Rxperts

Pharmacy inspection checklist

A working checklist for the areas a Board of Pharmacy surveyor, a DEA investigator or a PBM auditor reviews. Give every item an owner, a due date and a way to verify it. If it is not documented, it did not happen.

Licenses, registrations and postings

- [ ] Pharmacy license and permits current and displayed
- [ ] Pharmacist and technician licenses or registrations current, with continuing education met for renewal
- [ ] Pharmacist-in-charge designation current with the board
- [ ] DEA registration current and matching your physical address
- [ ] Required state and federal postings displayed
- [ ] Intern and extern supervision requirements met and on file

Premises and security

- [ ] Prescription department clean and organized, with no medication stored on the floor
- [ ] Adequate lighting where prescriptions are verified, counseled and stored
- [ ] Prescription department clearly defined, with access limited to authorized staff
- [ ] Sink with hot and cold running water in the prescription department
- [ ] Current drug information references available, and staff know where they are
- [ ] Emergency exits and fire extinguishers clear; no non-pharmacy items in the department
- [ ] Pharmacy locked and alarmed when no pharmacist is present
- [ ] Controlled substances kept in a safe or locked cabinet; key holders documented
- [ ] Security cameras cover the department and work

Temperature and stock

- [ ] Room temperature logged daily, including weekends and holidays (typically 20 to 25 C, 68 to 77 F)
- [ ] Refrigerator logged daily (typically 2 to 8 C, 36 to 46 F), and the freezer if you have one
- [ ] Every out-of-range reading has a documented corrective action and a note on what happened to the stock
- [ ] Expired medication pulled from the shelves monthly, with the removal documented
- [ ] Stock bottle labels legible and undamaged

Staffing

- [ ] Pharmacist-to-technician ratio met on every shift, breaks included, under your state rules
- [ ] Current week schedule and past staffing records ready to show
- [ ] Every technician on duty registered or certified with the board

Prescription records and counseling

- [ ] Filing system (three-file, or two-file with marking) meets your state rules
- [ ] Any prescription can be produced quickly on request, paper or electronic
- [ ] Prescriptions filed daily, with no backlog
- [ ] Written prescription record retention policy that meets your state minimum
- [ ] Offer to counsel, and counseling where required, documented the way your state requires
- [ ] Counseling area gives the patient privacy

Controlled substances

- [ ] Biennial inventory taken at least every two years (within two years of the previous one), recording the date and whether it was taken at opening or close of business
  21 CFR 1304.11
- [ ] Schedule II inventories and records kept separate from all other records
  21 CFR 1304.04(h)
- [ ] Schedule III to V inventories and records kept separate, or readily retrievable from your ordinary business records
  21 CFR 1304.04(h)

- [ ] Written process for investigating and resolving prescription red flags, with each resolution documented
  21 CFR 1306.04(a)
- [ ] Perpetual inventory reconciled daily, if you keep one

HIPAA privacy and security

- [ ] Risk analysis documented, dated and scheduled for its next update
  45 CFR 164.308(a)(1)
- [ ] Signed business associate agreement for every vendor that touches PHI, reviewed yearly
- [ ] Workstations with PHI access lock automatically
- [ ] Pharmacy system audit logs enabled and reviewed monthly
- [ ] Backup and recovery tested, not assumed
- [ ] Label printer output not visible to unauthorized people
- [ ] PHI disposal process documented, with certificates of destruction
- [ ] Breach response plan written, tested and reachable by staff
  45 CFR 164.400-414

Training, FWA and exclusion screening

- [ ] HIPAA training records for every employee, plus any FWA and compliance training your PBM contracts require: name, topic, date, trainer and signed attestation
- [ ] Current Policies and Procedures manual
- [ ] Designated compliance officer and a written compliance program
- [ ] Every employee, contractor and vendor screened against the OIG exclusion list, monthly as best practice, with results documented
  42 USC 1320a-7

PBM audit readiness

- [ ] Signature logs with dates that match dispensing records
- [ ] Documentation that supports every DAW code billed
- [ ] Compound claims backed by formulation records, ingredient NDCs and lot numbers
- [ ] Usual and customary pricing consistent and defensible

- [ ] Records filed so a PBM records request can be answered within your contract deadline

Compliance calendar

Daily	Temperature logs; controlled substance perpetual inventory (if kept); will-call bin review
Weekly	Prescription filing review; staff huddle on compliance topics
Monthly	OIG exclusion screening; expired medication removal; dispensing data review; HIPAA audit log review
Quarterly	Policy and procedure review; mock inspection of the physical plant; business associate agreement check
Yearly	Risk analysis update; HIPAA training, plus FWA and compliance training where PBM contracts require it; license and CE verification; PBM contract and documentation review
Every 2 years	DEA biennial inventory, within two years of the previous one

Want a second set of eyes? In an Rxperts mock inspection, a compliance consultant walks your pharmacy the way an inspector would, then gives you a risk score and a prioritized list of fixes.

rx-perts.com/mock-inspection

General information, not legal advice. Requirements vary by state and by contract: confirm each item against your state Board of Pharmacy rules and current DEA, HHS and CMS guidance.