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JOHN T. HASSLER Regulated Industries Complain Department of Commerce and State of Hawaii Leiopapa A Kamehameha Bui 235 South Beretania Street, Su Honolulu, Hawaii 96813 Telephone: 586-2660 Attorneys for Department of C	Consumer Affai lding lite 900	irs I	FROF A LICENSE ZOIL MAR DEPT OF CONSUM	IS DIVIS	2: 04 2: 04 RCE FAIRS	
and Consumer Affairs DEPARTMEN	T OF COMMER	F PHARMAC RCE AND CO OF HAWAII		R AFFA	HEARANGS	2016 APP - 1
In the Matter of the Miscellane	cous Permit of )	PHA 2016-	-43-L		ਸ <b>ਹ</b>	J A
HEALTHY OPTIONS, INC.,	)	SETTLEM FILING OF				
Respond	ient. ) )	ACTION A EXHIBITS	ND BOA	RD'S FI		
SETTLEMENT	AGREEMENT	PRIOR TO F	ILING O	F PETIT	ION	

# FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"), through its undersigned attorney(s), and Respondent HEALTHY OPTIONS, INC. (hereinafter "Respondent"), enter into this Settlement Agreement on the terms and conditions set forth below.

A. <u>UNCONTESTED FACTS</u>:

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1. At all relevant times herein, Respondent was the holder of miscellaneous permit number PMP 110, issued by the Board of Pharmacy (hereinafter the "Board"). The miscellaneous permit was issued on or about September 17, 1998. The miscellaneous permit will expire or forfeit on or about December 31, 2017.

2. Respondent's mailing address for purposes of this action is P.O. Box 42121, Portland, Oregon 97242.

3. RICO received a request for investigation from the Board after Respondent reported disciplinary actions taken by the states of Oregon and Washington.

4. RICO obtained a copy of a Consent Order issued against Respondent by the Oregon Board of Pharmacy in Case No. 2015-0015 (hereinafter "the Oregon Order") (Exhibit "1"). The Oregon Order was based on allegations Respondent combined three 30 count bottles of Torrent Pharmaceuticals Telmisartan into one bottle. The Oregon Order imposed a \$10,000.00 civil penalty and required Respondent to submit a Quality Assurance Plan to the Oregon Board.

5. RICO also obtained a copy of an Agreed Order issued against Respondent by the Washington Board of Pharmacy in No. M2015-245 (hereinafter "the Washington Order") (Exhibit "2"). The Washington Order was based on allegations Respondent combined three 30 count bottles of Torrent Pharmaceuticals Telmisartan into one bottle. The Washington Order imposed a \$5,000.00 fine.

6. RICO alleges that disciplinary action was taken against Respondent by the states of Oregon and Washington.

7. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statute(s) and/or rule(s): Hawaii Revised Statutes ("HRS") § 436B-19(13) (disciplinary action by another state or federal agency).

8. The Board has jurisdiction over the subject matter herein and over the parties hereto.

## B. <u>REPRESENTATIONS BY RESPONDENT</u>:

1. Respondent is fully aware that Respondent has the right to be represented by an attorney and voluntarily waives that right.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

4. Respondent being at all times relevant herein the holder of a miscellaneous permit acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of the permit and administrative fines, if the foregoing allegations are proven at hearing.

5. Respondent represents Exhibit "1" is a true and correct copy of the Consent Order issued by the Oregon Board of Pharmacy in Case No. 2015-0015; and Exhibit "2" is a true and correct copy of the Agreed Order issued by the Washington Board of Pharmacy in No. M2015-245.

5. Respondent understands that any false or untrue statement or any material misrepresentation or omission of fact by Respondent in this settlement agreement may be grounds for further disciplinary action under HRS chapters 436B and 461.

6. Respondent further understands that RICO enters into this settlement agreement, and agrees to the specific terms contained in this settlement agreement, based upon Respondent's representations made herein.

7. Respondent does not admit to violating any law or rule, but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's miscellaneous permit.

8. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

9. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2016-43-L.

10. Respondent understands that this Settlement Agreement may be subject to reporting requirements.

11. Respondent understands this Settlement Agreement is public record pursuant to Hawaii Revised Statutes chapter 92F.

## C. <u>TERMS OF SETTLEMENT</u>:

1. <u>Probation</u>. Respondent's miscellaneous permit is hereby placed on probation for a period of two (2) years. Probation shall become effective immediately upon the approval of this Settlement Agreement by the Board. During the probationary period, Respondent agrees to comply with the following terms and conditions:

2. <u>Comply with Oregon and Washington actions</u>. During the period of probation, Respondent agrees to comply with the terms of the Oregon Order and the Washington Order. Respondent agrees to report any failure to comply within fifteen (15) days.

3. <u>Administrative fine</u>. Respondent agrees to pay a fine in the amount of ONE THOUSAND AND NO/100 DOLLARS (\$1,000.00). Payment shall be made by **cashier's check** or money order made payable to "DCCA - Compliance Resolution Fund" and mailed to the Regulated Industries Complaints Office, Attn: John T. Hassler, Esq., 235 S. Beretania Street, 9<sup>th</sup> Floor, Honolulu, Hawaii 96813. Payment of the fine shall be due at the time this Settlement Agreement is returned to RICO.

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4. <u>Failure to Comply with Settlement Agreement</u>. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph(s) C.1 through C.3 above, Respondent's permit shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all indicia of the permit to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new permit until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become permitted again, Respondent must apply to the Board for a new permit pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

5. <u>Possible further sanction</u>. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of miscellaneous pharmacy permit holders in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

6. <u>Approval of the Board</u>. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.7, C.8, C.9 and C.10 below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.

7. <u>No Objection if Board Fails to Approve</u>. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent nor any attorney that Respondent may retain, will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

8. <u>Any Ambiguities Shall be Construed to Protect the Consuming Public</u>. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

9. <u>No Reliance on Representations by RICO</u>. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any representation of fact, opinion or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion or promise made by RICO or any of its agents, employees, representatives or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

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1. N. 1.

10. <u>Complete Agreement</u>. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.

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IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below.

872 DATED: March

HEALTHY OPTIONS, INC. Respondent

By:

DATED: Honolulu, Hawaii, March 14, 2016

DARIA A. LOY-GOTO JOHN T. HASSLER Attorneys for Department of Commerce and Consumer Affairs

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IN THE MATTER OF THE MISCELLANEOUS PERMIT OF HEALTHY OPTIONS, INC.; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBITS "1" AND "2"; CASE NO(S). PHA 2016-43-L

APPROVED AND SO ORDERED: BOARD OF PHARMACY STATE OF HAWAII

Ken Uam

3/31/16

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KERRI OKAMURA Chairperson

GARRETT A. LAU Vice Chairperson MARCELLA CHOCK

NS. J. MA

MARY JO KEEFE

PVL 07/01/15

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# IN THE MATTER OF THE MISCELLANEOUS PERMIT OF HEALTHY OPTIONS, INC.; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBITS "1" AND "2"; CASE NO(S). PHA 2016-43-L

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APPROVED AND SO ORDERED: BOARD OF PHARMACY STATE OF HAWAII

KERRI OKAMURA Chairperson

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GARRETT A. LAU Vice Chairperson

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MARCELLA CHOCK

PVL 07/01/15

STATE OF <u>Dregon</u> ) SS. COUNTY OF <u>Multhomath</u>
On this $\frac{8}{4}$ day of $\frac{1}{10}$ , 20 10, before me personally appeared
Jeff Welter, to me known to be the person described, and who executed the
foregoing instrument on behalf of teathy Options Inc. dla PPS as its
Gentra ( Manager, and acknowledged that he/she executed the same as
his/her free act and deed. This <u>six</u> -page <u>se the ment Agreement</u>
document dated rebruary 21, 2016 was acknowledged before me by
Teff Welter this 8th day of March , 20 16, in the
City of <u>Portland</u> , in the County of <u>Multhomah</u> , in the State of
Oregon.
Ani Karburge Branco



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Name: Notary Public, State of Oregon

My Commission expires: <u>5-14-</u>19

1	BEFORE THE BOARD OF PHARMACY							
2	OF THE STATE OF OREGON							
3	In the Matter of the ) Case No. 2015-0015							
4	Drug Outlet Registration of )							
5	Drug Ouner Registration of							
6 7	HEALTHY OPTIONS INC dba: ) CONSENT ORDER							
8	POSTAL PRESCRIPTION SERVICES )							
9								
10	Registrant )							
11	, j							
12	WHEREAS, the Board of Pharmacy of the State of Oregon has filed a Notice of							
13	Proposed Disciplinary Action; Answer Required ("Notice"), hereby incorporated by reference,							
14	regarding the registrant in the above-captioned matter; and							
15								
16	WHEREAS, the above-noted Notice was duly served on the registrant as required by law;							
17	and							
18	X							
19	WHEREAS, the parties are desirous of resolving and settling those matters contained in							
20	the above-noted Notice without further proceedings thereon; and							
21								
22	WHEREAS, the registrant is aware of the right to a hearing with the assistance of counsel							
23	and the right to judicial review of the Board's decision, and hereby freely and voluntarily waives							
24	those rights; and							
25								
26	WHEREAS, the registrant does not contest the facts alleged in the above-noted Notice;							
27	and							
28	WLUEDEAS Desistant asknowledges that the ellegations in the Nation if names in a							
29 30	WHEREAS, Registrant acknowledges that the allegations in the Notice, if proven in a							
31	contested case proceeding, would constitute grounds for imposition of a civil penalty as described herein; and							
32								
33	WHEREAS, the registrant consents to the civil penalty as set forth herein;							
34	the set of the reference of the set of benefit to set retering							
35	I. The registrant shall pay the Board a civil penalty in the amount of \$20,000 with							
36	\$10,000 stayed pending compliance with this Order, no similar violation for 3 years, and with the							
37	submission of a Quality Assurance Plan acceptable to the Board to correct violations as noted in							
38	Notice. Payment of the \$10,000 civil penalty and the Quality Assurance Plan with a copy of this							
39	order shall be submitted within ten days from the date this Consent Order becomes final.							
40	15							
41	2. The registrant shall submit MedWatch reports for the 18 patients in Oregon							
42	associated with the allegations noted in the above-noted Notice.							
43								
44	3. Failure of the registrant to comply with the sanctions of this Consent Order may,							
45	after notice and hearing, result in further disciplinary action.							
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Page 1 of 2 - CONSENT ORDER; Case No. 2015-0015

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EXHIBIT '2'

49	I hereby acknowledge that	I am the authorized a	representative of registrant. On behalf of
50			d understand the above-noted Notice and
51	the terms of the Consent Order. I	hereby acknowledge	that I understand that the Consent Order
52			ll be available via the Board's online
53	licensure verification; is available	upon written request	pursuant to public disclosure laws; and
54	shall be reported to the National Pr	actitioner Data Bank	as required by federal law. I agree to the
55	Board entering the Consent Order.		
56		4	
57			11 10 11-
58	· · · · · · · · · · · · · · · · · · ·	······	11-18-15
59	Authorized Representative		Date
60	HEALTHY OPTIONS INC dba		
61	Postal Prescription Services		
62	Registrant (Reg. No. RP-0002910)		
63			
64			
65			
66	IT IS SO ORDERED.		
67			
68			
69	BOARD OF PHARMACY		
70	FOR THE STATE OF OREGON		
71			
72			(1(19/15-
73	Control Control D Dh	<u> </u>	
74	Gary Miner, R.Ph.		Date
75	Compliance Director		

## CONSENT

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Page 2 of 2 - CONSENT ORDER; Case No. 2015-0015

## STATE OF WASHINGTON DEPARTMENT OF HEALTH PHARMACY QUALITY ASSURANCE COMMISSION

. In the Matter of

No. M2015-245

HEALTHY OPTIONS, INC. dba POSTAL PRESCRIPTION SERVICES Credential No. PHNR.FO.00056444

#### STIPULATED FINDINGS OF FACT, CONCLUSIONS OF LAW AND AGREED ORDER

#### Respondent

The Pharmacy Quality Assurance Commission (Commission), through Jo Anne Minor, Department of Health Staff Attorney, and Respondent, represented by counsel, Renee Howard, stipulate and agree to the following:

## 1. PROCEDURAL STIPULATIONS

1.1 On June 9, 2015, the Commission issued a Statement of Charges against Respondent.

1.2 Respondent understands that the Commission is prepared to proceed to a hearing on the allegations in the Statement of Charges.

1.3 Respondent understands that if the allegations are proven at a hearing, the Commission has the authority to impose sanctions pursuant to RCW 18,64,390,

1.4 Respondent has the right to defend against the allegations in the Statement of Charges by presenting evidence at a hearing.

1.5 Respondent walves the opportunity for a hearing on the Statement of Charges provided that the Commission accepts this Stipulated Findings of Fact, Conclusions of Law and Agreed Order (Agreed Order).

1.6. The parties agree to resolve this matter by means of this Agreed Order.

1.7 Respondent understands that this Agreed Order is not binding unless and until it is signed by the Commission and served by the Adjudicative Clerk Office.

1.8 If the Commission accepts this Agreed Order, it is a public document and will be placed on the Department of Health's website and otherwise disseminated as required by the Public Records Act (Chap. 42.56 RCW).

STIPULATED FINDINGS OF FACT, CONCLUSIONS OF LAW AND AGREED ORDER NO. M2015-245 AD-JEVEN

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1.9 If the Commission rejects this Agreed Order, Respondent waives any objection to the participation at hearing of any Commission members who heard the Agreed Order presentation.

#### 2. FINDINGS OF FACT

Respondent and the Commission stipulate to the following facts:

2.1 On August 31, 1999, the State of Washington issued Respondent a credential to practice as a nonresident pharmacy. Respondent's credential is currently active.

2.2 Between August 2014 and November 2014, Respondent dispensed to at least fifty-five (55) patients in the state of Washington a 90 days' supply of Torrent brand telmisartan tablets in a pharmacy stock prescription vial after removing the telmisartan from three (3) thirty (30) count manufacturer's containers. The warning label of the manufacturer's bottle states: "Moisture sensitive tablets – do not remove from container until immediately before administration."

2.3 On October 16, 2014, Torrent sent Respondent a letter stating as follows: "Regarding Torrent's Telmisartan Tablets, USP all strengths this product remains stable for 30 days, based on open bottle stability, when dispensed with or without desiccant in a prescription bottle or Torrent's 30-count shelf bottle. The sealed Torrent bottle is stable up to the expiration data printed on the label."

2.4 In or about January 2015, Respondent contacted by telephone patients who had unused medication and offered to replace their medication with telmisartan tablets dispensed in the manufacturer's bottle.

2.5 On June 3, 2015, Torrent sent Respondent a letter staling as follows: \*Regarding Torrent's Telmisartan Tablets, USP all strengths this product remains stable for 90 days, based on open bottle stability, when dispensed with or without desiccant in a prescription bottle or Torrent's 30-count shelf bottle. The sealed Torrent bottle is stable up to the expiration date printed on the label."

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STIPULATED FINDINGS OF FACT, CONCLUSIONS OF LAW AND AGREED ORDER NO: M2015-245 PAGE 2 OF 5

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## 3: CONCLUSIONS OF LAW

The Commission and Respondent agree to the entry of the following Conclusions of Law, which are for the purposes of this proceeding only, and shall not be admissible in any other administrative, criminal or civil proceeding:

3.1 The Commission has jurisdiction over Respondent and over the subject matter of this proceeding.

3.2 There is sufficient evidence to justify a finding that Respondent violated RCW 18.64.360(4) and WAC 246-869-210.

3.3 The Commission may impose a line on Respondent's nonresident pharmacy license under RCW 18,64.390.

#### 4. AGREED ORDER

Based on the Findings of Fact and Conclusions of Law, the Commission and Respondent agree to entry of the following Agreed Order:

4.1 Respondent shall pay a fine to the Commission in the emount of five thousand dollars (\$5,000.00), which must be received by the Commission within three (3) months of the effective date of this Agreed Order. The fine shall be paid by certified or cashier's check or money order, made payable to the Department of Health and mailed to the Department of Health, Pharmacy Quality Assurance Commission, at PO Box 1099, Olympia, WA 98507-1099. Credit or Debit cards can also be used for payment at the front counter of the Department of Health building at

111 Israel Road SE, Turnwater, WA 98501, during regular business hours.

4.2 Any documents required by this Agreed Order shall be sent to Department of Health Compliance at PO Box 47873, Olympia, WA 98504-7873.

4.3 Respondent is responsible for all costs of complying with this Agreed Order.

4.4 Respondent shall inform the Department of Health Office of Customer Service, In writing, of changes in Respondent's residential and/or business address within Ihirty (30) days of the change. The mailing address for the Office of Customer Service is PO Box 47865, Olympia, WA 98504-7855.

4.5 Respondent shall obey all federal, state and local laws and all administrative rules governing the practice of the profession in Washington.

STIPULATED FINDINGS OF FACT, CONCLUSIONS OF LAW AND AGREED ORDER NO, M2015-245 PAGE3 OF 5

AD- BEV. OHIS

4.6 The effective date of this Agreed Order is the date the Adjudicative Clerk Office places the signed Agreed Order into the U.S. mail. If required, Respondent shall not submit any fees or compliance documents until after the effective date of this Agreed Order.

## 5. FAILURE TO COMPLY

Protection of the public requires practice under the terms and conditions imposed in this order. Failure to comply with the terms and conditions of this order may result in suspension of the credential after a show cause hearing. If Respondent fails to comply with the terms and conditions of this order, the Commission may hold a hearing to require Respondent to show cause why the credential should not be suspended. Respondent will be afforded notice and an opportunity for a hearing on the issue of non-compliance.

## 6. ACCEPTANCE

I, <u>Jefffry Warne Weiffr</u>, have the legal authority to act on behalf of Healthy Options, Inc. dba Postal Prescription Services. I have read, understand and agree to this Agreed Order. This Agreed Order may be presented to the Commission without my appearance. I understand that I will receive a signed copy if the Commission accepts this Agreed Order.

 抗気人THYOPTIONS, INC, はba POSTAL PRESCRIPTION SERVICES RESPONDENT

DAT

Representionant

RENEE HOWARD, WSBA #38644 ATTORNEY FOR RESPONDENT

-12-15 11

DATE

STIPULATED FINDINGS OF FACT, CONCLUSIONS OF LAW AND AGREED ORDER NO. M2015-245 PAGE 4 OF 5

AO-REV. 87-1

7. ORDER

The Commission accepts and enters this Stipulated Findings of Fact, Conclusions of Law and Agreed Order.

2.0 2.015 DATED: 2015

STATE OF WASHINGTON DEPARTMENT OF HEALTH PHARMACY QUALITY ASSURANCE COMMISSION .

PRESENTED BY:

JO ANNE MINOR, WSBA #17246 DEPARTMENT OF HEALTH STAFF ATTORNEY

11/20/2015

DATE

STIPULATED FINDINGS OF FACT, CONCLUSIONS OF LAW AND AGREED ORDER NO. M2015-245

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