PRE-INSPECTION REQUIRED ATTESTATIONS AND QUESTIONNAIRE

-PRACTIONER: ADMINISTER FROM OWN STOCK & DISPENSE

-PHARMACY / CLINIC DISPENSARY

INSTRUCTIONS:

If you are a practitioner, clinic or pharmacy that will purchase controlled substances to dispense or administer you will need to complete the following questionnaire and may be subject to a possible site inspection.
Review the questionnaire prior to answering the questions. Ensure that you have all the required written documents necessary, to include policy and procedures, as listed in section 1, ATTESTATION OF WRITTEN POLICY/PROCEDURES, before filling out this form. Answer the questions to the best of your knowledge and submit the completed questionnaire and floor plan with security measures (motion, camera, locks, etc.).

Staff will contact you to clarify any questions and schedule a possible onsite, virtual or document inspection.

'PLAIN SPEAK' EXPLANATIONS AND ABBREVIATIONS (For the purpose of an inspection)

- **Dispense** for the purpose of this pre-inspection questionnaire means that you intend to purchase a stock of controlled substance medications that will be dispensed directly into the patient's control (they will leave the clinic/practice/pharmacy with the medication). This applies to ALL pharmacies and dispensing practitioners.

- **Administer** for the purpose of this pre-inspection questionnaire means a practitioner, clinic, hospital who will purchase a stock of controlled substances for the purpose of administering to patients by injection, direct application, and/or ingestion in the presence and direct supervision of healthcare facility or practice staff.

- **Prescribe** means to direct, designate, or order the use of a formula for the preparation of a medicine for a disease or illness and the manner of using them including the issuance of an order orally, electronically, or in writing.

- **CS** = Controlled Substance.

- **Rx** = A prescription (to include e-prescribed and telephone (oral) orders) by a prescriber that is dispensed by a pharmacy or clinic dispensary.

- **Registrant =** Holder of a Hawaii Controlled Substance Registration.

SECTION 1: ATTESTATION OF WRITTEN POLICY/PROCEDURES

Review your internal documents to ensure that you have written policy and procedures that address the requirements below. Place your initials next to each requirement to attest that there is a written policy/procedure available for the applicable activities that you have applied. Please be aware that NED staff may require you to produce the written policy/procedure as part of the initial inspection process or any administrative inspection or document review after registration is issued. **It is the registrant's responsibility to ensure that CS requirements are met and that employees of the business also adhere to the requirements.**

Initials acknowledge that there is a written policy / procedure that addresses the controlled substance registration requirement. The registrant or clinic/pharmacy director or pharmacist in charge will need to provide initials and review all answers before the form is submitted.

Place your initials for each requirement to attest to that there is a written policy/procedure.	**Activity / Requirement**
1. _____ **Initials** **REQUIRED FOR ALL ACTIVITIES (PRESCRIBE, ADMINISTER, DISPENSE).**	**1. CS Inventory/ Record Keeping** CS Inventory (How records will be maintained to include purchase documents, chart orders, dispensations, and prescriptions, pick up logs for dispensations, and disposal/wasting). Note: Hawaii Administrative rules state that ALL CS records be maintained for 5 years. Refer to Hawaii Administrative Rules (HAR) §§23-200-12.
2. _____ **Initials** **REQUIRED FOR DISPENSERS ONLY.**	**2. Pick up logs -CS record keeping.** Includes your **pickup customer ID** verification (e.g., patient or family member/friend, pet owner/agent of pet owner who picks up the medication on behalf of the patient) and recording of signature and identification. Hawaii Revised Statutes §HRS 329-41(6)(A). Note: The following elements much be captured at the time of CS medication pickup, Rx # (reference), printed name of person picking up the CS, Identification type and number of the person picking up the medication, signature of the pickup person and relationship of the pickup person to the patient. This information must be captured at every CS pickup. The information can be recorded into a software system, scanned into the patient's record, in a paper log or file system. Records must be kept for 5 years.

3. **Initials** **REQUIRED FOR ADMINISTER (OWN STOCK) AND DISPENSE.**	**3. CS Disposal for expired/used/spoiled medications** (Wasting, Reverse Distribution and/or Medication Destroyer) (HAR) 23-200-20. For Controlled Substances a registrant cannot utilize the state's medication drop boxes. A reverse distributor or a wasting/disposal policy needs to be used. A wasting/disposal process will need to render the CS medication unusable, and documentation must be kept which should include both the individual performing the disposal and a witness signature. CS disposal records from a reverse distributor or wasting procedure must be kept for a minimum of 5 years.
4. **Initials** **REQUIRED FOR ALL ACTIVITIES PRESCRIBE ADMINISTER and DISPENSE.**	**4. Mandatory Reporting**. A registrant who has reason to believe that a controlled substance in the inventory has been stolen, embezzled, or otherwise obtained by fraud or diversion shall report to the NED Administrator. HRS 329-37.5 Failure to Mandatory Report is a criminal offense -misdemeanor and subject to penalties, administrative fines, and possible registration revocation. Note: NED's main phone is (808) 837-8470. Email hawaiicsreg@hawaii.gov. After hour urgent duty phone is (808) 864-9437. **For emergencies call 911.**
5. **Initials** **REQUIRED FOR ALL ACTIVITIES: PRESCRIBE ADMINISTER and DISPENSE.**	**5. Employee criminal background check process.** Please note the employee requirements 21 CFR 1301.76. (This is a Federal Drug Enforcement Administration requirement, review the statute and contact the Drug Enforcement Administration with any questions or clarifications). Note: This Federal statute applies to employees who have access to CS. An exemption for an employee with a criminal drug history can be requested through the DEA.
6. **Initials** **REQUIRED FOR ALL PRESCRIBERS AND DISPENSING RACTITIONERS.**	**6. Opioid Informed Consent Policy**. HRS 329-39.5 You must have a policy whether you prescribe and/or dispense opioids *(does not apply to Veterinarians).* *Also, the law states the "practitioner" will review the risks and benefits of opioid therapy with the patient, therefore it is not acceptable that staff simply provide the consent form to the patient for signature.*

7. **Initials** **REQUIRED FOR ALL PRESCRIBERS AND DISPENSING RACTITIONERS.**	**7. Opioid Informed Consent Form.** The prescriber may develop their own Opioid informed consent form to review the risk and benefits of opioid therapies to other therapies. Examples of this type of form is also provided by the Hawaii Department of Health and National Institute of Health.
8. **Initials** **REQUIRED FOR ALL PRESCRIBERS AND DISPENSING RACTITIONERS.**	**8. Physician – Patient Relationship.** The establishment of a bona fide "Physician-patient relationship" for prescribing and practitioner dispensing of controlled substance medications requires an initial in-person face to face examination. HRS 329.41 (8b) with criteria set forth in HRS 329.1 definitions: "Physician-patient relationship". Note: Please review the criteria listed in the definitions.
9. **Initials** **REQUIRED FOR ALL PRESCRIBERS AND DISPENSING RACTITIONERS.**	**9. Prescriptions may not be issued when the prescriber is not physically in the State of Hawaii.** Hawaii Revised Statute 329.38 (i)(1) and 329.41 (8) Note: Violation of this law is a criminal felony and may result in prosecution, administrative fines and suspension or revocation of registration. A policy should include provisions for an in-State covering practitioner to prescribe controlled substance prescriptions to patients that meet the bona fide prescriber – patient criteria.
10. **Initials** **REQUIRED FOR ALL PRESCRIBERS AND DISPENSING PRACTITIONERS.**	**10. Opioid and Benzodiazepine concurrent prescribing/practitioner dispensing requirements** HRS (329-38(F)(c)(1-6). Policy must include restriction of **initial prescription being limited to a seven (7) day supply** and a requirement that prescribing practitioner **shall consult with a patient in person at least once every ninety (90) days** for the duration during which the practitioner concurrently prescribes opioids and benzodiazepines to the patient.
11. **Initials** **REQUIRED FOR DISPENSERS ONLY**	**11. Opioid warning label** [§329-39.5] Requires label contains wording substantially like the following warning: "Caution: Opioid. Risk of overdose and addiction." This label must be affixed to the container/packaging of ALL CS opioid medications, including codeine cough syrups, tramadol, and buprenorphine. It can be a separate label or included in the prescription's label/directions.

12. **Initials** **REQUIRED FOR DISPENSERS ONLY**	**12. Prescription Drug Monitoring Program** Reporting –Policy/Procedure for reporting to Hawaii PDMP (must include a process for reported error correction) as required in HRS §329-101 and §329-102. The Hawaii PDMP will accept daily dispensation and zero dispensation record submissions. For further assistance email hirxmonitor@hawaii.gov.

SECTION 2: GENERAL PRACTICE INFORMATION

1. Practitioner Name (First, MI, Last) or Name of Pharmacy or DOH OHCA licensed facility.

2. If using a doing business as name, what is the DBA name?

3. Hawaii Professional Vocational License number (Practitioner's license or Pharmacy license).(If applying as a Department of Health, Office of Health Care Assurance (OHCA) facility include the license number and attach your certificate.)

4. Hawaii Business Street Address, (Address number, Street Name, Suite#, City, Hawaii ONLY and zip code. If in large complex, include further directional cues (e.g., Mauka end of blue warehouse, near parking entrance, between ABC, Inc and XYZ, Inc.) If in rural area include land markers and GPS coordinates.

5. DEA number (If this is a new location, type "NEW".)

6. Proposed/Primary Business Activity relating to Controlled Substances (e.g., Retail Pharmacy, Urgent Care, Oral Surgeon-post surgery medications, General Practitioner, Specialty, Specialized Services.) Please be detailed, so we can determine the scope of your business activities with controlled substances.

7. What are your proposed days of operation and business hours?

8. For pharmacies and practices that operate within a retail store or healthcare facility, what are the business hours of the retail store or healthcare facility?

9. Who is/are the owner(s) of the pharmacy, practice, or clinic?

10. What controlled substance medications (common names) and approximate quantities will you be securing at any given time?

Item	Active Ingredient	Dose	Quantity/dose type
Example	e.g., hydrocodone/APAP	5mg/325 mg	#60 /Tablets
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

Note: The quantities can be a best estimate to provide an understanding of the scope of controlled substances that will be maintained on-site. If needed, a separate page may be attached to this form.

11. Will you use (check the box) to purchase controlled substances.

☐ CSOS ☐ DEA222 ☐ BOTH

12. Does the Practitioner/Pharmacy intend as part of the business model to regularly sell any part of your inventory to other practitioners or pharmacies?

☐ Yes (This is not a normal activity for a dispensing practitioner) ☐ No

12A. If yes, explain the proposed business model and necessity to do so, and provide names of dispensing doctor whom a portion inventory may be transferred.

13. (Dispensing Practitioner/Administering Practitioner) Will you be allowing other practitioners in your practice to dispense or administer from your controlled substance stock?

☐ Yes ☐ No

13A. If yes, provide names and professional vocational license numbers of these practitioners.

Practitioner's Name	Professional License Number
Example: Mary Ann Aloha	MD-34567

14. Do you intend to use a reverse distributor for CS disposal? (Note: The disposal policy and procedure should address disposal/wasting procedure and the possible use of a reverse distributor whether you believe that all medications will be dispensed prior to expiration.)

☐ Yes ☐ No

14A. If yes, company name(s) of proposed reverse distributor(s):

15. Do you have (an)other office(s), clinic(s) or pharmacy in Hawaii or on the mainland?

☐ Yes ☐ No

15A. If yes, please provide business name (if applicable), addresses and DEA numbers. (Attach a separate sheet if necessary and make a notation of such below.). Chain pharmacies, please provide the associated chain names only.

16. Dispense Activity Only: What elements are recorded at every pick-up of a CS medication? (check all that apply)

- ☐ Rx Number (or reference to specific dispensation)
- ☐ Printed Name of pick-up patient (this is the name of the person who picks up the medication)
- ☐ Signature of pick-up person.
- ☐ Identification Type presented.
- ☐ Identification number
- ☐ Relationship to patient (e.g., self, spouse, friend, caregiver)

17. Dispense Activity Only: How will recorded information about the pick-up person (above) be kept for 5 years? (Check all that apply)

- ☐ Paper log.
- ☐ Paper form.
- ☐ Paper form scanned into patient record.
- ☐ Electronic (EMR/EHR/Pharmacy Software) utilizing electronic signature.

18. Name(s) of EMR/EHR or pharmacy software used by the business. Please indicate if this is a server or cloud based or both.

SECTION 3: PERSONNEL AND SECURITY

A. Location, Security Guard and Physical Structural Security Information

19. Attach a floor plan that contains the location of the exterior/interior doors, security devices and where the controlled substance will be stored/used.

20. Is your clinic/practice/pharmacy in a standalone building or part of a commercial complex?

20A. If in a commercial complex, provide the name of the complex and brief description of layout (Office building, shopping mall, strip mall). Also provide if it is a standalone building, commercial construction, residential or converted residential construction.

21. If part of a retail store or commercial complex is there a security guard company that patrols the complex?

☐ Yes ☐ No

21A. If yes, what days of the week and the start and end times that a security guard is on-site. (You may approximate times if unknown)

22. What type of exterior doors and locks are used at the clinic/practice space? Be as specific as possible and include any reinforcements (e.g., front entrance is pre-hung steel door/steel frame with a single cylinder or double cylinder dead bolt lock, lock cover plates and door lock reinforced plates, door lock strike plates, reinforced windowed glass, etc.).

23. Are the controlled substances stored in a locked room, cabinet and/or safe?

Be as specific as possible and pictures must be uploaded. If you are a mobile practice, both the vehicle, home, and practice storage areas must be described.

24. Describe the windows and window locking mechanisms (this applies only to windows that can be opened and are in areas that provide direct access to where controlled substances are stored.)

25. Are the walls of the pharmacy, dispensary, or room that CS cabinet is kept complete from floor to hard physical ceiling?
This also means there is no easy access or ability for a person to pass above any drop ceiling from a neighboring business/common area.

- ☐ Walls complete from floor to ceiling (no drop ceiling)
- ☐ Walls complete from floor to ceiling/between drop ceiling and actual ceiling.
- ☐ Walls NOT complete from floor to ceiling but opening is covered with wire mesh or other obstructive measure in place. (Provide description below in 25A and detail the wire mesh gauge and/or other obstructive measure in place.)
- ☐ Walls NOT complete from floor to ceiling, but each opening(s) are less than 9” X 9”.
- ☐ Walls NOT complete from floor to ceiling, provide description/explain in 25A.

25A. Walls NOT complete from floor to ceiling. Provide further description/explanation and any other security measures in place such as motion detection in the room where CS is stored that will mitigate a breach through the ceiling.

B. Employee(s) with access to CS

26. Who will have access to the CS cabinet? (Provide names and their employee role/position.)

NAME	Role / Position

If more space is needed attach another sheet and indicate that here. ___

**Notate next to employee name if there are any previous convictions and/or DEA administrative actions against the employee. If there are drug convictions or CS administrative actions attach/upload an explanation of the conviction/administrative action and the approved DEA waiver for that employee to have access to the controlled substances. Note: Review the Federal law 21 CFR 1301.76 which prohibits employees with a drug (controlled substance) conviction to have access to controlled substance.

Also, employee practitioners who have a DEA registration revoked or surrendered for cause will need an approved waiver for access 21 CFR 1307.03.

C. Secured Controlled Substance Storage

27. How is the CS cabinet or safe physically secured? (e.g., Cabinet is bolted to the wall or floor).

28. Describe in detail or provide make /model/type of safe or locking cabinet. (Upload pictures)

D. Intrusion Monitoring Alarm

29. Is there an intrusion alarm system?

☐ Yes ☐ No

29A. Name of alarm company and contact person.

30. What technologies, does the intrusion/security monitoring alarm system utilize (check all that apply)

- ☐ Door Contact
- ☐ Motion Sensor
- ☐ Video with motion/person detection analytics
- ☐ Glass Break
- ☐ Duress Alarm
- ☐ Battery power back up.
- ☐ Cellular (LTE) transmission back up.
- ☐ Other, specify below.

A security diagram with placement of security elements must be attached. This can be a diagram provided by the security company or a self-drawn diagram of the floor plan with placement of these elements.

31. What is the Alarm monitoring company's notification process if there is a breach? Describe who gets contacted and in what order.

E. Video Surveillance

32. Is there video surveillance?

☐ Yes ☐ No

32A. What is your video surveillance software/Application?

33. How and where is your video surveillance storage kept?

☐ onsite (server or DVR) ☐ offsite server ☐ cloud ☐ backup SD card on camera

Please provide details, especially if multiple methods/systems are utilized.

If using an onsite server or DVR, how are these hidden/secured-including the network switch. If using SD card on camera, is the camera out of reach and is there a Cloud back up (either continuous or segments)?

34. Explain if the video is continuous or motion triggered. If motion triggered what is the recording period and is there a 'cooldown' period even if motion continues?

35. How many days (approximate) are your video surveillance recordings kept?

36. Attach an overall or individual photograph(s) of your camera views from the video surveillance monitor. An overall screenshot showing each camera view will suffice.

37. Are there any backup systems for the video surveillance?

- ☐ Battery power back up.
- ☐ Cellular (LTE) transmission back up.
- ☐ Other, specify below.

38. Any other security measures in place that were not previously described, but should be considered? If yes, explain.

SECTION 5: DISPENSE ACTIVITY ONLY (VETERINARIANS ARE EXEMPTED):

REPORTING CONTROLLED SUBSTANCE PRESCRIPTIONS TO HI- PDMP - PHARMACY AND DISPENSING PRACTITIONER'S ONLY

(For information and refence: HI-PDMP Data Submission Dispenser Guide)

39. EMR /EHR/ Pharmacy Software and vendor contact information being used for dispensations?

40. Who will be doing the reporting/uploading records of controlled substance dispensation to the HI-PDMP?

☐ Contractor/Software Vendor ☐ Self/Staff

41. If using a contractor/software vendor to report CS dispensations to the HI- PDMP, ensure that the vendor will be submitting on your behalf and please acknowledge that you have done so.

41A. Check the box to acknowledge that a contracted/software vendor has been procured/contracted to submit CS dispensations to HI-PDMP. ☐

41B. Name of Vendor and Vendor contact information person/phone number and email address.

41C. If unable to acknowledge, please explain why.

42. If the practitioner/clinic will be self-reporting CS dispensations and zero reports to the HI-PDMP, will the method of electronic submission be done by file transfer or universal claim form?

☐ File Transfer (SFTP) ☐ Universal Claim Form

42A. Have you set up a PDMP Clearinghouse account?

☐ Yes ☐ No

42B. Person/person responsible for CS dispensation reporting to HI-PDMP? Include name, direct phone number, email address.

SECTION 6: CONFIRMATION OF DOCUMENTATION

Attachment Acknowledgment Instructions

Acknowledge that the following attachments are complete by checking the boxes that apply. If an attachment is not provided, please specify in the comment section below and provide a reason.

A. Policy and Procedures attached.

☐ CS Inventory (How will records be maintained)
☐ CS Dispensation Record Keeping Procedure which includes your pickup customer ID verification.
☐ Loss, Theft and Criminal/suspicious Activity Reporting Procedure
☐ CS Disposal for expired/used/spoiled medications (Wasting, Reverse Distribution and/or Medication Destroyer) (Hawaii Administrative Rules
☐ Employee background check Process
☐ Informed Opioid Consent Policy (Veterinarian -Does not Apply)
☐ Informed Opioid Consent Patient Form (Veterinarian – Does not apply)
☐ Concurrent opioid/benzodiazepine prescription/dispense policy.

☐ PDMP reporting –Policy/Procedure (Veterinarian – Does not apply)

B. Photographs attached.

☐ Exterior General
☐ Interior General (Reception area, entries, and room with controlled substances
☐ CS safe/cabinet (overall showing placement), closeup of locking mechanism and how physically secured to wall/floor/counter.
☐ Security elements, door locks, alarm pad, motion sensor (showing over allocation in room), glass break etc. (Entries and areas where controlled substances are kept)
☐ Photograph(s) showing security camera views.
☐ Other relevant photographs (e.g. complete wall between drop ceiling and physical ceiling)

C. Security supplemental documents

☐ Floor plan/Diagram showing placement of doors/locks, alarm pad, door contacts, motion, video camera, duress alarm, etc.
☐ Invoice/Quote/Receipt for Alarm/Video System/include if available any battery and cellular back up technologies purchased.

D. Other types of documents/information attached and additional comments.

SECTION 7: CONTACT INFORMATION

Names of person(s) authorized by the applicant who filled out this form. Name, cell phone number and email address of the point of contact(s) to request further information and to schedule a virtual or onsite inspection.