare and Medicaid Services and published by the department in Medi-Cal pharmacy provider bulletins and manuals.

- "Generically equivalent drugs" means drug products with the same active chemical ingredients of the same strength, quantity, and dosage

form, and of the same generic drug name, as determined by the United States Adopted Names (USAN) and accepted by the federal Food and Drug Administration (FDA), as those drug products having the same chemical ingredients.

- "Legend drug" means any drug whose labeling states "Caution: Federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

- "Maximum Allowable Ingredient Cost" (MAIC) means the maximum amount the department will reimburse Medi-Cal pharmacy providers for generically equivalent drugs.

- "Innovator multiple source drug," "noninnovator multiple source drug," and "single source drug" have the same meaning as those terms are defined in Section 1396r-8(k)(7) of Title 42 of the United States Code, the National Rebate Agreement, and other Federal instructions.

- "Nonlegend drug" means any drug whose labeling does not contain one or more of the statements required to be a "legend drug".

- "Wholesale Selling Price" (WSP) means the weighted (by unit volume) mean price, including discounts and rebates, paid by a pharmacy to a wholesale drug distributor.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT STATE: California

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES - PRESCRIBED DRUGS

- "Physician-administered drug" means any legend, nonlegend drug, or vaccine administered or dispensed to a beneficiary by a Medi-Cal provider other than a pharmacy provider and billed to the department on a fee-for-service basis.
- "Pharmacy rate" means the Estimated Acquisition Cost (EAC) as defined in paragraph A.

D. For purposes of paragraph A, the department shall establish a list of MAICs for generically equivalent drugs, which shall be published in Medi-Cal pharmacy provider bulletins and manuals. The department will update the list of MAICs and establish additional MAICs in accordance with the following:

- The department will base the MAIC on the mean of the wholesale selling prices of drugs generically equivalent to the particular innovator drug that are available in California from wholesale drug distributors selected by the department.

- The department will update MAICs at least every three months and notify Medi-Cal providers at least 30 days prior to the effective date of a MAIC.

E. The federal upper limits of reimbursement, FUL, are initiated by CMS and provided to the State Agency for implementation in the State Medicaid Manual of Instructions. Periodic revisions to Addendum A of Section 6305.3 of the Manual, which is the list of multiple source drugs and the FUL prices, are implemented by the State Agency following notice by CMS of new FUL prices. New FUL prices are implemented within the timeframe required by the CMS notice and as required by applicable California statutes and regulations.

F. Overrides to both the state and federal price ceilings are available only through a state prior approval mechanism. Prior approval is limited to

those cases where the medical necessity of a specific manufacturer's brand of a drug, priced above the ceiling, is adequately demonstrated to a state consultant. The documentation of the approval is linked to the claims payment system assuring correct reimbursement for the brand dispensed. The same system is used for approval and payment for drugs not on the state Medicaid Drug Formulary, known as the Medi-Cal List of Contract Drugs.

G. The Medi-Cal List of Contract Drugs (List), a preferred drug list, is established pursuant to Section 1927 of the Social Security Act with prior authorization required for drugs not included on the List. Prior authorization will be provided with a 24-hour turn-around from receipt of request and a 72-hour supply of drugs in emergency situations. Prior authorization is applied to certain drug classes, particular drugs, or medically accepted indications for use and doses. The state will appoint a Pharmaceutical and Therapeutic Committee or utilize the drug utilization review committee in accordance with Federal law.

H. The Medicaid program restricts coverage of certain covered outpatient drugs through the operation of a prior authorization program. The prior authorization process provides for a turn-around response by telephone, fax, or other telecommunications device within twenty-four hours of receipt of a prior authorization request. In emergency situations, providers may dispense at least a 72-hour supply of medications in accordance with the provisions of Section 1927(d)(5) of the Social Security Act.

l. The State Agency believes reimbursement to long-term pharmacy providers to be consistent and reasonable with costs reimbursed to other providers. The State Agency maintains an advisory committee known as the Medi-Cal Contract Drug Advisory Committee in accordance with Federal law.

DRUG REBATE PROGRAM

The State Agency is in compliance with Section 1927 of the Social Security Act. The State Agency reimburses providers of drugs of manufacturers participating in the drug rebate program and is in compliance with reporting requirements for utilization and restrictions to coverage. Pharmaceutical manufacturers can audit utilization data to the extent allowed under the Health Insurance Portability and Accountability Act (HIPAA) in order to ensure that the Department is protecting information in accordance with HIPAA. The unit rebate amount is confidential and is not disclosed to anyone not entitled to the information for purposes of rebate contracting, invoicing and verification.

SUPPLEMENTAL REBATE PROGRAM

The State Agency negotiates supplemental rebates in addition to the federal rebates provided for in Title XIX. Rebate agreements between the state and a pharmaceutical manufacturer are separately identified from the federal rebates.

Supplemental rebates received by the State Agency in excess of those required under the national drug rebate agreement are shared with the Federal government on the same percentage basis as applied under the national rebate agreement. CMS has

authorized the State of California to enter into the Medi-Cal Supplemental Drug Rebate Average Manufacturer Price (AMP) Agreement. This supplemental drug rebate agreement was submitted to CMS on December 30, 2005 and has been authorized by CMS. CMS has authorized the State of California to enter into the Medi-Cal Net Cost Supplemental Drug Rebate Agreement. This supplemental drug rebate agreement was submitted to CMS on December 30, 2005 and has been authorized by CMS.
All drugs covered by the program, notwithstanding a prior authorization agreement, will comply with the provisions of the national drug rebate agreement.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
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METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES–PRESCRIBED DRUGS

J. The Medicaid program restricts coverage of certain covered outpatient drugs through the operation of a prior authorization program. The prior authorization process provides for a turn-around response by telephone, fax, or other telecommunications device within twenty-four hours of receipt of a prior authorization request. In emergency situations, providers may dispense at least a 72-hour supply of medications in accordance with the provisions of Section 1927(d)(5)of the Social Security Act.

K. The payment for drug products, including the drug product payment and the dispensing fee, as described in paragraph A and paragraph B, for drug products dispensed on or after March 1, 2011, through and including May 31, 2011, will be reduced by five percent.

L. The payment for drug products, including the drug product payment and the dispensing fee, as described in paragraph A and paragraph B, for drug products dispensed on or after June 1, 2011 and through March 30, 2012 will be reduced by ten percent.

M. The payment for drug products, including the drug product payment and the dispensing fee, as described in paragraph A and paragraph B, for drug products dispensed on or after March 31, 2012 will be reduced by ten percent, unless exempted pursuant to Paragraphs 1 or 2 below:

1. The Department will exempt specific drug products and/or categories of drugs from the reductions specified in paragraph M if the Department determines that such a reduction will result in reimbursement less than actual acquisition cost or will otherwise negatively impact beneficiary access.

   a. Individual drugs, or therapeutic categories of drugs meeting one or more of the following criteria will be considered for exemption:

      i. Drugs for which documentation exists that the reduction specified in paragraph M will result in reimbursement below the acquisition cost generally available to the Medi-Cal pharmacy provider community.
      ii. Drugs that are only dispensed through limited or specialized networks of pharmacy providers.
      iii. Drugs that are used to treat unique clinical conditions with relatively low prevalence in the Medi-Cal population.
      iv. Drugs for which immediate or rapid negative clinical impact(s) will occur if consistent and ongoing access is impeded (e.g. drugs used to treat cancer, life-threatening infections, end stage renal disease, hemophilia, etc.)

   b. The Department shall establish a list of the specific drug products and/or categories that are exempt from the ten percent payment reductions and shall:

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METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES–PRESCRIBED DRUGS

i. Publish the list online in the Pharmacy section of the Medi-Cal Provider Manual, which can be found by going to www.medi-cal.ca.gov, then selecting Publications>Provider Manuals>Pharmacy>Reimbursement.

ii. Re-evaluate the list of exempted drugs or categories of drugs for additions or deletions as needed, but not less than annually. Whenever a change is made to the list, pharmacy providers will be notified via the next monthly pharmacy provider bulletin and an updated list will be published online.

iii. Establish and publish in its provider manual a process for providers to seek a change to the list of exempted drugs and/or categories of drugs.

2. If a pharmacy provider notifies the Department that they intend to withdraw as a Medi-Cal provider as a result of the ten percent payment reduction for drugs dispensed on or after March 31, 2012 described in Paragraph M, the Department will exempt that provider from the ten percent reduction in payments if the Department determines that doing so is necessary in order to assure beneficiary access consistent with the following geographic metrics:

   - In urban areas, at least 90 percent of Medi-Cal beneficiaries, on average, live within 2 miles of a participating retail pharmacy.
   - In suburban areas, at least 90 percent of Medi-Cal beneficiaries, on average, live within 5 miles of a participating retail pharmacy.
   - In rural areas, at least 70 percent of Medi-Cal beneficiaries, on average, live within 15 miles of a participating retail pharmacy.

   a. The start date of exemptions granted pursuant to Paragraph M (2) will be the date the provider requests to be withdrawn as a provider, subject to the Department's determination that such a withdrawal would result in an access issue, per the above stated geographic criteria.

   b. At least annually, the Department will review exemptions granted pursuant to Paragraph M (2). If the Department determines that access has been restored consistent with the geographic criteria, (e.g. as a result of new pharmacies being built, or fewer beneficiaries residing in the area), the Department will notify exempted providers that their exemption no longer applies.

3. A complete description of the policies and procedures regarding the Medi-Cal reduction and exemptions described in paragraphs M (1) and (2), including the specific criteria the Department uses to determine the drug products and/or categories of drugs that are exempt from the payment reduction, can be located in

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the Pharmacy section of the Medi-Cal Provider Manual, by going to www.medi-cal.ca.gov, then selecting Publications>Provider Manuals>Pharmacy>Reimbursement.

N. The Department will monitor the effect of the payment reductions specified in paragraphs K, L and M in accordance with measures #7 and #16 of the monitoring plan at Attachment 4.19-F, entitled "Monitoring Access to Medi-Cal Covered Healthcare Services."

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O. Medi-Cal providers that are covered entities (as defined in Section 256b of Title 42 of the United States Code) and purchase drugs through the 340B Drug Pricing Program are required to use only 340B purchased drugs when dispensing drugs to Medi-Cal beneficiaries. If a covered entity is unable to purchase a specific 340B drug, the covered entity may dispense a drug purchased at regular drug wholesale rates to a Medi-Cal beneficiary.

1. For drugs purchased pursuant to the 340B program, a covered entity is required to bill and will be reimbursed an amount not to exceed the entity's actual acquisition cost for the drug, as charged by the manufacturer at a price consistent with Section 256b of Title 42 of the United States Code, plus the professional fee described in Paragraph B.

    a. When determining actual acquisition cost, a covered entity can include shipping and handling charges actually incurred by the covered entity in connection with the purchase of 340B drugs.

    b. The covered entity shall reduce from its incurred cost any discounts, rebates, refunds, price reductions or credits actually received by the covered entity, and that are directly attributable to 340B drugs. Costs of the covered entity that are incurred during the dispensing of a drug shall not be used to determine the acquisition cost of a drug.

2. If a covered entity dispenses a drug purchased at regular drug wholesale rates because it is unable to purchase it pursuant to the 340B program, the covered entity is required to maintain documentation of their inability to obtain the 340B drug and payment will be made as described in Paragraphs A and B.

3. Drugs billed to Medi-Cal programs by covered entities at an amount not to exceed the actual acquisition cost, as charged by the manufacturer at a price consistent with Section 256b of Title 42 of the United States Code plus the professional fee described in Paragraph B are exempt from legislatively mandated provider payment reductions.

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METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES - PRESCRIBED DRUGS

PAYMENT METHODOLOGY FOR PHYSICIAN ADMINISTERED DRUGS

The reimbursement rate for physician administered drugs shall be equal to the Medicare Part B reimbursement rate for drugs and biologicals, when available for a particular product and published by CMS, as described in Section 1847A of the Social Security Act and currently defined as Average Sales Price (ASP) plus 6%.

When a Medicare Part B reimbursement rate is not available or published by CMS for a physician administered drug, the reimbursement rate will be determined as follows:

i. If based on a National Drug Code (NDC), the NDC rate of reimbursement shall be equal to the pharmacy rate of reimbursement, or

ii. If based on a Healthcare Common Procedure Coding System (HCPCS) code, the HCPCS code rate of reimbursement shall be equal to the volume-weighted average of the pharmacy rate of reimbursement for generically equivalent drugs.

Reimbursement for physician administered drugs shall be exempt from legislatively mandated provider payment reductions.

MEDI-CAL AVERAGE MANUFACTUER PRICE SUPPLMENTAL DRUG REBATE AGREEMENT

This Agreement is made and entered into this ____ day of _____ **(Insert Year)**, by and between the State of California (State), represented by the Department of Health Services (Department), and **(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 'Average Manufacturer Price' (AMP) and 'Best Price' means the Contractor's price(s) for the Covered Product(s) as these terms are defined pursuant to Section 1927 of the Social Security Act [42 USC 1396r-8] and calculated as specified in Contractor's CMS Agreement.

2.2 'Covered Product(s)' means the pharmaceutical product(s) **[CHEMICAL ENTITY (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 Utilization Data' means the data used by the Department to reimburse providers under all programs eligible to receive the CMS Basic Rebate. Medi-Cal Utilization Data excludes data from covered entities identified in Title 42 USC 256b(a)(4) in accordance with Title 42 USC 256b(a)(5)(A) and 1396r-8(a)(5)(C), and those capitated plans that include a prescription drug benefit in the capitated rate and that have negotiated contracts for rebates or discounts with manufacturers.

2.7 '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.

2.8 '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.

2.9 '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) calculated as ___ **percent** of Contractor's AMP for the Covered Product(s). Contractor shall submit to the Department, on a quarterly basis, the AMP for each National Drug Code (NDC) number for each Covered Product. Such data shall be provided in the format and timeframe specified by the Department. Contractor agrees, pursuant to Welfare and Institutions Code Section 14105.332, that Rebates payable under this section shall not be reduced if the Contractor reports to CMS or the Department, a revised AMP or Best Price for any calendar quarter in which the rebate was due. In addition, the Contractor will remit an additional supplemental rebate payment equal to the difference between the initial CMS rebate paid and any revised CMS rebate amounts, as described in 3.1, should the rebate revision result in a reduction in the amount payable. as these terms are defined pursuant to Section 1927 of the Social Security Act [42 USC 1396r-8] The State Supplemental Rebate represents the discount obtained by multiplying the units of each Covered Product reimbursed by the Department in the preceding quarter by the applicable per unit amount specified above for each Covered Product for the same quarter. Contractor's obligation for State Supplemental Rebates will begin with the rebate billing period for **first, second, third, fourth** quarter **(Insert 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.**.

3.3 The quarters to be used for calculating the Rebates in Sections 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 in accordance with Welfare and Institutions Code Sections 14105.31 and 14105.33(k) - (u), and federal laws, regulations, and/or guidelines. Interest on the Rebates payable under Section 3.1 and 3.2 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 Con· ·actor's payment. For Rebates invoiced for **first, second, third, fourth** calendar quarter **(Insert Year)**, and thereafter, 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 **(Insert 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 Services
Accounting Section
1501 Capitol Avenue, Suite 2048, MS 1101
Sacramento, CA 95814

ARTICLE IV - DEPARTMENT RESPONSIBILITIES

4.1 The Department will add the Covered Product(s) to the Medi-Cal List of Contract Drugs. **(ADD 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 pharmacy 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 Services
Pharmacy Policy and Contracting Section
1501 Capitol Avenue, Suite 3041, 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 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.

_____	_____
Sandra Shewry	_____**(NAME)**
Director	_____**(TITLE)**
Department of Health Services,	
(COMPANY NAME)	
for the State of California	
Dated:_____	Dated:_____

MEDI-CAL NET COST DRUG REBATE AGREEMENT

This Agreement is made and entered into this _____ day of _____ **(Year)**, by and between the State of California (State), represented by the Department of Health 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 'Estimated Acquisition Cost' (EAC) means the highest cost of the drug, pursuant to Welfare and Institutions Code, Section 14105.45, during the 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 EAC 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' means the data used by the Department to reimburse providers under all programs eligible to receive the CMS Basic Rebate . Medi-Cal Utilization Data excludes data from covered entities identified in Title 42 USC 256b(a)(4) in accordance with Title 42 USC 256b(a)(5)(A) and 1396r-8(a)(5)(C), and those capitated plans that include a prescription drug benefit in the capitated rate and that have negotiated contracts for rebates or discounts with manufacturers.

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 **(Dollars & cents)** 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**.

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 Services
Accounting Section
1501 Capitol Avenue, Suite 2048, MS 1101
Sacramento, CA 95814

ARTICLE IV - DEPARTMENT RESPONSIBILITIES

4.1 The Department will add the Covered Product(s) to 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 pharmacy 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 Services
Pharmacy Policy and Contracting Section
1501 Capitol Avenue, Suite 3041, MS 4600
Sacramento, CA 95814

Notice to Contractor will be sent to:

_____(ENTER NAME)
_____(ENTER TITLE)
_____(ENTER COMPANY NAME)
_____(ENTER 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 contract end 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.

Sandra Shewry	_____(NAME)
Director	_____(TITLE)
Department of Health Services,	_____(COMPANY
NAME)	
for the State of California	
Dated:_____	Dated:_____