## **17A**

## **NEVADA STATE BOARD OF PHARMACY**

PH04191

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

## **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 ☐Ownership Change (Provide current license number if making changes: PH Check box below for type of ownership and complete all required forms.							
☑ Publicly Traded Corporation – Pages 1,2,3,7 ☐ Partnership - Pages 1,2,5,7 ☐ Non Publicly Traded Corporation – Pages 1,2,4,7 ☐ Sole Owner – Pages 1,2,6,7							
GENERAL INFORMATION to be completed by all types of ownership							
Pharmacy Name: Cardinal Health 414, LLC							
Physical Address: 201 Lathrop Way, Suite D, S	Sacramento, CA 95815						
Mailing Address: 7000 Cardinal Place, Q&R D	ept. NPHS						
City: Dublin Stat	te: Ohio Zip Code: 43017						
Telephone: 916-648-2192 Fax	916-648-2193						
Toll Free Number: 50-888-8041	(Required per NAC 639.708)						
E-mail: Eric.Siu@CardinalHealth.com Web	osite: _www.CardinalHealth.com						
Managing Pharmacist: Eric Siu	License Number: PHY46385						
TYPE OF PHARMACY AND	SERVICES PROVIDED						
Yes/No	Yes/No						
□ ⊠ Retail	☐ X Off-site Cognitive Services						
□	☑ □ Parenteral **						
□ 🖾 Internet	☑ □ Parenteral (outpatient)						
🖾 🗆 Nuclear	□ 🛛 Outpatient/Discharge						
☐       Ambulatory Surgery Center	r ⊠ □ Mail Service						
☐ ဩ Community	□ 🛛 Long Term Care						
□ 🛛 Other:							
	☑ □ Non Sterile Compounding						
All boxes must be checked	☑ ☐ Mail Service Sterile Compounding **						
For the application to be complete	□ ☑ Other Services:						
***************************************	of convince, you will be required to make an						

<sup>\*\*</sup>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.

Board	Use Only	Date Processed:	Amount: 500,00	<u> </u>
. , , , , ,				Page 2
	n Harmon lame of Autho	prized Person		
	_	f Person Authorized to Submit A	pplication, no copies or stamp	OS
	aux Ha			<del></del>
backgi	round, qualific	cation and reputation, as it may d	eem necessary, proper or de	sirable.
emplo	yees, to cond	thorize the Nevada State Board out	siness, professional, social ar	nd moral
under	penalty of per	tions, answers and statements a rjury, that the information furnished	ed on this application are true	, accurate and
			·	
correc	t. I understar	the answers given in this applicand that any infraction of the laws of the laws of the laws of the pround that any infraction of the laws	of the State of Nevada regula	ting the
dispos	sition may be	ments that identify the circumstar required.	nce or contain an order, agree	ement, or other
If the a	answer to que	estion 1 through 5 is "yes", a sign	ed statement of explanation n	nust be attached.
5)	interest, ever	oration, any owner(s), sharehold r surrendered a license, permit or r otherwise (other than upon volu	certificate of registration	Yes □ No ☒
5)			or/o) or portmor/o)id	Yes □ No 🏻
4)	interest, ever	oration, any owner(s), sharehold r been found guilty, pled guilty or o any offense federal or state, re	entered a plea of nolo	Vac 🗆 Na 🖼
		r been the subject of an administ roceeding relating to the pharma hed		Yes ☒ No □
3)	Has the corp	oration, any owner(s), sharehold	er(s) or partner(s) with any	
2)	Has the corp any interest, registration?	oration, any owner(s), sharehold ever been denied a license, perr	er(s) or partner(s) with mit or certificate of	Yes □ No Ⅸ
1)	any interest,	ooration, any owner(s), sharehold ever been charged, or convicted or (including by way of a guilty pla	of a felony or gross	Yes □ No ☒
vvitnir	i the last five	(5) years:		

#### APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

## **OWNERSHIP IS A PUBLICY TRADED CORPORATION**

State of Incorporation: Delaware				
Parent Company if any: <u>Cardinal Health In</u>	ıc			
Corporation Name: Cardinal Health 414, L	LC			
Mailing Address: 7000 Cardinal Place				
City: Dublin S	State: Ohio	Zip: <u>43017</u>		
Telephone: 614-757-7570 F				
Contact Person: Dawn Harmon				
If the corporation that holds an ownership in the applicant shall identify the officers of the registration with the SEC, the registration not being traded. You can provide a copy of the Date of Incorporation:	at corporation, the umber issued and le SEC report or co	date the corp the exchang	ooration receive at which the	ed its
Hours of Operation for the pharmacy:				
Monday thru Friday 1130 Propriet	n	Saturday	<u>030</u> am	1230 pm
Sunday <u>อเรอ</u> am <u>เวเรอ</u> pm	ח	24 Hours		
A Nevada business license is not required, icense please provide the number:		armacy has a -	Nevada busir	ness

## Must be included with the application for a publicly traded corporation

<u>Certificate of Corporate Status</u> (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

# STATEMENT OF RESPONSIBILITY FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Eric Siu
Responsible Person of Cardinal Health 414, LLC (Sacramento, CA)
hereby acknowledge and understand that in addition to the corporation's, any owner(s),
shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy la
that may occur in a pharmacy owned or operated by said corporation.
I further acknowledge and understand that the corporation's, any owner(s), shareholder(s)
or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a
pharmacy owned by or operated by said corporation.
I further acknowledge and understand that the corporation's, any owner(s), shareholder(s)
or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision
of any local, state or federal laws or regulations pertaining to the practice of pharmacy.
Original Signature of Person Authorized to Submit Application, no copies or stamps
Eric Siu 1/16/2020
Print Name of Authorized Person Date

## **AFFIDAVIT for Out-of-State Pharmacy License**

STATE OF) ssCOUNTY )
I, Eric Siu , 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 Manager for Cardinal Health 414, LLC (Sacramento, CA) (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, <u>Fric Siu</u> , do hereby swear under penalty of perjury that the assertions of this
affidavit are true.
SUBSCRIBED AND SWORN TO before me, a notary public this 22 day of <u>January</u> , 2020.
NOTARY PUBLIC  VERA I. WHITE  COMM. # 2257107  NOTARY PUBLIC-CALIFORNIA  EL DORADO COUNTY  FL DORADO COUNTY  COMMON PUBLIC-CALIFORNIA  EL DORADO COUNTY  OFFICIAL PORTADO C



Page 1

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF

DELAWARE, DO HEREBY CERTIFY "CARDINAL HEALTH 414, LLC" IS DULY

FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD

STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS

OFFICE SHOW, AS OF THE FOURTEENTH DAY OF JANUARY, A.D. 2020.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

THE PARTY OF THE P

2073291 8300 SR# 20200272805

Authentication: 202185090

Date: 01-14-20

You may verify this certificate online at corp.delaware.gov/authver.shtml



RECEIPT

N N

PHY 46385 00159242

Retail 1



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

Permit

VALID UNTIL JULY 01, 2020

In accordance with the Provisions of Chapter 9 of Division 2 of the Business and Professions Code, the firm name hereon is licensed at the address shown, 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 within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change)

administrator or pharmacist-in-charge.
This permit is valid only at the address shown.

---- NON-TRANSFERABLE --- POST IN PUBLIC VIEW 05/10/19 The official status of this license can be verified at www.pharmacy.ca.gov

CARDINAL HEALTH 414, LLC 201 LATHROP WAY STE D SACRAMENTO CA 95815

05/10/19

FORM WPHPHY (12/31/05) P



RECEIPT

NO. NO.

LSC 99110 00159241

License (916) 574-7900

1625 NORTH MARKET BLVD., SUITE N-219 SACRAMENTO, CA 95834

VALID UNTIL JULY 01, 2020

Pharmacy. address shown, and is subject to the rules and of Division 2 of the Business and Professions Code, the firm name hereon is licensed at the in accordance with the Provisions of Chapter 9 administrator or pharmacist-in-charge. days when there is a change of ownership, California State Board of Pharmacy within 30 This permit is non-transferable. Contact the regulations of the California State Board of lmore than 10 percent share change! location, corporate officer, director, shareholder

This permit is valid only at the address shown.

05/23/19

05/23/19 The official status of this license can be verified at www.pharmacy.ca.gov

CARDINAL HEALTH\_414, LLC 201 LATHROP WAY STE D SACRAMENTO CA 95815

NON-TRANSFERABLE POST IN PUBLIC VIEW ----

FORM WPHLSC (12/31/0



Officers list

201 Lathrop Way Suite D

Sacramento, California 95815

Officer Name

title

Tiffany Olson

President

Paul Gotti

Vice President-Operations

Luis E Garcia

**VP** Operations

David William Pellicciarini VP Pharmacy Safety, Practice and Technical Operations NPHS

**Home** 

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## **BOARD OF PHARMACY**

LICENSING DETAILS FOR: LSC 99110

NAME: CARDINAL HEALTH\_414,LLC

LICENSE TYPE: STERILE COMPOUNDING PHARMACY

LICENSE STATUS: CLEAR ADDRESS

201 LATHROP WAY STE D SACRAMENTO CA 95815 SACRAMENTO COUNTY

**ISSUANCE DATE** 

JULY 28, 2003

**EXPIRATION DATE** 

JULY 1, 2020

**CURRENT DATE / TIME** 

**FEBRUARY 12, 2020** 4:08:55 PM

#### LICENSE RELATIONSHIPS

NAME: CARDINAL HEALTH 414,LLC

LICENSE/REGISTRATION TYPE: PHARMACY (COMMUNITY)

LICENSE NUMBER: 46385 PRIMARY

STATUS: CLEAR

ADDRESS: 201 LATHROP WAY STE D SACRAMENTO CA 95815 SACRAMENTO COUNTY



### California State Board of Pharmacy 2720 Gateway Oaks Drive, Suite 100 Sacramento, CA 95833

Phone: (916) 518-3100 Fax: (916) 574-8618

www.pharmacy.ca.gov

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



February 25, 2020

Nevada State Board of Pharmacy 985 Damonte Ranch Pkwy Ste 206 Reno, NV 89521

## 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:

CARDINAL HEALTH 414, LLC

License Type:

PHARMACY

License Number: PHY 46385

Status:

ACTIVE

Issue Date:

07/25/2003

**Expiration Date:** 

07/01/2020

Address of Record: 201 LATHROP WAY STE D SACRAMENTO CA 95815

Disciplinary Action: NO RECORD OF DISCIPLINARY ACTION

Anne Sodergren

**Executive Officer** 

Ву

Barbera Schleiche

Public Inquiry Analyst

(916) 518-3081

Barbera.Schleicher@dca.ca.gov



Send to State Board of Pharmacy for Completion: A separate letter is acceptable. Do not return with application unless it has been completed by the licensing agency.

## NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane - Reno, NV 89509 - (775) 850-1440

#### LICENSE VERIFICATION

Name: Cardinal Health 414, LLC pharmacy license PHY46385							
Address: 201 Lathrop Way, Suite D							
City: Sacramento State: CA Zip: 95815  I hereby authorize the California Board of Pharmacy to furnish to the Nevada State Board of Pharmacy, the information requested below.  Signature of Applicant							
THIS FORM MUST BE FORWARDED TO THE HOME STATE LICENSING AGENCY FOR COMPLETION. DO <b>NOT</b> WRITE BELOW THIS LINE							
License Number License Status Date License Issued Date License Expires							
Has this license been cumbered in any way? ☐ Revoked ☐ Surrendered ☐ Limited ☐ Yes ☐ No ☐ Suspended ☐ Restricted ☐ Probation ☐ Please attach copies of any pertinent legal documents							
USE REVERSE SIDE OF THIS FORM FOR EXPLANATIONS IF NECESSARY							
Has the applicant been convicted of any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances? (If yes, please explain)							
Signature of State Official Title State Date State Seal							



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

#### ORDER OF CORRECTION

Date:

5/29/2019

Permit #: LSC99110

Time of Day:

2:36 PM

Name as shown on permit: CARDINAL HEALTH\_414,LLC

Address: 201 LATHROP WAY STE D

City: SACRAMENTO

Please be advised it appears there is a failure to comply with the following laws governing the practice of pharmacy, and/or the rules and regulations of the Board of Pharmacy:

1 CCR 1714(b)

Operational Standards and Security 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.

Top plastic grill on ceiling of hood 3 was cracked. Send correction.

CCR 1751.7(b)(1)

Sterile Compounding Quality Assurance and Process Validation. The pharmacy and each individual involved in the compounding of sterile drug preparations must successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug preparations. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of the types of manipulations, products and batch sizes the individual is expected to prepare and include a media-fill test. The validation process shall be as complicated as the most complex manipulations performed by staff and contain the same amount or greater amount of volume transferred during the compounding process. The same personnel, procedures, equipment, and materials must be used in the testing. Media used must have demonstrated the ability to support and promote growth. Completed medium samples must be incubated in a manner consistent with the manufacturer's recommendations. If microbial growth is detected, then each individual's sterile preparation process must be evaluated, corrective action taken and documented, and the validation process repeated.

BBL Trypticase soy broth was incubated at uncontrolled room temperature for sterility testing on 3/16/19 for 14 days in the restricted area per PIC. According to manufacture directions reviewed, it should be incubated at USP requirements which as 20-25C. Send revised incubation policy and procedure along with plan of correction.

380331

18 NA

171-3 (10/92)

LSC99110

Page 3 of 4



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



3 BPC 4169(a)(1)

Prohibited Acts. A person or entity shall not do any of the following: Purchase, trade, sell, warehouse, distribute, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler, third-party logistics provider, or pharmacy.

On 4/26/19, pharmacy acquired dangerous drugs such as Sestamibi and sterile water for injection from unlicened wholesaler Cardinal Health located in 1950 Bentley Court STE 300, Glendale Heights, IL. Send plan of correction.

4 BPC 4342(a)

Actions by Board to Prevent Sales of Preparations or Drugs Lacking Quality or Strength; Penalties for Knowing or Willful Violation of Regulations Governing Those Sales. The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code).

Hetastartch 6% 500ml bag was stored in the refrigerator and needs to be stored between 20-25C per manufacturer labeling. Send correction.

I have reviewed, discussed, understand and received a copy of this form.

Inspector (sign)

Inspector (print)

Date

Signed

Print Name

Title PIC RPL

Pursuant to Business and Professions Code §4083, a licensee of the California State Board of Pharmacy, may submit a written request within 30 days of service of the order of correction, for an office conference with the board's executive officer to contest the order of correction.

171-3 (10/02)

LSC99110

380331

18 NA



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

#### OFFICIAL RECEIPT

May 29, 2019

Receipt Number: 380331

Firm: CARDINAL HEALTH\_414,LLC

Address: 201 LATHROP WAY STE D, SACRAMENTO CA 95815

Permit #: LSC99110

Phone: (916) 648-2181

The following was obtained this date under provisions of the California Pharmacy Law (Chapter 9, Division 2, Business and Professions Code) or the Rules and Regulations adopted thereunder:

Units	Description
Page(s)	Incubation policy
Page(s)	Temperature log for March 2019
Page(s)	End product testing record for 3/16/19
Page(s)	Record of ordering/receiving drugs from Cardinal Health in Glendale Heights
	Page(s) Page(s) Page(s)

Voluntarily Released for Investigation

Receipt acknowledged by: Enc Sio

171-6 (Rev 3/99)

Page 1 of 1

Cardinal Health Nuclear Pharmacy Services 7000 Cardinal Place Dublin, OH 43017 614-757-3174 tel 614-652-4816 fax

www.cardinalhealth.com



29 June 2019

Joshua Lee, RPh.
Inspector
California State Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834
joshua.lee@dca.ca.gov

Dear Dr. Lee:

We are in receipt of the Pharmacy Inspection Report dated 29 May 2019 detailing the inspection of our radiopharmacy in Sacramento CA, permit # LSC99110 & PHY46385.

Cardinal Health is fully committed to complying with all applicable California Board of Pharmacy laws and regulations. We are also fully committed to dispensing quality products and to patient safety. We have endeavored to answer completely and fully the observations and areas of concern in the inspection report. Should the Board feel that Cardinal Health has not adequately addressed any of the items, we would welcome the opportunity to meet with Board staff to discuss.

The following deficiencies and alleged deficiencies were noted in the 29 May 2019 report (note that the deficiency or area of concern is listed first, followed by Cardinal Health's response):

#### "Order of Correction"

1. CCR 1714(b) Operational Standards and Security. 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.

"top plastic grill on ceiling of hood 3 was cracked. Send correction>

Response: The plastic diffuser grill was removed from hood 3.

2. CCR 1751.7(b)(l) Sterile Compounding Quality Assurance and Process Validation
The pharmacy and each individual involved in the compounding of sterile drug preparations must successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug preparations. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of the types of manipulations, products and batch sizes the individual is expected to prepare and include a media-fill test. The validation process shall be as complicated as the most complex manipulations performed by staff and contain the same amount or greater amount of volume transferred during the compounding process. The same personnel, procedures, equipment, and materials must be used in the testing. Media used must have demonstrated the ability to support and promote growth. Completed medium samples must be incubated in a manner consistent with the

manufacturer's recommendations. If microbial growth is detected, then each individual's sterile preparation process must be evaluated, corrective action taken and documented, and the validation process repeated.

"BBL Trypticase soy broth was incubated at uncontrolled room temperature for sterility testing on 3/16/19 for 14 days in the restricted area per PIC. According to manufacturer's directions reviewed, it should be incubated at USP requirements which are as 20-25C. Send revised incubation policy and procedure along with a plan of correction."

**Response:** We do not agree that the room temperature was "uncontrolled" as it is reviewed and documented daily. It is our belief that our incubation policy does not require any changes. However, the pharmacy will acquire an additional incubator that will be set to 20-25C for incubation of Trypticase soy broth. This new incubator will be obtained prior to the next time sterility testing is performed.

3. BPC 4169(a)(I) Prohibited Acts. A person or entity shall not do any of the following: Purchase, trade, sell, warehouse, distribute, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler, third-party logistics provider, or pharmacy "On 4/24/19, pharmacy acquired dangerous drugs such as sestamibi and sterile water for injection from unlicensed wholesaler Cardinal Health located in 1950 Bentley Court STE 300, Glendale Heights, IL. Send plan of correction."

#### Response

- In November 2013, Congress passed the Drug Supply Chain Security Act ("DSCSA"). One of the purposes of the DSCSA was uniform wholesale licensing across all states. DSCSA defined a number of common licensing terms and contained a preemption provision that no state shall continue with any definitions that are inconsistent with the Federal definitions. As of November 27, 2013, the State of California may not continue with any requirements with respect to wholesale licensing that are inconsistent with the Federal law. Excerpts of DSCSA are provided here and the entire law is attached for reference.
  - 21 U.S.C.353(e)(4) For the purposes of this subsection and subsection (d), the term 'wholesale distribution' means the distribution of a drug subject to subsection (b) to a person other than a consumer or patient, or receipt of a drug subject to subsection (b) by a person other than the consumer or patient, but does not include—

    (A) intracompany distribution of any drug between members of an affiliate or within a manufacturer;
  - 21 U.S.C. 353(e)(6) AFFILIATE. —For purposes of this subsection, the term "affiliate" means a business entity that has a relationship with a second business entity if, directly or indirectly—
    - (A) one business entity controls, or has the power to control, the other business entity; or
    - (B) a third party controls, or has the power to control, both of the business entities.
  - Federal preemption language:
     Chapter V, Subchapter H. SEC. 205: NATIONAL STANDARDS FOR THIRD-PARTY
     LOGISTICS PROVIDERS; UNIFORM NATIONAL POLICY.
     SEC. 585. UNIFORM NATIONAL POLICY
     (b) WHOLESALE DISTRIBUTOR AND THIRD-PARTY LOGISTICS PROVIDER
     STANDARDS.—
     (1) IN GENERAL.—Beginning on the date of enactment of the Drug Supply Chain
     Security Act, no State or political subdivision of a State may establish or continue
     any standards, requirements, or regulations with respect to wholesale
     prescription drug distributor or third-party logistics provider licensure that are
     inconsistent with, less stringent than, directly related to, or covered by the

standards and requirements applicable under section 503(e) (as amended by

such Act), in the case of a wholesale distributor, or section 584, in the case of a third-party logistics provider.

 Cardinal Health believes that we were in compliance at the time of the inspection and remains so today.

4. Actions by Board to Prevent Sales of Preparation or Drugs Lacking Quality or Strength; Penalties for Knowing or Willful Violation of Regulations Governing Those Sales. The board may institute any actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code). "Hetastarch 6% 500 ml bag was stored in the refrigerator and needs to be stored between 20-25C per manufacturer labeling. Send correction.

Response: The bag of Hetastarch 6% was removed from the refrigerator. We'd like to point out that USP (659) Packaging and Storage Requirements states; "An article for which storage at Controlled room temperature is directed may, alternatively, be stored and shipped in a cool place or refrigerated, unless otherwise specified in the individual monograph or on the label."

We appreciate the consultative, collaborative approach taken by the Board, and we wish to reaffirm our commitment to regulatory compliance and to providing safe and quality radiopharmaceutical care to patients in the Sacramento CA area. Should you have any questions or wish to discuss this reply, please contact me at (614) 757-3174.

Best regards,

Eric K. Siu, PharmD, RPh Pharmacist in Charge

Richard L. Green, BSPharm R.Ph. BCNP FAPhA

Nuclear Pharmacist on NRC's Advisory Committee on the Medical Uses of Isotopes Member of the USP Expert Panel authoring <825> Radiopharmaceutical Compounding Director of Radiopharmacy Practice

cc. Michael A. Moné, BSPharm, J.D., FAPhA



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

#### INSPECTION REPORT

Pharmacy X Hospital Pharmacy	Clinic	Exempt Hospital	Wholesaler	Hypodermic
Date:5/29/2019	Inspector: Josh	ua Lee		
Firm: CARDINAL HEALTH 414,LLC		-	Phone: (916) 648	-2181
Address: 201 LATHROP WAY STE D		City: SACRAMENTO	Zip:	95815
Ownership: CORPORATION				
Permit #: LSC99110 PHY46385 Permit Exp	o: <u>7/1/2019</u>	DEA#:	DEA Exp	);
Date of Self Assessment Form: 5/12/2019	Other Permit #	: <u>N/A</u> D	ate of DEA Inventory:	
Hours M-F: 2330-1730	Hours Saturday	y <u>0130-1230</u>	Hours Sund	lay: <u>0130-1230</u>
PIC ERICKSIU	RPH63692	Administrator		
RPH Consultant				
Staff RPH Name:	License #:	Staff Name	e:	License #:
JAMES W KORB	RPH43629	ANDREW	CFU	TCH23907
JAMES M BRIGHT	RPH49335	ROSE M K		TCH74031
ALAN D KIM (SR. DIR OPS)	RPH46730		The state of the s	1011/4031
SUNGJIN CHOI (MANAGER	RPH58391			

#### **Inspector Remarks:**

Annual Sterile Compounding Inspection: Chain closed door nuclear pharmacy. PIC present along with corporate officers and managers. No controlled substances on premise/DEA permit.

Acq: Cardinal Health PET manufacturing in suite D1, BWXT, Jubilant Draximage, Curium,

RD: Stericycle

BOP Emails: Receiving PDMP: Signed up

Facility: Pharmacy located in suite D. Cardinal PET manufacturing (batch FDG) located in suite D1.

Secured reception

Restroom/break room

Administrative offices/conference room

Volume: About 600 CSPs made daily

CSPs made include FDG patient units, Tc-99 based CSPs such as sestamibi, myoview, pentetate.

Restricted pharmacy room with incubator 33.5C

Sterile Compounding Area:

ISO 8 ante room with refrigerator/freezer combo unit, LOD, gowning supplies, cleaning supplies, sink with hot and cold running water ISO 7 buffer room with 3 x vertical flow hoods, 1 x ISO 5 hot cell for PET

The following was reviewed: Compounding self-assessment, community pharmacy self-assessment, county of Sacramento medical waste inspection report, rx labeling, documentation of compounding policy review by PIC, end product testing for potency for every CSP, end product testing for sterility done quarterly in house, documentation of training and competency in sterile compounding and manufacture procedure information for incubation.

Discussion:

17I-3 (10/02)

LSC99110

380331

18 NA



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



- 1. Discussed about extended BUD assignment for CSPs.
- 2. Pharmacy agreed to post the original pharmacy permits in public view.
- 3. Carabiner in hood 2 needs cleaning.
- 4. Licensed pharmacy staff must wear nametag with name and license status while on duty
- 5. Invoice for Cardinal Health PET manufacturing adjacent to pharmacy list address in D1 but the manufacturing facility is in suite D1. Possibly typo. Education provided.
- 6. Compounding record and master formula need to be a single document. Education provided.

For inquiries regarding the status of your sterile compounding licensure, please use the following: <a href="mailto:compounding.pharmacy@dca.ca.gov">compounding.pharmacy@dca.ca.gov</a>

To complete the inspection, PIC to send Inspector Lee via e-mail (Email joshua.lee@dca.ca.gov) a response to corrections issued within 30 days

#### Licensee Remarks:

I have reviewed, discussed,understand and received a copy of this form .	Pharmacist (sign)
	Pharmacist (print)
Inspector (sign)	Owner(sign)
Inspector (print)	Owner(print)

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

This summary is provided in response to our affirmative answer to the disciplinary history question on our Application. Please note that, based on the broadness of the application question; we are disclosing all discipline that has occurred at other Cardinal Health Nuclear Pharmacy sites within the last 5 years. None of the below citations involved the Cardinal Health Nuclear Pharmacy located in Sacramento, CA, the site to which this application pertains. The safety of the nation's pharmaceutical supply chain is among our highest priorities. We take this responsibility very seriously and work diligently to comply with all applicable laws and regulations governing pharmacy. If you have any questions specific to these matters, please contact Dawn Harmon at (614) 757-7570.

Paul Gotti

### 2019- New York State Department of Environmental Conservation

Actions Taken: Consent Order

Location Involved: Cardinal Health 414, LLC, radiopharmacy in Syracuse, NY

Violation that occurred: pharmacy did not obtain prior approval before relocating the HVAC system on the roof

**Final Disposition**: signed a consent order. An application to modify the radiation control permit to be submitted regarding the changes in the exhaust system. A Pharmacy Compliance Specialist will be hired. The qualifications, and job responsibilities must be reviewed and approved. In addition, a SOP for all New York licensed pharmacies to follow, that outlines prior approvals for changes must be submitted and approved by the New York State Department of Environmental Conservation.

**Effective date:** 10/11/2019

Fines: \$6000.00

#### 2019-Rhode Island Board of Pharmacy

Actions Taken: Consent Order

Location Involved: Cardinal Health 414, LLC, radiopharmacy in E Providence, RI

**Violation that occurred**: pharmacy did not require technicians who compound radiopharmaceuticals to become nationally certified.

**Final Disposition**: signed a consent order. Agreement to have specialized nuclear technicians become nationally certified in addition to their existing specialized examination.

**Effective date:** 08/15/2019

Fines: no fine

#### **2019-US Department of Transportation**

Actions Taken: Statement of Violation and Penalty issued

Location Involved: National Central Pharmacy-Abilene Nuclear LLC

Violation that occurred: Probable violation offered and transported in commerce a DOT specification 7A packaging containing a Class 7 hazardous material without maintaining complete documentation of tests and an engineering evaluation or comparative data

Final Disposition: Ticket for Noncompliance

**Effective date: 03/04/2019** 

Fines: \$1,740.00

**Summary**: During a compliance inspection involving a shipping paper review, it was alleged as a probable violation that the pharmacy transported 7A packaging containing Class 7 hazardous material without maintaining complete documentation.

#### 2018-Virginia Board of Pharmacy

Actions Taken: citation issued

Location Involved: Cardinal Health 414, LLC, radiopharmacy in Richmond, VA.

**Violation that occurred**: Wall electrical and data plates were not sealed. The flooring where it meets the wall was not sealed and parts of the wall were not smooth and free from cracks

Final Disposition: parties entered into a consent order

**Effective Date:** 01/08/2018

**Fines**: \$2,000

#### Summary:

The final signed consent order was received referencing the Cardinal Health nuclear pharmacy located in Richmond, VA. Improperly sealed wall electrical and data plates as well as the space where the floor meets the wall. In addition to parts of the wall were not smooth or free from cracks. These were noticed during a Virginia BOP inspection. The issue has been corrected. The pharmacy paid an administrative fine.

#### 2017-Tennessee Board of Pharmacy

Actions Taken: license reprimanded

Location Involved: Cardinal Health 414, LLC, radiopharmacy in Algood, TN

Violation that occurred: during a routine inspection, inspector alleged that the pharmacy was

non-compliant with some aspects of USP <797>

**Final Disposition**: parties entered into a consent order

**Effective Date:** 03/13/2017

Fines: \$2,674.48

#### Summary:

On March 13, 2017, a consent order was entered by the board referencing the Cardinal Health nuclear pharmacy located in Algood, TN. During an inspection on April 5, 2016, it was alleged that the pharmacy was non-compliant with USP <797>. The pharmacy was remodeled and was monitored by an independent consultant approved by the Executive Director of the Board of Pharmacy initially and agreed to be monitored for one year. The independent consultant will submit quarterly reports to the Executive Director of the Board of Pharmacy for one year. The pharmacy paid a fine.

#### 2017-California Board of Pharmacy

Actions Taken: citation issued against the pharmacy license

Location involved: Cardinal Health 414, LLC, radiopharmacy in Redding, CA

#### Violation that occurred:

Each individual involved in the preparation of sterile injectable products must successfully complete a validation process on technique before being allowed to prepare sterile injectable products.

Equipment used in the designated area or cleanroom must be made of a material which can be easily cleaned and disinfected/Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables and stools, must be disinfected weekly/Operational standards and security; the pharmacy must be maintained in a sanitary condition.

Final Disposition: paid the fine

**Effective Date:** 03/28/2017

**Fines**: \$5,000

#### Summary:

In December 2016, the radiopharmacy in Redding, CA received a citation from the California Board of Pharmacy, for process validation technique not being completed when pharmacists from another California licensed Cardinal Health radiopharmacy came to temporarily work at the Redding location as well as for a window in the pharmacy that had particulates. An area under one of the compounding hoods was also not free of particulates.

#### 2017-Virginia Board of Pharmacy

Actions Taken: citation issued

Location Involved: Cardinal Health 414, LLC, radiopharmacy in Charlottesville, VA

Violation that occurred: surfaces of walls and floors in the buffer area and blood mixing room were not smooth, impervious, or free from cracks and crevices.

Final Disposition: parties entered into a consent order

**Effective Date:** 01/30/2017

Fines: \$2,000

#### **Summary:**

On January 11, 2017, a consent order was entered by the board referencing the Cardinal Health nuclear pharmacy located in Charlottesville, VA. The surfaces of walls and floors in the buffer area and blood mixing room were not smooth, impervious, or free from cracks and crevices. The facility maintenance department was contacted and the issues corrected. The pharmacy paid an administrative fine.

#### 2017-Nevada Board of Pharmacy

Actions Taken: stipulation issued

Location Involved: Cardinal Health 414, LLC, radiopharmacy in Las Vegas, NV.

**Violation that occurred**: A pharmacy technician's registration was not timely renewed. The technician was further charged for continuing to work with an expired registration between November 1-8, 2016.

Final Disposition: parties agreed to a stipulation

**Effective Date: 01/11/2017** 

Fines: \$500

#### Summary:

On December 6, 2016, the Nevada Board of Pharmacy notified Cardinal Health of a violation of the Nevada Administrative Code when a pharmacy technician's registration was not timely renewed. The technician was further charged for continuing to work with an expired registration between November 1-8, 2016. The Pharmacist in Charge as well as the Technician Supervisor were also charged for allowing the technician to work with an expired license. Changes to the software system utilized by Cardinal Health will prevent future occurrences. The pharmacy paid a monetary penalty of \$500

#### 2016-Virginia Board of Pharmacy

Actions Taken: citation issued

Location Involved: Cardinal Health 414, LLC, radiopharmacy in Virginia Beach, VA.

**Violation that occurred**: Chipped paint on the front section of a sterile compounding hood was noticed during a Virginia BOP inspection.

Final Disposition: parties entered into a consent order

**Effective Date:** 08/10/2016

Fines: \$2,000

#### Summary:

On February 4, 2016, a consent order was entered by the board referencing the Cardinal Health nuclear pharmacy located in Virginia Beach, VA. Chipped paint on the front section of a sterile compounding hood was noticed during a Virginia BOP inspection. The facility maintenance department was contacted and the issue corrected. The pharmacy paid an administrative fine.

**17B** 

#### **NEVADA STATE BOARD OF PHARMACY**

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

#### 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 ☑Ownership Change (Provide current license number if making changes: PH Check box below for type of ownership and complete all required forms.								
☐ Publicly Traded Corporation – Pages 1,2,3,7 ☐ Partnership - Pages 1,2,5,7								
☐ Publicly Traded Corporation – Pages 1,2,3,7 ☐ Partnership - Pages 1,2,5,7 ☐ Sole Owner – Pages 1,2,6,7								
GENERAL INFORMATION to be completed by all types of ownership								
Pharmacy Name: Genoa Healthcare LLC								
Physical Address: 915 Airway Avenu	ue, Suite l	B, Kingn	nan, AZ 86409					
Mailing Address: 3140 Neil Armstro	ong Blvd.,	Suite 1	10					
City:Eagan	_State:	MN	Zip Code:55121					
Telephone: 928-377-1741	_Fax:	928-2	71-8550					
Toll Free Number: 1-866-458-0136	(F	Required	l per NAC 639.708)					
E-mail: licencoordinator@genoahealthcare.com	<u>_</u> Website	:w	ww.genoahealthcare.com					
Managing Pharmacist: Courtney M	iller		License Number: S014257					
TYPE OF PHARMACY	AND	SE	RVICES PROVIDED					
Yes/No		Yes	s/No					
⊠ □ Retail			☑ Off-site Cognitive Services					
☐      Hospital (# beds	_)		Parenteral **					
□ 🛚 Internet			☑ Parenteral (outpatient)					
□ 🗷 Nuclear			☑ Outpatient/Discharge					
☐ 🗷 Ambulatory Surgery	Center	X	☐ Mail Service					
☑ □ Community	図 口 Community 図 口 Long Term Care							
□ 図 Other:			☑ Sterile Compounding **					
			☑ Non Sterile Compounding					
All boxes must be checked			Mail Service Sterile Compounding **					
For the application to be com	plete		M Other Services:					
		·						

<sup>\*\*</sup>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.

Board	Use Only Date Processed: 2.11.2020 Amount: 500.6	<b>D</b>
	Taille of Additionage of Order	Page 2
	h Fenwick - VP Network Contracts  Name of Authorized Person  Date	9
Origin	al Signature of Person Authorized to Submit Application, no copies or sta	mps
	Darch Efference	
•	round, qualification and reputation, as it may deem necessary, proper or o	
	ct. I hereby authorize the Nevada State Board of Pharmacy, its agents, ser eyees, to conduct any investigation(s) of the business, professional, social	
under	penalty of perjury, that the information furnished on this application are tr	ue, accurate and
l have	e read all questions, answers and statements and know the contents there	of. I hereby certify,
correc	by certify that the answers given in this application and attached documer ct. I understand that any infraction of the laws of the State of Nevada regu tion of an authorized pharmacy may be grounds for the revocation of this	lating the
•	sition may be required.	
Copie	answer to question 1 through 5 is "yes", a signed statement of explanation s of any documents that identify the circumstance or contain an order, ago	
	voluntarily or otherwise (other than upon voluntary close of a facility)?	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	
	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 🛚
4)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any	
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 □
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 🛚
	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 🛚
1)	Has the corporation, any owner(s), shareholder(s) or partner(s) with	
vvitnin	ithe last five (5) years:	

#### APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

#### **OWNERSHIP IS A PUBLICY TRADED CORPORATION**

State of Incorpora	tion:	Pennsylv	/ania						
Parent Company i	pany if any: Specialized Pharmaceuticals, Inc.								
Corporation Name	):	Genoa H	ealthcare l	LC					
Mailing Address:		3140 Nei	Armstron	g Blvd., S	Suite 110				
City:		Eagan	State:_	MN	Zip: _	551	21		
Telephone: 2	253-218-08	30	Fax:	253-2	17-4306				
Contact Person: _	Joy	Kunz - Imp	lementing	Licensin	g Paralge	al			
If the corporation the applicant shall registration with the being traded. You	identify the e SEC, the can provid	e officers of registration de a copy	of that corp on number	oration, to issued a report o	he date thand the exc	e corp	oration re at which	ecei	ved its
Date of Incorporat	ion:								
Registration numb	er issued:	27	7-0556097						
Stock Exchange:		1X	NYS:UNH						
Hours of Operation	on for the	pharmacy		a al	l-	,	Dianad		On coll
Monday thru Frida	y8:00_a	m5:06	cios) 2_pm 12:0	ed for lui 0 -1:00 p	ncn m) Saturda	ay	Closed - ar		On-call pm
Sunday	Closed ai	On-ca		•	24 Hou		After ho	ours	service
A Nevada busines license please pro		•	red, howev N/A	er if the	pharmacy 	has a	Nevada	bus	ness

## Must be included with the application for a publicly traded corporation

<u>Certificate of Corporate Status</u> (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

#### APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

# OWNERSHIP IS A SOLE OWNER. All information relates to the person listed as the owner.

Owner's Name:		Specia	alized Pha	armaceutical	s, Inc.	
Business Name:		Genoa	Healthca	re LLC		
Current Business Ad	ddress: _	707 G	rady Way	, Suite 700		
City:					_Zip Code:	98057
Telephone:		0.0000			253-217	
List any physician sl Name: N/A				·		_%:
						%:
Name:						%:
Hours of Operation  Monday thru Friday  Sunday	8:00 ai	5:00 m I - On Call	– (Clo _pm <sup>12:0</sup>	sed for lunch 0 - 1:00 pm)		Closed - On Callpm After Hours Service
A Nevada business license please provi				ver if the ph	armacy has a	a Nevada business

## STATEMENT OF RESPONSIBILITY FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

Ι,	Sarah Fenwick
Responsible Person of	Genoa Healthcare LLC
hereby acknowledge and unde	rstand that in addition to the corporation's, any owner(s),
shareholder(s) or partner(s) res	sponsibilities, may be responsible for any violations of pharmacy law
that may occur in a pharmacy o	owned or operated by said corporation.
	and understand that the corporation's, any owner(s), shareholder(s) any action taken by the Nevada State Board of Pharmacy against a ed by said corporation.
or partner(s) cannot require or	nd understand that the corporation's, any owner(s), shareholder(s) permit the pharmacist(s) in said pharmacy to violate any provision ws or regulations pertaining to the practice of pharmacy.
Scraf 2 Original Signature of Person A	Uthorized to Submit Application, no copies or stamps
Sarah Fenwick - VP Network Co	ontracts \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\
Print Name of Authorized Person	on Date

## **AFFIDAVIT for Out-of-State Pharmacy License**

STATE OF MINNESOTA )
STATE OF MINNESUTA ) ) ss.  DAKOTA COUNTY )
I, Courtney Miller , 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 Pharmacy Manager for Genoa Healthcare LLC (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, Courtney Miller, do hereby swear under penalty of perjury that the assertions of this
affidavit are true.
Lowney Mille Pham)
SUBSCRIBED AND SWORN TO
before me, a notary public this day of <u>becamber</u> , 20 <u>19</u> .
Joint Rum
NOT/ARY/PUBLIC

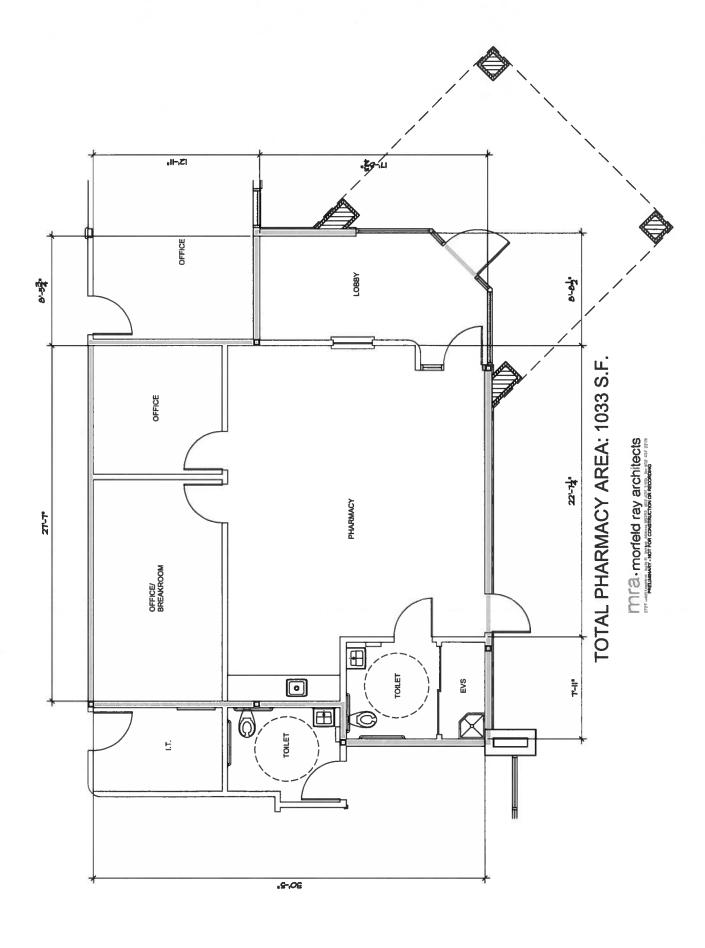


Owner	Ownership Percentage	FEIN	Address
Specialized Pharmaceuticals, Inc.	100%	25-1868213	707 S. Grady Way, Suite 700 Renton, WA 98057

# Officers and Directors of the Board FEIN: 27-0556097

Name	Title	Business Address & Phone	% Interest	Professional License Type; Number; State Issued
Mark James Peterson	Manager	3140 Neil Armstrong Blvd, Ste 110 Eagan, MN 55121 253-218-0830	0	Pharmacist, 115262, MN
Thomas Mullin (NMN)	Manager	9900 Bren Road East Minnetonka, MN 55343 952-936-1300	0	N/A
Mark James Peterson	CEO	3140 Neil Armstrong Blvd, Ste 110 Eagan, MN 55121 253-218-0830	0	Pharmacist, 115262, MN
Andrew Phillip Voss	CFO	707 S. Grady Way Ste 700 Renton, WA 98057 253-218-0830	0	N/A
William Robert Guptail	coo	3140 Neil Armstrong Blvd, Ste 110 Eagan, MN 55121 253-218-0830	0	N/A
Karen Elizabeth Peterson	Secretary	9900 Bren Road East Minnetonka, MN 55343 952-936-1300	0	Pharmacist, 051293213, IL Attorney, 6323320, IL Attorney, 4102158, NY Attorney, 19229, IA - inactive Pharmacist, 0202011356, VA - inactive Pharmacist, RPH-0008879, OR - inactive Pharmacist, 045653, NY - inactive
Kirsten Colleen Hines	Assistant Secretary	9900 Bren Road East Minnetonka, MN 55343 952-936-1300	0	Attorney, 6203446, IL
Heather Anastasia Lang	Assistant Secretary	9900 Bren Road East Minnetonka, MN 55343 952-936-1300	0	Attorney, 033151X, MN Attorney, 34220, CO - inactive
Peter Marshall Gill	Treasurer	9900 Bren Road East Minnetonka, MN 55343 952-936-1300	0	Residential Real Estate Salesperson, 545646,MN NASD Series 7 & 63 Unknown; DC NASD Series 24 Unknown; DC

<sup>\*</sup> Officers have 0% ownership in Genoa Healthcare, LLC





### (QUESTION 3)

Within the last five (5) years:

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

Genoa has been subject to the following Disciplinary Action:

Oregon Board of Pharmacy (2018) – Salem, Oregon (Case No. 2017-0523): Disciplinary action alleging an apparent failure to have a PIC at the Salem, OR pharmacy site for a period of six weeks in 2017. Although the site did have a PIC in place at all time, a requisite form documenting a change in PIC was not timely filed by the temporary PIC, creating a gap in Board of Pharmacy online filings. A Consent Order was received by the Oregon Board of Pharmacy on July 30, 2018 and a \$6,000 fine was paid.

Arizona State Board of Pharmacy (2019)—Gilbert, Arizona (Case No. 2018-0080): Disciplinary action alleging a failure of not complying with the Arizona state regulations regarding "shared" after-hours pharmacy service following a routine pharmacy inspection on March 5, 2018. In particular, the appropriate notice to customers as to the after-hours pharmacy service Genoa was using there was not sufficient policies and procedures regarding such service. There was no allegation that patient care was impacted. A new after-hours vendor was put in place and we have educated our pharmacies to ensure that patients are aware that their after-hour needs are being met by another pharmacy service that has compliant policies and procedures regarding "shared services". A Consent Order was received by the Arizona State Board of Pharmacy in March 2019 and a \$500 fine was paid.



## **Arizona State Board of Pharmacy**

Physical Address: 1616 W. Adams, Suite 120, Phoenix, AZ 85007 Mailing Address: P.O. Box 18520, Phoenix, AZ 85005 P) 602-771-2727 F) 602-771-2749 www.azpharmacy.gov

April 11, 2019

Genoa Healthcare, LLC Attn: Ms. Kathleen McGuan 18300 Cascade Ave S Suite 251 Tukwila, WA 98188

Re:

Consent Agreement for Civil Penalty – Board Case No. 18-0080

Dear Ms. McGuan,

Please find enclosed a copy of the Consent Agreement for Civil Penalty in Board Case No. 18-0080. After the Consent Agreement was signed, staff discovered a typographical error. Specifically, the permit number on page 1, line 13 was incorrect. Staff corrected the error and replaced page 1 of the document. The corrected permit number was the only change made to the document.

If you have any questions regarding this matter, please contact this office.

Sincerely,

Kamlesh Gandhi Executive Director

KG/jcm

**Enclosure** 



MARK BRNOVICH 1 Attorney General (Firm State Bar No. 14000) 2 3 JEANNE M. GALVIN Assistant Attorney General State Bar No. 015072 2005 North Central Ave. SGD/LES 5 Phoenix, Arizona 85004 Tel: (602) 542-7983 Fax: (602) 364-3202 6 7 Attorneys for the Arizona State Board of Pharmacy 8 BEFORE THE ARIZONA STATE BOARD OF PHARMACY 9 In the Matter of 10 Board Case No. 18-0080 11 12 Genoa Healthcare, LLC, #20120, CONSENT AGREEMENT FOR CIVIL PENALTY 13 Permit No. Y007067 As a Licensed Pharmacy In the State of Arizona 14 15 16 In the interest of a prompt and judicious settlement of this case, consistent with the 17 public interest, statutory requirements and the responsibilities of the Arizona State Board 18 of Pharmacy ("Board") under A.R.S. § 32-1901, et. seq., Genoa Healthcare, LLC, 19 #20120 ("Respondent"), holder of permit no. Y007067 as a licensed pharmacy in the 20 State of Arizona and the Board enter into the following Recitals, Findings of Fact, 21 Conclusions of Law and Order ("Consent Agreement") as a final disposition of this 22 matter. 23 24 RECITALS 25 26

- 1. Respondent has read and understands this Consent Agreement and has had the opportunity to discuss this Consent Agreement with an attorney, or has waived the opportunity to discuss this Consent Agreement with an attorney.
- 2. Respondent understands that it has a right to a public administrative hearing concerning this matter at which hearing it could present evidence and cross examine witnesses. By entering into this Consent Agreement, Respondent knowingly and voluntarily relinquishes all right to such an administrative hearing, as well as rights of rehearing, review, reconsideration, appeal, judicial review or any other administrative and/or judicial action, concerning the matters set forth herein.
- 3. Respondent affirmatively agrees that this Consent Agreement shall be irrevocable.
- 4. Respondent understands that this Consent Agreement or any part of the agreement may be considered in any future disciplinary action by the Board against it.
- 5. Respondent understands this Consent Agreement deals with Board Complaint No. 18-0080 involving allegations of unprofessional conduct against Respondent. The investigation into these allegations against Respondent shall be concluded upon the Board's adoption of this Consent Agreement.
- 6. Respondent understands that this Consent Agreement does not constitute a dismissal or resolution of any other matters currently pending before the Board, if any, and does not constitute any waiver, express or implied, of the Board's statutory authority or jurisdiction regarding any other pending or future investigation, action or proceeding.
- 7. Respondent also understands that acceptance of this Consent Agreement does not preclude any other agency, subdivision, or officer of this State from instituting any other civil or criminal proceedings with respect to the conduct that is the subject of this Consent Agreement.

- 8. Respondent acknowledges and agrees that, upon signing this Consent Agreement and returning this document to the Board's Executive Director, it may not revoke acceptance of the Consent Agreement or make any modifications to the document regardless of whether the Consent Agreement has been signed by the Executive Director. Any modification to this original document is ineffective and void unless mutually agreed by the parties in writing.
- 9. This Consent Agreement is subject to the approval of the Board and is effective only when accepted by the Board and signed by the Executive Director. In the event that the Board does not approve this Consent Agreement, it is withdrawn and shall be of no evidentiary value and shall not be relied upon nor introduced in any action by any party, except that the parties agree that should the Board reject this Consent Agreement and this case proceeds to hearing, Respondent shall assert no claim that the Board was prejudiced by its review and discussion of this document or any records relating thereto.
- 10. If a court of competent jurisdiction rules that any part of this Consent Agreement is void or otherwise unenforceable, the remainder of the Consent Agreement shall remain in full force and effect.
- 11. Respondent understands that this Consent Agreement is a public record that may be publicly disseminated as a formal action of the Board and may be reported as required by law to the National Practitioner Data Bank and the Healthcare Integrity and Protection Data Bank.
- 12. Respondent understands that any violation of this Consent Agreement constitutes unprofessional conduct and may result in disciplinary action. A.R.S. §§ 32-1901.01(A)(19) and A.R.S. §32 1927.02(A) (1).

13. Respondent agrees that the Board will adopt the following Findings of Fact, Conclusions of Law and Order.

ACCEPTED AND AGREED BY RESPONDENT



Dated: 3/27/19

On Behalf of Genoa Healthcare, LLC, Permit Holder NO. Y007067

# FINDINGS OF FACT

- 1. The Board is the duly constituted authority for licensing and regulating the practice of pharmacy in the State of Arizona.
- Respondent is Genoa Healthcare, LLC, #20120, holder of permit no.
   Y007067, to operate as a pharmacy in the State of Arizona. At all relevant times,
   Respondent was located at 5222 East Baseline Rd, Gilbert, AZ 85234.
- 3. On or about March 5, 2018, Board staff conducted a routine inspection of Respondent's premise. In response to staff's question about delivery services, Respondent's PIC, Mr. Kyle Clonts, responded that Genoa Healthcare, LLC, #20120 utilized Medcall to answer after-hours patient questions, noting that Medcall had access to patient profiles. In addition, it was revealed that Medcall was able to transfer prescriptions for patients after hours from Genoa to the pharmacy of choice.

- 4. At the time of inspection, the PIC was unable to produce the shared services agreement with Medcall or the Respondent's policies and procedures relating to shared services.
- 5. Subsequent to the investigation, the Respondent provided what it believed to be the appropriate shared services agreement, however, upon further review it was determined that the contract with Medcall listed only two Genoa Arizona locations.
- 6. Additionally, the permit on file with the Board is Y004817 and belongs to Homemed. There is no permit for Medcall that would allow it to conduct pharmacy business in the State of Arizona.
- 7. Subsequent to the inspection, Respondent notified the Board that it has discontinued using Medcall to ensure compliance with Arizona regulations.

### **CONCLUSIONS OF LAW**

- 1. The Board possesses jurisdiction over the subject matter and over Respondent pursuant to A.R.S. § 32-1901 et seq.
- 2. The Board may discipline a permittee who has engaged in unprofessional conduct. A.R.S. § 32-1927.02(A) (1).
- 3. The conduct and circumstances described above constitutes unprofessional conduct pursuant to A.R.S. § 32-1901.01(A)(5) as it relates to Arizona Administrative Code R4-23-621(A), (B)(2) and (C)(a) and (b).

### <u>ORDER</u>

Based upon the above Findings of Fact and Conclusions of Law, IT IS HEREBY ORDERED THAT:

- 1. Respondent shall pay to the Board as a civil penalty the sum of \$500.00 for not having complied with shared services regulations by providing advance notice to patients that their orders would be filled by a shared service pharmacy and having adequate policies and procedures regarding shared services. The civil penalty shall be paid in full to the Board within ninety (90) days of the effective date of this Consent Agreement and Order. The effective date of this Consent Agreement is the date it is signed by the Board's Executive Director.
- 2. If the Board determines that Respondent has not complied with all the requirements of this Consent Agreement, the Board, in its sole discretion, may institute proceedings for noncompliance with this Consent Agreement, which may result in the suspension or revocation of Respondent's permit. Failing to abide by this Consent Agreement and Order is a violation of A.R.S. §32-1901.01(A)(19), which is violating a formal order, terms of probation, a consent agreement or a stipulation issued or entered into by the board it its executive director."
- 3. Respondent understands that this Consent Agreement is a public record that may be publicly disseminated as a formal action.
- 4. If Respondent violates this Order in any way or fails to fulfill the requirements of this Order, the Board, after giving the Respondent notice and the opportunity to be heard, may revoke, suspend or take other disciplinary actions against Respondent's permit. The issue at such a hearing will be limited solely to whether this Order has been violated.

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DATED this What day of april, 2019.
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                                          ARIZONA STATE BOARD OF PHARMACY
    (Seal)
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 6
                                                       ESH GANDHI, PharmD
 7
                                                Executive Director
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    ORIGINAL OF THE FORGOING FILED
    this 1144 day of 2019, with:
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    Arizona State Board of Pharmacy
    1616 W. Adams Street
11
    Phoenix, Arizona 85007
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    EXECUTED COPY OF THE FOREGOING MAILED
    BY CERTIFIED MAIL this 11 day of april 2019, to:
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    Genoa Healthcare, LLC
    Attn: Ms. Kathleen McGuan
16
    18300 Cascade Ave. S., Ste. 251
17
    Tukwila, WA 98188
18
    EXECUTED COPY OF THE FOREGOING MAILED this little day of april, 2019, to:
19
    Jeanne M. Galvin
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    Assistant Attorney General
    2005 North Central Ave., SGD/LES
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    Phoenix, Arizona 85004
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    Attorneys for the Board
    Doc #7078160
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# RECEIVED

1	BEFORE THE BOARD OF PHARMACY OF THE STATE OF OREGON		JUL 3 0 2013	
2			SPECONDOIND OF BUILDING	
3			OREGON BOARD OF PHARMACY	
4				
5	In the Matter of the	) Case No. 2017-0523		
6	Drug Outlet Registration of	)		
7		)		
8	GENOA HEALTHCARE, LLC	) CONSENT ORDER		
9		)		
LO	Registrant	)		
11				
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15	registrant in the above-captioned matter;	and		
16				
١7				
18	and			
.9	MANDE VO 11 1 -	C 1 : - I II II II		
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21	the above-noted Notice without further p	roceedings thereon; and		
22	NATION AC ALCOHOLOGICAL COMPANY	Calii -lia aa - a lia - ii - a - aidh ali -		
23				
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25	those rights; and			
26	WHEDEAS the registrant admir	to that while they did not have a	pharmacist_in_charge	
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29	pharmacist completing the responsionate	s of a pharmacist-in-charge,		
30	W/UEDEAS the registreet admits	that legal cause exists nursuant to (	DS 680 405 and OBS	
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32	689.445 for disciplinary action and impos	Sition of a civil penalty by the Boar	id, and	
33	WHEDEAS the registrant conser	nts to the disciplinary action as set	forth herein:	
34 35	WIEREAS, the registrant consci	its to the disciplinary action as set	form nereni,	
36	The Board finds that the allegation	ns in the Notice are true and hereb	v·	
37	The Dome that and allogano	may 1 10 may may make 110100	, -	
38	1. The registrant shall pay t	he Board a civil penalty in the ar	nount of \$6,000, said	
19	navment to be made within ten days from			

41	2. Failure of the registrant to pay the civil penalty as required under this Consent Orde		
42	may, after notice and hearing, result in further disciplinary action.		
43	CONGENER		
44	CONSENT		
45 46	I hereby acknowledge that I am the authorized representative of registrant. On behalf o		
47	the registrant, I hereby acknowledge that I have read and understand the above-noted Notice and		
48	the terms of the Consent Order. I hereby acknowledge that I understand that the Consent Order		
49	with incorporated Notice is a public record and shall be available via the Board's online licensure		
50	verification; is available upon written request pursuant to public disclosure laws; and shall be		
51	reported to the National Practitioner Data Bank as required by federal law. I agree to the Board		
52	entering the Consent Order.		
53	onto mg and doubling disco.		
54	NH IN A		
55	Kattleen Me Gran 1-27-2018		
56	Authorized Representative Date		
57	GENOA Healthcare, LLC		
58	Registrant (Reg. No. RP-0002461)		
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62	IT IS SO ORDERED.		
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65	BOARD OF PHARMACY		
66	FOR THE STATE OF OREGON		
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68	7/2/10		
69	Diam Francisco Contractor Dela		
70	Brianne Efremoff, Pharm.D, R.Ph.,  Compliance Director		
71	Compliance Director		

#### BEFORE THE BOARD OF PHARMACY 1 OF THE STATE OF OREGON 2 In the Matter of the Case No. 2017-0523 Drug Outlet Registration of 5 6 NOTICE OF PROPOSED GENOA HEALTHCARE, LLC 7 DISCIPLINARY ACTION; 8 ANSWER REQUIRED 9 Registrant 10 11 Under the authority granted pursuant to ORS 689.135, 689.145, 689.335, 689.405 and 12 689.445, the Oregon Board of Pharmacy proposes to take disciplinary action against your 13 Certificate of Registration No. RP-0002461 because Genoa Healthcare, LLC violated the Oregon 14 Pharmacy Act and the Board of Pharmacy rules as set forth below: 15 16 Genoa Healthcare, LLC, located at 3180 NE Center St Ste 3360 in Salem, OR did not 17 have a pharmacist-in-charge from on or about June 10, 2017 through July 31, 2017, in violation 18 of OAR 855-041-1010(1) and OAR 855-019-0300(1), which is grounds for discipline and 19 imposition of a civil penalty pursuant to ORS 689.335(1), 689.405(1)(e)(B), 689.832(1) and 20 689.445(1)(d). 21 22 Based on these alleged violations, the Board proposes to impose a civil penalty in the 23 amount of \$1,000 per violation. 24 25 **HEARING RIGHTS** 26 27 The corporation is entitled to a hearing as provided by the Administrative Procedures Act 28 (ORS chapter 183). An attorney must represent the corporation, If the corporation wishes to have 29 a hearing, the corporation's attorney must file a written request for hearing with the Board within 30 21 days from the date this notice was mailed. The corporation's attorney may send or deliver a 31 request for hearing to: 32 Oregon Board of Pharmacy 33 800 NE Oregon Street, Suite 150 34 Portland, OR 97232 35 Fax: (971) 673-0002 36 37 If a request for hearing is not received within this 21-day period, the corporation's right 38 to a hearing shall be considered waived. 39 40 If the corporation requests a hearing, the corporation's attorney will be notified of the 41 time and place of the hearing. Before the commencement of the hearing, the corporation will be 42 given information on the procedures, right of representation and other rights of parties relating to 43 the conduct of the hearing. 44

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If the corporation does not request a hearing within 21 days, or if it withdraws a hearing

request, notifies the Board or Administrative Law Judge that it will not appear, or fails to appear

at a scheduled hearing, the Board may issue a final order by default imposing discipline. If the

Board issues a final order by default, it designates its file on this matter as the record. ANSWER REQUIRED Pursuant to OAR 855-001-0010 and OAR 855-001-0015, if you request a hearing you must also provide, within 21 days from the date this contested case notice was served, a written answer to the allegations set forth in this contested case notice. Your written answer must include an admission or denial of each factual matter alleged in the notice and a short and plain statement of each relevant affirmative defense you may have. Except for good cause, factual matters alleged in the notice and not denied in the answer shall be presumed admitted; failure to raise a particular defense in the answer will be considered a waiver of such defense; new matters alleged in the answer (affirmative defenses) shall be presumed to be denied by the agency; and evidence shall not be taken on any issue not raised in the notice and the answer. Hearing Request and Answers: Consequences of Failure to Answer 855-001-0015 (1) A hearing request, and answer when required, shall be made in writing to the Board by the party or his attorney and an answer shall include the following: An admission or denial of each factual matter alleged in the notice; A short and plain statement of each relevant affirmative defense the party (b) may have. Except for good cause; (2) Factual matters alleged in the notice and not denied in the answer shall be presumed admitted: Failure to raise a particular defense in the answer will be considered a (b) waiver of such defense: New matters alleged in the answer (affirmative defenses) shall be (c) presumed to be denied by the agency; and Evidence shall not be taken on any issue not raised in the notice and the (d) answer. **BOARD OF PHARMACY** FOR THE STATE OF OREGON

2/15/18

Brianne Efremoff, Pharm.D, R.Ph.,

Compliance Director

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DATE OF MAILING 2-16-2018

# COMMONWEALTH OF PENNSYLVANIA DEPARTMENT OF STATE

11/21/2019

#### TO ALL WHOM THESE PRESENTS SHALL COME, GREETING:

I DO HEREBY CERTIFY THAT,

#### Genoa Healthcare LLC

is duly registered as a Pennsylvania Limited Liability Company under the laws of the Commonwealth of Pennsylvania and remains subsisting so far as the records of this office show, as of the date herein.

I DO FURTHER CERTIFY THAT this Subsistence Certificate shall not imply that all fees, taxes and penalties owed to the Commonwealth of Pennsylvania are paid.

OF THE COMMONWEATH

IN TESTIMONY WHEREOF, I have hereunto set my hand and caused the Seal of the Secretary's Office to be affixed, the day and year above written

Secretary of the Commonwealth

Certification Number: TSC191121121127-1

Verify this certificate online at http://www.corporations.pa.gov/orders/verify



# **Arizona State Board of Pharmacy**

Physical Address: 1616 W. Adams, Suite 120, Phoenix, AZ 85007 Mailing Address: P.O. Box 18520, Phoenix, AZ 85005 (P): 602-771-2727 (F): 602-771-2749 www.azpharmacy.gov

# CERTIFICATION OF ARIZONA STATE BOARD OF PHARMACY PERMIT FOR THE ENTITY LISTED BELOW:

This document is not a license/permit but serves as the primary source of verification.

Name:

Genoa Healthcare LLC

Address:

915 Airway Ave Suite B Kingman AZ 86409

License No :

Y007796

**Permit Type:** 

**Pharmacy** 

Sub Type :

Chain

Date Issued:

10/25/2018

**Expiration Date:** 

10/31/2021

Status:

**OPEN** 

Discipline:

No

Xam Gardhi

# Kam Gandhi

Executive Director Arizona State Board of Pharmacy

Date: 12/16/2019



Receipt Date: 09/30/2019 Receipt Number: 201969776 Receipt Amount \$: 480.00

# Pharmacy - Chain

Closed Door,Long Term Care,Retail

PERMIT NO Y007796

> Genoa Healthcare LLC Genoa Healthcare LLC 3140 NEIL ARMSTRONG BLVD. SUITE 110 EAGAN, MN 55121

**EXPIRES** 10/31/2021

Genoa Healthcare LLC 915 AIRWAY AVE SUITE B KINGMAN, AZ 86409

EXECUTIVE DIRECTOR

ARIZONA STATE BOARD OF PHARMACY

P.O. Box 18520 Phoenix, AZ 85005 502-771-ASBP (2727) AX: 602-771-2749

Issued to:



WALLET CARD

NAME: Genoa Healthcare LLC LICENSE NUMBER: Y007796

EXPIRES: 10/31/2021

http://www.azpharmacy.gov

- Your license must be available for inspections during business hours.
- · Permit holder(s) must display permit in the location to which it is issued.
- · Please note it is your responsibility to keep this license/permit current.

### **Important Information**

ICENSE HOLDER (pharmacist, intern, technician, technician-trainee)

Holder of this license number, printed above, is authorized in accordance with A.A.C. R4-23-201(A), A.A.C. R4-23-301(A) or A.A.C R4-23-1101(A), to erform the duties associated within their profession. By holding this license, the licensee agrees to comply with state & federal law.

You are required by law to notify the Board of any home address and/or employment change within 10 business days

ERMIT HOLDER (pharmacy, non-prescription retailer (OTC), wholesale, manufacture, CMG, DME)

Holder of this permit number, printed above, is authorized to conduct business according to the classification specified in A.R.S. § 32-1908(A); A.A.C. R4-23-01 and A.A.C. R4-23-607. By holding this permit, the permittee agrees to comply with state & federal law

In-state pharmacy, wholesaler & manufacture permit holder(s) who plan to remodel or move locations, must submit a change-of-location/remodel form within 30 lays prior to move/remodel. In-state non-prescription (OTC), compressed medical gas (CMG) & DME providers who plan to move locations must notify the oard within 10 business days of move.

Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days of move. A revised copy of your state permit shall be ubmitted to the Board, when available.

Permits are non-transferable. Ownership changes of more than 30% require that a new application be submitted to the Board.