NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane - Reno, NV 89509

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

New Pharmacy or	comple	te all requir	ed forms.
GENERAL INFORMATION to be comp	leted b	y all type:	s of ownership
Pharmacy Name: Solder Gate Veterinary Physical Address: 8 Digital Drive, Suite 10			
Mailing Address: 8 Digital Drive Suite 104			
City: Novato	State	: CA	Zip Code: 94949
Telephone: 415-455-5590	Fax:	415-455-90	39
Toll Free Number: 1-888-855-6337		_ (Required	l per NAC 639.708)
E-mail: erik.clausen@ggprx.com		Website:	www.ggvcp.pharmacy
Managing Pharmacist: Travis	Wats	son	License Number: 72215
TYPE OF PHARMACY	AND	SE	RVICES PROVIDED
Yes/No	28 5	Yes	s/No
☑ □ Retail			☐ Off-site Cognitive Services
☐ ☑ Hospital (# beds	_)		☑ Parenteral **
☑ Internet			
☐ ☐ Nuclear			
☐ ☐ Ambulatory Surgery 0	Center		☐ Mail Service
☐ Community			☑ Long Term Care
□ ☑ Other:			☑ Sterile Compounding **
			☐ Non Sterile Compounding
All boxes must be checked			☑ Mail Service Sterile Compounding **
For the application to be com	plete		☑ Other Services:

^{**}If you check "yes" on any of these types of services, you will be <u>required</u> to make an appearance at the board meeting,

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Erik

Print Name of Authorized Person

vvitnii	n the last five (5) years:	
1)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?	Yes □ No ਓ
2)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?	Yes □ No ☑
3)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry?	Yes ☑ No □
4)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?	Yes □ No ⊡
5)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?	Yes □ No 🗹
Copie	answer to question 1 through 5 is "yes", a signed statement of explanation res of any documents that identify the circumstance or contain an order, agrees sition may be required.	nust be attached. ement, or other
correc	by certify that the answers given in this application and attached documentact. I understand that any infraction of the laws of the State of Nevada regulation of an authorized pharmacy may be grounds for the revocation of this pe	ting the
under correct emplo	e read all questions, answers and statements and know the contents thereof penalty of perjury, that the information furnished on this application are true of the true of the penalty of perjury, that the information furnished on this application are true of the perjury, that the information furnished on this application are true of the penalty of perjury, that the information furnished on this application are true of the penalty of perjury, that the information furnished on this application are true of the penalty of perjury, that the information furnished on this application are true of the penalty of perjury, that the information furnished on this application are true of the penalty of perjury, that the information furnished on this application are true of the penalty of perjury, that the information furnished on this application are true of the penalty of	, accurate and ants and nd moral
Origin	al Signature of Person Authorized to Submit Application	
Origin	al Signature of Person Authorized to Submit Application, no copies or stamp	JS

Board Use Only Date Processed: _____ Amount: _____

Clausen

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

	of Incorpora										1
Parent	Company	if any: Golde	n Gate	Pharmacy	/ Holdi	ngs, In	С	_			
Mailing	Address:	8 Digital Drive	Suite 104								_
City: N	lovato			State: CA		_ Zip:	94949				_
Teleph	one: 415-4	155-5590		Fax:	415-45	5-9039					_
	t Person:				Cla	usen				<u>-</u>	
For any	y corporation	on non publicly	traded, o	disclose the	followi	ng:					
1) i	List top 4 p	ersons to who	m the sha	ares were is	ssued b	y the co	rporati	on?			
•	a)N/A										
,	<u> </u>	Name		Addre	SS						_
ı	b)				•						
		Name		Addre	SS						
	c)	Name		Addre	ee						
	15	Name		Addie	33						
. (d)	Name		Addre	SS				· ·		—
2) i	Provide the	e number of sh	ares issu	ed by the c	orporati	ion. ^{1,0}	00				
		the price paid									_
		did the corpor									_
5) i	Provide a d	copy of the cor	poration's	stock regis	ster evid	dencing	the ab	ove in	ıformat	ion	
List any	y physician	shareholders	and perc	entage of o	wnersh	ip.					
Name:	N/A				•			. %: _			-
Hours	of Operati	on for the ph	armacy:		•						
Monday	y thru Frida	ay <u>8:00</u> am	6:00 p	om		Saturd	ay		_am		pm
9	Sunday	am	r	om		24 Hou	urs		_		
A Neva	ıda busines	ss license is no	ot required	d, however	if the pl	narmacy	/ has a	Neva	ıda bus	siness	
license	please pro	vide the numb	er: n/a		•	_					. IA
										Page	; 4

STATEMENT OF RESPONSIBILITY FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

⊦ _{I,} Erik		Clausen		
Responsible Person of	Golden Gate Veteri	nary Compo	unding Pharmacy, Inc	
hereby acknowledge an	d understand that in ac	ddition to the c	orporation's, any owner(s),	
shareholder(s) or partner	r(s) responsibilities, m	ay be respons	ible for any violations of pharr	nacy law
that may occur in a phar	macy owned or operat	ted by said cor	poration.	
I further acknowle	edge and understand t	hat the corpora	ation's, any owner(s), shareho	older(s)
or partner(s)may be nan	ned in any action taker	n by the Nevad	la State Board of Pharmacy a	gainst a
pharmacy owned by or o	pperated by said corpo	ration.		
I further acknowle	edge and understand the	hat the corpora	ation's, any owner(s), shareho	older(s)
or partner(s) cannot req	uire or permit the phar	macist(s) in sa	id pharmacy to violate any pro	ovision
of any local, state or fed	eral laws or regulations	s pertaining to	the practice of pharmacy.	
£/(
Original Signature of Pe	rson Authorized to Sub	omit Applicatio	n, no copies or stamps	
Erik	Clausen		5/2/19	
Print Name of Authorize	d Person		Date' /	

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF <u>CA</u>)
STATE OF
I, Erik Clausen , hereby certify that the assertions in this Affidavit
are true and correct to the best of my knowledge and belief, and state as follows:
1. I am the Chief Financial Officer for Golden Gate Veterinary Compounding Pharmacy, Inc. (the
Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile
products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out-
of-State Pharmacy License.
3. I understand and acknowledge that the Pharmacy and any of its Nevada-
registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells
or ships any compounded sterile product into Nevada without first obtaining written authorization
from the Board to do so.
4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile
product into Nevada, the Pharmacy, through an authorized representative, will first notify the
Board and obtain written approval to sell and ship such products into Nevada.
5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile
product into Nevada, an authorized representative of the Pharmacy may be required to appear
before the Board to answer questions before such approval is granted.
FURTHER AFFIANT SAYETH NOT.
I, Erik Clausen, do hereby swear under penalty of perjury that the assertions of this
affidavit are true.
Erik Clausen
SUBSCRIBED AND SWORN TO
before me, a notary public this
g may , 2019.
NOTARY PUBLIC INTO FORGUTE!!
JAVAD FOROUZEH COMM. # 2166757 NOTARY PUBLIC CALIFFORNIA MARIN COUNTY
MY COMM. EXP. Nov. 2, 2020

APPLICATION FOR CERTIFICATION AS A PROVIDER OF INTERNET PHARMACY SERVICES

Addendum to Pharmacy Application (Only required if providing internet services)

GENERAL INFORMATION
Name of Nevada license pharmacy: Golden Gate Veterinary Compounding Pharma
Nevada license number: Pending
Websites in use or intended to be used:www.ggvcp.pharmacy
Affiliated websites (websites that link to or otherwise direct users to your website):
www.ggvetrx.com
·
VIPPS CERTIFICATION
Is the pharmacy VIPPS (Verified Internet Pharmacy Practice Sites administered be NABP) certified? Please provide a copy with application. Yes ☑ No ☐
If yes, please sign and date page 3 and you will not need to answer questions 1 through 8.
PHARMACIES LACKING VIPPS CERTIFICATION
 Is the pharmacy licensed in each state in which the pharmacy will practice pharmacy Yes □ No □
PLEASE ATTACH A SEPARATE SHEET LISTING ALL THE STATES IN WHICH YOU ARE LICENSED, INCLUDING THE DATE OF INITIAL LICENSURE AND THE LICENSE NUMBER.

2.	Does the pharmacy maintain and enforce policies and procedures that ensure the following:		
	A) That the pharmacy will establish the authenticity of each prescription that the pharmacy receives?	Yes □	No □
	B) That the pharmacy will not fill any prescription which has been previously filled by another pharmacy?	Yes □	No □
	C) That for each pharmacy the pharmacy fills the prescription cannot be filled by another pharmacy?	Yes □	No □
	D) That the pharmacy will authenticate the identity of each patient and prescribing practitioner?	Yes □	No □
	E) That the prescriptions will be filled in compliance with all applicable federal and state laws?	Yes □	No □
	F) That a patient or the caregiver of the patient may make a complaint to the pharmacy regarding a prescription?	Yes □	No □
	G) That if a complaint is made, the complaint will be investigated thoroughly and that the results of the investigation will be communicated to the patient or caregiver?	Yes □	No □
	H) That if the investigation of a complaint reveals that the operations of the pharmacy resulted in an error in the processing or filling of the prescription, appropriate remedial action was taken by the pharmacy?	Yes □	No □
	I) That the pharmacy will communicate to a patient or a prescribing practitioner any delay that might jeopardize or alter the drug therapy of the patient with respect to delivering the prescribed drug or device?	Yes □	No □
	J) That the pharmacy will communicate to a patient information regarding recalls of drugs and the appropriate means to dispose of expired, damaged or unusable drugs or devices?	Yes □	No □
3.	Does the pharmacy obtain and maintain patient information necessary to facilitate review of drug utilization and counseling of patients pursuant to any applicable statutes?	Yes □	No □

4.	Will the pharmacy provide review of drug utilization and counseling of patients pursuant to the applicable statutes in the state in which the patient resides?	Yes □	No 🗆
5.	Does the pharmacy maintain controls of its computer system, information concerning patients, and other such confidential information and documents to prevent unauthorized or unlawful access to all such confidential information and documents?	Yes □	No □
6.	Does the pharmacy comply with applicable federal and state laws regarding the following:		
	A) To the dispensing of prescription drugs?	Yes □	No □
	B) To the record keeping related to the patients served by the pharmacy, the purchase of prescription drugs and the sale and dispensing of prescription drugs?	Yes □	No □
	C) To the sale of over-the-counter products, including any special requirements related to products that have been identified as precursors to the manufacture or compounding of illegal drugs?	Yes □	No □
7.	Does the pharmacy ship prescriptions to a patient using secure and traceable means?	Yes □	No 🗆
8.	Does the pharmacy ship prescriptions to a patient using packaging or devices which will ensure that the prescription is maintained within appropriate standards pertaining to temperature, light and humidity as described in the <i>United States Pharmacopoeia</i> , 25 th edition, 2002, which is hereby adopted by reference?	Yes □	No □
	PLEASE ATTACH A COPY OF YOUR POLICIES AND PROCED	URES.	
	gnature below certifies that the answers provided in this application t and complete.	are true	2,
	5/C/C 5/2	/19	
Signat	cure of Owner Date		



Ben Kirby

den.kirby@ggprx.com>

.Pharmacy Domain Renewal Approved

dotPharmacy Customer Service < custserv@safe.pharmacy> To: Ben Kirby

 den.kirby@ggprx.com>

Tue, Apr 9, 2019 at 1:25 PM

Dear Ben:

The National Association of Boards of Pharmacy® (NABP®) is pleased to re-approve your request for a .pharmacy domain name(s). You do not need to do anything at this time as you have already renewed your domain(s) with your registrar.

Please email us with any questions at custserv@safe.pharmacy.

Sign up now to start receiving .Pharmacy News emails!

NABP appreciates your support of the .pharmacy program. Thank you.

.Pharmacy Customer Service

National Association of Boards of Pharmacy

1600 Feehanville Drive

Mount Prospect, IL 60056

847/391-4406

State of California Secretary of State

CERTIFICATE OF STATUS

ENTITY NAME:

GOLDEN GATE VETERINARY COMPOUNDING PHARMACY, INC.

FILE NUMBER:

C3772128

FORMATION DATE:

JURISDICTION:

04/03/2015

TYPE:

DOMESTIC CORPORATION

CALIFORNIA

STATUS:

ACTIVE (GOOD STANDING)

I, ALEX PADILLA, Secretary of State of the State of California, hereby certify:

The records of this office indicate the entity is authorized to exercise all of its powers, rights and privileges in the State of California.

No information is available from this office regarding the financial condition, business activities or practices of the entity.



IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of March 07, 2019.

ALEX PADILLA Secretary of State







LICENSE NO. PHY 55535

ISSUE DATE OCTOBER 06, 2018

GOLDEN GATE VETERINARY COMPOUNDING PHARMACY INC

8 DIGITAL DR STE 104 -NOVATO CA 94949

The above is licensed with the State Board of Pharmacy as a Corporation.

PHARMACIST IN CHARGE

The official status of this license can be verified at www.pharmacy.ca.gov

PLACE RENEWAL LICENSE HERE

VALID UNTIL OCTOBER 01, 2019

RECEIPT NUMBER 00605067

This original license must be kept for the life of the license and posted in public view.

in accordance with the provisions of Chapter 9 of Division 2 of the Business and Professions Code, the business named above is hereby licensed at the above address, and is subject to the rules and regulations of the California State Board of Pharmacy.

This permit is non transferable. Contact the California State Board of Pharmacy when there is change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change), administrator or pharmacist—in—charge.

CALIFORNIA STATE BOARD OF PHARMACY 1625 NORTH MARKET BLVD., SUITE N-219 SACRAMENTO, CA 95834 (916) 574-7900

---- POST IN PUBLIC VIEW ----

Owner/ Officer Information for Golden Gate Veterinary Compounding Pharmacy, Inc

Name/Title SSN/FEIN Address:

Golden Gate Pharmacy Holdings, Inc 47-3741430 8 Digit

8 Digital Drive Suite 200 Novato, CA 94949

Rebecca Lofholm, President

Ralston Lane Newcastle, CA 95658

Paul Lofholm, Vise President

5 Ralston Lane Newcastle, CA 95658

- 99.9% of parent company jointly with Rebecca Lofholm through the Paul W. and Rebecca Ellen
Trust

Nicole Lofholm Clausen, Secretary

! Zandra Place, Novato, CA 949453

- 0.05% of parent company

Erik Clausen, CFO

? Zandra Place, Novato, CA 949453

- 0.05% of parent company



California State Board of Pharmacy

1625 N. Market Blvd, N219 Sacramento, CA 95834

Phone: (916) 574-7900 Fax: (916) 574-8618

www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency **Department of Consumer Affairs** Gavin Newsom, Governor



March 22, 2019

GOLDEN GATE VETERINARY COMPOUNDING PHARMACY INC 8 DIGITAL DR STE 104 **NOVATO CA 94949**

California State Board of Pharmacy License Verification

This document reflects the license status of the person or entity identified below on this date with the California State Board of Pharmacy. It may be used as prima facie evidence of the facts recited below pursuant to California Business and Professions Code section 162.

Licensee Name:

GOLDEN GATE VETERINARY COMPOUNDING PHARMACY INC.

License Type:

PHARMACY

License Number: PHY 55535

Status:

ACTIVE

Issue Date:

10/06/18

Expiration Date:

10/01/19

Address of Record: 8 DIGITAL DR STE 104 NOVATO CA 94949

Disciplinary Action: NO RECORD OF DISCIPLINARY ACTION

Anne Sodergren

Interim Executive Officer

By

Barbera Schleicher **Public Inquiry Analyst**

(916) 574-7922

Barbera.Schleicher@dca.ca.gov





05/08/2019

Nevada State Board of Pharmacy 431 West Plumb Lane Reno, NV 89509

Re: Golden Gate Veterinary Compounding Pharmacy – CA Permit PHY 53848

Application for Out-of-State Pharmacy Permit/License

Dear Sir or Madam:

Please accept this letter as additional information related to Golden Gate Veterinary Compounding Pharmacy's application for out-of-state pharmacy license in the state of Nevada. Specifically, as it relates to the inquiry whether the pharmacy or its owners and corporate officers entered into a settlement agreement with any government regulatory agency or whether the owners or corporate officers were subject to any administrative or disciplinary action by licensing agency within the last five (5) years.

On or about March 31, 2017, the owners of Golden Gate Pharmacy Holdings, Inc., the parent company of Golden Gate Veterinary Compounding Pharmacy, entered into a Settlement Agreement (hereinafter "Agreement") with the United States of America for the purpose of resolving allegations of record keeping deficiencies that occurred at other facilities held under the corporate umbrella of Golden Gate Pharmacy Holdings., Inc.

Please note that the aforementioned Agreement and the alleged deficiencies did not involve any activities conducted by Golden Gate Veterinary Compounding Pharmacy. The Agreement was entered into by all parties without any admission of wrongdoing and solely for the purpose of expedient resolution of the matter.

Subsequently, shareholders Rebecca Lofholm and Nicole Lofholm-Clausen were cited by the California State Board of Pharmacy in February of 2018 for the same deficiencies that gave rise to the aforementioned settlement. Please note that Citation or Citation & Fine are not disciplinary actions in the State of California. Attached hereto, please find copies of the aforementioned Agreement and citations.

Please feel free to contact me with any questions or concerns related to this matter.

Sincerely,

Erik Clausen, PharmD/MBA Chief Financial Officer

> 8 Digital Drive, Suite 104 Novato, CA 94949 415-455-5590

SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement ("Agreement") is entered into by and between the United States of America ("United States"), acting through the United States Attorney's Office for the Northern District of California, Civil Division ("USAO") (collectively the "United States"), and Golden Gate Pharmacy Holdings, Inc.; Golden Gate Pharmacy Services, Inc.; Ross Valley Compounding Pharmacy, Inc.; Paul W. Lofholm, and Rebecca E. Lofholm (collectively the "Lofholm Parties"), through their authorized representatives. All parties to the Agreement are collectively referred to as "the Parties."

II. <u>RECITALS</u>

The Parties agree to the following recitals:

- The Drug Enforcement Administration ("DEA") is the component agency of the
 United States Department of Justice primarily responsible for administering the Controlled
 Substances Act, 21 U.S.C. § 801 et seq. ("the Act"), and is vested with the responsibility for
 investigating violations of the Act.
- 2. Golden Gate Pharmacy Services, Inc., and Ross Valley Compounding Pharmacy ("Ross Valley Pharmacy") are wholly-owned subsidiaries of Golden Gate Pharmacy Holdings, Inc. Golden Gate Pharmacy Services, Inc., d/b/a Golden Gate Pharmacy ("Golden Gate Pharmacy") is registered as a retail pharmacy with the DEA, under registration number BG4451251, with current authorization to handle Schedules II, III, IIIN, IV, and V controlled substances, and are subject to periodic audits and inspections.

Golden Gate Pharmacy/Ross Valley Pharmacy Settlement Agreement For Covered Conduct Between 9/4/2012 and 9/4/2014

- 3. Ross Valley Compounding Pharmacy, Inc. ("Ross Valley Pharmacy") is registered as a retail pharmacy with the DEA, under registration number FR5051216¹, with current authorization to handle Schedules II, III, IIIN, IV, and V controlled substances, and is subject to periodic audits and inspections. Ross Valley Pharmacy currently identifies as a compounding-only pharmacy, following the sale of its retail pharmacy operation in June 2013.
- 4. Golden Gate Pharmacy and Ross Valley Pharmacy are each required to operate in accordance with the statutory provisions of the Act and its implementing regulations.
- 5. The Attorney General, through the United States Attorney's Office, has primary authority to bring civil actions to enforce the Act. See 21 U.S.C. § 871 and 28 C.F.R. § 0.55(c).
- 6. The Act creates a closed system of distribution for those authorized to handle controlled substances and listed chemicals. The Act is designed to prevent diversion of controlled substances by, among other things, requiring DEA registrants to maintain and keep certain records.
- 7. The Act provides that it is unlawful for a person to "refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under this subchapter or subchapter II of this chapter" of the Act. 21 U.S.C. § 842(a)(5). By creating this closed system of distribution and the attendant recordkeeping requirements and imposing penalties for recordkeeping violations, the Act seeks to prevent harm to the general public and threats to the public safety created by

¹ At the time of the Scheduled Investigation, Ross Valley's DEA registration number was BG3090848.

- diversion of controlled substances from the Act's permitted distribution scheme to prohibited uses of the controlled substances.
- 8. A registrant may not distribute to locations other than DEA-registered locations. 21 C.F.R. § 1301.12(a). A registrant may not engage in unauthorized manufacture of controlled substances to supply practitioners with stock for office-based dispensing. 21 C.F.R. § 1301.13(e). A registrant may not include Schedule III controlled substances on Schedule II inventory. 21 C.F.R. § 1304.04(h)(1). A registrant must account for all controlled substances on hand when the inventory is taken. 21 C.F.R. § 1304.11(a). A registrant must take inventory of a controlled substance on the effective date classifying it as a controlled substance. 21 C.F.R. § 1304.11(d). A registrant must include the finished form of each controlled substance on the biennial inventory. 21 C.F.R. § 1304.11(e)(1)(iii)(B). A registrant must include the number of . units or volume of each finished form of controlled substance in each container on the biennial inventory. 21 C.F.R. § 1304.11(e)(1)(iii)(C). A registrant must include the number of commercial containers of each finished form of controlled substances on the biennial inventory. 21 C.F.R. § 1304.11(e)(1)(iii)(D). A registrant must include accurate weights on bulk forms. 21 C.F.R. § 1304.11(e)(1)(iv)(B). A registrant must include reasons for expired controlled substances being maintained and whether substances could be used in manufacture in biennial inventory. 21 C.F.R. § 1304.11(e)(1)(iv)(C).
- 9. A registrant must keep records documenting the receipt, manufacture, or distribution of controlled substances. 21 C.F.R. § 1304.21(a). A registrant must keep records including the number of units or volume of finished form of any controlled substances; acquisition records including the number of units, date, name, address and registration number;

and distribution records including the number of units, date, name, address and registration number. 21 C.F.R. §§ 1304.22(a)(2)(ii), 1304.22(a)(2)(iv), 1304.22(a)(2)(vii).

- 10. A registrant must keep records of the date shipped and number of packages shipped on the DEA Form 222; must complete and execute accurate DEA Form 222s; must retain the Purchaser Copy of the executed DEA Form 222; must retain the Supplier Copy of the DEA Form 222; must retain the Purchaser Copy of the executed electronic DEA Form 222; and must not distribute a Schedule II controlled substance without the requisite DEA 222 Form at the time of distribution. 21 C.F.R. §§ 1305.13(b), 1305.15(a), 1305.17(a), 1305.17(b), 1305.27(a), 1305.03.
- 11. A registrant must not fill a prescription issued for the purpose of obtaining controlled substances for general office dispensing, must not fill prescriptions signed by an individual without prescribing authority and must not fill improperly executed prescriptions. 21 C.F.R. §§ 1306.04(a), 1306.05(f).
- 12. A registrant must take and record a biennial inventory and must keep accurate and complete records of power of attorney designations matching the name of the person who signed the application for re-registration. 21 C.F.R. §§ 1304.11(c), 1305.05(d).
- Gate Pharmacy and Ross Valley Pharmacy (the "Scheduled Investigation"). In the Scheduled Inspection, DEA reviewed the records of Golden Gate Pharmacy and Ross Valley Pharmacy covering a two year period from September 4, 2012 through September 4, 2014. The Scheduled Investigation revealed alleged record-keeping violations of the Act, which are described in the following paragraphs as the conduct covered by this Agreement.

- 14. The United States alleges that, between September 4, 2012 through September 4, 2014, Golden Gate Pharmacy and Ross Valley Pharmacy failed to keep and maintain adequate records pertaining to controlled substances, as required by 21 C.F.R. § 1304, et seq.
- 15. The United States alleges at least 4,777 violations by Golden Gate Pharmacy of the Act's recordkeeping requirements for the period in question - September 4, 2012 through September 4, 2014. For example, the United States alleges that, in at least 3,271 instances between September 4, 2012 and September 4, 2014, Golden Gate Pharmacy failed to keep records documenting the manufacture of controlled substances, in violation of 21 C.F.R. § 1304.21(a). The United States further alleges that, in at least 369 instances between September 4, 2012 through September 4, 2014, Golden Gate Pharmacy engaged in the unauthorized manufacture of controlled substances to supply practitioners with stock for office-based dispensing, in violation of 21 C.F.R. § 1301.13(e). By way of further example, the United States alleges that in at least 355 instances between September 4, 2012 through September 4, 2014, Golden Gate Pharmacy failed to keep distribution records including the number of units, date, and name, address and registration number of the recipient, in violation of 21 C.F.R. § 1304.22(a)(2)(vii). The United States also alleges that in at least 347 instances between September 4, 2012 through September 4, 2014, Golden Gate Pharmacy failed to keep records including the number of units or volume of finished form, in violation of 21 C.F.R. § 1304.22(a)(2)(ii). In addition, the United States alleges that a Golden Gate Pharmacy janitorial employee pilfered approximately 8,000 Oxycodone tablets during 2014-2015.
- 16. The United States alleges at least 384 violations by Ross Valley Pharmacy of the Act's recordkeeping requirements for the period in question September 4, 2012 through

September 4, 2014. For example, the United States alleges that, in at least 151 instances between September 4, 2012 through September 4, 2014, Ross Valley Pharmacy filled improperly executed prescriptions in violation of 21 C.F.R. § 1306.05(f). The United States further alleges that, in at least 108 instances, Ross Valley Pharmacy failed to include reasons for expired controlled substances being maintained and whether substances could be used in manufacture in its biennial inventory, in violation of 21 C.F.R. § 1304.11(e)(1)(iv)(C). By way of further example, the United States alleges that Ross Valley Pharmacy, in at least 53 instances, failed to keep records documenting the manufacture of controlled substances, in violation of 21 C.F.R. § 1304.21(a).

- 17. For the purposes of this Agreement, "Covered Conduct" shall mean the violations alleged in paragraphs 13 through 16 above.
- 18. At all times relevant to the Covered Conduct, the Act authorizes the imposition of a civil penalty of as much as \$10,000 or as much as \$25,000 for each violation of 21 U.S.C. § 842(a), depending on the category of violation, and a civil penalty of as much as \$25,000 for each violation of 21 U.S.C. § 842(b)(1).
- 19. This Agreement is neither an admission by any of the Lofholm Parties of liability for any allegations made by the United States nor a concession by the United States that its claims are not well founded.
- 20. In consideration of the mutual promises, covenants, and obligations set forth in this Agreement, the Parties reach a full and final settlement pursuant to the Terms and Conditions below.

TERMS AND CONDITIONS

In reliance on the recitals and representations contained herein, and in consideration of the mutual promises, covenants, and obligations set forth below, and intending to be legally bound hereby, the Parties agree as follows:

- 21. The Lofholm Parties shall pay to the United States Seven Hundred Seventeen Thousand Two Hundred Fifty Dollars (\$717,250.00) (hereafter, the "Settlement Amount"), by electronic funds transfer, pursuant to written instructions to be provided by the Office of the United States Attorney for the Northern District of California upon execution of this Agreement, according to the schedule in Paragraph 22.
- 22. The Settlement Amount described in Paragraph 21 above shall be made by the Lofholm parties as follows:
 - a. the Lofholm Parties shall pay Three Hundred Thousand Dollars
 (\$300,000.00) according to the terms of Paragraph 21 on or before May 31, 2017;
 and
 - b. the Lofholm Parties shall pay Four Hundred Seventeen Thousand Two Hundred Fifty Dollars (\$417,250) according to the terms of Paragraph 21 on or before June 30, 2017.
- 23. In consideration of the payment of the Settlement Amount described in

 Paragraphs 21 and 22 above in full, the United States agrees to settle and relinquish all claims for
 civil penalties it may have against the Lofholm Parties, including Golden Gate Pharmacy

 Holdings, Inc., Golden Gate Pharmacy, Ross Valley Pharmacy and any officers, directors,

agents, and employees of either Golden Gate or Ross Valley Pharmacies for possible violations of the Act, and the regulations promulgated thereunder, based on the Covered Conduct.

- 24. Nothing in this Agreement shall prevent, preclude, limit, or prejudice the United States' right to enforce compliance with any other requirements under the Act and regulations promulgated thereunder by commencing a civil or administrative action against one or more of the Lofholm Parties or any officers, directors, agents or employees of either Golden Gate or Ross Valley Pharmacies for violations of the Act that occurred or may occur subsequent to the period of the Covered Conduct described in this Agreement. In the event of such violations under the Act or the regulations promulgated thereunder, DEA will not be precluded from alleging and proving this Agreement and the evidence of the violations that led to this Agreement in any future actions taken against the Lofholm Parties, Golden Gate Pharmacy's DEA registrations, or Ross Valley Pharmacy's DEA registrations under 21 U.S.C. §§ 823 and 824.
- 25. The Lofholm Parties fully and finally release the United States, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which have been asserted, could have been asserted, or may be asserted in the future against the United States, its agencies, employees, servants, and agents, related to the investigation, prosecution and settlement of this matter.
- 26. Notwithstanding any term of this Agreement, specifically reserved and excluded from its scope and intent as to any entity or person are the following:
 - Any potential criminal liability;
 - Any criminal, civil, or administrative claims arising under Title 26 of the
 United States Code (Internal Revenue Code);

- c. Any liability to the United States for any conduct other than the Covered Conduct; and
- d. Any claims based on such obligations as are created by this Agreement.
- any of the Losholm Parties and each of them waives and shall not assert any defenses any of the Losholm Parties may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.
- 28. This Agreement is not intended by the Parties, and shall not be interpreted to constitute, a release of any person or entity not identified or referred to herein.
- 29. This Agreement shall be governed by the laws of the United States. Exclusive jurisdiction and venue for any dispute arising under this Agreement shall be the United States District Court for the Northern District of California.
- 30. This Agreement constitutes the entire agreement between the Parties, and cannot be amended, except in writing and signed by all the Parties to this Agreement.
- 31. Each of the signatories below represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever. For purposes of construction, this Agreement shall be deemed to have been drafted by all Parties to this

Agreement and shall not, therefore, be construed against any party for that reason in any subsequent dispute.

- 32. All parties to this Agreement understand that it will be a matter of public record and consent to the United States' disclosure of this Agreement and information about this Agreement to the public.
- 33. Each person who signs this Agreement in a representative capacity warrants that he or she is fully authorized to do so.
- 34. This Agreement is binding on the Lofholm Parties' successors, transferees, heirs, and assigns.
- 35. The parties agree that the Lofholm Parties are jointly and severally liable for any failure by any one of them to satisfy the terms and conditions of this settlement agreement, including but not limited to the payment of the Settlement Amount described in Paragraph 21 or the schedule of payments described in Paragraph 22.
- 36. The Parties agree that in the event the Lofholm Parties do not make the payments described in Paragraphs 21 and 22 in full, the United States shall have the option of (a) filing suit to enforce this Agreement, or (b) rescinding this Agreement and seeking any and all available remedies against the Lofholm Parties arising from the Scheduled Investigation, including but not limited to the imposition of civil fines and penalties in the full amounts provided by the Controlled Substances Act and the pertinent regulations. Should the United States choose to rescind the agreement and pursue remedies under subsection (b) of this Paragraph, the Lofholm Parties agree not to plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that are

filed by the United States by July 31, 2017, except to the extent such defenses were available on the Effective Date of this Agreement.

- 37. The Parties further agree that in the event the Lofholm Parties fail to make either payment described in Paragraph 22 as provided, the Lofholm Parties shall be liable for interest calculated from the Effective Date of this Agreement, at a rate of 1.0% per annum.
- 38. If the Lofholm Parties' obligations under this Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases in this Agreement and bring any civil and/or administrative claim, action, or proceeding against the Lofholm Parties for the claims that would otherwise be covered by the releases in this Agreement. The Lofholm Parties agree that (i) any such claims, actions, or proceedings brought by the United States are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) and the Lofholm Parties shall not argue or otherwise contend that the United States' claims, actions, or proceedings are subject to an automatic stay; (ii) the Lofholm Parties shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceeding that are brought by the United States within 30 calendar days of written notification to the Lofholm Parties that the releases have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on the Effective Date of this Agreement; and (iii) the United States has valid claims against the Lofholm Parties for the full amount under relevant statutory and regulatory authority for each of the violations identified in the Scheduled Investigation.

39. This Agreement shall be effective on the date of signing by the last signatory to this Agreement ("Effective Date"). It may be executed in counterparts, each of which shall constitute an original and all of which shall constitute one and the same agreement. Facsimiles of signatures shall have the same effect as originals.

On behalf of the United States:

BRIAN J. STRETCH United States Attorney Northern District of California

DATED: april 3, 2017

JONATHAN U. LEE
Assistant U.S. Attorney
Attorneys for the United States

On behalf of the Lofholm Parties:

GOLDEN GATE PHARMACY HOLDINGS,

DATED: 3-31-2017

REBECCA E. LOFHOLM

President

DATED: 3-31-2017

GOLDEN GATE PHARMACY SERVICES,

INC.

REBECCA E. LOFHOLM

President

Golden Gate Pharmacy/Ross Valley Pharmacy Settlement Agreement For Covered Conduct Between 9/4/2012 and 9/4/2014

ROSS	VALLE	Y	COMPOUNDING
PHAR	MACY.	n	VC.

DATED: 3-31-2017

EBECCA E. LOFHOLM

President

DATED: 3-31-2017

REBECCA E LOFHOLM

DATED: 3-31-2017

PAUL W. LOFHOLM

CALIFORNIA PHARMACY LAWYERS

April 2, 2017

DATED:

IVAN PETRZELKA, ESQ.

Attorneys for the Lofholm Parties



California State Board of Pharmacy 1625 North Market Boulevard, Suite N219, Sacramento, CA 95834 Phone (916) 574-7900 Fax (916) 574-8618 www.pharmacy.ca.gov BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY DEPARTMENT OF CONSUMER AFFAIRS GOVERNOR EDMUND G BROWN JR.

February 21, 2018

DATED MATERIAL ENGLOSED

NICOLE MARIE LOFHOLM CLAUSEN 1525 E FRANCISCO BLVD SUITE 2 SAN RAFAEL, CA 94901

RE: CI 2017 78781 NICOLE MARIE LOFHOLM CLAUSEN RPH 60056

The attached Citation and Fine, Order of Abatement ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Forms and Publications).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation and indicates, within the Order of Abatement, information and/or material to be submitted to the Board.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

- March 23, 2018: Unless the Citation is contested, Proof of Abatement and payment of fine(s) must be received by the Board.
- March 07, 2018: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- March 23, 2018: Any contest of the Citation by request for a formal Appeal must be received by the Board.

Page two NICOLE MARIE LOFHOLM CLAUSEN CI 2017 78781

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is rot requested to contest the Citation(s), timely payment of any fine(s) and the submission of Proof of Abatement shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations title 16 section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Christina Metzen, Associate Enforcement Analyst at (916) 574-7924.

Sincerely

Virginia Herold Executive Officer Board of Pharmacy

Attachments

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

CITATION AND FINE ORDER OF ABATEMENT

Citation Number
CI 2017 78781

Name, License No.
NICOLE MARIE LOFHOLM CLAUSEN, RPH 60056

VIOLATION CODE SECTION	§ 4314; CCR, title 16, § 1775; Bus. & Prof. Code OFFENSE	AMOUNT	OF FINE
Bus. & Prof. Code § 4081 subd. (a)	Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory	\$2,5	0.00
Bus. & Prof. Code § 4113 subd. (c) /CCR, Title 16, § 1714 subd. (b)	Pharmacist in Charge shall be responsible for compliance with all state and federal laws pertaining to the practice of pharmacy/Operational Standards and Security; pharmacy responsible for pharmacy security	\$2,5	0.00

CONDUCT:

Business and Professions Code Section 4113(c) states the pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. California Code of Regulations Section 1714 subdivision (b) states, in pertinent parts, each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy. Specifically, between 9/22/2014 and 9/14/2015, Nicole Lofholm Clausen (RPH 60056), as pharmacist-in-charge, was responsible when Golden Gate Pharmacy (PHY 40742) located at 1525 E. Francisco Blvd Suite#2, San Rafael, CA 94901 did not secure the controlled substance cabinet resulting in the following loss:

- 287 tablets of oxycodone 5mg
- 826 tablets of oxycodone 10mg
- 6453 tablets of oxycodone/apap 10/325mg
- 291 tablets of Oxycontin 10mg

Failure to secure the controlled substance cabinet which resulted in the loss of 7857 tablets of controlled substances is a violation of California Code of Regulations Section 1714 subdivision (b).

Business and Professions Code Section 4081 subdivision (a) states all records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept

by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 1200) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices. California Code of Regulations Section 1718 states "Current Inventory" as used in Section 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332. Specifically, between 9/22/2014 and 9/14/2015, when Nicole Lofholm-Clausen, RPH 60056, was the pharmacistin-charge, Golden Gate Pharmacy (PHY 40742) located at 1525 E. Francisco Blvd Suite#2 San Rafael, CA 94901 failed to maintain a current inventory resulting is the loss of 7,857 tablets of controlled substance.

The Source State State	1. Varience
Oxycodone 5mg	287
Oxycodone 10mg	826
Oxy/APAP10/325mg	6,453
Oxycontin 10mg	291
Total Totals	785/ 4

Not maintaining a current inventory of controlled substances is a violation of Business and Professions Code Section 4081(a).

ORDER OF ABATEMENT

By the abatement date submit to the Board the following:

Either (1) full payment (\$5,000.00) of the assessed fine(s), or (2) \$4,000.00 and written notice to the Board of Pharmacy that you will be attending a Board of Pharmacy/Drug Enforcement Agency Rx Drug Abuse training within the next 12 months.

If Nicole Lofholm-Clausen chooses option (2), Nicole Lofholm-Clausen shall submit proof of attendance at the Board of Pharmacy/Drug Enforcement Agency Rx Drug Abuse training within 12 months of the date of this citation. Any failure to do so shall be deemed a jailure to meet the abatement requirements of this citation.

If Nicole Lofholm-Clausen timely attends the Board of Pharmacy/Drug Enforcement Agency Rx Drug Abuse training within 12 months, the fine(s) levied by this citation shall be reduced to \$4,000.00 and completion of the Board of Pharmacy/Drug Enforcement Agency Rx Drug Abuse training shall be considered satisfactory abatement of the citation. If Nicole I otholm-Clausen fails to timely submit proof of attendance at the Board of Pharmacy/Drug Enforcement Agency Rx Drug Abuse training, the stay shall be lifted and the fine(s) shall be due and owing from Nicole Lofholm-Clausen within thirty (30) days of any such failure.

MOTERATIONNISSUEDIONETED MAINE

TOTAL AMOUNT OF FINE(S) #55,000.00

PAYMENT OF THIS (S) TO US BY MATCH

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No.
CI 2017 78783	REBECCA ELLEN LOFHOLM, RPH 33497

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)			
VIOLATION CODE SECTION	OFFENSE	AMOUNT OF FINE	
CCR, Title 16, § 1714 subd. (b)	Operational Standards and Security; pharmacy responsible for pharmacy security	\$2,500.00	
Bus. & Prof. Code § 4081 subd. (a) & (b)/CCR, Title 16, § 1718	Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory/Current Inventory Defined	\$2,500.00	

CONDUCT:

California Code of Regulations Section 1714 subdivision (b) states, in pertinent parts, each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy. Specifically, between 9/22/2014 and 9/14/2015, Rebecca Lofholm (RPH33497), as a pharmacist owner, was responsible when Golden Gate Pharmacy (PHY 40742) located at 1525 E. Francisco Blvd Suite#2, San Rafael, CA 94901 did not secure the controlled substance cabinet resulting in the following loss:

- 287 tablets of oxycodone 5mg
- 826 tablets of oxycodone 10mg
- 6453 tablets of oxycodone/apap 10/325mg
- 291 tablets of Oxycontin 10mg

Failure to secure the controlled substance cabinet which resulted in the loss of 7857 tablets of controlled substances is a violation of California Code of Regulations Section 1714 subdivision (b).

Business and Professions Code Section 4081 subdivision (a) states all records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 1200) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices. California Code of Regulations Section 1718 states "Current Inventory" as used in Section 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all

dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332. Business and Professions Code Section 4081 (b) states the owner, officer, and partner of a pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge, responsible manager, or designated representative-in-charge, for maintaining the records and inventory described in this section. Specifically, between 9/22/2014 and 9/14/2015, when Rebecca Lofholm, RPH 33497, was the pharmacist owner, Golden Gate Pharmacy (PHY 40742) located at 1525 E. Francisco Blvd Suite#2, San Rafael, CA 94901 failed to maintain a current inventory resulting is the loss of 7,857 tablets of controlled substance.

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Oxycodone 5mg	287
Oxycodone 10mg	826
Oxy/APAP10/325mg	6,453
Oxycontin 10mg	291
total Ebleis	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1

Not maintaining a current inventory of controlled substances is a violation of Business and Professions Code Section 4081(a).

CITATION ISSUED ON FEBRUARY 21, 2018.

TO ALAMOUN COFFINE(S): \$5,000.00

PAYMENT OF FINE(S) DUE BY, March 28, 2018

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

CITATION AND FINE

Citation Number CI 2015 67462 Name, License No.

GOLDEN GATE PHARMACY, PHY 40742 (cancelled)

Code § 4301, subd. (o)		
VIOLATION CODE SECTION	OFFENȘE	AMOUNT OF FINE
CCR, Title 16, § 1714 subd. (b)	Operational Standards and Security; pharmacy responsible for pharmacy security	\$2,500.00
Bus. & Prof. Code § 4081 subd. (a)/CCR, Title 16, § 1718	Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory/Current Inventory Defined	\$2,500.00

CONDUCT:

California Code of Regulations Section 1714 subdivision (b) states, in pertinent parts, each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy. Specifically, between 9/22/2014 and 9/14/2015, Golden Gate Pharmacy (PHY 40742) located at 1525 E. Francisco Blvd Suite#2, San Rafael, CA 94901 did not secure the controlled substance cabinet resulting in the following loss:

- 287 tablets of oxycodone 5mg
- 826 tablets of oxycodone 10mg
- 6453 tablets of oxycodone/apap 10/325mg
- 291 tablets of Oxycontin 10mg

Failure to secure the controlled substance cabinet which resulted in the loss of 7857 tablets of controlled substances is a violation of California Code of Regulations Section 1714 subdivision (b).

Business and Professions Code Section 4081 subdivision (a) states all records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 1200) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices. California Code of Regulations Section 1718 states "Current Inventory" as used in Section 4081 and 4332 of the

Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332. Specifically, between 9/22/2014 and 9/14/2015, Golden Gate Pharmacy (PHY 40742) located at 1525 E. Francisco Blvd Suite#2, San Rafael, CA 94901 failed to maintain a current inventory loss of 7,857 tablets of controlled substance.

Drig Vame	V alice
Oxycodone 5mg	287
Oxycodone 10mg	826
Oxy/APAP10/325mg	6,453
Oxycontin 10mg	291
Testo an able :	

Not maintaining a current inventory of controlled substances is a violation of Business and Professions Code Section 4081(a).

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TOTAL AMOUNT OF EINERS): \$5,966.00

PAYMENT OF FINE(S) DUE BY: March 28, 2018