

The National Association of Boards of Pharmacy (NABP) developed this inspection form for sole use by NABP and its member boards of pharmacy for inspection of facilities licensed by a member board. Disclosure of the form to or use of the form by a third party, other than a facility being inspected by NABP or a member board, is strictly prohibited without NABP's prior written permission or unless required by state law.

**National Association of Boards of Pharmacy®
Universal Inspection Form**

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>. An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: 0

Inspection Date: 01/00/1900

		Finding	Notes
General Pharmacy			
1.00	Is the PIC (or pharmacy manager/director) present for the inspection? <i>If no, list the pharmacist on duty.</i>		
2.00	Is the PIC employed full-time at the pharmacy? <i>List the number of hours worked per week onsite.</i>		
3.00	Are there any other businesses located at this address? <i>If yes, note type of business and name.</i>		
4.00	Does the pharmacy have any other websites? <i>Provide list of other names/URLs.</i>		
4.01	Does the pharmacy hold .pharmacy verification?		
5.00	Do any other websites link to the pharmacy website (such as a provider, or other affiliate)? <i>If yes, list.</i>		
6.00	Does the pharmacy allow patients to securely enter/update profile and medical information through the website (such as through a secure patient portal)?		
7.00	Are patients able to order or refill prescriptions through the website? <i>If yes, describe.</i>		
8.00	Are photographs allowed during the inspection (no PHI)?		
9.00	List of additional personnel interviewed as part of the inspection, including name and title:		
Types of Practice Additional Questions			
If any part of a question is no, enter "No" and explain the observation.			
10.00	If the pharmacy mails or delivers filled prescriptions (patient specific, labeled with patient name when it leaves the pharmacy), are any of the deliveries to a provider or facility for administration to the patient? <i>If yes, indicate volume or percentage of deliveries going to a provider or facility in this state, and volume or percentage of deliveries going to a provider or facility in other states.</i>		
11.00	Does the pharmacy provide prescription products to a provider or facility for "office use" (not pursuant to a prescription received prior to delivery, not patient specific, not labeled with the patient name)? <i>If yes, indicate volume or percentage provided to a provider or facility within this state, and volume or percentage provided to a provider or facility in other states.</i>		
12.00	Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributor (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?		
13.00	If yes, is the percentage of product distributed at wholesale to providers or facilities within this state less than 5%? <i>Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.</i>		

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14.00	If yes, is the percentage of product distributed at wholesale to providers or facilities in other states less than 5%? <i>Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.</i>		
General Operations and Licensure If any part of a question is no, enter "No" and explain the observation.			
15.00	Are pharmacy licenses, permits, and registrations (state, controlled substance, DEA, etc) posted in customers' view and current? <i>If no, provide details such as closed-door pharmacy, expired licenses, etc.</i>		
16.00	Is the most recent board of pharmacy inspection report available for review? <i>Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.</i>		
17.00	Were any deficiencies noted? <i>Indicate the deficiencies and note whether they were corrected.</i>		
18.00	Does the pharmacy hold ANY wholesale, distributor, or manufacturer licenses? <i>Document information in the license grid above for Resident State and in the Notes for Non-Resident States.</i>		
19.00	Has this pharmacy been inspected by any other state for which it holds a license? <i>If yes, note the state and the date of the inspection and frequency of inspections by other states.</i>		
20.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? <i>If yes, note the exemption or restriction.</i>		
21.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? <i>If yes, note the waiver or variance.</i>		
22.00	Does the pharmacy have any additional restrictions, limitations, or waivers with regards to any federal licenses or registrations (FDA, DEA, etc)? <i>If yes, note the agency and additional item.</i>		
23.00	Has the pharmacy been inspected or visited by the DEA? <i>If yes, indicate the inspection/visit date and note any deficiencies. Also note how frequently the pharmacy is inspected/visited by the DEA.</i>		
24.00	Has the pharmacy been inspected by the FDA? <i>If yes, indicate the inspection date and note any deficiencies, significant correspondence, or if a "483" was issued and date, and response and date. Also note how frequently the pharmacy is inspected by the FDA.</i>		
25.00	Does the pharmacy hold any accreditations or certifications? <i>If yes, indicate which and collect most recent date of survey.</i>		
26.00	Has the pharmacy held any accreditations or certifications in the past that they no longer hold? <i>Provide a list and the reasons for such.</i>		

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27.00	Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc? <i>Verify that the lab director is current (usually the PIC is the lab director named). If yes, record the Clinical Laboratory Improvement Amendments (CLIA) waiver information, expiration date, and the name of lab director listed.</i>		
28.00	Does the pharmacy maintain all required records, including but not limited to prescription files and invoices on site? <i>Record how long records are kept. If not on site, where?</i>		
28.01	Are written and verbal prescriptions (reduced to writing) kept on site for the entire retention period? <i>If not, explain including how long they are stored on site?</i>		
28.02	Are electronic prescriptions (such as fax, e-scripts) kept on site for the entire retention period? <i>Describe how they are kept (electronically or printed and kept in hard copy).</i>		
28.03	Are all dispensing records (such as refills, verifications, DUR overrides) kept on site for the entire retention period? <i>Describe how they are kept (electronically or printed and kept in hard copy).</i>		
28.04	Are there systems in place to prevent a pharmacy record from being deleted after the prescription has been dispensed? <i>Describe how they are kept (electronically or printed and kept in hard copy).</i>		
28.05	If record are stored off site are they secure in a HIPAA compliant manner and readily retrievable?		
29.00	Is there a statement in the P&P, or are other means used to ensure that the most stringent laws/regulations are followed? <i>Describe system details.</i>		
Personnel			
<i>If any part of a question is no, enter "No" and explain the observation.</i>			
30.00	Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations with the board current and in good standing? <i>Describe how this is documented.</i>		
31.00	Is there a process for periodic verification of validity of licenses? <i>Describe the process.</i>		
32.00	If pharmacists are providing patient services that require additional training or certification, are they appropriately trained and certified? <i>(Immunization, CPR, MTM, etc.). Mark NA if no patient services that require additional training/certification. If yes, list certifications and if current?</i>		
33.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio? <i>Mark N/A if not required by resident state. Indicate ratio used and the maximum number of staff who work at the same time.</i>		

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Facility and Security			
If any part of a question is no, enter "No" and explain the observation.			
34.00	Does the pharmacy have a working security/alarm system in place? <i>If yes, describe.</i>		
35.00	Are Schedule II controlled substances secured in a locked cabinet or safe? <i>If not, describe how controlled substances are secured or stored.</i>		
36.00	Are there contingency plans in the event the pharmacy cannot be secured? <i>Describe how the drug products will be secured and handled.</i>		
37.00	Is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume? <i>Look for clutter, or crowded counters or stacks of prescriptions to be checked. If no, document with photo.</i>		
37.01	Is the working area well lit and free of tripping hazards? <i>If no, document with photo.</i>		
37.02	Is there a sink with hot and cold running water?		
37.03	If the pharmacy destroys prescription products on site (such as expired, damaged, recalled, etc), do they appropriately document the destruction? <i>View destruction logs. Mark NA if no destruction on site.</i>		
37.04	Does the pharmacy return prescription products to the manufacturer, distributor, or send to a reverse distributor for destruction? <i>If yes, indicate name of reverse distributor used.</i>		
37.05	Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, or hazardous drug compounding waste. <i>If yes, indicate how often the bin is emptied/collected and the vendor used.</i>		
38.00	Does the pharmacy have a private area for patient counseling and providing patient services? <i>Describe.</i>		
39.00	Is temperature in the drug storage area maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements? <i>Describe. Record the temperature at the time of inspection.</i>		
39.01	Is temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max? Temperature records are maintained. <i>If yes, describe the process</i>		
39.02	Are excursion action plans in place including evaluating excursion effects on drug product integrity?		
40.00	Are the refrigerator and freezer restricted to drug products only (no food)?		
41.00	Does the pharmacy have a process for how the refrigerator temperature is monitored for excursions 24/7? <i>If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?</i>		

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41.01	Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46 °F) or as specified by FDA approved labeling for drug product storage? <i>Record the temperature of the refrigerator at the time of inspection.</i>		
42.00	Does the pharmacy have a process for how the freezer temperature is monitored for excursions 24/7? <i>If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?</i>		
42.01	Is the temperature in the freezer within the USP range (between -25° to -10°C or -13° to 14 °F) or as specified by FDA approved labeling for drug product storage? <i>Record the temperature of the freezer at the time of inspection.</i>		
43.00	Are there contingency plans in the event of power outage or refrigerator/freezer failure? <i>Describe process.</i>		
44.00	Are there contingency plans in the event of heating or air conditioning failure? <i>Describe processes.</i>		
45.00	Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?		
46.00	Does the pharmacy utilize any automated apparatuses for prescription processing/counting (such as robotics, Baker cells, etc)? <i>List numbers and types.</i>		
46.01	If yes, do they have and follow policies and procedures addressing cross-contamination and identification of drug products?		
Product Receipt and Inventory If any part of a question is no, enter "No" and explain the observation.			
47.00	Does the pharmacy have a documented process for establishing sources (vendors) of prescription drugs? <i>Describe.</i>		
47.01	Does the pharmacy purchase all prescription drugs directly from the manufacturer?		
47.02	Does the pharmacy purchase (obtain) prescription drugs from other pharmacies? <i>If yes, list pharmacy source information, and circumstances leading to the purchase.</i>		
47.03	Does the pharmacy purchase (obtain) prescription drugs from wholesale distributors (non-manufacturer sources)? <i>List non-manufacturer sources.</i>		
47.04	Does the pharmacy require wholesale distributor sources to purchase prescription drugs directly from the manufacturer? <i>If yes, how is this verified?</i>		
47.05	Does the pharmacy purchase drugs from wholesale distributors that purchased the drug from other wholesale distributors? <i>If yes, Describe the due diligence steps to determine the source's legitimacy and legitimacy of the drugs sold by the vendor. (For instance, does the pharmacy examine transaction histories and limit the number of movements of drugs between wholesale distributors, and look for pharmacies in the supply chain?)</i>		

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47.06	Does the pharmacy determine that all sources listed on transaction histories have requisite state licensing? <i>If yes, describe the process.</i>		
47.07	Does the pharmacy determine that all sources listed on transaction histories have reported to FDA's Wholesale Distributor database? <i>If yes, describe the process.</i>		
47.08	Does the pharmacy have a process to handle suspect and illegitimate product investigations? <i>If yes, describe the process.</i>		
47.09	Has the pharmacy conducted any suspect or illegitimate product investigations? <i>If yes, describe the details, including the drug, circumstances, outcome, and identification of agencies to whom reported.</i>		
47.10	Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement, also known as 3T data) is received at the same time or before the product is received? <i>Examine recent purchases to determine if the pharmacy is receiving and maintaining 3T data for a minimum of 6 years.</i>		
47.11	Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting?		
48.00	Does the pharmacy utilize paper DEA-222 forms to procure Schedule II substances? <i>If yes, how are they secured? Who has the authority (Power of Attorney) to sign the DEA-222 forms?</i>		
49.00	Does the pharmacy utilize CSOS (electronic Schedule II ordering) to procure Schedule II substances? <i>If yes, who can place orders in CSOS?</i>		
50.00	Is the receipt of Schedule II orders documented appropriately? <i>DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification.</i>		
51.00	Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices signed/initialled and dated upon receipt and every item checked in?		
52.00	Are all orders received when the pharmacy is open? <i>Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.</i>		
53.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? <i>If so, describe which products and from where they are purchase (collect name and license of other entity).</i>		
54.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? <i>Describe (for example, inventory or shrink report tools used, perpetual inventory in computer, etc).</i>		
54.01	Are incidents of diversion or resignation/termination of personnel for cause reported? <i>Indicate agencies/law enforcement to whom reports are made.</i>		
55.00	Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)?		

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56.00	Is the Schedule II perpetual inventory log reconciled regularly? <i>Indicate how often the Schedule II controlled substances are counted. View the perpetual log and verify that reconciliation is taking place.</i>		
57.00	Is the most recent complete controlled substances inventory available for review? <i>Indicate the date of the last inventory and frequency taken (minimum every two years).</i>		
57.01	Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc)?		
58.00	Does the pharmacy stock and sell OTC pseudoephedrine (and/or ephedrine) products? If yes, indicate if the sale is recorded electronically or manually in a logbook.		
58.01	Are these products mailed, sent, or delivered into other states? <i>View logs. If yes, list the other states.</i>		
59.00	Does the pharmacy stock and sell other OTC restricted products for which ID is required and a log kept of the sale? <i>If yes, indicate product types.</i>		
59.01	Are these products mailed, sent, or delivered into other states? <i>View logs. If yes, list the other states.</i>		
60.00	Are outdated, damaged, or recalled products segregated? <i>If yes, how often does the pharmacy check for out-of-date products? Does it include OTC products?</i>		
60.01	Are all drugs within active-stock within expiration date? <i>Examine shelves, refrigerator and freezer.</i>		
60.02	How often is active-stock examined for drugs past the expiration date?		
61.00	Does the pharmacy prepackage bulk containers of prescription medications into smaller containers for ease of use? <i>What BUD is used on the prepackaged container?</i>		
62.00	Does the pharmacy prepack multiple drugs into a single container for compliance packaging? <i>What BUD is used on the prepacked containers?</i>		
63.00	Does the pharmacy return to stock prescription drugs that were filled but never picked up?		
63.01	If yes, are they maintained in the appropriate container, with PHI removed and BUD adjusted?		
Prescription Processing			
If any part of a question is no, enter "No" and explain the observation.			
64.00	Patient Profile: Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver? <i>Indicate who enters patient profile data into the computer system and how often it is updated?</i>		
64.01	If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include the species, and name of the animal/owner as required by resident state law? <i>Describe how it is indicated in the computer system that the patient is an animal? And how is it indicated in the system the prescription is a veterinary prescription?</i>		

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65.00	Prescription: Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders? <i>Staff is familiar with detecting fraud in hard copy, faxed, verbal, and electronic prescriptions.</i>		
65.01	Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent? <i>Describe the steps and reporting process.</i>		
65.02	Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship? <i>Describe. Do the processes include comparing the physical addresses of the patient and prescriber?</i>		
65.03	Does the pharmacy have electronic prescription capability? <i>Indicate whether it is for non-controlled substances, controlled substances, or both.</i>		
65.04	If the pharmacy accepts electronic prescriptions for controlled substances, are they in compliance with federal regulations?		
66.00	Accuracy: Is the accuracy of the information entered into the computer system verified (patient information and prescription information)? <i>Indicate how and by whom.</i>		
67.00	DUR: Does staff conduct prospective DUR prior to the dispensing of a medication or product? <i>Describe at what point in the process does the DUR take place?</i>		
67.01	Does the DUR include: <ul style="list-style-type: none"> • drug-drug interaction (Prescription and OTC), • drug-allergy interaction, • therapeutic duplication, • under- or over-utilization (including clinical abuse/misuse), • disease state or condition contraindication, • Incorrect dosage or duration of therapy, and • gender or age related contraindications. <i>Indicate if there are other parameters routinely included in the DUR.</i>		
67.02	In addition to the pharmacy DUR software, does the pharmacy staff obtain other information to use in the DUR process? <i>Describe.</i>		
67.03	Does the pharmacy have adequate resources/references related to the type of pharmacy practice it operates?		
67.04	Does the pharmacy report required data to the state PMP (in this state and the other states in which the pharmacy is licensed)? <i>Describe.</i>		
67.05	Does the pharmacy access state PMP/PDMP data for specific patients? <i>Verify there is a policy regarding access and follow-up or reporting and that pharmacist can access the PMP data.</i>		
67.06	Are DUR overrides/bypasses documented? <i>Indicate how the override is documented and who has override capability.</i>		
67.07	Is the DUR process performed electronically by the computer system? <i>Identify integrated drug database used.</i>		

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67.08	If the DUR is manual, is there a system to document: <ul style="list-style-type: none"> • How manual DUR is performed • Specific issues that were identified • Pharmacist that considered the identified issues and gave the okay to proceed 		
67.09	If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database integrated into the computer system for electronic DUR? <i>List veterinary product electronic database used. If not, list compendia used for performing manual DUR.</i>		
68.00	Are filled prescriptions verified for accuracy prior to dispensing? <i>Indicate process, by whom, and how documented.</i>		
69.00	Are filled prescriptions appropriately labeled? <i>Describe.</i>		
70.00	Confidentiality: Does the system have adequate safeguards to prevent a user from performing functions under a different user account or beyond what they are authorized to perform? <i>Password protected, access limited by job type, access revoked as appropriate such as upon termination. Record name/brand of pharmacy computer system used.</i>		
70.01	Does the pharmacy destroy PHI including labeled prescription vials?		
71.00	Mail/Delivery: If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?		
72.00	Off-Site Processes: Are any portions of the prescription processing (in the questions below) performed at a different location? Note: Please ask each question below to verify.		
72.01	If yes, is the other location under common ownership? <i>If not commonly owned, explain if there is a central fill/shared services or other agreement in place. Record the name and license number for the other location.</i>		
72.02	If yes, is that location in a different state than this facility? <i>If so, explain.</i>		
72.03	If yes, are there policies and procedures for identifying who is responsible for each step of prescription processing?		
73.00	Off-Site Inventory: Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? <i>Note name(s) of facilities or entities.</i>		
73.01	Do the emergency kits contain any compounded products? <i>If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?</i>		
74.00	Off-Site Inventory: Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc? <i>Note types and locations.</i>		

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74.01	If yes, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? <i>Provide details.</i>		
74.02	Do the automated dispensing devices contain any compounded products? <i>If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?</i>		
Patient Counseling and Communication If any part of a question is no, enter "No" and explain the observation.			
75.00	Does the pharmacist provide counseling for all <u>new</u> prescriptions picked up at the pharmacy (proactively, no "offer")?		
75.01	Is an "offer" to counsel made for all <u>new</u> prescriptions picked up at the pharmacy? <i>Indicate who makes the "offer".</i>		
76.00	Does the pharmacist provide counseling for all <u>refilled</u> prescriptions picked up at the pharmacy (proactively, no "offer")?		
76.01	Is an "offer" to counsel made for all <u>refilled</u> prescriptions picked up at the pharmacy? <i>Indicate who makes the "offer".</i>		
77.00	Does the pharmacist provide counseling for <u>refilled</u> prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist (proactively, no "offer")?		
77.01	Is an "offer" to counsel made for all <u>refilled</u> prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist? <i>Indicate who makes the "offer".</i>		
78.00	Is patient counseling provided for <u>delivered</u> prescriptions? <i>Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.</i>		
79.00	Is patient counseling provided for <u>mailed</u> prescriptions? <i>Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.</i>		
80.00	Are patient package inserts (PPIs) provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc)? <i>Describe how.</i>		
81.00	Are MedGuides provided with every fill and refill of medications for which they are required (such as NSAIDS, antidepressants, etc)? <i>Describe how.</i>		
82.00	Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Confirm that procedures are in place. <i>List programs (such as iPledge for isotretinoin, or Tikosyn).</i>		
83.00	Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? <i>Describe how.</i>		
84.00	Do patients have 24-hour access to a pharmacist? <i>Note: may not be required by the resident state. Describe how (such as posted contact information and hours of operation).</i>		

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Universal Inspection Form**

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>. An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: 0

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		Finding	Notes
85.00	Are processes in place to handle a drug recall?		
86.00	Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?		
86.01	Does the take-back program include controlled substances?		
86.02	Does the pharmacy have a modified DEA registration for controlled substance take-back? <i>If yes, list.</i>		
Quality Assurance/Quality Improvement Program			
If any part of a question is no, enter "No" and explain the observation.			
87.00	Is there a documented continuous quality improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing quality related events (QREs)? <i>If yes, list who oversees the program.</i>		
87.01	Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form. <i>Indicate if hard copy, electronic, or both.</i>		
87.02	"Quality-Related Event" (QRE) is defined to mean any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication including (but not limited to): <ol style="list-style-type: none"> 1. a variation from the prescriber's prescription drug order such as incorrect drug, strength, form, or patient; or inadequate or incorrect packaging, labeling, or directions; 2. a failure to identify and manage over-utilization or under-utilization; therapeutic duplication; drug-disease contraindications; drug-drug interactions incorrect drug dosage or duration of drug treatment; drug-allergy interactions; or clinical abuse/misuse. 3. packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, or the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy. 		
87.03	There is documentation of initial/ongoing (at least yearly) review and training of all pharmacy employees on the CQI program and processes. <i>For example, may be formal training or reviewed at a yearly meeting.</i>		
88.00	Documentation of QREs starts as soon as possible, but no more than three days, after determining their occurrence. <i>Indicate if documentation/forms are hard copy or electronic.</i>		
88.01	Documentation includes all the pertinent data about the prescription involved including personnel involved at each step.		
88.02	Documentation includes documenting the type of QRE details and how/who discovered the QRE.		
88.03	Documentation includes possible contributing factors such as day and time the QRE occurred, number of pharmacists and technicians on duty, prescription volume that day, equipment failure, or other factors affecting work-flow at the time.		

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		Finding	Notes
88.04	Documentation includes steps taken to remediate including communications with the patient and the provider, and if the medication was ingested, disposition of the patient.		
89.00	QRE data collected is analyzed to assess causes and any contributing factors (root cause). <i>Indicate who performs the analysis and frequency (with each event, weekly, monthly, quarterly, etc).</i>		
89.01	The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients.		
89.02	For pharmacies utilizing a drug formulary, a periodic review of such formulary is undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.		
90.00	Quality meetings are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.		
90.01	The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients.		
90.02	Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.		
91.00	Reporting: Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization. <i>Indicate which organizations are reported including if the pharmacy reports QREs to the board of pharmacy.</i>		
91.01	Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc?		
91.02	Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc) are documented and reported to the manufacturer or distributor.		
92.00	Quality Self-Audits are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.		
93.00	Consumer Surveys are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying every patient. Each pharmacy should use the results of its consumer survey to evaluate its own performance at a particular time and over a period of time.		

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	Finding	Notes
94.00	Patient Complaints are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.	