

# Safety Net Support Program

## Application for Community Clinics and Health Centers

**Step 1: Please return the completed application via email, mail, or fax, to the contact information listed below. Applications that are missing required information will not be processed until the information is received.**

Direct Relief, 27 S. La Patera Lane, Santa Barbara, CA 93117  
[usaprograms@directrelief.org](mailto:usaprograms@directrelief.org) | (877) 303-7872 phone | (805) 823-7201 fax

**Step 2: Once the application has been approved, the primary contact will be notified with information on how to navigate the Direct Relief Network. They will also receive a copy of the signed Memorandum of Understanding (MOU), along with a Welcome Packet.**

### Eligibility Requirements

Your organization must:

- Have federal 501(c)(3) non-profit tax-exempt status
- Be a qualified facility that provides health care to patients regardless of their ability to pay (i.e. FQHC, FQHC Look-Alike, Free Clinic, Community-Based Clinic, etc.)
- Comply with all State Board of Pharmacy regulations in storing and dispensing medications
- Have a Medical Director with valid state license
- Dispense donated products to patients within the United States

**Note:** \* indicates a required field.

### Main Site

Please enter the administrative site as the "Main Site" address on this page. *If you'd like to include additional sites in our donation program, please provide an attachment with the following information for each site: site name, address, phone number, fax number, as well as the name, job title, phone and email for the primary contact.*

**Note:** We cannot ship to P.O. Boxes or personal residences.

<b>Clinic/Health Center Name*:</b> _____	
<b>UDS Grantee ID Number</b> (only if you are a FQHC): _____	
<b>Attention:</b> _____	
<b>Address*:</b> _____	<b>City, State, Zip*:</b> _____
<b>Telephone*:</b> _____	<b>Fax*:</b> _____
<b>Website:</b> _____	
<b>Will this location receive shipments from Direct Relief?*</b> <input type="checkbox"/> Yes <input type="checkbox"/> No	

## EIN/Tax ID Information\*

Per the IRS, to be tax-exempt under section 501(c)(3) of the Internal Revenue Code, an organization must be organized and operated exclusively for exempt purposes set forth in section 501(c)(3), and none of its earnings may inure to any private shareholder or individual.

Format: (XX-XXXXXXX)

## Number of Patients

Please enter the total number of unduplicated patients (not encounters) served by your clinic corporation in the last year. This should include the aggregate number of patients seen at all clinic sites.

**Total Number of Unduplicated Patients\*:** \_\_\_\_\_

**Total Number Uninsured Patients\*:** \_\_\_\_\_

## About Your Facility

**Type of Facility\*** (check one)

- Federally Qualified Health Center (FQHC/Look-Alike FQHC)
- Community Clinic
- Free Clinic
- Charitable Pharmacy
- Social Services
- Public Health Department
- Other (please list): \_\_\_\_\_

**Total Number of Health Delivery Sites\*:** \_\_\_\_\_

## Storage Capabilities

**How many pallets (4'X3.3'X7.5') can you receive and store securely under appropriate conditions?\*** \_\_\_\_\_

**Does your facility have the capacity to store products requiring refrigeration?\***  Yes  No

## Memberships

**Is your facility a member of any professional association?\*** (mark all that apply)

- National Association of Community Health Centers (NACHC)
- National Association of Free and Charitable Clinics (NAFCC)
- State Primary Care Association
- None
- Other (Regional, Local, Homeless, Mental Health, etc.) Please list: \_\_\_\_\_

## Facility Licenses

Please provide license numbers and their expiration dates for each of the following licenses, if applicable.

<b>Clinic/Health Center License</b>		
State License #: _____	Expiration Date: _____	Authority: _____
<b>Pharmacy/Dispensary License</b>		
State License #: _____	Expiration Date: _____	Authority: _____

## Contacts

Please provide us with contact information for your primary contact person, CEO/Executive Director, and Medical Director.

**Primary Contact** - The primary contact will be issued a login, receive notifications of product offers, and place orders on behalf of the entire corporation.

**Prefix\*:** \_\_\_\_\_ **Name\*:** \_\_\_\_\_

**Job Title\*:** \_\_\_\_\_ **Phone Number\*:** \_\_\_\_\_ **Ext:** \_\_\_\_\_

**Email Address\*:** \_\_\_\_\_

**CEO/Executive Director** - The director listed here acts as the CEO/Executive Director for your entire corporation.

**Prefix\*:** \_\_\_\_\_ **Name\*:** \_\_\_\_\_

**Job Title\*:** \_\_\_\_\_ **Phone Number\*:** \_\_\_\_\_ **Ext:** \_\_\_\_\_

**Email Address\*:** \_\_\_\_\_

**Medical Director** - The contact listed here acts as the Medical Director for your entire corporation. The Medical Director assumes responsibility for the appropriate storage and dispensing of all donated prescription medications and products to only uninsured and low income patients.

**Prefix\*:** \_\_\_\_\_ **Name\*:** \_\_\_\_\_

**Job Title\*:** \_\_\_\_\_ **Phone Number\*:** \_\_\_\_\_ **Ext:** \_\_\_\_\_

**Email Address\*:** \_\_\_\_\_

**State Medical License Number\*:** \_\_\_\_\_ **Expiration Date\*:** \_\_\_\_\_

**DEA License Number:** \_\_\_\_\_ **Expiration Date:** \_\_\_\_\_



## MEDICAL PRODUCTS DONATION AGREEMENT

**THIS MEDICAL PRODUCTS DONATION AGREEMENT** is made as of this \_\_\_\_ day of \_\_\_\_\_, 20\_\_ (the “Effective Date”), by and between Direct Relief, a California nonprofit public benefit corporation (“Direct Relief”), with its primary place of business located at 27 S. La Patera Lane, Santa Barbara, CA 93117 and \_\_\_\_\_ (hereinafter referred to as “Partner”) whose principal place of business is located at \_\_\_\_\_.

**WHEREAS**, Direct Relief is a non-profit corporation dedicated to providing access to affordable medical care and medicines to individuals who cannot afford health insurance and are not covered by any form of third-party prescription drug coverage or government programs including Medicaid or Veteran’s benefits, and who are not enrolled in a Medicare Part D prescription drug benefit plan, and

**WHEREAS**, Partner is a non-profit, licensed clinic, health center, or charitable pharmacy dedicated to providing community-directed high quality, comprehensive and affordable health care for medically underserved and indigent populations, and

**WHEREAS**, Direct Relief wishes to provide donated prescription pharmaceuticals, vouchers, equipment and/or supplies to Partner (as provided hereunder by Direct Relief to Partner, the “Donated Products”), to be distributed to patients who are eligible to receive Donated Products pursuant to the criteria set forth in this Agreement, including but not limited to the criteria set forth in Exhibit A attached hereto (such patient, an “Eligible Patient”), which may be modified from time to time in the sole discretion of Direct Relief.

**NOW, THEREFORE**, in consideration of the foregoing premises which are hereby incorporated into the operative provisions of this Agreement by this reference and the mutual covenants and agreements contained herein, the parties hereby agree as follows:

1. Supply of Donated Products.

- a) Partner agrees to distribute all Donated Products strictly on the basis of need and without regard to race, color, national origin, ancestry, age, sex, sexual orientation, gender identity, marital status, religion, disability, political affiliation or other characteristic protected by applicable statute. In no case will Partner withhold Donated Products from Eligible Patients because of their inability to pay for such Donated Products.
- b) Partner will only distribute Donated Products to Eligible Patients pursuant to the eligibility criteria set forth in Exhibit A attached hereto. Further, Partner agrees to use reasonable efforts, consistent with applicable law, to verify that such individual: (i) is not covered by any form of third-party prescription drug coverage; and (ii) is not currently enrolled in any federal or state governmental assistance including, Medicaid, Medicare, and Veterans benefits.
- c) In addition to complying with the eligibility criteria set forth in Exhibit A, Partner agrees that it will only distribute Donated Products to Eligible Patients with valid prescription(s) from licensed health care providers for the applicable Donated Product. Partner further agrees that it will only dispense Donated Products to Eligible Patients who are patients of Partner’s facility and only during such time as such Eligible Patient is being treated as an outpatient.
- d) If Partner becomes aware of information about an individual that would affect the individual’s continued eligibility to receive Donated Product, Partner must discontinue the individual’s participation.
- e) Partner will abide by all applicable federal, state, and local regulations in the dispensation of Donated Products. Partner agrees that Donated Products will not be sold, traded, or further

donated, nor will Donated Products be returned to the original manufacturer for credit. Partner understands that any unused prescription Donated Products shall be returned to Direct Relief for proper disposal.

- f) Direct Relief will, in its sole discretion and at its sole expense, select the mode of shipment and route Donated Products to Partner. Title to Donated Products and risk of loss shall pass to Partner upon delivery of the Donated Products to Partner at a mutually determined location. The shipping location must be a Partner healthcare delivery site where patients are receiving care.
  - g) In the event that Partner receives Donated Product shipments at multiple shipping locations, Partner will have written policies and procedures for re-distribution of Donated Product which must be in compliance with State and Federal dispensation requirements. Further, Partner will have appropriate patient screening at each dispensing site in order to identify Eligible Patients.
  - h) Partner shall ensure that Donated Products are securely stored and handled properly, including but not limited to refrigeration and/or capacity to store unopened product pursuant to package label and other clinically appropriate measures. Partner shall notify Direct Relief within 90 days of any expired or damaged prescription Donated Product. Expired and/or damaged prescription Donated Products shall be returned to Direct Relief and disposed of in compliance with Direct Relief's policy and procedures provided to Partner and as set forth in Exhibit B attached hereto ("Policies and Procedures"). The Policies and Procedures shall be subject to change by Direct Relief without notice.
  - i) Partner shall segregate the prescription Donated Products from other medical products that Partner receives.
  - j) Partner shall maintain books and records sufficient to create an audit trail for the distribution of Donated Products to Eligible Patients.
  - k) In the event Partner becomes aware (directly or indirectly) of any Quality Complaint, Partner shall, within 24 hours of becoming aware of the Quality Complaint, inform Direct Relief of the Quality Complaint. Direct Relief will evaluate and investigate each Quality Complaint, provide instructions to Partner on any immediate actions to be taken, and issue an investigation report at the conclusion of the investigation. For purposes of this Agreement, "Quality Complaint" shall mean any complaint or correspondence Partner becomes aware of (directly or indirectly) that relates to potential defects with regards to the quality, safety or efficacy of the Donated Products but does not otherwise meet the criteria of an "Adverse Event" as defined below.
  - l) In the event that Partner becomes aware of an Adverse Event, Partner agrees to contact the manufacturer of the Donated Product within 24 hours of becoming aware of an Adverse Event or follow the federal guidelines for reporting via U.S. Food and Drug Administration ("FDA") Form 3500. Partner agrees to have policies and procedures, and provide training for its applicable staff, that includes instructions on how to report Adverse Events. For purposes of this Agreement, "Adverse Event" shall mean any untoward medical occurrence in a patient who has been administered a Donated Product and which does not necessarily have a causal relationship with the treatment associated with the Donated Product. Without limiting the foregoing, an Adverse Event includes any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporarily associated with the use of the Donated Product, whether or not related to the Donated Product, and results in one or more of the following: (i) death; (ii) life-threatening condition; (iii) hospitalization; (iv) disability or permanent damage; (v) congenital abnormality or birth defect; (vi) requiring an intervention to prevent permanent impairment or damage; or (vii) any other event that may jeopardize the patient and may require medical or surgical intervention to prevent any of the foregoing outcomes.
2. Product Recalls. In the event Direct Relief shall be required (or shall voluntarily decide) to initiate a recall, withdrawal or field correction of, or field alert report with respect to, any Donated Product, whether or not

such recall, withdrawal, field correction or field report has been requested or ordered by the FDA, Direct Relief shall notify Partner, and Partner shall fully cooperate with Direct Relief, to implement the same. Direct Relief shall make all contacts with the manufacturer of the subject Donated Product and shall be responsible for coordinating all of the necessary activities in connection with any such recall, withdrawal, field correction, or field alert report. Partner agrees to make no statement to the media except in accordance with Section 14 of this Agreement.

3. Reporting; Data Protection. Partner shall not disclose any “protected health information” (“PHI”) as that term is defined by the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), as amended. Accordingly, Direct Relief shall not have access to, nor shall Direct Relief be entitled to receive, any PHI obtained by Partner through its performance of services hereunder. Direct Relief agrees to accept de-identified information which Partner has de-identified in accordance with 45 C.F.R. §164.514(b)(2).

4. Representations, Warranties and Covenants.

a) Partner represents and warrants to Direct Relief as follows:

- i. Partner has not received anything of value from Direct Relief as a condition to receiving the Donated Products. Partner will provide the Donated Products received under this Agreement free of charge and only to Eligible Patients, except that a nominal dispensing fee shall not be a breach of this Agreement, provided, that such fee must be waived if the Eligible Patient cannot afford payment thereof;
- ii. Partner acknowledges that Eligible Patients may not seek reimbursement for any Donated Products dispensed hereunder from any government program (including Medicare or Medicaid) or third party insurer, nor can Donated Products received through the program be counted towards any Medicare beneficiary’s TROOP expenditures;
- iii. Partner will maintain adequate books and records on the receipt, distribution and disposition of all Donated Product for review by Direct Relief or its designee;
- iv. Partner will maintain and retain for three (3) years adequate documentation and complete records verifying patient eligibility to receive Donated Product for review by Direct Relief or its designee;
- v. Partner will not bill any insurance program (including Medicare or Medicaid) for any Donated Products provided to Eligible Patients hereunder;
- vi. Partner will ensure that written policies and procedures are in place to adequately determine patient eligibility at each site where patient screening will occur;
- vii. Donated Products are solely for the uses set forth herein, and will not be transferred by or to any third party for money, property, services or any other remuneration of any kind; and
- viii. Partner is exempt from federal income taxes under Section 501(c)(3) of the Internal Revenue Code of 1986, as amended (the “Code”) or is a government instrumentality as such term is described in Section 170(c)(1) of the Code. Partner represents that it is not a private foundation and that the use by it of the Donated Products is related to the purpose for which Partner received tax exemption under the Code.

b) Partner covenants that it is not a party to any commercial agreement with the manufacturer(s) of the Donated Products under which it receives a rebate or incentive based upon Partner’s utilization hereunder of the Donated Products, and in the event Partner does enter into any such commercial agreement, Partner agrees to immediately notify Direct Relief of such agreement. The Donated Products will be excluded from utilization data required to be provided under any such other commercial agreement.

- c) Partner covenants that upon receiving the Donated Products, it will sign and retain a copy of the original packing slip included with each Donated Product shipment. Partner acknowledges that the packing slip will contain an additional representation as to how the Donated Products will be used and Partner's obligation not to bill its patients or any third party payor, including Medicare and Medicaid, for Donated Products administered to Eligible Patients under this Agreement. Any defects, shortages or problems with the Donated Products shipment must be reported to [Direct Relief] within 3 days of receipt of the shipment.
- d) Both parties shall comply with all applicable federal, state, and local laws, regulations and guidelines, including any licenses, permits, or registrations necessary to be able to provide the Donated Products, which shall include but are not limited to all laws, rules, regulations and guidelines regarding pharmacy, privacy, anti-bribery and anti-kickback actions.
- e) Without limiting the foregoing, Partner covenants and agrees that neither Partner nor any of its officers, directors, employees, agents or representatives shall offer, promise or give any undue pecuniary or other advantage, whether directly or through intermediaries, to any public official, for that official or for any third party, in order that the official act or refrain from acting in relation to that performance of his or her official duties, in order to obtain or retain business or other improper advantage in the conduct of Partner's obligations.
- f) Both parties represent that this Agreement has not been made in exchange for any explicit or implicit agreement that Partner will purchase, recommend, or otherwise arrange for the use of any Donated Products.

**5. DISCLAIMER OF WARRANTIES AND LIABILITY BY DIRECT RELIEF**

- a) Partner understands and agrees that in providing the Donated Products to Partner, Direct Relief does not act as a seller, reseller, or manufacturer for purposes of products liability law or for any other purpose.
- b) NEITHER DIRECT RELIEF NOR ANY OF ITS SUBSIDIARIES OR AFFILIATES IS RESPONSIBLE FOR ANY LIABILITY, CLAIM, LOSS, INJURY, OR DAMAGE CAUSED BY THE USE OF ANY MEDICINE, EQUIPMENT, OR SUPPLIES OF ANY KIND THAT IS PROVIDED BY DIRECT RELIEF HEREUNDER NO MATTER WHAT MANNER THEY ARE USED IN. INDIVIDUALS AND ORGANIZATIONS WHO USE OR DISPENSE OF THE PHARMACEUTICALS, EQUIPMENT OR SUPPLIES DONATED BY DIRECT RELIEF DO SO AT THEIR OWN RISK AND MAY SUFFER SERIOUS PERSONAL INJURY OR DEATH OR PROPERTY DAMAGE. DIRECT RELIEF MAKES, AND HAS MADE, NO WARRANTIES OR REPRESENTATIONS, EXPRESS OR IMPLIED, CONCERNING THE SUITABILITY OR SAFETY OF ANY OF THE PHARMACEUTICALS, EQUIPMENT OR SUPPLIES, AND IT EXPRESSLY DISCLAIMS ALL SUCH WARRANTIES, INCLUDING WITHOUT LIMITATION, IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR PARTICULAR PURPOSE. DIRECT RELIEF IS A CHARITABLE ORGANIZATION AND DOES NOT HAVE THE EXPERTISE TO INSPECT, AND THEREFORE HAS NOT INSPECTED, ANY OF THE PHARMACEUTICALS, EQUIPMENT OR SUPPLIES THAT IT HAS DONATED. DIRECT RELIEF IS NOT RESPONSIBLE FOR LIABILITY, CLAIM, DAMAGE, LOSS, OR INJURY OF ANY KIND, INCLUDING CONSEQUENTIAL DAMAGES, RESULTING FROM THE USE OF ANY OF THE PHARMACEUTICALS, EQUIPMENT, OR SUPPLIES THAT IT HAS DONATED.

- 6. Indemnification. Partner agrees to indemnify, defend and hold Direct Relief, its subsidiaries and their respective directors, officers, employees and agents, harmless from any claims, liability, loss, damage or injury of any kind, including attorneys' fees and costs of litigation, directly or indirectly resulting from or associated with the Donated Products delivered herewith, and that Partner will not seek indemnity from Direct Relief for damages arising out of the condition or use of Donated Products delivered herewith. This indemnity obligation by Partner shall be without regard to any act or omission by Direct Relief, its directors,

officers, employees, or agents unless such act or omission is proven by a court of competent jurisdiction to be willful misconduct or gross negligence.

7. **Change of Status.** In the event of a change in its licensure status, including clinic or health center license, pharmacy license, dispensary license, or medical director license for its facility, Partner agrees to notify Direct Relief within seven (7) calendar days of the change in status, and Direct Relief shall have the right to terminate this Agreement effective immediately.
8. **Term and Termination.** This Agreement shall be effective as of the Effective Date and shall continue until terminated by either party in accordance with the terms hereof:
  - a) Either party may terminate this Agreement upon sixty (60) days' prior written notice to the other party (with or without cause).
  - b) If Partner breaches Section 1(a)-(e), (h) or (k), or any provision of Section 4, or Direct Relief has a reasonable basis (determined in its sole discretion) to believe that either Partner or any officer, director, employee, agent or representative of Partner is involved in counterfeiting, illegal diversion, bribery, or handling of stolen medicines, medical equipment and supplies or other medical products or that Partner has failed to establish appropriate controls against such activities, Direct Relief has the right to terminate this Agreement immediately upon notice to Partner.
  - c) Upon expiration or termination of this Agreement, (i) any remaining prescription Donated Products shall be returned to Direct Relief pursuant to the Policies and Procedures, and (ii) at the sole discretion of Direct Relief, any remaining non-prescription Donated Products shall be returned to Direct Relief pursuant to the Policies and Procedures.
  - d) Upon expiration or termination of this Agreement for any reason, (i) Sections 2, 4, and 10 shall survive for so long as Partner retains any Donated Products, (ii) Sections 5, 6, 17, and 18 shall survive indefinitely, and (iii) Section 9 shall survive for such period until Direct Relief's audit rights expire.
9. **Audit Right.** During the term of this Agreement and for a period of three (3) years thereafter, upon thirty (30) days prior written notice to Partner and during regular business hours, Direct Relief or its designee shall have the right to audit and inspect Partner, its facilities, and its books, records and procedures relating to activities contemplated by this Agreement, in order to verify that Partner has operated in accordance with the terms of this Agreement. Partner shall, at the time of treatment, obtain from their Eligible Patients any authorizations required by federal, state or local law to allow Direct Relief or its designee to conduct the audit activities contemplated by this Section 9. Except as required by law or court order or other governmental order, Direct Relief shall maintain all information it obtains regarding Eligible Patients as strictly confidential.
10. **Debarment and Exclusion.** Partner represents and warrants that neither it, nor any of its employees or agents, performing hereunder, have ever been, are currently, or are the subject of a proceeding that could lead to it or such employees or agents becoming, as applicable, a Debarred Entity or Individual, an Excluded Entity or Individual or a Convicted Entity or Individual (all as defined herein). Partner further covenants, represents and warrants that if, during the term of this Agreement, it, or any of its employees or agents performing hereunder, become or are the subject of a proceeding that could lead to that party becoming, as applicable, a Debarred Entity or Individual, an Excluded Entity or Individual or a Convicted Entity or Individual, Partner shall immediately notify Direct Relief, and Direct Relief shall have the right to immediately terminate this Agreement. For purposes of this provision, the following definitions shall apply:
  - a) A "Debarred Individual" is an individual who has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from providing services in any capacity to a person that has an approved or pending drug product application.



- b) A “Debarred Entity” is a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from submitting or assisting in the submission of any abbreviated drug application, or a subsidiary or affiliate of a Debarred Entity.
  - c) An “Excluded Individual” or “Excluded Entity” is (i) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General of the U.S. Department of Health and Human Services, or (ii) is an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration.
  - d) A “Convicted Individual” or “Convicted Entity” is an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of 21 U.S.C. §335a (a) or 42 U.S.C. §1320a - 7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible.
11. Notices. Any notice required or otherwise made pursuant to this Agreement shall be in writing, personally delivered or sent by certified mail, return receipt requested, or recognized courier service, properly addressed, or by facsimile with confirmed answer-back, to the other party at the address set forth above. Notices shall be deemed effective (a) on the date received if personally delivered or sent by certified mail or recognized courier, or (b) upon the date of confirmed answer-back if sent by facsimile or such other address as may be provided by each party in writing from time to time.
12. Independent Contractors. The relationship of the parties under this Agreement is that of independent contractors and neither party shall have authority to bind or act on behalf of the other party except as otherwise agreed in writing by the parties. Nothing herein shall be deemed to be a partnership or joint venture between the parties.
13. Assignment. Neither party may assign this Agreement or any rights or obligations hereunder, whether directly or indirectly, without the prior written consent of the other party; provided, however, that Direct Relief may assign this Agreement to one of its wholly owned subsidiaries or affiliates.
14. Publicity. Neither party shall disclose the terms of this Agreement nor use the other party’s name, logo, trademark, or service mark in any promotional or general announcement without the other party’s prior written approval.
15. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.
16. Severability. If any provision of this Agreement is held invalid or unenforceable by any court of competent jurisdiction, the other provisions of this Agreement will remain in full force and effect. Any provision of this Agreement held invalid or unenforceable only in part or degree will remain in full force and effect to the extent not held invalid or unenforceable.
17. Attorneys’ Fees. Should either party be required to bring legal action to enforce the terms of this Agreement, it is agreed that the prevailing party shall be entitled to an award of its costs and reasonable attorneys’ fees.
18. Governing Law. This Agreement shall be interpreted and governed by the laws of the State of California, without reference to conflict of laws principles, with venue for all purposes proper only in the County of Santa Barbara, State of California.
19. Interpretation. In this Agreement, except to the extent otherwise provided or the context otherwise requires, any statute, rule or regulation defined or referred to herein or in any exhibit attached hereto

means such statute, rule or regulation as from time to time amended, modified or supplemented, including by succession of comparable successor statutes, rules and regulations.

**20. Entire Agreement.** This Agreement and Exhibits constitute the entire and exclusive agreement between the parties hereto with respect to the subject matter hereof and supersedes and cancels all previous oral or written communications, proposals, agreements, and commitments. Except as otherwise set forth herein, no modification to this Agreement shall be effective unless signed by both parties.

**IN WITNESS WHEREOF**, each of the parties has caused this Agreement to be executed by its authorized representatives in its names and on its behalf.

**PARTNER ORGANIZATION:**

**Medical Director (Print Name):** \_\_\_\_\_

**Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**CEO/Executive Director (Print Name):** \_\_\_\_\_

**Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**If Employed - Pharmacist (Print Name):** \_\_\_\_\_

**Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**DIRECT RELIEF:**

**Executive Vice President, COO, and CFO: Bhupi Singh**

**Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

## **Exhibit A**

### **ELIGIBLE PATIENT CRITERIA**

#### General Criteria

- The patient is a resident of the United States of America.

#### Insurance and Financial Criteria

- The patient has no third party prescription drug benefit through federal or state governmental assistance programs including Medicare, Medicaid, Veterans Administration benefits, workers compensation benefits or any other forms of insurance or health benefits that provide prescription drug coverage for the Donated Product.
- The patient qualifies as indigent.
- The patient's eligibility criteria should be evaluated at least annually.

## Exhibit B

### RETURN GOODS POLICIES AND PROCEDURES

Returns of Donated Products must follow the returned goods procedure specified herein. Direct Relief reserves the right to change these procedures at any time without notice.

Returns of Donated Products must be made to Direct Relief for destruction in compliance with all federal, state or local laws pertaining to the returned Donated Products.

#### 1. RETURN POLICY

- a) Incorrect Shipments, Shortages and/or Damaged Product. Incorrect shipments, shortages or damages must be reported to Direct Relief upon receipt of the Donated Products. Unless exceptions are clearly noted on the delivery receipt by the delivery agent, the entire shipment of the Donated Products should be declined when there is damage or when shipment is incorrect.

Please include the following necessary information in your claim:

- Name and address.
- Order number, Delivery Number, Partner number and date.
- Describe error, shortage, or visible damage noted on receipt of delivery.

- b) Ordering Errors. Donated Products delivered to Partner as a result of ordering errors may be returned to Direct Relief subject to the following conditions: (1) the Donated Product is returned in original, full and unopened condition, and (2) the Donated Product is able to be restocked by Direct Relief. Partner should immediately notify Direct Relief of any ordering errors.
- c) Shipping Errors. Partner shall notify Direct Relief within three (3) days of receipt of the Donated Product for prompt resolution of any shipping errors by Direct Relief.
- d) Damaged Shipments. Partner is required to notify Direct Relief within ten working (10) days after receipt of the Donated Product and is required to provide the carrier's damaged goods report or other similar documentation.
- e) Lost Shipments. Promptly upon determination that a shipment from Direct Relief has been lost and not received by Partner, Partner shall contact Direct Relief.

#### 2. GENERAL RETURN PROCEDURE. All Donated Product returns must follow the returned materials procedure specified below:

- a) Authorization for returns must be obtained from Direct Relief. A Return Authorization Form (RAF) form to be provided by Direct Relief must be completed by Partner. Partner must inform Direct Relief of any expired pharmaceutical Donated Product within 90 days of expiration and provide NDC product code, lot number, expiration date, delivery number, and quantity to be returned. An authorized and completed RAF must be received by Direct Relief before Donated Product can be returned. Upon receipt of RAF, quantities returned, and product condition must be verified by Direct Relief.
- b) Returns must be shipped to the location designated by Direct Relief. The Donated Products must be returned within thirty (30) days from the date the RAF was approved by Direct Relief.
- c) Direct Relief will help arrange and pay for a carrier to pick up product returned.
- d) Direct Relief reserves the right to destroy Donated Products which are returned outside the above policy, or which are considered unfit or unsafe for use. Direct Relief is solely responsible for determining if returned Donated Product is usable.