



COUNTY OF HUMBOLDT

AGENDA ITEM NO.

C-7

For the meeting of: December 15, 2015

Date: November 26, 2015

To: Board of Supervisors

From: Phillip R. Crandall, Director
Department of Health and Human Services – Public Health

Subject: Charitable Product Donation Agreement between Kaléo Inc. and Department of Health and Human Services (DHHS), Public Health.

RECOMMENDATION(S):

That the Board of Supervisors:

- 1.) Accept the donation of 200 cartons of EVZIO™ from Kaléo Inc.
- 2.) Authorize the Chair of the Board to sign three (3) originals of the Charitable Product Donation Agreement between DHHS– Public Health and Kaléo Inc.
- 3.) Direct the Clerk of the Board to return three (3) signed originals to Department of Health and Human Services (DHHS) – Contracts Unit.
- 4.) Authorize the Director of Public Health or designee to sign the Kaléo Receipt of Donated Product form when the donation is received.

SOURCE OF FUNDING:

Public Health Fund

DISCUSSION:

Kaléo Inc. has agreed to donate 200 kits of Naloxone hydrochloride injection, an overdose reversal drug, for distribution through the North Coast AIDS Project (NorCAP). The agreement before your Board today will accept this donation so that NorCAP can receive the Naloxone kits. The product name for the kits is EVZIO™, a user friendly kit which contains two auto injectors as well as one for training. The kits will be

Prepared by Karen Baker

CAO Approval

REVIEW:

Auditor County Counsel

Human Resources Other

TYPE OF ITEM:

☒ Consent

☐ Departmental

☐ Public Hearing

☐ Other

PREVIOUS ACTION/REFERRAL:

Board Order No. _____

Meeting of: _____

BOARD OF SUPERVISORS, COUNTY OF HUMBOLDT

Upon motion of Supervisor Seconded by Supervisor Bass

Ayes Lovelace, Fennell, Bohn, Bass

Nays

Abstain

Absent

and carried by those members present, the Board hereby approves the recommended action contained in this Board report.

Dated: Dec. 15, 2015

By:

Kathy Hayes, Clerk of the Board

distributed to community members who are at risk of opioid overdose.

Humboldt County has the highest opioid overdose hospitalization rate among all the California counties at 77.2 per every 100,000 people; this is more than five times the state average. It also has the fourth highest opioid overdose death rate. There have been between 32-39 overdose deaths per year in the last five years. The Centers for Disease Control and Prevention recommend Naloxone distribution as an essential part of reducing overdose deaths. Other states and jurisdictions have seen reductions in overdose deaths and hospitalizations when Naloxone is more widely available, and providers prescribe fewer opioids.

Opioids produce their effects by acting on opioid receptors in the brain and nervous system. Naloxone works by blocking these opioid receptors, thus stopping opioids from acting on them. This reverses the effects of the opioid such as respiratory depression, sedation and hypotension. In the presence of physical dependence on opioids, Naloxone will produce immediate withdrawal symptoms, however if given to a person who has not taken opioids, it will not have any effect on him or her, since there is no opioid overdose to reverse.

NorCAP has been dispensing Narcan/Naloxone for several years. The program dispensed 42 Naloxone kits since July 2015. Public Health provides overdose prevention education, detailed instructions for delivering Naloxone, and calling 911. These donated EVZIO™ kits provide spoken instructions on the administration, so this will make it easier for people without medical training to administer the injection. It also comes with a trainer for practice and the single-use needle is retractable to prevent accidental sticks.

The program's distribution has been limited by the rising cost of Naloxone. This donation will allow NorCAP to work with our community partners to have them distribute Naloxone and reach the people in the most need.

Public Health has additionally been working with the Humboldt Independent Practice Association (IPA) to reduce the number of opioid prescriptions in the county and improve prescribing practices.

FINANCIAL IMPACT:

Acceptance of the Charitable Product Donation Agreement between Kaléo Inc. and DHHS - Public Health will allow Public Health to receive more Naloxone kits than the budget initially would support for Fiscal Year (FY) 2015-16. The donation is valued at \$11,200, this will increase the number of Naloxone kits that the program is able to provide to the community. Funding for Naloxone kits was previously supported by NorCAP donations and a newly acquired grant from Partnership HealthPlan of California (PHC) in fund 1175, budget unit 437 NorCAP CARE. There will be no impact to the County General Fund.

This agreement supports your Board's Strategic Framework by protecting vulnerable populations and creating opportunities for improved safety and health.

OTHER AGENCY INVOLVEMENT:

Kaléo Inc.

ALTERNATIVES TO STAFF RECOMMENDATIONS:

If the Board chose not to approve the recommendations, it would result in loss of product and additional expenditure of funds.

ATTACHMENTS:

Attachment #1	Kaléo Charitable Product Donation Agreement
Attachment #2	Kaléo Receipt of Donated Product Form

Attachment #1

CHARITABLE PRODUCT DONATION AGREEMENT

CHARITABLE PRODUCT DONATION AGREEMENT

This Charitable Product Donation Agreement ("Agreement") is entered into as of this 16th day of November, 2015 between kaléo, Inc. (the "Company") and County of Humboldt, a political subdivision of the State of California, through its Department of Health & Human Services – Public Health ("Grantee").

RECITALS

A. Grantee is a licensed health care provider under the State of California that operates an opioid overdose prevention and treatment training program and is authorized by law to prescribe an opioid antagonist for certain emergency uses.

B. The Company is willing to donate EVZIO™ (naloxone hydrochloride injection) Auto-Injector (the "Product") to Grantee, free of charge and with no express or implied purchase obligation or commitment.

In consideration of the mutual covenants and agreements set forth herein, the parties agree as follows:

1. **Product Donation.** The Company will use reasonable efforts to provide and deliver to Grantee free of charge 200 cartons of the Product. Each carton contains two auto-injectors and one trainer for practice. It is expressly understood that the Company, by entering into this Agreement, has no obligation to provide funding, additional Product or additional support to Grantee for any purposes.

2. **Shipment.** The Product will be shipped to Grantee at its address listed on the signature page (which Grantee certifies is authorized to receive shipments of prescription drug products). Grantee shall send a written confirmation to the Company evidencing receipt of all Products.

3. **Representations and Warranties.**

- (a) Grantee represents and warrants that it: (i) is a licensed health care provider and is authorized to by law to prescribe an opioid antagonist in the State of California for certain emergency uses; (ii) is duly authorized to enter into this Agreement; (iii) will use the Product received pursuant to this Agreement only for Grantee's own use in the emergency treatment of Grantee's clients, compliant with applicable law and product labeling, and not for resale; (iv) will not directly or indirectly bill, invoice, charge or collect for payment of any type from clients, insurance companies, governmental entities or any other entity or individual for the Product; and (v) will comply with any applicable institutional conflict of interest, disclosure or approval policies.
- (b) Company represents and warrants that: (i) it has the degree of learning and skill ordinarily possessed by reputable professionals practicing in similar localities in the same profession and under similar circumstances; (ii) the

Product has been approved by the Food and Drug Administration for the emergency treatment of known or suspected opioid overdose, characterized by respiratory system depression, central nervous system depression, or both, prior to professional medical care; (iii) each carton of Product contains two active auto-injectors, each containing naloxone 0.4 mg., and one trainer; and (iv) each carton of Product is designed with a built-in electronic voice instruction system and written instructions printed on the device.

4. **No Consideration.** The parties acknowledge and agree that the Company is providing the Product to Grantee free of any and all consideration whatsoever. Grantee agrees that the donation of the Product by the Company is not: (i) provided as payment for services or goods; (ii) is not a price term or offered in lieu of a price concession; (iii) is not intended to encourage off-label use; and (iv) is not contingent on Grantee's, or its Agents (as defined below), purchase of the Company's products. Grantee further agrees that the donation of the Product by the Company is not intended to encourage Grantee to order, prescribe, or recommend the Company's products or to reward or compensate Grantee for having ordered, prescribed, or recommended the Company's products.

5. **Grantee Agents.** Grantee shall select and shall have full and complete control of and responsibility for all actions of its agents, affiliates, officers, directors, employees and subcontractors, if any, of Grantee (collectively, the "Agents") and none of its Agents shall be, or shall be deemed to be, the agents, affiliates, officers, directors, employees or subcontractors of the Company for any purpose whatsoever by virtue of this Agreement. The Company shall have no duty, liability or responsibility of any kind, to or for the acts or omissions of Grantee or any of its Agents. Grantee hereby acknowledges and agrees that Grantee shall cause each of its Agents to comply with the terms of this Agreement. Grantee hereby acknowledges and agrees that Grantee shall be responsible for the failure of any of its Agents to comply with the terms of this Agreement.

6. **Independent Relationship.** The relationship of the Company and Grantee for purposes of this Agreement is completely independent and unrelated to any other relationship that exists or may exist in the future between the parties or any individuals or entities affiliated with the parties (including without limitation any health care professionals).

7. **Product Reference, Nondisclosure and No Use of Trademarks.**

(a) Grantee may disclose that it has received Product from the Company and shall refer to the Product as EVZIO (naloxone HCl injection). Grantee may not refer to the Product as Narcan®.

(b) Except as set forth in Section 8(a) above, neither the Company nor Grantee shall use the name, logos, trademarks or trade names of the other party in any press release or other public document without the prior written consent of such other party; provided, that either party may use the name of the other party in any document required to be filed with, or provided to, any governmental authority or regulatory agency to comply with applicable legal or regulatory requirements.

8. **Inspection and Audit.** The Company shall have the right to inspect and audit Grantee's books and records relating to the Product upon reasonable notice to Grantee. Such audit shall take place at Grantee's premises and shall be limited to verifying compliance with this Agreement. The parties agree that such an audit shall be conducted in accordance with any applicable federal or state law including, but not limited to, the Federal, State and local laws relating to the confidentiality of individual medical information. Under no circumstances shall the Company be permitted to access, review, audit, or otherwise inspect any records containing protected health information of any of Grantee's clients.

9. **Entire Agreement.** This Agreement constitutes the sole agreement of the parties and supersedes all oral negotiations and prior writings with respect to the subject matter hereof.

10. **Notices.** Any notice required or permitted by this Agreement shall be in writing and shall be deemed sufficient upon receipt, when delivered personally or by courier, overnight delivery service, confirmed email or confirmed facsimile, 48 hours after being deposited in the regular mail as certified or registered mail (airmail if sent internationally) with postage prepaid, if such notice is addressed to the party to be notified at such party's address or facsimile number as set forth below, or as subsequently modified by written notice.

Company: Ned Ruffin

Vice President & General Counsel
111 Virginia Street, Suite 300
Richmond, Virginia 23219
Fax: (804) 545-6219

Grantee: Humboldt County Department of Health & Human Services -
Public Health
Attn: Karen Baker
908 7th St.
Eureka, CA 95501

11. **Jurisdiction and Venue.** This Agreement shall be construed and governed by the laws of the State of California, and any dispute arising hereunder or relating to this Agreement shall be litigated in the State of California. Venue shall lie in the County of Humboldt, unless transferred by court order pursuant to California Code of Civil Procedure sections 394 or 395.

12. **Counterparts.** This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together will constitute one and the same instrument.

The parties have caused this Agreement to be duly executed by an appropriate representative as of the date and year first written above.

KALÉO, INC.

By: Ned Ruffin
Ned Ruffin
Vice President & General Counsel

111 Virginia Street, Suite 300
Richmond, Virginia 23219
Fax: (804) 545-6219

Date: 11/19/15

COUNTY OF HUMBOLDT

By: Estelle Fennel
Estelle Fennel
Chair, Humboldt County Board of
Supervisors

825 5th Street, Rm 111
Eureka, California 95501
(707) 476-2390

Date: 12/15/2015

Attachment #2

RECEIPT OF DONATED PRODUCT FORM



Receipt of Donation Form

INSTRUCTIONS FOR COMPLETION OF FORM UPON RECEIPT OF DONATED PRODUCT

Within 24 hours of receipt of Donated Product please complete form below and scan and e-mail or fax all sections of this form to the following:

Kaleo, Inc.

donationrequest@kaleopharma.com

Tel 804-545-6365

Fax 804-545-6219

**** Receipt of Donated Product****

[To be completed by Grantee upon receipt of Donated Product]

Grantee receiving site name:

Grantee's Name:

Date shipment opened: _____

Name of Individual who opened the shipment _____

Confirmation of Investigational Product Received:

1. Does the shipment contain XX Evzio 2+1 cartons?

Yes ☐ No ☐

*If you answered "**No**", explain discrepancies below and contact kaleo, Inc. immediately:

2. Was any of the Donated Product damaged? Yes ☐ No ☐

*If you answered "**Yes**", enter the total # damaged by product and Lot # and contact kaleo, Inc. immediately:

Print and sign your name below, and provide the date:

Grantee Agent (print name): _____

Signature of Agent: _____

Date of signature: _____