

Indiana Tele-Pharmacy Inspection Report Questions

Pharmacy General Information

1. Type of Inspection
- 1.5 County
- 1.6 Telephone
- 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 QP listed on pharmacy permit?
- 1.15b If no, has pharmacy submitted change in QP form?
- 1.15c Qualifying Pharmacist's average weekly hours
- 1.16 Name of pharmacist-of-record at the time of inspection
- 1.17 Name of Qualifying Pharmacist's pharmacy supervisor
- 1.19 Size of company/number of pharmacies nationwide
- 1.20 Average number of prescriptions filled daily
- 1.21 Dates & Times of operation
- 1.22 Is pharmacy open 24 hours a day?
- 1.24 Does the pharmacy have a sign visible to public identifying location is a remote dispensing facility?
- 1.24a Does sign indicate services are supervised remotely?
- 1.24b Does sign identify name and address of supervising pharmacy?
- 1.24c Does sign include disclosure of mandatory counseling for new drugs or devices dispensed?
- 1.24d Does sign indicate whether counseling is available for refills?
- 1.24e Does sign indicate facility is under continuous, recorded video surveillance?

Absence of Pharmacist (Institutional)

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?
- 3.2g If no pharmacist present, list name of PTCB-certified technician with 2,000 hours of experience.
- 3.2h If no pharmacist present, are there any technicians-in-training working?
- 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 registration 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 If yes, how many ancillary personnel are working in the licensed area at the time of inspection?
- 3.5 Are the technician files complete?

- 3.6 Is the technician ration proper?
- 3.7 Do technicians properly answer the telephone stating to the caller they are a technician?
- 3.8 Does the staff properly make an offer for counseling?
- 3.8a Does the pharmacy have a patient counseling area?

Pharmacy Specifications (Equipment, Security)

- 4.1 Is the pharmacy area properly equipped including the following?
 - 4.1a Scale
 - 4.1b Proper documentation from Department of Weights and Measures
 - 4.1c Refrigerator
 - 4.1d Sink (proper sewage outlet)
 - 4.1e Hot and cold water
 - 4.1f Stationary
 - 4.1g Well lit
 - 4.1h Ventilated
 - 4.1i Sanitary
 - 4.1j Proper temperature
- 4.2 Does the refrigerator contain only pharmaceutical products?
- 4.3 Is pharmacy properly secured to protect and deter theft and diversion of controlled substances?
 - 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 Other
 - 4.3h Does the pharmacy record entrance and exit of individuals?
 - 4.3i Does qualifying pharmacist periodically review record of entries?
 - 4.3j Does pharmacy use two-factoring credentials for employee entry?
- 4.4 What is the method of entry into the pharmacy?
- 4.5 What are the number of entrances to the pharmacy?
- 4.6 If supervising pharmacy is closed and remote dispensing facility is open, is a pharmacist present?

References

- 5.1 How does the pharmacy access current Indiana pharmacy law?
 - 5.1f If pharmacy uses on-line references, are employees able to access?
- 5.2 For sterile compounding, does pharmacy have at least one of the following reference materials?
 - 5.2a The Handbook on Injectable Drugs
 - 5.2b The King Guide to Parenteral Admixtures
 - 5.2c another board-approved, printed or electronic database
- 5.3 If pharmacy dispenses veterinary medications, do they have the appropriate references?

Automated Medication Systems & Automatic Counting Devices

- 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) i.e. Pyxis, Omnicell, Proscript?
 - 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 Are quality assurance protocols followed and documented?
- 6.4d Is there proper documentation of drugs dispensed?

AMS

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 info.
- 8.3 How often does the pharmacy check for expired drugs?
- 8.4 Are 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 have a NPLEX account for PSE sales?
- 8.7a How are ephedrine and pseudoephedrine products stored?
- 8.8 Are samples stored in the license pharmacy area?
- 8.8a If yes, is storage and distribution in accordance with federal regulations?
- 8.9 If technician accepts delivery of drugs, does a pharmacist ensure technician has accurately restocked the drugs?

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 hard copy 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 HIPPA 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 filing 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?
- 9.12 Does the electronic recordkeeping system allow electronic records to be accessible from both the supervising pharmacy and the remote dispensing facility?
- 9.13 Does the electronic recordkeeping system distinguish between prescriptions filled at the supervised pharmacy and the remote dispensing facility?
- 9.14 Does pharmacist verify each prescription prior to dispensing using an electronic verification system?

Fax/e-prescribing/Transfers

- 10.1 Is the fax 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, are CII's dispensed only upon receipt of original written prescription?
- 10.1c Does pharmacy validate the origin of faxed order/prescription?
- 10.1d If no, has pharmacist reduced to writing to comply with requirements of law?
- 10.2 Do all e-prescriptions contain all of the information required by law?
- 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

Generic Substitution

Controlled Substances

- 13.1 Does the pharmacy maintain a perpetual inventory for controlled substances?
- 13.1a If no, record of the last biennial inventory.
- 13.1b Is inventory completed within 2 years of last biennial inventory?
- 13.1c How is the inventory recorded?
- 13.1d Is the inventory signed by the pharmacist with date and time?
- 13.1e Is the inventory complete?
- 13.1f If incomplete, provide details
- 13.2 What 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?
- 13.4a Are controlled substance dispensing records maintained on-site or in a centrally approved located?
- 13.4b If records are not maintained on-site, did the remote dispensing facility receive Board approval to centrally store records?
- 13.5 List all the Wholesale Drug Distributor/supplier(s) for controlled substances.
- 13.6 Does the pharmacy purchase legend &/or controlled substances from a 503B facility?
- 13.6a If so, name of facility and products.
- 13.7 Does supervising pharmacist check INSPECT prior to verification of finished prescription and counseling?

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 years?
- 14.2b Which type of DEA Form 222 do you use for ordering CII's?
- 14.2c Is receipt of CII properly recorded or electronically documented?
- 14.2d Are DEA Form 222's properly executed?
- 14.2e If applicable, are CSOS orders verified?
- 14.2f Has the invoice been signed?
- 14.2g Are DEA Form 222's filed separately from other drug order forms?
- 14.2h Are invoices attached to DEA Form 222's?
- 14.2i Are there discrepancies between order forms and inventory?
- 14.2j Are unused order forms in a secure location and unsigned?
- 14.2k 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 the pharmacy have DEA Form 41 on file?
- 14.5 Has the pharmacy reported theft of controlled substances to DEA within one business day?
- 14.6 Have all theft/losses been reported to the Board upon discovery (within 1 pharmacy business day)?

INSPECT

- 15.1 Is the pharmacy currently reporting all controlled substance prescription data to INSPECT daily or by the end of the next business day?
- 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?
 - 15.2b If no, has the pharmacy resubmitted the records?
- 15.3 Is the pharmacy aware of the laws/rules permitting practitioners to use/access INSPECT to obtain controlled substance prescription information?
- 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?
- 15.6 If agent or delegate 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?

Sterile Compounding: Policies and Procedures

Sterile Compounding: Engineering Controls

Sterile Compounding: Personnel

Sterile Compounding: Labeling/Documentation

Non-sterile compounding

Remote Locations (Type II only)

Emergency Drug Kits/Crash Carts

Sentinel and Quality-Related Events/Patient's Own Medications (Institutional Pharmacies)

Special Medications

- 24.1 Does the inpatient pharmacy report the dispensing of Clozapine with seven (7) days to the REMS program?
 - 24.1a Does the retail/outpatient pharmacy obtain a pre-dispense authorization (PDA) from the REMS program before dispensing?
- 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)?

Immunization

- 25.1 Does the pharmacy administer immunizations?
- 25.2 Does the pharmacy have a physician's standing order in place for influenza immunizations?
 - 25.2a If administering per a standing protocol, does the protocol contain all the information required by law?
 - 25.2b Is the protocol up to date (renewed annually)?

- 25.3 What ACPE accredited training program has the pharmacist completed?
- 25.4 Is the pharmacist CPR certified?
- 25.5 Is the pharmacist the only person administering the vaccine?
- 25.6 What are the procedures in place to address emergency situations?
- 25.7 Are adverse events being reported to VAERS (Vaccine Adverse Events Reporting Systems)?
- 25.8 Does the pharmacy notify the authorizing physician and primary care physician within 14 days?

Patient Confidentiality (HIPPA)

- 26.1 How does the pharmacy handle HIPPA trash?
- 26.1a Is the dumpster locked and secure?
- 26.1b What is the name of the off-site HIPPA vendor?
- 26.2 Are HIPPA policies available electronically or posted?
- 26.3 Are employees HIPPA 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 CS prescriptions meet Indiana security feature requirements?
- 27.2 Do all CS prescriptions contain all information required by law?

Communication Systems

- 28.1 Is the A/V communication system with the supervising pharmacy working properly?
- 28.1a If not, is the facility closed, or if not closed, is a pharmacist present?
- 28.2 Does the facility retain surveillance recordings for at least 45 days?
- 28.3 Does qualifying pharmacist maintain constant visual supervision and auditory communication?
- 28.4 Does facility have a video monitor to identify and communicate with patients?
- 28.4a Is the monitor high definition and at least 12" wide?
- 28.4b Does the monitor provide direct visual contact between the pharmacist and patient?
- 28.4c Is the monitor HIPPA compliant?