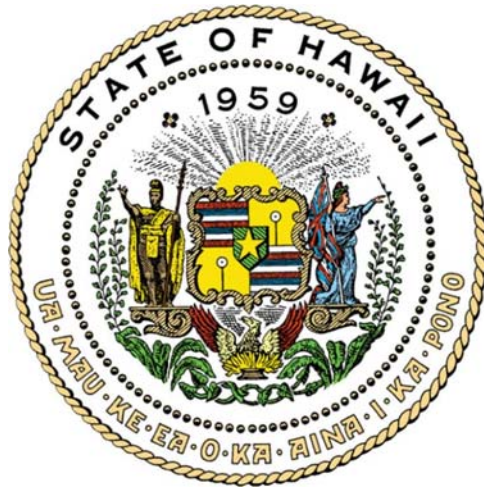


# Pharmacist's Corresponding Responsibility When Dispensing Controlled Substances



Guidance Statement from the



Hawaii State Board of Pharmacy



State Narcotics Enforcement  
Division

December 2016

## **Opioid Overdose Epidemic in the U.S.**

According to the Centers for Disease Control and Prevention, the United States is in the midst of an opioid overdose epidemic. [Opioids](#) (including [prescription opioid pain relievers](#) and [heroin](#)) killed more than 28,000 people in 2014, more than any year on record. At least half of all opioid overdose deaths involve a prescription opioid. For more updated information, visit [www.cdc.gov/drugoverdose](http://www.cdc.gov/drugoverdose).

The Drug Enforcement Agency (“DEA”) Diversion Control Division also refers to the increase in opioid overdoses as an “epidemic” that is partly due to inappropriate prescribing. According to the DEA, pharmacists have a corresponding responsibility to that of the provider to ensure all medications are used for the legitimate medical purpose. The DEA has significant guidance documents on their web page at [www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov).

Ultimately, the safe and appropriate use of medication is the backbone of the pharmacy profession. Opioid pain medications, when used appropriately have tremendous analgesic effects that may enhance a patient’s quality of life. However, opioids carry high risk including respiratory arrest, hyperalgesia, addiction and death especially when used inappropriately.

## Corresponding responsibility

Title 21, United States Code of Federal Regulations (CFR), Section 1306.04. and Hawaii Revised Statutes (“HRS”), states “a prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper dispensing of controlled substances is upon the prescribing practitioner, but a **corresponding responsibility** rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of Section 309 of the Controlled Substances Act (Title 21, US code, Section 829) and HRS section 329-38, and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.”

These guidelines are focused on several key areas that can impact pharmacists of any practice setting. Focal points include assessing the appropriateness of opioid pain medication at the point of dispensing, recognizing “red flags” on prescriptions as well as high risk medication combinations.

The purpose of these guidelines is to aid pharmacists in ensuring that the dispensed opioid pain medication is both safe and appropriate for each patient. These guidelines are only a supplement to and does not replace clinical and professional judgement of a pharmacist.

## Pharmacist's "Checklist"

"Checklist" to ensure that the prescription is filled for legitimate medical purposes:

- Prescriptions for controlled substances contain all required information, including but not limited to:
  - Patient Name ( patient specific prescription)
  - Physical address
  - Physician Name and Address
  - DEA number
  - Date
  - Signature of the prescriber
  - Drug name, strength, directions for use and quantity (words and figures)
- Prescriptions must be patient specific. "For office use" is not allowed.
- Filling a post-dated prescription is not allowed;
- Account for accurate inventories of controlled substances;
- Fill only "valid" prescriptions;
- Maintain record keeping requirements;
- Ensure that the prescriber has the authority to prescribe the particular drugs within their scope of practice by checking the NED licensing website to ensure the prescriber is authorized to prescribe controlled substances, especially with a new prescriber who is not known to the pharmacist;
- Check HIPDMP database for patient history

## “Red” Flags

- ✓ Patients coming to the pharmacy in groups, especially if their home addresses are outside of the pharmacy’s local trade area, each with the same prescriptions issued by the same prescriber;
- ✓ The same diagnosis codes for many patients;
- ✓ Prescriptions written for potentially duplicative drug therapy;
- ✓ The same combinations of drugs prescribed for multiple patients;
- ✓ Excessively celebratory patient demeanor;
- ✓ Prescriptions written outside the usual course of professional practice of the prescriber;
- ✓ Multiple individuals presenting prescriptions for the same drugs in the same quantities from the same prescriber;
- ✓ Individuals with the same address presenting substantially similar prescriptions;
- ✓ Patient has insurance coverage but insists on paying cash;
- ✓ Only prescriptions for controlled substances in patient’s profile;
- ✓ Early refills for controlled substances, especially multiple times for lost or vacation supply;
- ✓ Be aware of drug-drug interactions, in particular:
  - “The Holy Trinity”: Carisoprodol + Alprazolam + Oxycodone or any medication combinations within these classes.
  - Tramadol + Zolpidem + Trazodone especially amongst elderly patients.
- ✓ >100 Morphine Equivalent Dose;
- ✓ Comorbid conditions;
- ✓ Filling a new oxycodone prescription for a customer when fewer than 30 days had elapsed since the customer had filled their previous prescription for a 30-day supply;
- ✓ History in HIPDMP database shows multiple providers for controlled substances;
- ✓ Individuals utilizing various forms of payment;
- ✓ Patient reluctant to present identification;
- ✓ Change of prescriber’s prescribing habits;
- ✓ Previously rejected prescription

## FAQs

1. As a pharmacist, can I refuse to fill a prescription?

Yes, if a pharmacist cannot resolve a “red” flag discovered during a reasonable inquiry to determine the legitimacy of a controlled substance prescription.

2. What happens if I fill a prescription from a practitioner for a controlled substance when I believe that the prescription may not be for a “legitimate medical purpose”?

A pharmacist who deliberately ignores a questionable prescription when there is a reason to believe it was not issued for a legitimate medical purpose may be prosecuted along with the issuing prescriber.

3. Can I fill a prescription for controlled substances from a practitioner who has not been convicted, but was arrested by the NED or DEA for issuing prescriptions NOT for legitimate medical purposes or any other violation of the Controlled Substances Act?

Yes, if you are able to ascertain that the prescription is valid, was issued for a legitimate medical purpose, and does not indicate any of the “red” flags and the prescriber continues to hold a valid license to practice and current controlled substances registrations. An arrest is an accusation and every defendant so charged is, under our Constitution, presumed innocent until proven guilty.

4. When should a pharmacist report questionable prescriptions for controlled substances, and who shall they report it to?

When in doubt, communicate with the prescriber. If the pharmacist is unable to resolve any discrepancies after discussing with the prescriber, contact the NED.

### Useful Resources:

- <https://awarerx.pharmacy/resources/pharmacists#RedFlags>
- <https://www.cdc.gov/drugoverdose/pdf/policyimpactprescriptionpainkillerod-a.pdf>
- [https://www.deadiversion.usdoj.gov/21cfr/crf/1306/1306\\_04](https://www.deadiversion.usdoj.gov/21cfr/crf/1306/1306_04)
- [www.capitol.hawaii.gov/hrscurrent/Vol06\\_Ch0321-0344/HRS0329/HRS\\_0329-0038.htm](http://www.capitol.hawaii.gov/hrscurrent/Vol06_Ch0321-0344/HRS0329/HRS_0329-0038.htm)