

Aras #136
6/7/2023

Disp Pract. #1002490
9/1/2023

LICENSURE UNIT

MAY 12 2023

RECEIVED

ACCOUNTING
Business Unit #25550346

**APPLICATION FOR LICENSE TO OPERATE A PHARMACY
-Dispensing Practitioner-**

Application Fee: \$625.00 (Make check payable to DHHS Licensure Unit)

The Department will issue a **Provisional Dispensing Practitioner Pharmacy License** after review and approval of your application by a pharmacy inspector up to FIVE WEEKS prior to the anticipated date your dispensing is planned to begin (as listed on this application). Due to the statutory requirements in place regarding the timing of the inspection, it is **IMPERATIVE** that you list an accurate date your dispensing is planned to begin and notify the Department AS SOON AS POSSIBLE if this date changes. A Provisional License is good for up to one year from the date of issuance and is not renewable. The Pharmacy Inspector will conduct an Initial Onsite Inspection within 60 days of issuance of the Provisional License.

A **permanent license** will be issued after successful passage of the Initial Onsite Inspection. You may contact the DEA at www.deadiversion.usdoj.gov or 888-803-1179 to apply for a Federal Controlled Substances Registration.

****NOTE: DISPENSING UNDER THIS LICENSE MAY OCCUR ONLY AT THE LOCATION LISTED ON THIS APPLICATION. IF YOU DISPENSE AT MULTIPLE LOCATIONS, A SEPARATE CREDENTIAL MUST BE ISSUED FOR EACH LOCATION.**

SECTION A - License Information			
Practitioner applying for credential:	Name: Garry Siegel	License type & #: MD, CP179	License expiration: 10/1/2024
Practitioner applying for credential must check the appropriate box(es):	<input checked="" type="checkbox"/> Social Security Number (SSN); <input type="checkbox"/> Alien Registration Number ("A#"); or <input type="checkbox"/> Form I-94 (Arrival-Departure Record) number:	SS# [REDACTED] A# _____ I-94 # _____	NOTE: If you have both a SSN & an A# or I-94 #, you must report both. Neb. Rev. Stat. §38-123 mandates disclosure of your social security number to DHHS. Although your number is not public information, DHHS may disclose it for child support enforcement purposes and to the Nebraska Department of Revenue.
Additional Practitioner(s) dispensing under this credential: Attach additional page if necessary <input type="checkbox"/> NA	Name(s): Marilee Hanson	License type(s) & #: MD CP072	License expiration:
Information regarding the physical location where the dispensing will take place:	Street/PO/Route: 1002 W Mission Ave Telephone #: 402-292-4164	City/State/Zip: Bellevue, NE 68005 Fax #: 402-291-4643	
Anticipated date dispensing will begin:	April May 24th, 2023		
Please supply a contact person for questions:	Name: Janine Weatherby Phone: 402-510-4402	E-mail: CareClinics.J9@gmail.com	
Days/ Hours Open for Business:	phones M-F 9-530, Sat 9-3, Patients 2 days a week every other week Th/Fr and Fri/Sat.		

SECTION B – CONTROLLED SUBSTANCES REGISTRATION☐ YES☒ NO

Are controlled substances to be dispensed?
If so, a Federal Controlled Substances Registration is required.

You may apply for a federal controlled substances registration on-line at www.deadiversion.us.doj.gov

SECTION C – STANDARDS FOR THE OPERATION OF A PHARMACY

Please type or print clearly a detailed description of how your pharmacy will meet the following requirements in compliance with 175 NAC 8, Sections 8-006 and 8-007. If you need additional room, you may attach a separate sheet.

1.	How will the prescription inventory and prescription records of the pharmacy be secured when there is no pharmacist/dispensing practitioner on the premises? (see 8-006.02C) have a locked 'pharmacy room'
2.	How will your pharmacy ensure that drugs, devices, and biologicals are kept at the proper temperature? (see 8-006.02A) Room Controlled temp. also fridge in laboratory but don't have any specialty Controlled meds
3.	How will your pharmacy ensure that none of its saleable inventory contains any drug, device, or biological which is misbranded or adulterated? (see 8-006.02D) We don't sell, just included in cost of visit. Limited type of medications/drugs that have.
4.	What services will your pharmacy be providing? (Examples of services which may be provided by a pharmacy include, but are not limited to: ambulatory dispensing, unit-dose dispensing, sterile compounding, non-sterile compounding, and administration of vaccinations or injections.) None of these. We provide 3 types of drugs to our patients Ondansetron, Mifeprex + misoprostol
5.	What facilities, utilities, and equipment will you be providing at your pharmacy? (see 8-007 and 8-006.02) (Facilities include such items as counters, drawers, shelves, etc. Utilities include such items as lights, heat/air conditioning, electricity, hot/cold running water. Equipment includes such items as mortar and pestle, IV hood, balance, etc.) pharmacy room has Running water/hot cold. lights and heat/air.

* taking over a previous pharmacy / doctor passed away. With Patients being rescheduled. Thank you

SECTION C – STANDARDS FOR THE OPERATION OF A PHARMACY (continued)

What specific reference materials will be provided to the pharmacist/dispensing practitioner in your pharmacy? (Please indicate if these are printed or electronic form) (see 8-007.03)

6.

Since only using the 3 meds / drugs. All reference materials online

SECTION D – ATTESTATION (All applicants must complete this section)

Application Attestation: I attest that I have read the application or have had the application read to me; all statements on the application are true and complete; I am of good character; and I have not committed any act that would be grounds for denial under Neb. Rev. Stat. §38-178 and/or 38-179. If you have committed act(s), you must provide an explanation of all such act(s).

GARRY SIEGEL

(Printed Name of Applicant)

[Redacted Signature]

(Signature of Applicant)

5/10/2023

(Date)

NOTE: All supporting documentation required to complete your application must be submitted within 150 days from the date your application is received by the Department. If such documentation is not submitted within this time, your application and supporting documentation will be destroyed and a refund will be processed, less the administrative fee of \$25.00.

Application Revised 07/2012

From: Pollard, Melissa

Sent: Tuesday, July 18, 2023 3:32 PM

To: Cushman, Jesse <Jesse.Cushman@nebraska.gov>; Apking, Vonda <Vonda.Apking@nebraska.gov>

Subject: Initial Disp Practitioner Garry Siegel (Lic 136) 1002 W Mission Ave, Bellevue, NE 68805

This dispensing practitioner was non-compliant with items # 1 - 2. See Statement of Compliance page for further details.

This inspection is OK and with the deficiencies corrected, fully complies and should be issued a dispensing practitioner license.

Melissa Pollard, PharmD | *Pharmacy Inspector*

Division of Public Health, Licensure Unit

Nebraska Department of Health and Human Services

CELL PHONE: 402-405-7595

FAX NUMBER: 855-795-9394

STATE OF NEBRASKA
DEPARTMENT OF HEALTH & HUMAN SERVICES
DIVISION OF PUBLIC HEALTH
Licensure Unit
P. O. Box 94986
Lincoln, NE 68509-4986

PHARMACY QUALITY ASSURANCE REPORT

Pharmacy (Dispensing Practitioner) License Number: #136 Exp. Date: 6/7/24

DEA Registration Number: # Exp. Date:

Owner's Name: Garry Siegel

Pharmacy (Dispensing Practitioner) Name: Garry Siegel

Pharmacy (Dispensing Practitioner) Street Address: 1002 W Mission Ave

Pharmacy (Dispensing Practitioner) City, State, Zip: Bellevue, NE 68805

Pharmacy (Dispensing Practitioner) Telephone #: (402) 292-4164

Pharmacy (Dispensing Practitioner) Fax #: (402) 291-4643

Pharmacy (Dispensing Practitioner) E-mail: careclinics.J9@gmail.com

Pharmacy (Dispensing Practitioner) Hours: Thur/Fri every other week alternating with
Fri/Sat - Thur and Fri 9 am - 5:30 pm; Sat 9 am - 3 pm

List Pharmacy (Dispensing Practitioner) Personnel:

Name of Practitioner responsible for compliance: Garry Siegel

Practitioner Medical License Number: #CP179

Name & NE License # of other practitioners [pursuant §38-2850(1)] that are dispensing under this license	
<u>Marilee Hanson / #CP072</u>	
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SOFTWARE: Manual

Melissa Pollard, RP
(Pharmacy Inspector)

RX'S PER DAY: 12-30

7/6/23
(Date of Inspection)

Section Cited	Requirement	C	NC	NA
<u>CFR</u> = 21 CFR Ch.II <u>NAC</u> = Nebraska Administrative Code <u>NRS</u> = Nebraska Revised Statute <u>USC</u> = United States Code <u>USP</u> = United States Pharmacopeia	<u>C</u> = In Compliance <u>NC</u> = Not in Compliance <u>NA</u> = Not Applicable			
175 NAC 8-003.01A	1. All information provided on the current pharmacy license document is correct, including the physical address where dispensing occurs and the name of the responsible Dispensing Practitioner (DP). If non-compliant, contact the Department at: dhhs.medicaloffice@nebraska.gov	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC 8-006.02C NRS 28-410, CFR 1301.71	2. Adequate security is maintained for the prescription inventory and prescription records.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC 8-006.02A	3. Drugs, devices and biologicals are stored under proper conditions. Storage conditions shall be monitored regularly.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC 8-007.02 NRS 38-2866	4. The pharmacy is: a. maintained in a clean, orderly, and sanitary manner; b. open for the practice of pharmacy only when a pharmacist (or dispensing practitioner) is physically present.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
175 NAC 8-007.03	5. The pharmacy maintains in printed or electronic form appropriate reference material for the practice of pharmacy.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC 8-007.01 USP 795 USP 797	6. The pharmacy provides access to all utilities/equipment needed to practice pharmacy. Water used for compounding is at USP standards. When applicable, water purification systems are maintained.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
175 NAC 8-006.04H NRS 38-2869 (2)(a)	7. Patient counseling is being provided as required.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NRS 38-2869 (2)(a)	8. The pharmacy maintains documentation of a patient's refusal of counseling.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC 8-006.04H	9. Patient counseling is being done by only a pharmacist or pharmacist intern. [or Dispensing Practitioner (DP)]	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NRS 38-2869	10. Prior to the dispensing or the delivery of each new or refill prescription, a pharmacist (or DP) is conducting a prospective drug utilization review.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NRS 28-414.02 CFR 1304, 1306 CFR 1311.305	11. All computer or electronic record keeping requirements are met including requirements for electronic prescriptions for controlled substances.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
175 NAC- 8-005.03A5	12. The poison control phone number is posted in the pharmacy.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CFR 1305 CFR 1311.45 CFR 1311.60	13. Acquisition and distribution requirements for Schedule II controlled substances are met regarding the use of an official order form or the electronic equivalent. Power of Attorney forms completed and filed when applicable.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
NRS 28-411(4) CFR 1304.21 CFR 1304.22(c)	14. The pharmacy maintains complete and accurate records of all controlled substances received and/or distributed.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

<u>Section Cited</u>	<u>Requirement</u>	<u>C</u>	<u>NC</u>	<u>NA</u>
NRS 28-414.05 CFR 1304.22 CFR 1317	15. The pharmacy complies with all transfer and/or destruction requirements for controlled substances.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
21 U.S. Code 351 21 U.S. Code 352 NRS 71-2461 NRS 71-2470	16. The pharmacy does not have in its saleable inventory any drug, device or biological which is misbranded or adulterated, as defined in statute.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC- 8-006.04C, .04D, .04E NRS 38-28,107	17. The pharmacy assures that all requirements pertaining to unit dose packaging and returned product labeling are met.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
175 NAC- 8-006.04G	18. The pharmacy assures that all requirements pertaining to multi-drug containers are met, including proper labeling.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
NRS 28-410 CFR 1304.11	19. All requirements pertaining to the inventory of controlled substances are met. Date of Current Inventory: _____ Controlled substance inventories require the following Information: 1. Name of your facility (or of the DP) . 2. Address of your facility. 3. Date and time of day the inventory was taken. 4. Indicate open or close of business. 5. Facility's (or DP's) DEA# . 6. Signature of the Pharmacist-In-Charge (or DP) , who is responsible for the inventory. 7. Schedule II inventory pages must be separate from the Schedule III, IV, V inventory pages.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
NRS 28-410(4)	20. All controlled substances are properly stored.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
CFR 1306.05 NRS 28-414 NRS 28-414.01 NRS 71-2478	21. All prescriptions contain the required information prior to being filled.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC- 8-006.04B.9a, 172 NAC- 128-014.01(9a), CFR 1306.22	22. All refill requirements for prescriptions are in compliance.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
CFR 1306.13 CFR 1306.23 NRS 28-414 NRS 28-414.01	23. Partial fillings of controlled substances are recorded and dispensed appropriately.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
CFR 1306.05(f) NRS 38-179(13)	24. The pharmacy is not utilizing pre-populated request forms for controlled substance prescriptions.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
175 NAC 8-006.05D CFR- 1306.11(d)(1,2,3,4) NRS 28-414	25. All emergency Schedule II prescription procedures are followed. Only direct verbal authorization from the prescribing practitioner is allowed.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
NRS 28-414 NRS 28-1437 NRS 38-2870	26. All requirements for filling electronic prescriptions (e-prescribing) and faxed prescriptions are followed. A manual "wet" signature is required for all written or faxed controlled substance prescriptions.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Section Cited	Requirement	C	NC	NA
NRS 28-414.03 NRS 28-415 NRS 38-2867.01 NRS 71-2451, 2479	27. All prescription containers are properly labeled.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
NRS 71-5401 to NRS 71-5409	30. The pharmacy is in compliance with the Drug Product Selection Act.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC- 8-006.03A1, NRS 28-414(3a)(3c)	31. A two or three file system for prescriptions is used and maintained.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NRS 71-2413(1) CFR 1306.11 CFR 1306.21	32. Proper records are maintained for Emergency Drug Box use including: a. receipt upon delivery signed by the Director of Nursing b. proof of use forms. c. a list of emergency box drugs identical to the list on the exterior of the emergency box. Controlled substance drugs cannot be removed from the Emergency Drug Box until the pharmacy receives a valid oral, faxed, or written prescription from the practitioner.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
NRS 38-2847 NRS 38-2866.01 NRS 38-2890 thru NRS 38-2896 172 NAC 128- 012.04	33. All requirements and documentation are met for the utilization of Pharmacy Technicians, including: a. documentation of training by the pharmacist in charge. b. pharmacy technicians are identified as technicians. c. a pharmacist's supervision of pharmacy technicians and/or pharmacist interns does not exceed three people. d. verification confirmation of a pharmacy technician's acts, tasks, or functions undertaken to assist the pharmacist in the practice of pharmacy. e. all technicians are registered with NE DHHS. f. all technicians are certified (as required). Check credential status at: http://www.nebraska.gov/LISSearch/search.cgi If non-compliant, contact the Department at: dhhs.medicaloffice@nebraska.gov	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
175 NAC 8-006.07	34. Pharmacy has written disaster preparedness policies and procedures.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
175 NAC 128-013	35. The pharmacy is compliant with "Pharmaceutical Care Agreement" requirements: a. a copy of the agreement with written protocols is available for review by the Department. b. practice agreements and written protocols must be signed by the physician and participating pharmacists. c. practice agreements and written protocols must be reviewed, signed and dated every 12 months.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Section Cited	Requirement	C	NC	NA
NRS 38-2867.01 USP 795	36. The pharmacy is compliant with USP 795 (non-sterile compounding) including Master Formulation and Compounding Records. The preparation labeling shall include the beyond use date and storage conditions.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
USP 797	37. The pharmacy is compliant with USP 797 (sterile compounding).	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
NRS 28-456 NRS 28-457 NRS 28-458 NRS 28-459 CFR 1314	38. The pharmacy is compliant with all State and federal regulations pertaining to the retail sale of scheduled listed chemical products/methamphetamine precursors, including: a. a purchaser signature logbook that displays the warning listed under Section 1001 Title 18, US Code. b. records of training and annual self-certification. c. the name or initials of the seller who sold the product is submitted to the exchange.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
NRS 71-7444(2)(d) NRS 71-7454(1)	39. The sale, purchase or trade of a prescription drug for emergency medical reasons or for a practitioner to use for routine office procedures does not exceed five percent of sales as provided in section 71-7454.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
NRS 71-7444 (2)(a-h); NRS 71-7454	40. All prescription drugs purchased or received are from entities licensed under the Nebraska Wholesale Drug Distributor Licensing Act, with exceptions in 71-7444 or 71-7454.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

STATEMENT OF COMPLIANCE PAGE

For each item not in compliance, please list below (may continue on a separate page if needed):

- a) The item number that is not in compliance;
- b) Why it is not in compliance;
- c) How the deficiency will be corrected; and
- d) How long it will take to do so

2023 Initial On-Site Inspection Item # 1

a) 27

b) Inspector found multiple prescriptions dispensed by Dr. Hanson that were labeled with Dr. Siegel's name in violation of NE Revised Statute 71-2479. Legend drug not a controlled substance; prescription; retention; label; contents. (2) Before dispensing a legend drug which is not a controlled substance pursuant to a written, oral, or electronic prescription, a label shall be affixed to the container in which the drug is dispensed. Such label shall bear (a) the name, address, and telephone number of the pharmacy or practitioner and the central fill pharmacy if central fill is used, (b) the name of the patient, (c) the date of filling, (d) the serial number of the prescription under which it is recorded in the practitioner's prescription records, (e) the name of the prescribing practitioner, (f) the directions for use, (g) the name of the drug, device, or biological unless instructed to omit by the prescribing practitioner, (h) the strength of the drug or biological, if applicable, (i) the quantity of the drug, device, or biological in the container, except unit-dose containers, (j) the dosage form of the drug or biological, and (k) any cautionary statements contained in the prescription.

c) All prescription dispensed labels will have the dispensing physician name printed on label.

d) Immediately

2023 Initial On-Site Inspection Item # 2

a) 34

b) The Disaster Preparedness Policies and Procedures are incomplete as required by 175 NAC 8-007.02 DISASTER PREPAREDNESS AND MANAGEMENT. The licensee must have and implement disaster preparedness plans and procedures to protect the potency, efficacy, safety, and security of the drugs, devices, or biologicals in the pharmacy in instances of natural or other disasters, disease outbreaks, interruption of utility services, or other similar situations. Such plans and procedures must address how the licensee will: (A) Provide for the storage of drugs, devices, and biologicals at the proper temperature; (B) Provide for the disposal of drugs, devices, and biologicals if the pharmacy determines their potency, efficacy, or safety has been adversely affected; (C) Secure the drugs, devices, and biologicals from the public; and (D) Maintain patient records and inventory records.

c) The Disaster Preparedness Policies and Procedures will be updated and changed to meet all requirements listed.

d) 60 days 9/18/2023

- a)
- b)
- c)
- d)

Apking, Vonda

From: Janine Weatherby <careclinics.j9@gmail.com>
Sent: Tuesday, August 29, 2023 1:23 PM
To: Apking, Vonda
Subject: Fwd: CARE New Physician
Attachments: 1225115298-NEBRASKA BOARD OF MEDICINE AND SURGERY-10_1_2024 _
2023-07-17T06_13_13.13-LI[5732].pdf

Melissa said to send you the secondary physicians for our pharmacy Bellevue Health, dispensing license Garry Siegel. I will be sending you 2 more. Also can you please take Marilee Hanson off of our dispensing? Please and thank you.

Thank you, Janine

----- Forwarded message -----

From: **KAROLINA OGOREK** <Karolina@carerepro.org>
Date: Wed, Jul 19, 2023, 3:28 PM
Subject: CARE New Physician
To: Pollard, Melissa <Melissa.Pollard@nebraska.gov>
Cc: Janine Weatherby <careclinics.j9@gmail.com>

Good afternoon,

I have begun the process of hiring new physicians for our clinic. You advised me to email all of the information to add the physicians to the dispensing license.

Our first physician to be added is Dr. Middleton. I am attaching her Compact License for Nebraska her [REDACTED]. Please advise if any additional information or documentation is needed.

Thank you,

Karolina

Sent from [Mail](#) for Windows

MEDICAL LICENSE ISSUANCE INFORMATION

Physician's Name Tamer Yvette Middleton
First Middle Last

Please fill in your respective Member Board's information for the qualified Physician named above.

National Provider Identifier Number 1225115298

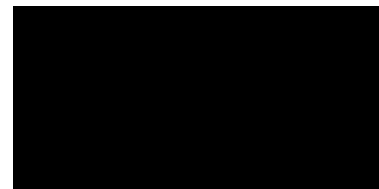
Medical Board Name NEBRASKA BOARD OF MEDICINE AND SURGERY

Member Board License Number CP278

Date License Issued 7/17/2023
mm/dd/yyyy

Date of Expiration 10/1/2024
mm/dd/yyyy

Member Board Signature



Name Tara L Anderson

Date 7/17/2023