

**SANTA CLARA VALLEY MEDICAL CENTER
DEPARTMENT OF PHARMACY SERVICES**

PHARMACIST NALOXONE PROTOCOL IN OUTPATIENT PHARMACIES

<u>Section</u>	<u>Page</u>
Purpose	2
Content	2
Inclusion Criteria	2
Exclusion Criteria	2
Procedures	3
Patient Education	3
Ongoing Monitoring and Documentation	3
Prescriptions	3
Requirements of Pharmacist	4
Appendix A - List of Terms & Abbreviations	6
Appendix B – Naloxone Dispensing Protocol	7
Appendix C – Opioid Conversion Chart	8

- I. **TITLE:** Pharmacist Naloxone Protocol in Outpatient Pharmacies
- II. **PURPOSE:** To outline the Pharmacists' responsibilities when dispensing naloxone through SCVMC pharmacies. SCVMC Pharmacists will prescribe and dispense naloxone to patients meeting one or more of the inclusion criteria under this protocol.
- III. **DEFINITIONS:** Refer to Appendix A.
- IV. **SUPPORTIVE DATA:** This protocol is performed by SCVMC Pharmacists who have been authorized through evaluation and approval to perform this protocol. No direct supervision of the Pharmacist is required.

V. **CONTENT:**

According to the Center for Disease Control (CDC), the United States saw more people die from drug overdoses in 2014 than from any other previous year on record, with California leading all other states with the most overdose deaths.¹ Of those deaths, opioids were responsible for 61% that year in the US, claiming a total of 28,647 lives, or one in about every 18 minutes.^{1,2} Unfortunately, this problem is nothing new; since 1999, the number of overdose deaths involving opioids has nearly quadrupled.¹ Unsurprisingly, the number of opioid prescriptions issued to patients are a driving force in this increase in opioid overdose deaths³, and they too have quadrupled since 1999 with rates increasing more for general practice, family practice, and internal medicine compared to other departments and specialties.⁴ In fact in 2012, US health care providers wrote a total of 259 million opioid medication prescriptions: enough for every adult in the country to have one bottle of pills.⁵ Yet despite all of those efforts, there hasn't been a corresponding drop in the amount of pain reported by Americans.^{6,7}

In 2014, Governor Jerry Brown signed the assembly bill that allowed for pharmacists to furnish naloxone without a doctor's prescription. At present, Business and Professions Code section 4052.01 allows pharmacists to furnish naloxone hydrochloride as follows⁸: "“Notwithstanding any other provision of law, a pharmacist may furnish naloxone hydrochloride in accordance with standardized procedures or protocols developed and approved by both the board and the Medical Board of California, in consultation with the California Society of Addiction Medicine, the California Pharmacists Association, and other appropriate entities.” Per Section 1714.22 of the California Civil Code⁹: “A licensed health care provider who is permitted by law to prescribe an opioid antagonist may, if acting with reasonable care, prescribe and subsequently dispense or distribute an opioid antagonist in conjunction with an opioid overdose prevention and treatment training program, without being subject to civil liability or criminal prosecution. This immunity shall apply to the licensed health care provider even when the opioid antagonist is administered by and to someone other than the person to whom it is prescribed.”

According to the CDC's 2016 Chronic Opioid Management guidelines, opioid doses ≥ 50 Morphine Milligram Equivalents (MMEs) per day may increase overdose risk by 2 times without necessarily providing any additional benefits for pain control or function.¹⁰ Therefore, patients with opioid dosages ≥ 50 MMEs/day should be closely monitored, offered naloxone, and periodically reassessed whether the benefits outweigh the risks.

Pharmacist prescriptive authority of naloxone to eligible patients allows for increased patient access, enhanced educational opportunities for our patients, and a potential for lower event rates due to opioid overdose in Santa Clara County.

A. **PATIENT INCLUSION CRITERIA**

1. Recipient currently uses or has a history of using illicit or prescription opioids.
2. Recipient is in contact with anyone who uses or has a history of using illicit or prescription opioids.
3. Patient receiving an opioid regimen ≥ 50 Morphine Milligram Equivalents (MMEs) per day

B. **PATIENT EXCLUSION CRITERIA**

1. If the patient or person to whom the naloxone would be administered has a known hypersensitivity to naloxone.
2. If the recipient declines to give consent for entry of information in HealthLink or Willow Ambulatory to be shared with the recipient's SCVMC primary care provider (PCP).

C. PROCEDURES – refer to Appendix B for overview of procedures

1. Patient Selection
 - a. Naloxone should be considered for all recipients that meet at least one of the inclusion criteria (see V-A) and has no exclusion criteria (see V-B).
 - b. For every patient who reports to a VMC pharmacy with an opioid prescription, the pharmacist will calculate the total daily MMEs of the opioid regimen shown on Controlled Substance Utilization Review & Evaluation System (CURES) using the CDC conversion table listed in Appendix C. If it is found to be ≥ 50 MMEs/day, the pharmacist will offer naloxone to the patient.
2. Screening
 - a. Ascertain recipient meets criteria for naloxone by asking the following screening questions:
 - i. Do you currently use or have a history of using illicit or prescription opioids? *If yes, you make skip question 2.*
 - ii. Are you in contact with anyone who uses or has a history of using illicit or prescription opioids? *If yes, you may continue to question 3.*
 - iii. Does the person whom the naloxone will be administered to have a known allergy to naloxone? *If yes, the pharmacist may NOT continue.*
3. Obtain informed consent
 - a. The pharmacist must obtain verbal or written consent to enter recipient information in HealthLink or Willow Ambulatory to be shared with SCVMC PCPs. Fax information if recipient wants to notify outside PCP.
4. Interview and evaluate recipient to determine the most optimal naloxone formulation:
 - a. Patient preference
 - b. Ease of use
 - c. Insurance coverage
 - d. Pharmacy stock availability
 - e. Clinical judgment

The Pharmacist may also recommend optional items when appropriate: alcohol pads, rescue breathing masks, and rubber gloves.
5. Prescribing naloxone
 - a. Use available Ordersets to E-prescribe naloxone on HealthLink using the pharmacist name as the Ordering Provider and the name of the signed medical doctor below this protocol as the Authorized Provider.
 - b. All naloxone prescriptions will have zero refills.
 - c. All naloxone prescriptions will have quantity of 2.
6. Consultation – the Pharmacist must:
 - a. Provide training in opioid overdose prevention, recognition, response, and administration of naloxone – *consultation cannot be waived.*
 - b. Provide appropriate counseling and information on the product furnished including dosing, effectiveness, adverse effects, storage conditions, shelf-life and safety.
 - c. Provide the recipient with appropriate resources or referrals to addiction treatment, recovery services, or medication disposal resources at this time, if requested.
 - d. Provide the recipient a copy of the current naloxone fact sheet approved by the California Board of Pharmacy.
7. Documentation – the Pharmacist must:
 - a. Document answers to screening questions in the relevant database.
 - b. Document consent for information to be entered in HealthLink or Willow Ambulatory.
 - c. Document consent to notify PCP.
 - d. Document any interest the patient expresses for addiction treatment, recovery services, or medication disposal resources at this time.
 - e. Document PCP notification.
 - f. Document recipient's acknowledgment of teaching.

All relevant records shall be readily retrievable and shall be kept for at least 3 years.

D. PATIENT EDUCATION – refer to V-C5 (consultation)

E. ONGOING MONITORING AND DOCUMENTATION – refer to V-C6 (documentation)

F. PRESCRIPTIONS – refer to V-C4

G. REQUIREMENTS OF THE PHARMACIST

1. Education/Training: Current license by the California State Board of Pharmacy required. Graduate from an accredited School of Pharmacy. Possess a Doctor of Pharmacy degree or equivalent. The Pharmacist must complete a training program consisting of at least one hour of approved continuing education on the use of naloxone hydrochloride in all routes of administration prior to furnishing naloxone.
2. Experience: Minimum of one year as a pharmacist with familiarity in ambulatory pharmacy operations
3. Initial Evaluation: New hires must complete the naloxone continuing education program and obtain a passing score on the online test within six (6) months of hire.
4. Continuing Evaluation: Annual review of competency

VI. DEVELOPMENT & APPROVAL OF THE STANDARDIZED PROCEDURE

- A. Method: Developed and approved by authorized representatives of Administration and Medical Staff.
- B. Review: Annual.

AUTHORIZED PROVIDER:

Andrea Cervenka, MD Date: _____

SIGNATURES OF AUTHORIZED REPRESENTATIVES:

Narinder Singh, MBA, PharmD.
Director of Pharmacy Date: _____

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RESOURCES

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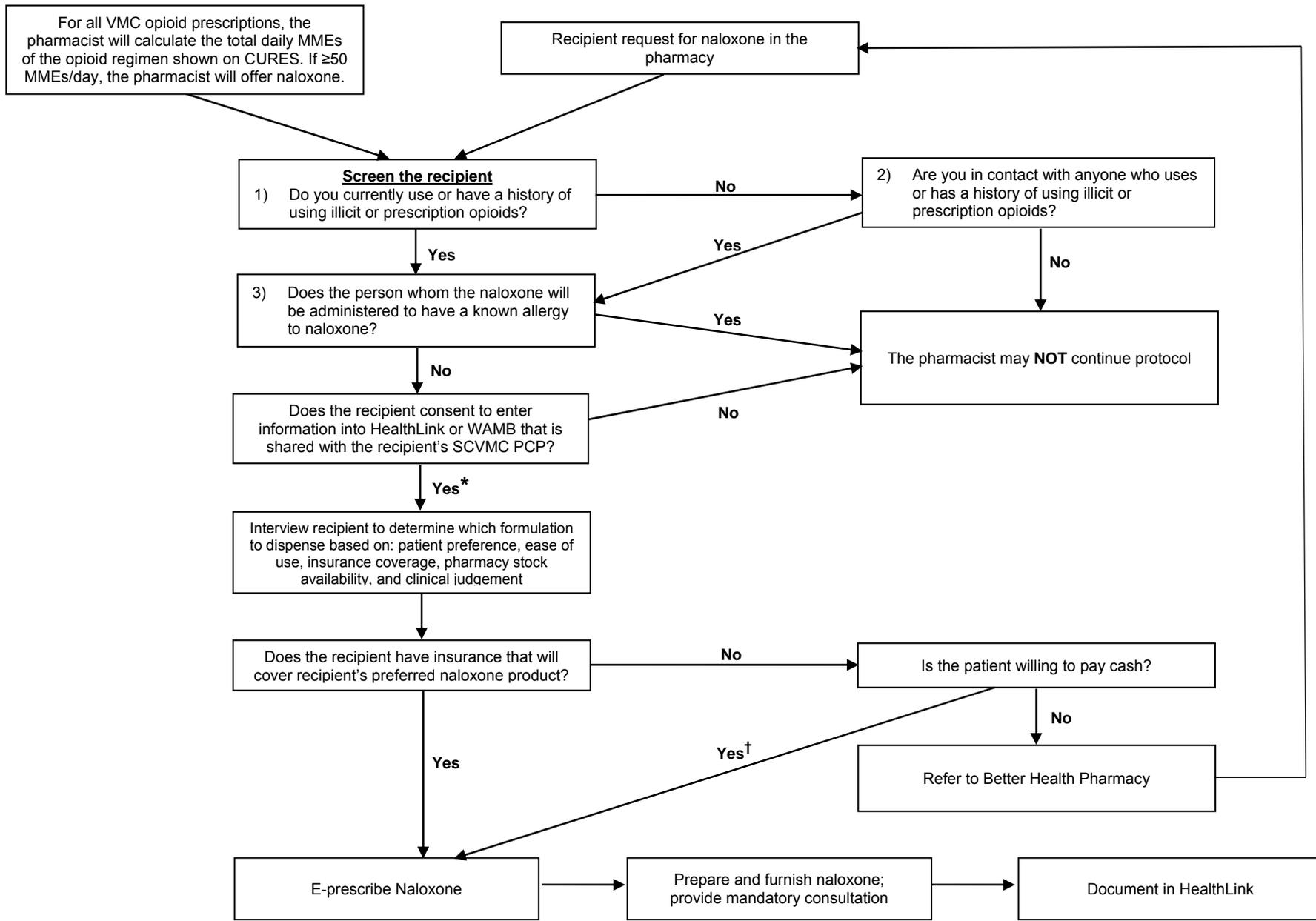
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APPENDIX A: LIST OF TERMS AND ABBREVIATIONS

Authorizing provider	Medical doctor (MD) who has endorsed and signed this protocol
HealthLink	Electronic medical record system used at SCVMC
Naloxone	Antidote that reverses the effects of opioid overdose
Opioid	Naturally derived opiates as well as synthetic/semi-synthetic opioids
Ordering provider	Refer to pharmacist (see below)
Patient	Person whom the naloxone would be administered to
Pharmacist	Individual who is employed by or affiliated with SCVMC with a California Pharmacy License in good standing
Recipient	Person who is administered naloxone
Willow Ambulatory (WAMB)	SCVMC outpatient pharmacy prescription data base system

APPENDIX B: Naloxone Dispensing Protocol



Modified from: Title 16, Section 1746.3 of the California Code of Regulations, California Board of Pharmacy

*Fax documentation if recipient wants to notify outside PCP

†Use cash code when billing on WAMB

APPENDIX C: Opioid Conversion Table¹⁰

Opioid (doses in mg/day except where noted)	Conversion Factor
Codeine	0.15
Fentanyl transdermal (in mcg/hr)	2.4
Hydrocodone	1
Hydromorphone	4
Methadone	
1-20 mg/day	4
21-40 mg/day	8
41-60 mg/day	10
61-80 mg/day	12
Morphine	1
Oxycodone	1.5
Oxymorphone	3