From: WA Department of Health <waDOH@public.govdelivery.com>
Sent: Monday, August 20, 2018 8:25 AM
Subject: Application for Direct Relief's Naloxone Program
Attachments: Safety_Net_Support_Application_%282018%29.pdf

Attached is the application for Direct Relief's Naloxone Program.

The program started last year and has had over 630 distributions to a network of community health centers, free and charitable clinics, and public health departments in 45 different U.S. states and territories. This is an ongoing donation commitment with Pfizer that will provide up to 250,000 doses annually. They also have syringes, needles, and alcohol swabs available if organization's choose to make naloxone kits—all of their naloxone product is in the injectable form. Through the program, naloxone is made available to partner facilities about every two months.

Any health clinic/health center (including tribal clinics) should be eligible to receive free naloxone (and related supplies) through the program, so long as the facility is a non-profit and has a physician medical director.

More information in the attached application.

Washington State Department of Health

STAY CONNECTED

Safety Net Support Program

Application for Safety Net Health Facilities

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, 6100 Wallace Becknell Rd., Santa Barbara, CA 93117
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.***

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
- 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.

Health Facility Name*: _____

UDS Grantee ID Number (only if you are a FQHC): _____

Attention: _____

Address*: _____ **City, State, Zip*:** _____

Telephone*: _____ **Fax*:** _____

Website: _____

Will this location receive shipments from Direct Relief?* ☐ **Yes** ☐ **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): _____

Does your facility operate a licensed pharmacy?* ☐ **Yes** ☐ **No**

Do you have a pharmacy software system?* ☐ **Yes** ☐ **No**

Does your facility operate a mobile medical unit?* ☐ **Yes** ☐ **No**

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.

Clinic/Health Center License

State License #: _____ Expiration Date: _____ Authority: _____

Pharmacy/Dispensary License

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**: _____

U.S. MEDICAL PRODUCTS DONATION AGREEMENT

THIS U.S. MEDICAL PRODUCTS DONATION AGREEMENT (this "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 6100 Wallace Becknell Road, Santa Barbara, CA 93117 and [_____] ("Partner") whose principal place of business is located at [_____], with reference to the following facts and intentions:

WHEREAS, Direct Relief is a nonprofit public benefit 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; and

WHEREAS, Partner is a nonprofit, 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 and non-prescription pharmaceuticals, vouchers, equipment and/or supplies to Partner (as provided hereunder by Direct Relief to Partner, the "Donated Products") from time to time in Direct Relief's sole discretion, to be dispensed 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 (each such patient being an "Eligible Patient"), which may be modified from time to time in the sole discretion of Direct Relief; and

WHEREAS, Partner has the ability to obtain from pharmaceutical companies, manufacturers, and distributors Donated Products for Partner's patients, but instead finds it to be more effective and leads to greater patient efficiencies, to work directly with Direct Relief for Direct Relief to obtain and provide Donated Products to Partner for Partner's patients.

NOW, THEREFORE, in consideration of the foregoing premises which are hereby incorporated into the operative provisions of this Agreement by this reference, the mutual covenants and agreements contained herein, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereby agree as follows:

1. Supply of Donated Products. Notwithstanding anything to the contrary herein, nothing in this Agreement obligates Direct Relief to donate or otherwise provide to Partner any prescription or non-prescription pharmaceuticals, vouchers, equipment and/or supplies, as Partner acknowledges and agrees that Direct Relief's donation of any prescription or non-prescription pharmaceuticals, vouchers, equipment and/or supplies is dependent solely on a supply of such products made available to Direct Relief by pharmaceutical companies, manufacturers and/or distributors.

   a) Partner shall provide 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 shall only provide prescription Donated Products to Eligible Patients pursuant to the eligibility criteria set forth in Exhibit A attached hereto, and shall use reasonable efforts, consistent with applicable law, to verify that such individual is not covered by any form of third-party prescription drug benefit. Partner shall provide non-prescription Donated Products on the basis of need. Employed Partner staff will be responsible for dispensing non-prescription Donated Products directly to any qualifying recipient, in the appropriate quantity.

c) Direct Relief will not provide Donated Products directly to Eligible Patients. Instead, Partner shall provide prescription Donated Products to Eligible Patients who receive treatment at Partner's outpatient facility and present a valid prescription for such product(s) from a licensed healthcare provider at the time of treatment. In the case of dispensation of a Donated Product pursuant to medical treatment provided by Partner in response to a declared State of Disaster or Emergency as set out in Exhibit A, a prescription shall not be required, and dispensation and treatment need not take place at Partner's outpatient facility.

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 shall 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 must be returned to Direct Relief or its authorized third-party returns processor for proper disposal, as well as comply with the provisions of Section 1, clause (h) below.

f) Direct Relief will, in its sole discretion and at its sole expense, select the mode of shipment and route the Donated Products to Partner. Title to the Donated Products and risk of loss will 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, except that patient screening shall not be required at sites where dispensation takes place pursuant to medical treatment provided by Partner in response to a declared State of Disaster or Emergency as set out in Exhibit A.

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 30 days of any expired prescription Donated Product. Expired and/or damaged prescription Donated Products must 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 are subject to change by Direct Relief without prior notice.

i) Partner shall segregate the prescription Donated Products from other medical products that Partner receives, and if required by Direct Relief, to label such prescription Donated Products as having been donated to Partner.

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 three (3) days 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 generate an investigation report at the conclusion of the investigation. For purposes of this Agreement, "Quality Complaint" means any complaint or correspondence Partner becomes aware of (directly or indirectly) that relates to potential packaging or shipping defects and/or errors 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 (directly or indirectly) of an Adverse Event, Partner shall contact the manufacturer of the Donated Product within 24 hours of becoming aware (directly or

indirectly) of an Adverse Event in addition to following the Federal guidelines for reporting via U.S. Food and Drug Administration ("FDA") Form 3500. Partner shall 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" means 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.

2. Product Recalls. In the event Direct Relief is required by the manufacturer of a Donated Product (or voluntarily decides) 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 will make all contacts with the manufacturer of the subject Donated Product and will 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 in respect to the subject matter of this Section 2 except with the prior written approval of Direct Relief.

3. Reporting; Data Protection. Partner warrants (a) that it will not disclose any "protected health information," as that term is defined by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended ("PHI"), to Direct Relief, and (b) that Partner is not required to disclose any PHI to Direct Relief in order for Direct Relief to provide its services on behalf of Partner. In the event of an inadvertent disclosure of PHI by Partner to Direct Relief hereunder, Partner shall notify Direct Relief immediately and the parties shall work together to immediately return or destroy the applicable PHI.

4. Representations, Warranties and Covenants.

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

      i. Partner has not received and will not receive anything of value from Direct Relief as a condition to receiving the Donated Products;

      ii. Partner will inform Eligible Patients that they 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 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;

      iv. 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

      v. 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) 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.

   c) Partner covenants that in the event Partner becomes 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, Partner shall 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.

d) Partner covenants that it shall provide the Donated Products received under this Agreement free of charge and only to Eligible Patients, except that a nominal dispensing fee will not be a breach of this Agreement, provided that such fee must be waived if the Eligible Patient cannot afford payment thereof.

e) Partner covenants that it shall (i) maintain adequate books and records on the receipt, distribution, and disposition of all Donated Product for review by Direct Relief or its designee, (ii) ensure that written policies and procedures are in place to adequately determine patient eligibility at each site where patient screening will occur, and (iii) maintain and retain for six (6) years following the termination or expiration of this Agreement, adequate documentation and complete records verifying patient eligibility to receive Donated Product for review by Direct Relief or its designee. Patient eligibility screening is not required at sites where dispensation takes place pursuant to medical treatment provided by Partner in response to a declared State of Disaster or Emergency as set out in Exhibit A.

f) Partner covenants that it shall not bill any insurance program (including Medicare or Medicaid) for any Donated Products provided to Eligible Patients hereunder.

g) 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. Direct Relief will make available any transaction information ("T3 Data") required under the Drug Supply Chain Security Act ("DSCSA"), if applicable to the Donated Products. Any defects, shortages or problems with the Donated Products shipment must be reported to Direct Relief within three (3) days of receipt of the shipment.

h) 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 include, but are not limited to, all laws, rules, regulations and guidelines regarding pharmacy, privacy, anti-bribery and anti-kickback actions.

i) Without limiting the foregoing or anything to the contrary in this Agreement, Partner covenants and agrees that neither Partner nor any of its affiliates or any of their respective officers, directors, employees, agents or representatives will 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.

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 DONATED PRODUCTS THAT ARE PROVIDED BY DIRECT RELIEF HEREUNDER NO MATTER WHAT MANNER THEY ARE USED IN. INDIVIDUALS AND ORGANIZATIONS WHO USE OR DISPENSE OF THE DONATED PRODUCTS 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 DONATED PRODUCTS, 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 DONATED PRODUCTS THAT IT HAS DONATED OR WILL DONATE TO PARTNER. NEITHER DIRECT RELIEF NOR ANY OF ITS SUBSIDIARIES OR AFFILIATES IS RESPONSIBLE FOR ANY LIABILITY, CLAIM, LOSS, INJURY OR DAMAGE OF ANY KIND, INCLUDING LOSS OF PROFITS, INDIRECT, SPECIAL, EXEMPLARY, PUNITIVE OR CONSEQUENTIAL DAMAGES, RESULTING FROM THE USE OF ANY OF THE DONATED PRODUCTS THAT IT HAS DONATED OR WILL DONATE UNDER THIS AGREEMENT.

6. Indemnification. Partner agrees to indemnify, defend and hold Direct Relief, its subsidiaries and affiliates and their respective directors, officers, employees and agents ("Direct Relief Parties"), harmless from any claim, 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 hereunder, and further agrees that it will not seek indemnity from any Direct Relief Party for damages arising out of the condition or use of Donated Products delivered hereunder. This indemnity obligation by Partner is without regard to any act or omission by Direct Relief, its subsidiaries and affiliates or their respective 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 shall notify Direct Relief within seven (7) calendar days of the change in status, and Direct Relief will have the right to terminate this Agreement effective immediately.

8. Term and Termination. This Agreement is effective as of the Effective Date and will continue until terminated in accordance with the terms hereof:

a) Either party may terminate this Agreement upon 60 days' prior written notice to the other party, with or without cause or reason.

b) If Partner breaches Section 1(a)-(e), (h), (k) or (l), Section 4, Section 7, Section 10, or if Direct Relief has a reasonable basis (determined in its sole discretion) to believe that Partner or any of Partner's affiliates or any of their respective officers, directors, employees, agents or representatives 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 must be returned to Direct Relief pursuant to the Policies and Procedures, and (ii) at the sole discretion of Direct Relief, at the request of Direct Relief, any remaining non-prescription Donated Products must be returned to Direct Relief pursuant to the Policies and Procedures.

d) Upon expiration or termination of this Agreement, (i) Sections 2, 4, and 10 shall survive for so long as Partner retains any Donated Products, (ii) Sections 5, 6, 18, and 19 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 30 days prior written notice to Partner and during regular business hours, Direct Relief or its designee has 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 its 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 or its designee 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 or are currently 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. Partner further covenants that if, during the term of this Agreement, it, or any of its employees or agents performing hereunder, becomes or is 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 has the right to immediately terminate this Agreement. For purposes of this Section, 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 must 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 or such other address as may be provided by each party to the other party in writing from time to time. Notices are 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 delivery if sent by facsimile.

12. Independent Contractors. The relationship of the parties under this Agreement is that of independent contractors and neither party has any authority to bind or act on behalf of the other party except as otherwise agreed in writing by the parties. Nothing herein is 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 a wholly owned subsidiary or an affiliate.

14. Publicity. Neither party may disclose the terms of this Agreement or use the other party's name, logo, trademark, or service mark in any promotional or general announcement or media release without the other party's prior written approval.

15. Counterparts and Facsimile Signatures. This Agreement may be executed in two or more counterparts, each of which is deemed an original, but all of which together constitutes one and the same instrument. The parties agree that facsimile or other electronically transmitted signatures will be deemed originals of the executed signature pages.

16. Electronic Storage. Each party may copy this completed Agreement for electronic storage in a non-editable format, at which time the paper form of this Agreement may be destroyed. Each party agrees that following the electronic storage of this Agreement, any hard copy printout of that electronically stored information will constitute an original of this Agreement.

17. 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.

18. Dispute Resolution. The parties shall resolve any dispute, controversy or claim arising out of or relating to this Agreement, or the breach, termination or invalidity thereof (each a "Dispute"), under this Section 18, which is the exclusive mechanism for resolving any Dispute.

    a) Negotiations. The parties shall first attempt in good faith to resolve any Dispute by negotiation and consultation between themselves. In the event that such Dispute is not resolved on an informal basis within ten (10) business days after one party provides notice to the other party of such Dispute ("Dispute Notice"), either party may initiate mediation pursuant to this Section 18.

    b) Mediation. Subject to clause (a) above, either party may, at any time by notice to the other party, demand mediation of the Dispute ("Mediation Notice"). The parties shall cooperate with one another to select a neutral mediator and in scheduling mediation proceedings. If the parties are unable to agree on a mediator within five (5) days of the Mediation Notice, the mediation will occur under the rules of JAMS with a mediator selected under JAMS' rules. The parties agree that the mediator's fees and expenses and costs incidental thereto will be shared equally by the parties. The parties agree that all offers, promises, conduct and statements, whether oral or written, made in the course of the mediation by any party, its agents, employees, experts and attorneys, and by the mediator, are confidential, privileged and inadmissible for any purpose, including impeachment, in any litigation, arbitration or other proceeding involving the parties, provided that evidence that is otherwise admissible or discoverable shall not be rendered inadmissible or non-discoverable as a result of its use in the mediation.

    c) Litigation or Arbitration. If the parties are unable to resolve the Dispute by mediation within 30 days of the Mediation Notice, either party may file an action in a court of competent jurisdiction (as provided herein) or commence binding arbitration.

19. Attorneys' Fees. If any legal action or any arbitration or other proceeding (other than mediation pursuant to Section 18(b)) is brought for the enforcement or interpretation of this Agreement, it is agreed that the prevailing party is entitled to an award of its costs and reasonable attorneys' fees, in addition to any other relief to which it may be entitled.

20. Governing Law; Venue. This Agreement is to 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.

21. 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.

22. 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 is effective unless signed by both parties.

[Signature Page Follows]

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 as of the day and year written above.

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:** 08/20/2018

Exhibit A

ELIGIBLE PATIENT CRITERIA

General Criteria

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

Insurance and Financial Criteria

- The patient is not covered by any form of third-party prescription drug benefit.
- The patient qualifies as indigent.
- The patient's eligibility criteria are evaluated at least annually.

Medical Treatment Pursuant to a State of Disaster or Emergency

- Patient eligibility screening shall not be required, and the above General Criteria and Insurance and Financial Criteria need not be met, where Donated Product is dispensed pursuant to medical treatment provided by Partner in response to a State of Disaster or Emergency, including but not limited to a Public Health Emergency, as declared by a duly authorized Federal, state, and/or local Executive Authority or governing body.

Exhibit B

RETURN GOODS POLICIES AND PROCEDURES

Donated Product returns must follow the procedures specified below. Direct Relief reserves the right to change these procedures at any time without notice.

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

1. RETURN DONATED PRODUCT POLICY

   1.1. Expired and overstocked prescription medications must be returned to Direct Relief. Over-the-counter products and medical supplies should be disposed of by Partner.

   1.2. Donated Products are NOT to be returned for credit to the manufacturer or processed through a reverse wholesaler where credit might occur. Unused Donated Products may NOT be supplied to other organizations.

   1.3. Partner must inform Direct Relief of any expired drug within 30 days of expiration.

   1.4. Incorrect shipments, shortages or damages to Donated Products must be reported to Direct Relief within three (3) days of receipt of the Donated Products. The entire shipment of the Donated Products should be declined when there is damage.

   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.

   1.5. Donated Products delivered to Partner as a result of ordering errors may be returned to Direct Relief subject to the following conditions: (a) the Donated Product is returned in original, full and unopened condition, and (b) the Donated Product is able to be restocked by Direct Relief. Partner should immediately notify Direct Relief of any ordering errors.

   1.6. Promptly upon determination that a shipment from Direct Relief has been lost and not received by Partner, Partner shall contact Direct Relief.

2. DONATED PRODUCT RETURN PROCEDURE.

   2.1. A Return Authorization Form ("RAF") to be provided by Direct Relief must be completed by Partner. Partner must provide product name and strength, NDC number, lot number, expiration date, and quantity to be returned. An authorized and completed RAF must be received by Direct Relief from Partner before Donated Product can be returned.

   2.2. 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.

   2.3. Direct Relief will arrange and pay for a carrier to pick up Donated Product to be returned.

   2.4. Upon receipt of returned Donated Product, product condition will be verified by Direct Relief and either sent for destruction, or if appropriate, restocked.