Indiana Pharmacy Inspection Report Questions

Pharmacy General Information

1.1 Type of Inspection
1.5 County
1.6 Telephone number
1.7 District
1.8 Is permit properly displayed?
1.9 Controlled Substance Registration (CSR) number
1.10 Controlled Substance Registration (CSR) status
1.11 Controlled Substance Registration expiration date
1.12 DEA registration number
1.13 DEA registration status
1.14 DEA expiration date
1.15 Qualifying pharmacist name
1.15a - Is qualifying pharmacist listed on pharmacy permit?
1.15b - If no, has pharmacy submitted change in QP form?
1.15c - Qualifying Pharmacists's average weekly hours
1.16 Name of pharmacist-of-record at the time of inspection
1.17 Name of district manager
1.18 E-mail of district manager
1.19 Size of company/number of pharmacies nationwide
1.20 Average number of prescriptions filled daily
1.21 Days and Times of operation?
1.22 Is pharmacy open 24 hours a day?
1.23 Total weekly hours

Absence of Pharmacist

2.1 If institutional pharmacy, how are drugs obtained for patient use when pharmacy is closed?
2.2 If institutional pharmacy, is a pharmacist reconciling drug removal against the order within 24 hours?
2.3 If institutional pharmacy employs after hours pharmacy access, does only one (1) supervisory licensed nurse per shift have access?
2.3a - Is the proper drug information recorded as required by law?
2.3b - Is a copy of the drug order left in the pharmacy?
2.4 Excluding after hours access by a supervisory nurse in an institutional pharmacy, is the licensed area unoccupied when the pharmacist is absent?
2.5 If institutional pharmacy, is there an emergency access policy for closed pharmacy?
2.6 If retail pharmacy, does prescription department have appropriate signage for pharmacist absence?

Staff/Personnel

3.1 How many pharmacists are employed by the pharmacy?
3.1a - Do all pharmacists possess a valid license?
3.1b - Are any of the licensees on probation?
3.1c - Are any of the licenses "Valid to Practice While Being Reviewed"?
3.2 How many technicians are employed by the pharmacy?
3.2a - Do all technicians possess a valid certification?
3.2b - Are any of the certifications on probation?
3.2c - Are any of the certifications "Valid to Practice While Being Reviewed"?
3.2d - What training does the pharmacy require of technicians?
3.2e - Are all technicians wearing a nametag stating their profession?
3.2f - Are all technicians engaging in legally permitted activities
3.3 How many interns are employed by the pharmacy?
3.3a - Do all interns possess a valid registration?
3.3b - Are any of the registrations on probation?
3.3c - Are any of the registrations "Valid to Practice While Being Reviewed"?

3.4 Does the pharmacy have ancillary personnel working in the licensed area?
3.4a - Are ancillary personnel engaging in permitted activities?
3.4b - How many ancillary personnel are working in the licensed area at the time of inspection?
3.5 Are all Blue Cards properly displayed?
3.6 Are the pharmacy techncian files complete?
3.7 Is the technician ratio proper?
3.8 Do technicians properly answer the telephone stating to the caller they are a technician?
3.9 Does staff properly make an offer for counseling?

Pharmacy Equipment/Security

4.1 Is the pharmacy area properly equipped, and include the following?
4.1a - scale
4.1b - proper documentation from Department of Weights and Measures
4.1c - refrigeration
4.1d - sink (proper sewage outlet)
4.1e - hot and cold water
4.1f - stationary / immobile
4.1g - well lit
4.1h - ventilated
4.1i - sanitary
4.1j - proper temperature
4.2 Does refrigerator contain only pharmaceutical products?
4.3 Is the pharmacy properly secured?
4.3a - Does the pharmacy have a motion detector?
4.3b - Does the pharmacy have an alarm?
4.3c - Does the pharmacy have a camera(s)?
4.3d - Does the pharmacy have locking doors?
4.3e - Does the pharmacy have a panic button?
4.3f - Does the pharmacy have a locking cage/gate?
4.3g - List any additional security measures.
4.4 What is the method of entry into the pharmacy?
4.5 Is the drive thru secure?
4.6 When closed, do non-pharmacist personnel have access to the perscription department?
4.7 What are the number of entrances to the pharmacy?

References

5.1 How does the pharmacy access current Indiana pharmacy law?
5.1a - Does the pharmacy have Facts and Comparisons?
5.1b - Does the pharmacy have Remington: The Science and Practice of Pharmacy?
5.1c - Does the pharmacy have PDR (Physician's Desk Reference)?
5.1d - Does the pharmacy have The Merck Manual?
5.1e - Does the pharmacy have on-line subscriptions (Micromedex, Clinical Pharmacology, etc)?
5.1f - If pharmacy uses on-line service, are employees able to access?
5.2 For sterile compouding, does the pharmacy have at least one of the following reference materials?
5.2a - The Handbook on Injectable Drugs
5.2b - The King's Guide to Parenteral Admixtures
5.2c - another Board approved, printed or electronic database

Automated Medication Systems & Automatic Counting

6.1 Does the pharmacy utilize a counting device(s)?
6.1a - Are policies and procedures in place?
6.1b - Are maintenance protocols followed and documented?
6.1c - Are quality assurance protocols followed and documented?

6.1d - Is there proper documentation of drugs dispensed?
6.2 Does the pharmacy utilize a cabinet(s)?
6.2a - Are policies and procedures in place?
6.2b - Are maintenance protocols followed and documented?
6.2c - Are quality assurance protocols followed and documented?
6.2d - Is the cabinet only accessible by authorized personnel?
6.2e - Is there proper documentation of drugs dispensed?
6.3 Does the pharmacy utilize an automated will-call machine?
6.3a - Are policies and procedures in place?
6.3b - Are maintenance protocols followed and documented?
6.3c - Are quality assurance protocols followed and documented?
6.3d - Is there proper documentation of drugs dispensed?
6.4 Does the pharmacy utilize another form of automation?
6.4a - Are policies and procedures in place?
6.4b - Are maintenance protocols followed and documented?
6.4c - Is there proper documentation for drugs dispensed?
6.4d - Are quality assurance protocols followed and documented?

AMS Automated Packaging Systems

7.1 Is the pharmacy properly logging the lot and expiration date for the drugs?
7.2 Are the drugs properly labeled if repackaged?
7.3 Do the drugs properly fit in the bubble pack?
7.4 Does the pharmacy have written policies and procedures of operation?
7.5 Has the automation been inspected and approved by the Pharmacy Board?
7.6 Does the pharmacy have a written plan for recovery in an emergency that includes the following?
7.6a - Planning and preparation for an emergency
7.6b - Procedures for response to an emergency
7.6c - Procedures for notifying the Board, patients, and those they have contracts with
7.6d - Procedures for maintenance and testing of recovery plan
7.7 Does the pharmacy have a written policy for quality assurance that includes the following?
7.7a - Testing and accuracy of the system on a biannual basis
7.7b - Retaining all quality documents for two (2) years
7.7c - Continuous monitoring of the system
7.7d - Reporting recurring errors to the Board
7.7e - What is the protocol for measuring effectiveness of AMS?
7.8 Is all pharmacy personnel with access to AMS trained in the pharmacy's policies and procedures?
7.9 Does the pharmacy have a written program for preventative maintenance of the system?

Drug storage/labeling/destruction

8.1 Are all drugs properly labeled including lot number and expiration or beyond use dating as required?
8.2 Have any drugs in active inventory exceeded expiration or beyond use dating?
8.2a - If yes, provide detailed information.
8.3 How often does the pharmacy check for expired drugs?
8.4 Are all drugs properly stored?
8.5 Does the pharmacy properly maintain a logbook for schedule V controlled substances dispensed without a prescription?
8.6 Does the pharmacy properly maintain a logbook for syringes dispensed without a prescription?
8.7 Does the pharmacy properly maintain a logbook for the sale of ephedrine or pseudoephedrine-containing drugs?
8.7a - How are ephedrine and pseudoephedrine products stored?
8.8 Are samples stored in the licensed pharmacy area?
8.8a - If yes, is storage and distribution in accordance with federal regulations?
8.9 Does the pharmacy have current pseudoephedrine purchasing limits posted?

Dispensing/Records Retention

9.1 Has the data processing system been approved by the Indiana Board of Pharmacy?

9.2 What type of software application does the pharmacy use?

9.3 Does the pharmacy scan a hard copy of prescriptions?

9.4 How does the pharmacy back up files?

9.5 Does the pharmacy have internet access?

9.6 How does the pharmacy maintain daily dispensing records?

9.7 Does the pharmacy retain these records for five (5) years?

9.8 Are HIPAA logs verifying all drugs dispensed that day signed by the pharmacist-in-charge?

9.9 What type of auxiliary procedure does the pharmacy have in place during system down time?

9.10 What type of filling system is used for prescriptions?

9.11 Does the pharmacy maintain digital copies of prescriptions?

9.11a - If yes, where are the records stored?

9.11b - Is the data readily retrievable by the pharmacy?

9.11c - Who may access the data?

Fax/e-prescribing/Transfers

10.1 Is the facsimile machine in the prescription department or a nonpublic area of the pharmacy?

10.1a - Does the facsimile prescription contain all information required by law (IC 25-26-13-2)?

10.1b - Excluding Rule 31 exceptions, have schedule II controlled substances been dispensed pursuant to a faxed prescription?

10.1c - Does original presciption have "valid only if transmitted by facsimile machine" on its face?

10.1d - If the facsimile does not contain required information, has the pharmacist verified the prescription with appropriate documentation (i.e., reduced to writing)?

10.2 Do all e-presciptions contain all of the information required by law?

10.2a - Is the Electronic Data Intermediary (EDI) approved by the Board of Pharmacy?

10.2b - Does the pharmacy maintain policies and procedures to ensure security of all information?

10.2c - Does the manual address the safety of the prescription?

10.2d - Does the manual address the safety of the practitioner's identity and privacy?

10.2e - Does the manual address the safety of the patient's identity, privacy and confidentiality?

10.3 If observed, are pharmacists properly processing transfers?

10.3a - Is prescription pad form completed on transfer?

10.3b - On transfer out, is all required information recorded on the invalidated prescription?

10.3c - On transfer in, is all required information recorded on the transferred prescription?

10.3d - Does the pharmacy print out a "transfer in" and "transfer out" report to confirm it has been transmitted?

Remote Order Entry and Centralized Processing

11.1 Is the pharmacy performing or contracting centralized processing services?

11.2 Do the parties involved have the same owner or a written contract?

11.3 Does the pharmacy have a written policies and procedures manual for performing or contracting CPS?

11.3a - Does the manual address how the parties will comply with federal and state laws and regulations?

11.3b - Does the manual address maintenance records to identify the responsible pharmacist(s) in the dispensing and counseling processess?

11.3c - Does the manual address a mechanism for tracking the prescription drug order during each step in the dispensing process?

11.3d - Does the manual address a mechanism to identify on the prescription label all pharmacies involved in dispensing the prescription drug order?

11.3e - Does the manual address the provision of adequate security to protect the product integrity?

11.3f - Does the manual address the provision of adequate security to prevent the illegal use or disclosure of protected health information?

11.3g - Does the manual address the maintenance of a continuous quality improvement program for centralized prescription processing pharmacy services?

Generic Substitution

12.1 Do substitutions have proper labeling?

12.2 Was the prescription followed and generic properly substituted?
12.3 Did the pharmacist inform the customer of substitution?
12.4 Was prescription dispensed with generically equivalent drug product (A, AB)?
12.5 Did the pharmacist list the name of the manufacturer, distributor or both of the drug actually dispensed?
12.6 What resource does the pharmacy use to determine generic equivalence?

Controlled Substances

13.1 Does the pharmacy maintain a perpetual inventory for controlled substances?
13.1a - If yes, which controlled substance schedules are inventoried perpetually?
13.1b - If no record, date of last biennial inventory.
13.1c - Is inventory within 2 years of last biennial inventory?
13.1d - How is the inventory recorded?
13.1e - Is the inventory signed by the pharmacist with date and time?
13.1f - Is the inventory complete?
13.1g - If incomplete, provide details.
13.2 Which controlled substances are stored in a locked cabinet?
13.2a - What is the method of storage?
13.2b - If method of storage is improper, provide explanation.
13.3 Who is your reverse distributor for destruction of controlled substances?
13.3a - Does the pharmacy properly maintain reverse distribution receipts?
13.4 Are controlled substance records maintained separately from all other pharmacy records?
13.5 Who is your primary Wholesale Drug Distributor for Controlled Substances?

DEA Forms

14.1 Are federal DEA Forms properly kept?
14.2 Does the pharmacy retain proper copies (i.e. Copy 1 or 3) of DEA Form 222?
14.2a - Are records retained for two (2) years?
14.2b - Which type of DEA Form 222 do you use for ordering CII's?
14.2c - Is receipt of CII properly recorded?
14.2d - Are DEA Form 222's properly executed?
14.2e - Has the invoice been signed?
14.2f - Are DEA Form 222's filed separately from other drug order forms?
14.2g - Are invoices attached to DEA Form 222's?
14.2h - Are there discrepancies between order forms and inventory?
14.2i - Are unused DEA Form 222's in a secure location and unsigned?
14.2j - Does the pharmacy have power of attorney that enables employees to place the order?
14.3 Does the pharmacy maintain copies of DEA Form 106 (theft and loss), if applicable?
14.4 Does pharmacy have DEA Form 41 on file if destroyed with witness of special agent or compliance officer?
14.5 Has the pharmacy reported theft of controlled substances to DEA within one (1) business day?
14.6 Have all thefts/losses been reported to the Pharmacy Board?
14.7 How many theft/losses have occurred since the previous routine inspection?

INSPECT

15.1 Is the pharmacy currently reporting all controlled substance prescription data to INSPECT within seven (7) days of dispensing to a patient?
15.1a - If yes, provide verification of previous two submissions. Enter "Automatic Submission", if applicable.
15.1b - If no, has the pharmacy made arrangements with INSPECT to begin reporting?
15.2 After uploading prescription data to INSPECT, does the pharmacy regularly check to see if the system found errant records?
15.2a - If yes, does the pharmacy have an error correction procedure in place?
15.3 How many practitioners within the pharmacy utilize an individual practitioner INSPECT account?
15.4 Is the pharmacy part of a chain or is it a single location?
15.5 How does the pharmacy staff access the INSPECT account?

15.5a - Does the pharmacy (or parent corporation) prohibit staff from accessing INSPECT and/or the Internet?

15.6 If Agent Access, is the practitioner aware of professional liability associated with the INSPECT account?

15.7 How many employees are trained to upload dispensing data to INSPECT?

15.7a - Is there a standard policy in place for uploading?

15.8 Does the pharmacy have procedures to properly dispose hardcopy INSPECT reports?

15.8a - How long are hardcopy INSPECT reports saved before they are destroyed?

15.9 Has the pharmacy copied, faxed, e-mailed or transmitted INSPECT reports in any way?

Sterile Compounding: Policies and Procedures

16.1 What is the highest risk level of sterile compounding performed?

16.2 Does the pharmacy have a policy and procedure manual that includes the information required by 856 IAC 1-30-7?

16.2a - Do the quality assurance procedures cover recall procedures?

16.2b - Do the quality assurance procedures cover storage and expiration dating?

16.2c - Do the quality assurance procedures cover educational procedures for professional and non professional staff, and the patient, if needed, in the case of home administration?

16.2d - Do the quality assurance procedures cover sterile procedures to include monitoring the temperature of the refrigerator, routine maintenance and report of hood certification?

16.2e - Do the quality assurance procedures cover sterility testing or monitoring, if employed, in the case of routine bulk compounding from nonsterile chemicals-high risk level compounding?

16.3 Is the policy and procedure manual reviewed annually by the Pharmacist-in-Charge or the Qualifying Pharmacist and revised if needed?

Sterile Compounding: Engineering Controls

17.1 Does the pharmacy have proper engineering controls based on compounding risk level?

17.2 What type of primary engineering control (PEC) is used?

17.2a - Total number of PEC's used

17.2b - Do the PEC's maintain ISO class 5 environment during in-use activity?

17.5 If using CAI, is it located in an ISO class 7 buffer room?

17.5a - If no, does pharmacy have proper manufacturer documentation that it can maintain ISO class 5 environment during use?

17.7 Is there a cleaning log for the PEC?

17.8 Is there a daily cleaning log for the counters, floors and work surfaces?

17.9 Is there a monthly cleaning log for the walls, ceiling and shelving?

17.10 Is there a cleaning log for the cleaning of BSC between uses if preparing both hazardous and non-hazardous preparations?

17.11 Are there proper containers for disposal of waste?

17.12 Does the pharmacy have records of necessary environmental sample testing maintained for two (2) years?

17.13 Does the pharmacy have total particle counts of each ISO classified area - performed not less than every six (6) months and when PEC is moved?

17.14 Does the pharmacy have volumetric air sampling for microorganisms in each ISO classified area - performed not less than every six (6) months?

17.3 Are PECs located within appropriate secondary engineering controls?

17.4 Do secondary engineering controls (buffer area, ante area) maintain appropriate ISO classification?

17.6 Is appropriate pressure differential or airflow between control environments and the general pharmacy maintained and documented at least every work shitf?

Sterile Compounding: Personnel

18.7 Are personnel engaging in appropriate aseptic technique, garbing, and cleaning/disinfecting at the time of inspection?

18.1 Is there documentation of all personnel preparing sterile pharmaceuticals?

18.2 Is there documentation of all support personnel assisting with sterile pharmaceuticals?

18.3 Are personnel assessments/competencies related to aseptic technique, garbing, and cleaning/disinfecting performed at least annually?

18.4 Does the pharmacy have documentation of training and assessment for all personnel engaging in preparation of sterile pharmaceuticals, including support personnel (housekeeping, environmental services) as related to garbing (assessment: observation, gloved fingertip sampling)?

18.5 Does the pharmacy have documentation of training and assessment for all personnel engaging in preparation of sterile pharmaceuticals, including support personnel (housekeeping, environmental services) as related to aseptic technique (assessment: written test, media-fill test)?

18.6 Does the pharmacy have documentation of training and assessment for all personnel engaging in preparation of sterile pharmaceuticals, including support personnel (housekeeping, environmental services) as related to cleaning/disinfecting procedures (assessment: observation, surface sampling via contact plates/swabs)?

Sterile Compounding: Labeling/Documentation

19.1 Does the label on the dispensed sterile pharmaceutical contain all information required by law?

19.2 Does the label have the additional information required if dispensed at home or outside the facility?

19.3 Is there documentation of patient training by the pharmacists to patients in the home?

19.5 Does the pharmacy have disposable needles, syringes and other supplies needed for aseptic admixture?

19.6 Does the pharmacy have disinfectant cleaning tools and solutions (i.e. sterile 70 % IPA)?

19.7 Does the pharmacy have a hand washing agent with antibacterial action?

19.8 Does the pharmacy have disposable towels or wipes?

19.9 Does the pharmacy have filters and filtration equipment, if utilized?

19.10 Does the pharmacy have a hazardous drug spill kit if hazardous drugs are prepared?

19.11 Does the pharmacy have disposable gowns and gloves?

19.12 Does the pharmacy have a refrigerator with a thermometer and temperature log?

19.13 Does the pharmacy have an infusion device, if appropriate?

19.14 Does the pharmacy have a sink with hot and cold running water, outside of the buffer area?

19.15 Does the pharmacy use a computer system to monitor 797 compliance? (i.e. Simplify 797)

19.4 Are single- and multiple-dose containers (e.g., vials) being properly used and stored with appropriate BUD when applicable?

Non-sterile Compounding

20.1 What is the pharmacy's commitment to non-sterile compounding?

20.2 Does the pharmacy have an affiliation with a professional compounding organization?

20.2a - If yes, which one?

20.3 Does the regular pharmacy software application produce formula sheets?

20.4 Does the pharmacy record lot numbers and expiration dates of compounded prescriptions on the formula sheet?

20.5 Does the pharmacy label compounded pharmaceuticals in accordance with USP 795?

20.6 Does the pharmacy check expiration dates of compounding chemicals?

20.7 Does the pharmacy assign beyond use dates to the compounded pharmaceuticals in accordance with USP 795?

20.7a - If yes, where does the pharmacy obtain it's information?

20.8 Who is responsible for preparing compounded pharmaceuticals?

20.8a - If technicians are preparing compounded pharmaceuticals, how were they trained?

20.8b - Does the pharmacy submit sample compounds to outside testing labs for verification of the product strength and concentration?

Remote Locations (Type II only)

21.1 If hospital (Type II) pharmacy, does pharmacy operate remote location(s)?

21.1a - If yes, how many remote locations?

21.2 Does the remote location have a pharmacist present?

21.3 Is a mechanical device used at the remote location(s)?

21.4 Is the remote location properly secured?

Emergency Drug Kits/Crash Carts

22.1 For hospital pharmacies, do policies and procedures include determination of drugs and quantities to be included?

22.1a - For hospital pharmacies, do policies and procedures include labeling for expiration date?

22.1b - For hospital pharmacies, do policies and procedures include process for restocking the cart(s) or box(es)?

22.1c - For hospital pharmacies, do policies and procedures include security measures to prevent unauthorized access?

22.2 For Type III and Type VI permits, is the list of drugs/quantities included in each kit reviewed at least annually?

22.2a - Does the exterior labeling of the kit(s) meet the requirements of 859 IAC 1-28.1-9?

22.2b - Are all drugs contained in the kit(s) labeled as required by 856 IAC 1-28.1-9?

22.2c - Are controlled substances contained in the kit(s) included in the pharmacy's biennial inventory?

22.2d - Is the nurse responsible for removing drugs from the kit recording the information as required by 856 IAC 1-28.1-9?

22.2e - Is the restocking and resealing of the kit(s) being performed by the pharmacy?

Quality-Related Events/Patient Own Medications

23.1 Have any sentinel events occurred as a result of pharmacy operations since the last inspection?

23.1a - If yes, how many?

23.1b - Are records of analysis and corrective action available for review?

23.2 Have any quality-related events occurred as a result of pharmacy operations since the last inspection?

23.2a - If yes, how many?

23.2b - Are records of analysis and corrective action available for review?

23.3 Are patient's own medications maintained exclusively in the patient care area or at the bedside?

23.4 Upon discharge or death, are such medications handled according to 856 IAC 1-28.1-14?

Special Medications

24.1 Does the pharmacy report the dispensing of clozapine within five (5) days to the CNR?

24.1a - Which method does the pharmacy use for reporting the dispensing of clozapine?

24.2 Has the pharmacy received authorization from the iPLEDGE program to dispense isotretinoin (Accutane)?

24.2a - Is the MedGuide included with the prescription?

24.2b - Does the pharmacy have a record of pharmacist training for the iPLEDGE program?

24.3 Is the authorization number on all prescriptions for Thalomid?

24.3a - Is the pharmacy registered in the STEPS program for dispensing?

24.4- Does the pharmacy dispense any other "special medications" with an RDDS program?

24.5 Does the pharmacy follow proper FDA and manufacturers practices for other "special" medications such as Ticocin?

Immunization Rule

25.1 What type of immunizations do pharmacists administer?

25.2 Does the pharmacy have a doctor's standing order in place for influenza immunizations?

25.2a - If administering per a standing order, does the protocol contain all the information required by law?

25.2b - Is the protocol up to date (renewed annually)?

25.3 Have all pharmacists administering immunizations completed an ACPE accredited training program?

25.4 Is the pharmacist CPR certified?

25.5 Is the pharmacist the only person administering vaccinations within the licensed area?

25.6 What are the procedures in place to address emergency situations?

25.7 Does the pharmacy maintain records of adverse event reporting to the necessary physicians and VAERS as required?

25.8 Does the pharmacy notify the authorizing physician and the individual's primary care physician of immunization administration within 14 days?

Patient Confidentiality (HIPAA)

26.1 How does the pharmacy dispose HIPAA trash?

26.1a - Is the dumpster locked and secure?

26.1b - What is the name of off-site HIPAA vendor?

26.2 Are HIPAA policies posted?

26.3 Are employees HIPAA trained?

26.3a - Is there documentation of training?

26.4 Does the pharmacy have policies and procedures in place to protect health information?

26.5 Has the pharmacy had a complaint filed with DHHS?

Prescription Audit

27.1 Do all Controlled Substance prescriptions meet Indiana security feature requirements?

27.2 Do all Controlled Substance prescriptions contain all information required by law?