

MODEL CONTRACT

For a California 340B Participant Clinic Contracting with a Retail Pharmacy to Dispense Drugs Owned by that Clinic to the Clinic's Patients

MEDPIN™ - Medicine for People in Need

This Model Contract is provided for general information only, and is not offered or intended as legal or financial advice. When a clinic is confronted with a specific legal or financial question regarding their organization, it should seek the advice of an attorney or other appropriate professional for an independent evaluation of the issues and their application to that organization.

PRESCRIPTION DRUG SERVICES AGREEMENT

THIS PRESCRIPTION DRUG SERVICES AGREEMENT (“**AGREEMENT**”) is made and entered into by and between [Legal Name of Clinic] (“**CLINIC**”) and [Legal Name of Retail Pharmacy] (“**PHARMACY**”), as of [Date] (“**EFFECTIVE DATE**”)

RECITALS

A. The 1992 Veteran’s Health Care Act created Section 340B of the Public Health Services Act, which classifies certain health care clinics, including CLINIC, as “**Covered Entities**” eligible to purchase outpatient prescription drugs for their patients at favorable discounts from drug manufacturers who enter into drug purchasing agreements with the United States Department of Health and Human Services (“**DHHS**”).

B. California Business & Professions Code §4126, effective January 1, 2002, authorizes Covered Entities, including CLINIC, to contract with pharmacies licensed under California state law, such as PHARMACY, to dispense Covered 340B Drugs for the Covered Entity, provided certain requirements are met, including adequate inventory control and limitation of dispensing to eligible outpatients of the Covered Entity.

C. CLINIC and PHARMACY mutually desire to enter into a “ship to/bill to” arrangement under which PHARMACY will order Covered 340B Drugs and receive shipment, maintain inventory and controls, dispense such drugs on behalf of CLINIC only to eligible CLINIC outpatients, and charge and collect for such drugs, all on CLINIC’s behalf, and CLINIC will be billed and will pay for such drugs, in compliance with applicable laws and regulations.

D. CLINIC and PHARMACY mutually acknowledge that their intent in entering into this Agreement is solely to facilitate CLINIC’s participation in the 340B drug purchasing program, without having to establish and operate its own pharmacy. The services provided each to the other are only those necessary in order to fulfill this intent, and all financial arrangements established herein are mutually determined to represent either cost or fair market value for the items and services received. The parties expressly do not intend to take any action that would violate state or federal anti-kickback prohibitions, such as those appearing in Section 1128B of the Social Security Act, 42 USC Section 1320a-7b. Instead, it is the intention of the parties that this Agreement and all actions taken in connection herewith shall fully comply with the regulatory requirements of the safe harbor for personal services and management contracts appearing in 42 CFR Section 1001.952(d), and this Agreement shall in all respects be construed consistent therewith.

NOW, THEREFORE, in consideration of the promises, covenants and agreements hereinafter set forth, CLINIC and PHARMACY hereby agree to the following terms and conditions:

1. Covered 340B Drugs. The prescription outpatient drugs covered by this Agreement (hereinafter “**Covered 340B Drugs**”) include “Legend” drugs, that is those drugs which by federal law can be dispensed only pursuant to a prescription and which are required to bear the legend “Caution – Federal Law prohibits dispensing without prescription.” Other qualified prescriptions include insulin (on prescription only) and over the counter medications as long as

prescribed by an authorized medical provider. All Covered 340B Drugs purchased under this Agreement are the property of CLINIC. All Covered 340B Drugs subject to this Agreement are also subject to the Limiting Definition of “covered outpatient drug” set forth in Section 1927(k) of the Social Security Act, 42 USC 1396r-8(k)(2) & (3), which is incorporated as the applicable definition for the section of the 1992 Veterans Affairs Act that created Section 340B of the Public Health Services Act.

2. Eligible Patients. Only outpatients of CLINIC, excluding CLINIC’s patients who are Medicaid beneficiaries and for whom claims for pharmaceuticals will be submitted to a state Medicaid program (see paragraph 12 below), are eligible to purchase or receive Covered 340B Drugs from PHARMACY (“**Eligible Patients**”). Under no circumstances will PHARMACY dispense Covered 340B Drugs to anyone other than Eligible Patients of CLINIC. Pharmacy shall dispense Covered 340B Drugs to Eligible Patients only in the following circumstances:

2.1 Upon presentation of a prescription form bearing CLINIC's name, the Eligible Patient's name, a designation that the patient is an Eligible Patient, a designation of the dispensing fee, if any, to be charged by the PHARMACY to the Eligible Patient, and the signature of a legally qualified health care provider affiliated with CLINIC; or,

2.2 Upon receipt of a prescription ordered by telephone or electronically on behalf of an Eligible Patient by a legally qualified health care provider affiliated with CLINIC who states that the prescription is for an Eligible Patient, and designating the dispensing fee to be charged by the PHARMACY. CLINIC will furnish a list to Pharmacy of all such qualified health care providers and will update the list of providers to reflect any changes. PROVIDED, however, that no electronic transmission of patient specific information hereunder shall occur on or after the compliance date for healthcare providers of final HIPAA regulations, currently scheduled for October 16, 2003, unless and until the Parties have provided for strict compliance with applicable Health Insurance Portability and Accountability Act (HIPAA) rules, as described in paragraph 21 hereof.

3. Restocking and Inventory Maintenance.

3.1 Restocking. PHARMACY agrees to place orders as necessary with one or more pharmaceutical supplier (“**SUPPLIER**”) to maintain and replenish the drugs consumed pursuant to this Agreement. CLINIC and PHARMACY shall arrange with SUPPLIER to ship directly to PHARMACY. PHARMACY shall provide CLINIC a copy of each and every order so placed, as well as shipping orders and invoices showing prices.

3.2 Inventory Maintenance. PHARMACY and CLINIC agree that PHARMACY shall dispense no controlled substances that might be purchased by CLINIC.

3.3 Inventory Maintenance. PHARMACY agrees to maintain [**OPTION 1:** an electronic inventory of Covered 340B Drugs accurately and in sufficient detail **OR OPTION 2:** a stock of Covered 340B Drugs physically separate from its other drug inventory, and] to protect its inventory of Covered 340B Drugs against intentional or unintentional dispensing to anyone other than Eligible Patients, and to reduce the possibility of

this or other occurrences of drug diversion. PHARMACY shall maintain such records as are adequate to permit it to prepare the reports required under paragraph 7 hereof, and to permit CLINIC, DHHS, or any eligible drug manufacturer to determine upon audit to whom such Covered 340B Drugs have been dispensed. Upon termination of this Agreement, PHARMACY shall deliver all unused items of inventory purchased by or on behalf of CLINIC hereunder to CLINIC, if CLINIC has a valid permit, or, in the absence of such a permit, return them to SUPPLIER for CLINIC's credit, if possible, or destroy them, if they cannot be returned or transferred within thirty days following termination.

4. Payment to SUPPLIER by CLINIC. CLINIC agrees to timely pay SUPPLIER amounts owing to SUPPLIER for Covered 340B Drugs purchased hereunder. In the event that SUPPLIER is not paid and does not ship Covered 340B Drugs in sufficient quantity to PHARMACY, PHARMACY shall notify CLINIC in writing of its lack of 340B Drugs, and, if CLINIC continues to write prescriptions for PHARMACY to fill, may thereafter, in its sole discretion, fill prescriptions from its non-340B inventory, and charge for its own account Eligible Patients or CLINIC according to its own, non-340B prices as described in paragraph 5.2, or PHARMACY may refuse to fill prescriptions of CLINIC, until satisfactory arrangement is made by CLINIC.

5. Payments to PHARMACY by CLINIC.

5.1 PHARMACY Dispensing Fee. PHARMACY and CLINIC agree that PHARMACY shall receive a Dispensing Fee, as specified in Exhibit A, for each prescription of Covered 340B Drugs filled for Eligible Patients and that such Dispensing Fee covers PHARMACY's costs and constitutes the sole and exclusive payment PHARMACY is entitled to receive hereunder. With respect to each prescription, CLINIC shall designate whether such Dispensing Fee is to be collected from the Eligible Patient, from CLINIC, or in part from the Eligible Patient and in part from the CLINIC. If CLINIC is to pay all or part of the Dispensing Fee, PHARMACY shall bill CLINIC not more frequently than monthly for the amounts owing. CLINIC agrees to make payment within fifteen (15) days of receipt of PHARMACY's invoice for such Dispensing Fees. In the event that payment is late, CLINIC agrees to pay interest at the rate of seven percent (7%) per annum on the late balance.

5.2 PHARMACY Use of Non-340 B Stock. If PHARMACY fills prescriptions out of its non-340B stock after notifying CLINIC of a lack of 340B Drugs due to CLINIC nonpayment to SUPPLIER pursuant to paragraph 4, CLINIC agrees to make payment within fifteen (15) days of receipt of PHARMACY's invoice for such costs. In the event that payment is late, CLINIC agrees to pay interest at the rate of seven percent (7%) per annum on the late balance.

5.3 In the event that the amount owed under paragraphs 5.1 or 5.2 by CLINIC to PHARMACY exceeds _____ dollars, PHARMACY shall have the right to refuse to fill further prescriptions of CLINIC, unless satisfactory arrangement is made by CLINIC.

6. Payment to PHARMACY by Patient. CLINIC may assign a share of the cost of the drug by the patient. The patient's share of the cost shall be written on the prescription by the CLINIC. In the event the patient is to share in the cost of the drug, PHARMACY shall collect payment from the patient prior to dispensing the drug. PHARMACY shall maintain records of all patient payments and submit such records monthly to CLINIC. PHARMACY shall either remit cumulative payments to CLINIC each month, or shall deduct payments from what CLINIC would otherwise owe PHARMACY under paragraphs 4 and 5.

7. Reports. By the tenth (10th) day of each month, PHARMACY shall transmit to CLINIC a detailed report showing each Eligible Patient served, the prescription filled, with specific details about each claim, including the drug name, strength, unit dose, appropriate identification codes, manufacturer, quantity dispensed, amount charged and collected, for the previous month.

8. Maintenance of Records. PHARMACY will preserve all records of shipment, receipts, and dispensing of 340B drugs for audit at any reasonable time for a period of three years following date of provision of services. It is understood by both parties under this Agreement that, under Section 340B(a)(5)(C) of the PHS Act, they are subject to audit by the drug manufacturers and the U.S. Public Health Service of DHHS of records that directly pertain to compliance with the Act.

9. Pharmacy Compliance Responsibility. PHARMACY shall be solely responsible for all professional advice and services rendered by it for the Eligible Patients. PHARMACY is responsible for and agrees to render services as herein provided in accordance with the rules and regulations of the California State Board of Pharmacy [or other applicable state, if PHARMACY is located in such state], all laws of the State of California, and all applicable laws and regulations resulting from the Veteran's Health Care Act of 1992 (P.L. 102-585, sec 602). It is expressly understood that relations between the Eligible Patients and PHARMACY shall be subject to the rules, limitations, and privileges incident to the pharmacy-patient relationship. PHARMACY shall be solely responsible, without interference from the CLINIC or its agents to said Eligible Patient for pharmaceutical advice and service, including the right to refuse to serve any individual where such service would violate pharmacy ethics or any pharmacy laws or regulations.

10. Insurance. Pharmacy shall at its own expense maintain a policy of insurance covering professional acts and omissions with a licensed insurance carrier to be in an amount not less than one million dollars (\$1,000,000) per incident and three million dollars (\$3,000,000) in the aggregate, and said policy shall be maintained during the term of this agreement. PHARMACY shall cause its insurer to name CLINIC as an additional named insured on such policy, and shall provide CLINIC with a certificate to such effect.

11. Indemnification.

11.1 CLINIC shall indemnify, defend and hold harmless PHARMACY from any and all liability, loss, claim, lawsuit, injury, cost, damage or expense whatsoever (including reasonable attorneys fees and court costs) arising out of, incident to or in any manner occasioned

by the performance or nonperformance of any duty or responsibility under this Agreement, by CLINIC or any of its employees, agents, contractors or subcontractors.

11.2 PHARMACY shall indemnify, defend and hold harmless CLINIC from any and all liability, loss, claim, lawsuit, injury, cost, damage or expense whatsoever (including reasonable attorneys fees and court costs) arising out of, incident to or in any manner occasioned by the performance or nonperformance of any duty or responsibility under this Agreement, by PHARMACY or any of its employees, agents, contractors or subcontractors.

11.3 Without limiting any other indemnification provisions set forth in this Agreement, neither party shall be liable to the other party pursuant to this Section for any claim covered by insurance, except to the extent that the liability of such party exceeds the amount of such insurance coverage.

12. Medicaid Prescriptions. Notwithstanding anything herein to the contrary, PHARMACY will not use Covered 340B Drugs to dispense prescriptions paid for by a state Medicaid agency, but will use its non-340B inventory, and bill and collect Medicaid on its own account. When a Medicaid agency pays for drugs for its beneficiaries, it is generally entitled to claim a rebate from the drug manufacturer, to reduce its effective cost to a statutorily established price. Section 340B extends a similar price to Covered Entities, and requires that there be a mechanism to protect drug manufacturers from Medicaid rebate claims for Covered 340B Drugs purchased pursuant to Section 340B. To avoid any chance that a State Medicaid agency will pay for 340B Drugs purchased hereunder and then submit prohibited rebate claims to the drug manufacturers, PHARMACY agrees to dispense non-340B drugs from its own inventory in filling Medicaid prescriptions for CLINIC patients who are Medicaid beneficiaries, and all charges collected in connection therewith shall be for PHARMACY's account. PHARMACY further agrees that, for CLINIC patients who are Medicaid beneficiaries, PHARMACY will take all reasonable steps necessary to obtain coverage from Medicaid for the costs associated with drugs prescribed for those patients, including activities necessary for requesting a Treatment Authorization Request from Medicaid. CLINIC shall not be liable to PHARMACY for dispensing fees or other costs in connection with prescriptions filled for Medicaid beneficiaries receiving a prescription whose cost will be covered by Medicaid.

13. Patient Choice. PHARMACY understands and agrees that Eligible Patients of CLINIC may elect not to use PHARMACY for pharmacy services. In the event that an Eligible Patient elects not to use PHARMACY for such services, the patient may obtain the prescription from the pharmacy provider of his or her choice. Subject to a patient's freedom to choose a provider of pharmacy services, CLINIC will inform Eligible Patients that they may be eligible for a discount on prescription drugs ordered by CLINIC, other than Medicaid prescriptions, and advise them that such discount has been arranged for only at PHARMACY.

14. Pharmacy Site. Pharmacy agrees it will provide pharmacy services contracted for under this Agreement at one site only, as specified in Exhibit B.

15. Inspection by Manufacturer. PHARMACY and CLINIC understand and agree that a copy of this Pharmacy Services Agreement will be provided, upon request, to a drug

manufacturer who has signed a purchasing agreement with DHHS. In the event either party receives such a request, it shall immediately inform the other party.

16. Non-Assignment. This Agreement may not be assigned by either party without the prior written agreement of the other party.

17. Term and Termination. This Agreement shall commence on the EFFECTIVE DATE, and shall continue for a period of one year until the first anniversary of the EFFECTIVE DATE, and thereafter shall automatically renew for consecutive one year renewal terms, unless either party provides prior written notice to the other of such party's intention not to renew, at least thirty (30) days prior to such anniversary date, or until terminated by:

17.1 Mutual agreement of the parties;

17.2 Sixty (60) days prior written notice by either party;

17.3 CLINIC, immediately and without prior notice, upon a material breach of this Agreement by PHARMACY. Without limiting CLINIC's right to assert any other act or failure to act as constituting a material breach by PHARMACY, PHARMACY's dispensing of a Covered Drug to an individual who is not an Eligible Patient or any other diversion of a Covered Drug shall be deemed to be a material breach. CLINIC's failure to take action with respect to PHARMACY's failure to comply with any term or provision of this Agreement shall not be deemed to be a waiver of CLINIC's right to insist on future compliance with such term or provision.

17.4 PHARMACY, immediately and without prior notice, upon a material breach of this Agreement by CLINIC. Without limiting PHARMACY's right to assert any other act or failure to act as constituting a material breach by CLINIC, CLINIC's prescribing of a Covered Drug to an individual who is not an Eligible Patient or any other diversion of a Covered Drug shall be deemed to be a material breach. PHARMACY's failure to take action with respect to CLINIC's failure to comply with any term or provision of this Agreement shall not be deemed to be a waiver of PHARMACY's right to insist on future compliance with such term or provision.

17.5 Either party, immediately upon written notice to the other, for material breach of patient confidentiality requirements under HIPAA, as specified in paragraph 21.

18. Choice of Law. This Agreement shall be interpreted according to the laws of the State of California.

19. Dispute Resolution.

19.1 Any controversy or claim arising out of or relating to this Agreement or breach of the Agreement that cannot be resolved by the parties meeting and conferring shall first be referred to mediation at a mediation service agreed to by the parties, or, in the absence of agreement, at JAMS in San Francisco, pursuant to JAMS rules for commercial mediation. The parties covenant that they will engage in mediation in good faith, and will share equally in the

cost of mediation. In the event that mediation is unsuccessful, or the parties are unable to agree upon a mediator, the dispute shall be settled by one arbitrator in accordance with the commercial rules of the JAMS. The venue for any arbitration proceedings under this Agreement shall be in _____ County, California. Judgment on the award rendered by the arbitrator shall be binding on the parties and may be entered in any court having jurisdiction over the dispute. The cost of the arbitration shall be paid by the losing party.

19.2 The arbitrator's authority to grant remedies shall be limited to those remedies that could be granted or awarded by a judge of the Superior Court of the State of California applying California law to the claims asserted. The arbitrator shall prepare and provide to the parties a written decision on all matters subject to the arbitration, including factual findings and the reasons that form the basis of the arbitrator's decision. The arbitrator shall not have the power to commit errors of law, and the award of the arbitrator shall be vacated or corrected for any such error or any other grounds specified in Code of Civil Procedure Section 1286.2 or Section 1286.6. The award of the arbitrator shall be mailed to the parties no later than thirty (30) days after the close of the arbitration hearing. The arbitration proceedings shall be reported by a certified shorthand court reporter. Written transcripts of the proceedings shall be prepared and made available to the parties. In any arbitration proceedings, the parties shall have the right to discovery in accordance with California Code of Civil Procedure Section 1283.05.

19.3 The parties shall each have the right to file with a court of competent jurisdiction an application for temporary or preliminary injunctive relief, writ of attachment, writ of possession, temporary protective order, or appointment of a receiver if the arbitration award to which the applicant may be entitled may be rendered ineffectual in the absence of such relief or if there is no other adequate remedy. This application shall not waive a party's mediation and arbitration rights under this Agreement.

20. Confidentiality of Records. The parties agree to protect the confidentiality of each other's records and business information disclosed to it and not to use such information other than as necessary and appropriate in connection with performance of this Agreement. Each party acknowledges that disclosure of confidential information of the other would cause the other party irreparable harm and may, without limiting the remedies available for such breach, be enjoined at the instance of the harmed party. Upon termination of the Agreement, each party agrees to cease use of the other's information and to return it, or destroy it, as appropriate.

21. Patient Privacy and HIPAA Compliance. The parties recognize that each may be a healthcare provider and a covered entity within the meaning of the federal Health Insurance Portability and Accountability Act ("HIPAA"), and therefore responsible for compliance with HIPAA standards for electronic transactions by not later than October 16, 2003, and for HIPAA privacy standards by not later than April 26, 2003 or April 26, 2004 (the earliest of whichever date applies to either of the parties). The Parties agree to protect and respect the rights of the patients of CLINIC and PHARMACY to privacy and confidentiality concerning their medical and pharmaceutical records, and to protect all individually identifiable health information as protected health information from misuse or disclosure, in compliance with all applicable state and federal law.

21.1 Without limiting the generality of the foregoing, the parties agree to use patient-specific information only for permitted treatment, billing and related record-keeping purposes, and to protect patient-specific information from unnecessary disclosure to persons not employed or contracted for by the parties, and from their own employees and contractors unless they have a need to know and agree to maintain the confidentiality of patient specific information. In the event that any patient information created, maintained or transmitted in connection with this agreement is to be transmitted electronically, the Parties agree that they shall comply in all respects with the requirements of HIPAA governing electronic transmission of individually identifiable patient information. See 42 CFR Section 160 et seq. Failure by either party to abide by these requirements shall be a basis for immediate termination of this agreement.

22. Entire Agreement. This Agreement represents the entire understanding of the parties. There are no other agreements or understandings between the parties, either oral or written, relating to Covered 340B Drugs. Any amendments to this Agreement shall be in writing and signed by both parties.

24. Notice. Any notice required or given under this Agreement shall be provided in writing by one of the following methods: hand delivery, placing in the U.S. Postal Service, first class postage prepaid, facsimile transmission or e-mail transmission, to the addresses and to the attention of the person specified below, or as modified at any time by either party by written notice hereunder.

CLINIC:

PHARMACY:

[Company Name]

[Company Name]

By: _____

By: _____

Title: _____

Title: _____

Date: _____

Date: _____

Address: _____

Address: _____

Provide notice at this address to:

Provide notice at this address to:

Attention: _____

Attention: _____

Telephone: _____

Telephone: _____

Facsimile: _____

Facsimile: _____

E-Mail: _____

E-Mail: _____

EXHIBIT A

PRICING.

1. *Dispensing Fee.* The Parties agree that the Dispensing Fee to be paid for each 340B prescription filled hereunder shall be _____ & ____/100 Dollars (\$_____.____) CLINIC will determine in each case whether CLINIC will pay the Dispensing Fee, or the patient. If CLINIC will pay the Dispensing Fee, the prescription written by the CLINIC shall specify that there shall be no Dispensing Fee charged to the patient. Otherwise, PHARMACY shall collect the Dispensing Fee for each prescription filled. CLINIC will pay PHARMACY for Dispensing Fees in each case where it specifies that no Dispensing Fee shall be collected by PHARMACY, pursuant to paragraph 5 of the Agreement. CLINIC is also free to charge the patient all or a portion of the cost of the drug, but CLINIC will make clear upon collecting any such charge from the patient that such charge is not inclusive of the Dispensing Fee which PHARMACY will collect.
2. *Medicaid Patients.* If CLINIC determines that patient is an eligible beneficiary under a state Medicaid program, and that Medicaid coverage for the cost of the drug is available, the CLINIC shall identify the patient as a Medicaid patient, and PHARMACY shall charge and collect the amount permitted by Medicaid on PHARMACY's own account, dispensing non-340B drugs from its own inventory. For all of CLINIC's Medicaid-eligible patients, PHARMACY will take all reasonable steps necessary to obtain coverage from Medicaid for the costs associated with drugs prescribed for those patients, including activities necessary for requesting a Treatment Authorization Request from Medicaid.

EXHIBIT B

PHARMACY LOCATION. The sole location at which PHARMACY will provide prescription drug services hereunder is:

[Insert name and address of PHARMACY location.]