

# Pharmacist-In-Charge (PIC) Ethical and Legal Responsibilities

**November 2016**

## **Continuing Pharmacy Education (CPE) Information:**

- This CPE program is approved for two (2) hours of home study CPE in Pharmacy Law for Idaho pharmacists.
- To satisfactorily complete this program, a pharmacist must:
  - Fully read the CPE monograph and complete the accompanying post-test evaluation
  - Mail the post-test answer sheet, postmarked no later than April 1, 2017 to:  
Idaho State Board of Pharmacy  
Home Study CPE Program  
PO Box 83720  
Boise, Idaho 83720-0067
  - Pass the post-test with a score of at least 80%; and
  - Include a self-addressed stamped envelope (SASE) for the return of a statement of credit. No statement of credit will be awarded unless a SASE is provided by the pharmacist.

## **Background**

In Idaho, the pharmacist-in-charge (PIC) serves a critical role in protecting the public and improving patient care as it relates to the practice of pharmacy. The PIC has many responsibilities, and importantly serves as the manager of record, responsible for the operation of a pharmacy. The PIC is charged with upholding all federal and state laws pertinent to the practice of pharmacy and the distribution of drugs, and is held legally responsible by the Board of Pharmacy for these functions. The aim of this CPE program is to assist retail pharmacy PICs in better understanding the roles and responsibilities in the state. Specifically this CPE program aims to:

- Describe the legal responsibilities of a retail pharmacy PIC in Idaho;
- Review the requirements for becoming a PIC and staying in the position; and
- Outline the common deficiencies noted during inspections that the PIC would be held responsible for

## **Who May Serve as PIC?**

The rules of the Board of Pharmacy state that a PIC must be an actively licensed Idaho pharmacist who spends a substantial part of his or her working time each month at the pharmacy in which he or she is designated as the PIC. Each pharmacy must have a PIC by the date of opening, and each pharmacy must have a PIC at all times thereafter, allowing only for brief vacancies of no more than thirty (30) sequential days.

Thus, the qualifications for becoming a PIC in Idaho are broad, as there are no specific experience or training requirements delineated in law as is often the case in other states. It is imperative, however, that each PIC have the requisite education, training, and experience necessary to perform the legal duties of a PIC. This starts with a robust understanding of federal and state laws pertinent to the practice of pharmacy and the distribution of drugs. **Table 1** reviews the critical resources that a PIC must familiarize themselves with in order to effectively carry out their role.

**Table 1. Critical Idaho Pharmacy Law Resources**

Resource	Description
Law Book with Idaho Pharmacy Code and Administrative Rules ( <a href="#">Link</a> )	<p>The Board provides this searchable PDF of collated Idaho statutes and administrative rules relevant to the practice of pharmacy and the distribution of drugs. It is updated annually to engross new law changes.</p> <p>Rule 603 requires a hard copy or electronic edition of this resource be made available at each pharmacy. Each PIC should spend time reviewing the law book, and should refer to this resource often as new questions arise at the pharmacy.</p>
DEA Pharmacist's Manual ( <a href="#">Link</a> )	<p>The DEA provides this resource as an informational outline of the federal Controlled Substances Act. It serves as a guide to assist pharmacists in their understanding of the federal Act and its implementing regulations as they pertain to the pharmacy profession.</p>
Idaho State Board of Pharmacy Newsletter ( <a href="#">Link</a> )	<p>Rule 007 designates the Newsletter as the official journal of the Board, and thus it serves as an official means of notification of law changes, trends, and recent disciplinary cases. Board licensees and registrants are presumed to have knowledge of the contents of the newsletter on the date of publication. The newsletter may be used in administrative hearings as proof of notification.</p> <p>Newsletters are sent quarterly: March, June, September, and December. You may receive an electronic version by sending an email to <a href="mailto:IdahoBOPNewsletter@nabp.net">IdahoBOPNewsletter@nabp.net</a> with the word "Subscribe" in the subject heading.</p> <p>In general, rule changes take effect at the end of each Idaho legislative session, which typically occurs in March or April. By contrast, statute changes typically take effect July 1. It is important for each PIC to monitor the newsletter and ensure compliance with law changes by the effective date.</p>

**What Should a PIC Do As They Begin Their New Role?**

When taking over as a new PIC, several tasks must be prioritized:

1. **Formally Notify the Board of PIC Change.** Both an outgoing and incoming PIC must report to the Board a change in PIC designation within ten (10) days of the change.
2. **Complete a Controlled Substances Inventory.** Board rule 206(03) requires a complete controlled substances inventory to be conducted on or by the first day of employment of the incoming PIC.

To notify the Board of a PIC change, the Board makes available a fillable PDF. A copy of this form is provided in **Appendix A** for reference. This form should be completed and mailed to the Board or sent to the licensing team via email to [info@bop.idaho.gov](mailto:info@bop.idaho.gov). The PIC must report the following elements in the form:

- Date of PIC change
- Name and pharmacist license number of the incoming PIC

- Pharmacy name, pharmacy license number, and contact information for the pharmacy (address, phone number, fax, and email address)
- Name and license number for all pharmacists, pharmacy technicians, and student pharmacists at the designated pharmacy

With respect to the controlled substance inventory upon change in PIC, this is perhaps the most critical task to complete as an incoming PIC. The inventory is an actual physical count of all controlled substances in the pharmacy's possession. The inventory guards against loss, theft, or diversion of controlled substances. The PIC can be held responsible for inventory discrepancies, and thus this initial inventory upon PIC change ensures that the incoming PIC is not held responsible for issues that arose prior to their tenure. Completing the initial inventory serves as a significant risk mitigation strategy for the incoming PIC and should not be taken lightly!

The inventory must include the following elements, as detailed in the DEA Pharmacists Manual:

- The date of the inventory
- Whether the inventory was taken at the beginning or close of business
- The name of each controlled substance inventoried
- The finished form of each of the substances (e.g., 10 milligram tablet)
- The number of dosage units of each finished form in the commercial container (e.g., 100 tablet bottle)
- The number of commercial containers of each finished form (e.g., four 100 tablet bottles), and
- A count of the substance
  - If the substance is listed in Schedule II, an exact count or measure of the contents is required
  - If the substance is listed in Schedule III, IV, or V, an estimated count or measure of the contents is permissible, unless the container holds more than 1,000 tablets or capsules in which case an exact count of the contents is required.

The DEA recommends an inventory record also include the name, address, and DEA registration number of the pharmacy, and the signature of the person or persons responsible for taking the inventory. There is no requirement to submit a copy of the inventory to the Board or to the DEA, but the inventory must be stored in the records of the pharmacy for at least three (3) years. Inventories of Schedule I and II substances must be maintained separately from the other records of the pharmacy. Similarly, inventories of Schedule III, IV, and V substances must be maintained separately from all other records or in a manner that the information is readily retrievable. More information on recordkeeping is reviewed later in this CPE program.

Inventories of all controlled substances are required annually in Idaho. Upon completion of an inventory upon the change in PIC, the pharmacy may reset its date for the required annual inventory. The next year's annual inventory may be completed anytime within seven days of the same date of the previous year's inventory. Several other instances trigger the requirement for a controlled substance inventory. A PIC is encouraged to review Rule 206 to review these inventory requirements.

It may be prudent for an incoming PIC to also complete a self-inspection using the forms provided by the Board on their website at [www.bop.idaho.gov](http://www.bop.idaho.gov). Inspections will be covered later in this CPE program.

### What Ongoing Activities is a PIC Responsible For?

Rule 301 specifies that the PIC is responsible for the management of every part of the pharmacy and its regulated operations, and that the PIC must maintain full and complete control of such. This definition is purposefully broad, as the PIC should have a solid understanding of all applicable federal and state pharmacy laws. There are a few areas in which a PIC must specifically focus, including:

- Reporting Requirements;
- Licensing Maintenance Requirements; and
- Recordkeeping

To reiterate, the PIC is responsible for ensuring all state and federal pharmacy laws are upheld. The limited focus in this CPE program does not absolve the PIC of a more holistic understanding of pharmacy law, and the PIC should review frequently the legal resources referenced in **Table 1**.

### **Reporting Requirements**

The PIC is charged with specific reporting requirements under state law. In addition, the PIC should be aware of other reporting requirements incumbent on any pharmacist under both state and federal law. A summary of select reporting requirements is provided in **Table 2**. Reports that are specifically required of a PIC are highlighted in **yellow**. Failing to provide a required report may constitute grounds for discipline by the Board.

**Table 2. Summary of Reporting Requirements.**

Required to Report	Law Citation	Agency to Submit Report	Description	Time Frame to Report
PIC Change	Rule 302 and 622	Board	Both an outgoing and incoming PIC must report to the Board a change in PIC. A copy of the requisite form is available in <b>Appendix A</b> .	Within ten (10) days of the change
Annual Personnel Report	Rule 302	Board	Coinciding with the annual renewal of the drug outlet registration (deadline: June 30), the PIC must report the names of the designated PIC, each employee pharmacist and technician, and each student pharmacist currently training in the pharmacy. This report is completed in concert with the annual pharmacy registration renewal, and a screenshot of the requisite form is available in <b>Appendix B</b> .	Annually on the pharmacy renewal application by June 30
Employment Changes	Rule 302	Board	In addition to the annual personnel report, the PIC must provide timely updates on changes in employment of pharmacists, technicians, or student	Within ten (10) days of the change

			pharmacists. Updates must be provided on both new employees and employees who have left. The requisite form is available in <b>Appendix C</b> .	
Theft or Loss of Controlled Substances	CFR 1301.76(b) ; Rule 208	DEA and Board	<p>A pharmacy must notify in writing the local DEA Diversion Field Office within one business day of discovery of a theft or significant loss of a controlled substance. If there is a question as to whether a theft has occurred or a loss is significant, a pharmacy should err on the side of caution and report it to DEA, the Board, and local law enforcement authorities.</p> <p>A pharmacy must complete DEA Form 106 to report theft or loss of controlled substances. A copy of this form is provided as <b>Appendix D</b>.</p> <p>In addition to the required report, a complete inventory must be completed within forty-eight (48) hours of the discovery of a theft or loss of a controlled substance.</p>	Within one (1) business day of discovery of loss or theft.
Personal Information Change	Rule 017	Board	Any changes in personal contact information, or employment of pharmacists, student pharmacists, and technicians must be reported to the Board. This includes legal name (including married name), home address, or mailing address. The requisite form for a name change is available in <b>Appendix E</b> ; the form for an address change is available in <b>Appendix F</b> ; and the form for an individual's employment change is available in <b>Appendix G</b> .	Within 10 days of change
Termination of employee for adulteration and/or misappropriation of controlled substances	Section 37-117(a) Idaho Code	Board	When the employment of a health care provider has been terminated, either voluntarily or involuntarily, for adulteration or misappropriation of controlled substances, the employer shall, within thirty (30) days of the termination, furnish written notice of	Within 30 days of termination

			the termination to the Board. This notice shall include a description of the controlled substance adulteration or misappropriation involved in the termination. While there is no specific form required, pharmacists are encouraged to contact the Board to ensure all necessary information is appropriately provided.	
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The Board often hears complaints over the necessity of reporting personal information changes. The Board uses the self-reported address on file for official mailings, such as continuing education audit requests, official Board newsletters, or official complaints, among other things. Thus, it is critical to keep such information up-to-date to ensure notices are properly received and responded to as necessary.

***Licensing Maintenance Requirements***

Every member of the pharmacy team is required to be licensed or registered by the time they begin working in the pharmacy. No personnel may begin working in a pharmacy until after they have received notification of their licensure/registration.

The Board makes an exception to licensure only for the purpose of job shadowing -- for a maximum of forty (40) hours without having to register as a pharmacy technician. The unregistered individual must be under the direct supervision of the pharmacist at all times while conducting shadowing activities, and is not permitted to touch any drugs, conduct any computer work, answer the phone, or interface individually with customers.

The PIC is responsible for enforcing this rule, and making certain that each and every member of the pharmacy team is licensed if they are to be working in the pharmacy. This includes ensuring that the pharmacy staff has completed their licensure or registration requirements and have not simply submitted their paperwork and left their status as “pending” or incomplete. A summary of licensing and registration requirements that the PIC should ensure maintenance of is provided in **Table 3**.

***Table 3. Summary of Personnel Licensing and Registration Renewals.***

<b>License/Registration Category</b>	<b>Annual Renewal Date</b>	<b>Renewal Requirements</b>
Pharmacy	June 30	N/A
Pharmacist	June 30	Must attain the continuing education requirements specified in Rule 052.
Student Pharmacist	June 30 for pharmacy interns and July 15 for pharmacy externs	Must currently be enrolled and in good standing in an accredited school or college of pharmacy, pursuing a degree in pharmacy.
Certified Pharmacy Technician	June 30	Must maintain certified pharmacy technician (CPhT) status through the Pharmacy Technician

		Certification Board (PTCB) or National Healthcareer Association (NHA)
Grandfathered Technician	June 30	Must remain in good standing and be continuously employed by the same employer with whom the grandfathered status was received.
Technician-in-Training	June 30	Registration may only be renewed twice.

A common deficiency observed with respect to the PIC’s licensing duty involves certified technicians. A certified technician’s registration must be renewed annually by June 30. The status of the registration is contingent on the technician maintaining their national certification, however. The Board has identified several technicians whose registration was current, but whose national certification later lapsed. The PIC is jointly responsible for ensuring all registration requirements, particularly maintenance of national technician certification, are continuously met, and maintained between registration renewal periods.

**Recordkeeping**

The PIC is ultimately responsible for maintaining records as required under state and federal law. Complete, current, and accurate records – appropriately maintained – can streamline Board inspections and investigations. Further, good recordkeeping can ultimately provide significant protection to the PIC by providing a record of satisfactory compliance with applicable law.

Every pharmacy must maintain complete and accurate records on a current basis for each controlled substance purchased, received, stored, distributed, dispensed, or otherwise disposed of. These records are required to provide accountability of all controlled substances from the manufacturing process through the dispensing pharmacy and to the ultimate user. The closed system reduces the potential for diversion of controlled substances.

All pharmacy records must be maintained as required and retained in a readily retrievable form and location for at least three (3) years unless otherwise specified. While federal law requires records be kept for two (2) years, the more stringent law applies, and pharmacies should consequently follow Idaho’s recordkeeping law.

These records are subject to inspection by agents of the Board and, in some cases, agents of the DEA. Financial and shipping records including invoices, but excluding controlled substance order forms and inventories, may be retained at a central location if the registrant has provided DEA notification of central recordkeeping as required by federal law. A summary of select recordkeeping requirements is provided in **Table 4**.

**Table 4. Summary of Recordkeeping Requirements**

Required Record to be Maintained	Description of Requirements Related to Record
DEA Form 222	Schedule II substances must be ordered on a DEA Form 222 or its electronic equivalent. When using this form, the purchaser is responsible for filling in the number of packages, the size of the package, and the name of the item. Each DEA Form 222 must be signed and dated by a person authorized to sign a

	<p>registration application or a person granted power of attorney. An order cannot be filled if the order form is not complete, legible, or properly prepared, executed, or endorsed, or if the order shows any alteration, erasure, or change of any description.</p> <p>When the items are received, the pharmacist must document on the purchaser's copy (copy three) the actual number of packages received and the date received.</p> <p>The executed DEA Form 222 or its electronic equivalent must be maintained separately from the pharmacy's other business records. However, this does not preclude a registrant from attaching a copy of the supplier's invoice to the related DEA Form 222.</p>
<p>Power of Attorney Forms</p>	<p>A pharmacy may authorize one or more individuals, whether or not they are located at the registered location, to obtain and execute DEA Forms 222 by granting a power of attorney to each such individual. The power of attorney must be signed by the same person who signed the most recent application for registration or renewal registration, as well as the individual being authorized to obtain and execute the DEA Forms 222.</p> <p>The power of attorney may be revoked at any time by the person who granted and signed the power of attorney. Only if the renewal application is signed by a different person is it necessary to grant a new power of attorney when the pharmacy completes a renewal registration. The power of attorney should be filed with executed DEA Forms 222 as a readily retrievable record. The power of attorney is not submitted to DEA.</p> <p>A sample format for granting and revoking a power of attorney is available in the DEA Pharmacists Manual.</p>
<p>Receipts and/or invoices for schedules III, IV, and V controlled substances</p>	<p>Whereas schedule II substances are ordered on a DEA Form 222 or its electronic equivalent, an invoice is used to order schedule III, IV, and V controlled substances. These records must be maintained separately from all other pharmacy records, or in a manner that the information is readily retrievable.</p>
<p>All inventory records of controlled substances, including the initial, biennial, and newly scheduled CS inventories, dated as of beginning or close of business</p>	<p>As discussed previously, there are certain instances that trigger the requirement to complete an inventory of all controlled substances. Further, inventories require certain elements, reviewed above.</p> <p>Inventories of Schedule I and II substances must be maintained separately from the other records of the pharmacy. Similarly, inventories of Schedule III, IV, and V substances must be maintained separately from all other records or in a manner that the information is readily retrievable.</p>
<p>Records of controlled</p>	<p>A pharmacy registered to dispense controlled substances may distribute such substances (without being registered as a distributor) to another pharmacy or</p>

<p>substances distributed (i.e., sales to other registrants, returns to vendors, distributions to reverse distributors) and records of transfers of controlled substances between pharmacies (note that under federal law, all drugs being distributed to other practitioners require wholesaler-provided tracking information)</p>	<p>to a registered practitioner for the purpose of general dispensing by the practitioner to patients, provided that the following conditions are met:</p> <ol style="list-style-type: none"> <li>1. The pharmacy or practitioner that will receive the controlled substances is registered under the CSA to dispense controlled substances – and only at the registered address;</li> <li>2. The distribution is recorded by the distributing practitioner in accordance with 21 C.F.R. § 1304.22(c) and the receipt is recorded by the receiving practitioner in accordance with 21 C.F.R. § 1304.22(c);</li> <li>3. If the pharmacy distributes a schedule II controlled substance, it must document the transfer on an official order form (DEA Form 222) or the electronic equivalent.</li> <li>4. “Five Percent Rule” – the total number of dosage units of all controlled substances distributed by a pharmacy may not exceed five percent of all controlled substances dispensed by the pharmacy during a calendar year. If at any time the controlled substances distributed exceed five percent, the pharmacy is required to register as a distributor.</li> </ol> <p>To distribute or transfer schedule II substances, the receiving registrant must issue an official order form (DEA Form 222) or an electronic equivalent to the registrant transferring the drugs. The transfer of schedules III-V controlled substances must be documented in writing to show the drug name, dosage form, strength, quantity, and date transferred. The document must include the names, addresses, and DEA registration numbers of the parties involved in the transfer of the controlled substances.</p>
<p>Reports of Theft or Significant Loss (DEA Form 106), if applicable</p>	<p>Federal regulations require that registrants notify the DEA Field Division Office in their area, in writing, of the theft or significant loss of any controlled substance within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in their area, DEA Form 106, "Report of Theft or Loss of Controlled Substances" regarding the theft or loss.</p> <p>The DEA Form 106 must include the following information:</p> <ol style="list-style-type: none"> <li>1. Name and address of the firm (pharmacy);</li> <li>2. DEA registration number;</li> <li>3. Date of theft or loss (or when discovered if not known);</li> <li>4. Name and telephone number of local police department (if notified);</li> <li>5. Type of theft (e.g., night break-in, armed robbery);</li> <li>6. List of identifying marks, symbols, or price codes (if any) used by the pharmacy on the labels of the containers; and</li> <li>7. A listing of controlled substances missing, including the strength, dosage form, and size of container (in milliliters if liquid form) or corresponding National Drug Code numbers.</li> </ol> <p>DEA controlled substance registrants are strongly encouraged to complete and submit the DEA Form 106 online here:  <a href="https://www.deadiversion.usdoj.gov/webforms/dtlLogin.jsp">https://www.deadiversion.usdoj.gov/webforms/dtlLogin.jsp</a></p>

<p>DEA registration certificate</p>	<p>Every pharmacy that dispenses a controlled substance must be registered with the DEA. First, a state license must be obtained.</p> <p>To register as a new pharmacy, the DEA Form 224 must be completed. The cost of the application fee is indicated on the application form. The certificate of registration must be maintained at the registered location and kept available for official inspection. If a person owns and operates more than one pharmacy, each place of business must be registered.</p> <p>A pharmacy registration must be renewed every three years utilizing DEA Form 224a, Renewal Application for DEA Registration. The cost of the application fee is indicated on the application form.</p> <p>To renew a registration, the most current information from the pharmacy's existing registration must be utilized. A registrant can renew online no more than 60 days prior to the current expiration date. The DEA Form 224a should be completed online and can be found at <a href="http://www.DEAdiversion.usdoj.gov">www.DEAdiversion.usdoj.gov</a>.</p>
<p>Self-certification certificate and logbook (or electronic equivalent) as required under the Combat Methamphetamine Epidemic Act (CMEA) of 2005</p>	<p>As part of the requirements of the Combat Methamphetamine Epidemic Act (CMEA) of 2005, an annual self-certification is required for all regulated sellers of scheduled listed chemical products (SLCPs) such as pseudoephedrine. A regulated seller must not sell SLCPs unless it has self-certified with DEA. In self-certifying, the regulated seller is confirming:</p> <ul style="list-style-type: none"> <li>• The employees who will be engaged in the sale of SLCPs have undergone training regarding provisions of CMEA.</li> <li>• Records of the training are maintained.</li> <li>• Sales to individuals do not exceed 3.6 grams of ephedrine, pseudoephedrine, or phenylpropanolamine per day.</li> <li>• Non-liquid forms are packaged as required.</li> <li>• SLCPs are stored behind the counter or in a locked cabinet.</li> <li>• A written or electronic logbook containing the required information on sales of these products is properly maintained.</li> <li>• The logbook information will be disclosed only to Federal, State, or local law enforcement and only to ensure compliance with Title 21 of the United States Code or to facilitate a product recall.</li> </ul> <p>The only way to self-certify is through the DEA's Diversion website at <a href="http://www.DEAdiversion.usdoj.gov">www.DEAdiversion.usdoj.gov</a>. A certificate will be generated by the DEA upon receipt of the self-certification application. The regulated seller may print this certificate, or if the regulated seller is unable to print it, the DEA will print and mail the certificate to the regulated seller. Chain stores wishing to file self-certifications for more than 10 locations must print or copy the form electronically and submit the information to the DEA by mail. The DEA will work with these persons to facilitate this process. Persons interested in this self-certification option should contact DEA for assistance at 1-800-882-9539. For current DEA registrants, the system will pre-populate the form with basic information if the registrant enters his DEA registration number in the field provided.</p>

	<p>The regulated seller must self-certify to DEA as described above on an annual basis. It is the responsibility of the regulated seller to ensure that all employees have been trained prior to self-certifying each time.</p> <p>It is the regulated seller’s responsibility to annually renew before the certificate expires if the regulated seller intends to continue selling SLCPs at retail. The certificate contains a self-certification number in the upper right corner. The expiration date of the certificate is listed under the self-certification number. Regulated sellers may verify the expiration date of their certificate at <a href="http://www.DEAdiversion.usdoj.gov">www.DEAdiversion.usdoj.gov</a>.</p>
<p>Prescription Records</p>	<p>Pharmacies have two options for filing prescription records:</p> <p><i>Paper Prescriptions Records Option 1 (Three separate files):</i></p> <ol style="list-style-type: none"> <li>1. A file for schedule II controlled substances dispensed.</li> <li>2. A file for schedules III, IV, and V controlled substances dispensed.</li> <li>3. A file for all non-controlled drugs dispensed.</li> </ol> <p><i>Paper Prescriptions Records Option 2 (Two separate files):</i></p> <ol style="list-style-type: none"> <li>1. A file for all schedule II controlled substances dispensed.</li> <li>2. A file for all other drugs dispensed (non-controlled and those in schedules III, IV and V). If this method is used, a prescription for a schedule III, IV or V drug must be made readily retrievable by use of a red "C" stamp not less than one inch high. If a pharmacy has an electronic recordkeeping system for prescriptions which permits identification by prescription number and retrieval of original documents by prescriber’s name, patient’s name, drug dispensed, and date filled, the requirement to mark the hard copy with a red “C” is waived.</li> </ol> <p><i>Electronic Prescription Records</i></p> <ol style="list-style-type: none"> <li>1. If a prescription is created, signed, transmitted, and received electronically, all records related to that prescription must be retained electronically.</li> <li>2. Electronic records must be maintained electronically for two years from the date of their creation or receipt. However, this record retention requirement shall not pre-empt any longer period of retention which may be required now or in the future, by any other Federal or State law or regulation, applicable to pharmacists or pharmacies.</li> <li>3. Records regarding controlled substances must be readily retrievable from all other records. Electronic records must be easily readable or easily rendered into a format that a person can read.</li> </ol> <p>Records of electronic prescriptions for controlled substances shall be maintained in an application that meets the requirements of <a href="#">21 C.F.R. §1311</a>. The computers on which the records are maintained may be located at another location, but the records must be readily retrievable at the registered location if</p>

	requested by the DEA or other law enforcement agent. Electronic copies of prescription records must be sortable by prescriber name, patient name, drug dispensed, and date filled.
Documentation of Counseling and Offer to Counsel	<p>The Board is concerned with a lack of required counseling and offers to counsel. The Board believes counseling to be a pillar of the profession of pharmacy and a safeguard of public safety. Per rule 105, documentation must be created and retained sufficient to evidence compliance with the offer to counsel and counseling requirements of the Idaho Pharmacy Act.</p> <p>As a reminder, the counseling requirements under I.C. 54-1739(2) states:</p> <p>“Before dispensing a prescription for a new medication, or when otherwise deemed necessary or appropriate, a pharmacist shall counsel the patient or caregiver. In addition to the counseling requirements provided in section 54-1705, Idaho Code, counseling shall include such supplemental written materials as required by law or as are customary in that practice setting. For refills or renewed prescriptions, a pharmacist or a technician shall extend an offer to counsel the patient or caregiver. If such offer is accepted, a pharmacist shall provide such counseling as necessary or appropriate in the professional judgment of the pharmacist. All counseling and offers to counsel shall be face to face with the patient or caregiver when possible, but if not possible, then a reasonable effort shall be made to contact the patient or caregiver. Nothing in this section shall require a pharmacist to provide counseling when a patient or caregiver refuses such counseling or when counseling is otherwise impossible. Patient counseling shall not be required for inpatients of a hospital or institutional facility when licensed health care professionals administer the medication.</p>
Inspection Forms	Completed inspection forms from Board compliance officers should be maintained in a readily retrievable fashion.

**How Does the Board Enforce Pharmacy Law?**

The Board primarily enforces pharmacy law through licensing, inspections, and investigations. This CPE program will focus on the last two items.

***Pharmacy Inspections***

All pharmacies in the state are subject to inspection by Board compliance officers at any time. In general, Board inspectors conduct an annual inspection of each pharmacy. In addition, an inspection is required prior to the opening of a new pharmacy, or upon remodel of an existing pharmacy. Per Rule 008(02), it is unlawful to refuse to permit or to obstruct a Board inspection.

The Board is not required to give notice of inspections – and the PIC is not required to be present -- so the PIC should always be prepared and instruct staff on the location and importance of required documents in case of their personal absence. Advising staff on what to expect, and who will be in charge of assisting the inspector will allow the inspection to progress smoothly. Invite staff to ask questions and/or contact the Board with any concerns.

PICs should organize all required records and maintain them in a secure location that is readily accessible for at least three years. Consolidating documentation into one location or clearly indicating where it can be found is a useful organizational strategy. Creating policies and procedures that incorporate federal and state regulations for inspection requirements can also help increase compliance.

The length of time an inspection can last varies depending on the type of inspection. Pharmacies compounding medications for sterile or non-sterile use are required to have these processes inspected as a supplement to the retail pharmacy inspection. Even pharmacies that only practice simple non-sterile compounding will be required to undergo a supplemental compounding inspection.

All inspection forms are available on the Board’s website. PICs should review all relevant inspection forms prior to Board inspections to assess current compliance. Completing a self-inspection can help PICs identify issues and correct them before they become violations, ultimately saving time and hassle down the road. A self-inspection is essentially an open-book exam in which the PIC can identify the items in which Board inspectors will assess compliance. The PIC is encouraged to answer the self-inspection honestly, and he or she should not assume the way it’s “always been” is indeed compliant.

A listing of current Board inspection forms is available in **Table 5**.

**Table 5. Current Board Inspection Forms for Community Pharmacies**

Type of Inspection	Inspection Form
Retail Pharmacy	<a href="https://bop.idaho.gov/forms/inspection_forms/2016-03-22_PHARMACY_INSPECTION_REPORT.pdf">https://bop.idaho.gov/forms/inspection_forms/2016-03-22_PHARMACY_INSPECTION_REPORT.pdf</a>
Non-Sterile Compounding Supplemental	<a href="https://bop.idaho.gov/forms/inspection_forms/2016-03-22_COMPOUNDING_SUPPLEMENTAL.pdf">https://bop.idaho.gov/forms/inspection_forms/2016-03-22_COMPOUNDING_SUPPLEMENTAL.pdf</a>
Sterile Compounding Supplemental	<a href="https://bop.idaho.gov/forms/inspection_forms/2016-03-22_STERILE_COMPOUNDING_SUPPLEMENTAL.pdf">https://bop.idaho.gov/forms/inspection_forms/2016-03-22_STERILE_COMPOUNDING_SUPPLEMENTAL.pdf</a>
Telepharmacy	<a href="https://bop.idaho.gov/forms/inspection_forms/2016-03-22_TELEPHARMACY_SUPPLEMENTAL.pdf">https://bop.idaho.gov/forms/inspection_forms/2016-03-22_TELEPHARMACY_SUPPLEMENTAL.pdf</a>
New or Remodel	<a href="https://bop.idaho.gov/forms/inspection_forms/2016-03-22_NEW_REMODEL_PHARMACY_INSPECTION_REPORT.pdf">https://bop.idaho.gov/forms/inspection_forms/2016-03-22_NEW_REMODEL_PHARMACY_INSPECTION_REPORT.pdf</a>
Durable Medical Equipment Supplemental	<a href="https://bop.idaho.gov/forms/inspection_forms/2016-03-22_DURABLE_MEDICAL_EQUIPMENT_INSPECTION.pdf">https://bop.idaho.gov/forms/inspection_forms/2016-03-22_DURABLE_MEDICAL_EQUIPMENT_INSPECTION.pdf</a>

Any deficiencies or violations identified by a Board inspector should be addressed immediately. PICs should notify compliance officers as soon as the issue has been resolved. Depending of the type of violation, a new inspection may be necessary to confirm the pharmacy complies with applicable law.

The Board’s compliance staff routinely sees the following deficiencies upon inspection:

- Finding expired products on shelves;
- Pharmacy technicians not wearing a name badge identifying them as such;
- PIC failing to notify the Board within 10 days of staff change;
- No documentation for counseling (either accepted or declined). Documentation for refills seems to be missed the most;
- Controlled substance inventory not performed with PIC change;

- Annual controlled substances inventory not performed within the required timeframe;
- No policy and procedures (P&P) are present for compounding. This is mainly missed in pharmacies that compound simple things such as magic mouthwash and they don't realize they are also required to have a P&P; and
- Incorrect labeling of compounded products.

The PIC is encouraged to reach out to the compliance officer assigned to his or her area with questions on compliance with pharmacy law. A current list of Board compliance contacts is provided in **Table 6**.

**Table 6. Board of Pharmacy Compliance Contacts**

Position	Name	Phone Number	Email Address
East Idaho Compliance Officer	Jamie Sommer	208-589-4731	<a href="mailto:jaime.sommer@bop.idaho.gov">jaime.sommer@bop.idaho.gov</a>
Southwest Idaho Compliance Officer	Lisa Culley	208-861-0241	<a href="mailto:lisa.culley@bop.idaho.gov">lisa.culley@bop.idaho.gov</a>
North Idaho Compliance Officer	Wendy Shiell	208-413-3344	<a href="mailto:wendy.shiell@bop.idaho.gov">wendy.shiell@bop.idaho.gov</a>
Chief Investigator – Controlled Substances	Fred Collings	208-334-2356	<a href="mailto:fred.collings@bop.idaho.gov">fred.collings@bop.idaho.gov</a>

### **Investigations**

Investigations are conducted to confirm compliance with laws enforced by the Board of Pharmacy, or to enforce disciplinary action. Investigations can be initiated pursuant to a complaint or a violation. In the first case the Board investigators gather information pertinent to the complaint. Complaints can be submitted to the Board by patients or practitioners. An online complaint form is available on the Board's website: <https://bop.idaho.gov/complaint/>

Violations are identified during pharmacy inspections and -- if not resolved as directed by the Board -- can proceed into investigations. Licensees must fully cooperate with the investigations. Pharmacists involved may submit personal statements as part of the investigation.

### **How Should a PIC Handle an Impaired Employee?**

In their course of duty, a PIC may recognize warning signs of substance abuse in a colleague – whether a pharmacist, technician. Help is available through the Board's Pharmacist Recovery Network (PRN). Knowing what resources are available to help and how to access them can expedite treatment and prevent patient harm.

PRN is a confidential, non-coercive and non-punitive alternative to formal disciplinary action offered by the Idaho Board of Pharmacy. The PRN is a program to facilitate prevention, identification, intervention, and rehabilitation for Idaho pharmacy professionals who have, or are at risk for developing disorders, which are associated with functional impairment, or suffering from chemical abuse or dependency, mental health issues, or behavioral problems. The program operates in a manner consistent with the pharmacy laws and medical practice acts of the State of Idaho to provide staff and patients a safe environment in any medical setting.

The purpose of the PRN is to assist pharmacy professionals in identifying alcohol, drug, or behavioral problems that pose a potential threat to the professional or their patients/clients. The PRN will work to identify and facilitate acute treatment and to provide long-term support and a safe return to their profession.

Treatment has proven to be effective for both the individual and society. By providing an opportunity to enter into treatment and to recover from their diseases early in the disease process, the PRN can serve to minimize negative impacts on the professionals, patients/clients and their families and friends.

### **What Should a PIC Do Upon Completion of His or Her Job?**

When completing his or her role as a PIC, there are several tasks that must be prioritized:

1. **Formally Notify the Board of PIC Change.** Both an outgoing and incoming PIC must report to the Board a change in PIC designation within ten (10) days of the change.
2. **Ensure All Records Are in Good Order.** An outgoing PIC should take care to ensure all required records are easily identifiable and retrievable by the incoming PIC.

If the new PIC has been named, it may be prudent for the outgoing PIC to complete the inventory with the incoming PIC.

## **Pharmacist-In-Charge (PIC) Ethical and Legal Responsibilities**

### **Post-Test Questions**

1. The \_\_\_ is ultimately charged with upholding all federal and state laws pertinent to the practice of pharmacy and the distribution of drugs, and is held legally responsible by the Board of Pharmacy for these functions.
  - a. Technician
  - b. Manager
  - c. Pharmacist on duty
  - d. Pharmacist-in-charge (PIC)
  
2. Critical law resources for the PIC include:
  - a. Law Book with Idaho Pharmacy code and Administrative Rules
  - b. DEA Pharmacist's Manual
  - c. Idaho State Board of Pharmacy Newsletter
  - d. A and B only
  - e. All of the above
  
3. A PIC must report the following elements within the form to notify the Board of a PIC change:
  - a. Date of PIC change, name and pharmacist license number of the incoming PIC, and why the PIC left
  - b. Date of PIC change, name and pharmacist license number of the incoming PIC, pharmacy name, pharmacy license number, contact information for the pharmacy, and length of time outgoing PIC was employed
  - c. Date of PIC change, name and pharmacist license number of the incoming PIC, pharmacy name, pharmacy license number, contact information for the pharmacy, and name and license number for all pharmacists and pharmacy technicians at the designated pharmacy
  - d. Date of PIC change, name and pharmacist license number of the incoming PIC, pharmacy name, pharmacy license number, contact information for the pharmacy, name and license number for all pharmacists and pharmacy technicians at the designated pharmacy and why the PIC left
  
4. What is the maximum amount of time that is allowed between an outgoing PIC and an incoming PIC starting?
  - a. 3 days
  - b. 5 days
  - c. 10 days
  - d. 30 days
  
5. When formally notifying the board of a PIC change, only the incoming PIC must report to the board a change in PIC designation.
  - a. True
  - b. False

6. Inventories of Schedule I and II substances must be:
  - a. Maintained with other controlled substances
  - b. Maintained separately from other records of the pharmacy
  - c. Maintained within other schedules as long as they are readily retrievable
  - d. Destroyed to prevent tampering once inspection has occurred
  
7. A complete controlled substance inventory must be conducted on or by the:
  - a. First day of employment as PIC
  - b. Fifth day of employment as PIC
  - c. Tenth day of employment as PIC
  - d. Thirtieth day of employment as PIC
  
8. When counting a controlled substance for inventory, which of the following are true?
  - a. If listed as a scheduled substance, an exact count or measure is required
  - b. Only schedule II substances require a count
  - c. If listed as a schedule II, an exact count or measure is required and if the substance is listed in schedule III, IV, or V, an estimated count is permissible, unless the container holds more than 1,000 tablets or capsules in which case the exact count of the content is required
  - d. You are able to transfer counts from the most recent inventory
  
9. Once the inventory occurs with a PIC change, the next annual inventory must be completed within:
  - a. One year from the previous inventory
  - b. One year and seven days from the previous inventory
  - c. Two years from the previous inventory
  - d. Two years and seven days from the previous inventory
  
10. In addition to the required report, a completed inventory must be completed within \_\_\_ hours of the discovery of a theft or loss of a controlled substance.
  - a. 24 hours
  - b. 48 hours
  - c. 72 hours
  - d. 30 days
  
11. The annual Personnel Report for Rule 302 is due:
  - a. January 31<sup>st</sup>
  - b. June 30<sup>th</sup>
  - c. October 31<sup>st</sup>
  - d. December 31<sup>st</sup>
  
12. The Board makes an exception to licensure only for the purpose of job shadowing, for a maximum of \_\_\_ hours without having to register as a pharmacy technician.
  - a. 10 hours
  - b. 20 hours
  - c. 30 hours
  - d. 40 hours

13. All personnel licensing and registration renewals are due by June 30<sup>th</sup> (including pharmacy, pharmacist, interns, externs, certified pharmacy technician, grandfathered technician, and technician-in-training):
- True
  - False
14. In Idaho, a technician does not have to maintain certification if they maintain registration:
- True
  - False
15. In Idaho, all pharmacy records must be maintained as required and retained in a readily retrievable form and location for:
- One year
  - Three years
  - Five years
  - Seven years
16. A PIC must provide timely changes in personal contact information, or of changes in employment of pharmacists, student pharmacists, or technicians. These must be reported to the Board of Pharmacy within \_\_\_\_ of change:
- 48 hours
  - 72 hours
  - 10 days
  - 30 days
17. All pharmacies in the state of Idaho are subject to inspection by Board compliance officers. The PIC is not required to be present.
- True
  - False
18. An inspection is required:
- Prior to opening of a new pharmacy
  - Upon remodel
  - Every 4 months
  - Both A and B
  - All of the above
19. Inspection forms are available:
- By request from the board in writing
  - Never, you are not allowed to know what the Board is looking for
  - On the Boards website and encouraged to be used for self-inspection
  - Available only when being inspected by compliance officer
20. The Pharmacist Recovery Network (PRN) is designed to be:
- Confidential
  - Non-coercive
  - Non-punitive
  - All of the above

**Pharmacist-In-Charge (PIC) Ethical and Legal Responsibilities**

**Post-Test Answer Sheet**

Mail the post-test answer sheet, postmarked no later than April 1, 2017 to:

- Idaho State Board of Pharmacy Home Study CPE Program  
1199 Shoreline Lane, Suite 303  
Boise, Idaho 83720-0067

Include a self-addressed stamped envelope (SASE) for the return of a statement of credit. No statement of credit will be awarded unless a SASE is provided by the pharmacist.

Pharmacists Name: \_\_\_\_\_

Idaho License Number: \_\_\_\_\_

Answers:

- |           |           |
|-----------|-----------|
| 1. _____  | 12. _____ |
| 2. _____  | 13. _____ |
| 3. _____  | 14. _____ |
| 4. _____  | 15. _____ |
| 5. _____  | 16. _____ |
| 6. _____  | 17. _____ |
| 7. _____  | 18. _____ |
| 8. _____  | 19. _____ |
| 9. _____  | 20. _____ |
| 10. _____ |           |

Feedback on this CPE Program:

Ideas for future Board-approved Home Study CPE Programs: