

Community Pharmacy Quality Assurance Policy Manual

NOTICE OF CONFIDENTIALITY

This quality assurance policy and procedure manual is intended solely for the use of the CARE Pharmacies Inc; if you are not the intended recipient, you are hereby notified that any use, disclosure, dissemination, or copying of this communication is strictly prohibited. Thank you for your cooperation.

Community Pharmacy Quality Assurance Policy Manual

SYNOPSIS: Who is expected to do what and when and how? The intent of the QA manual is to establish and maintain a cohesive approach to daily pharmacy operations. While documented procedures aim to reduce confusion and enhance clarity they also empower accountability and responsibility which serves to improve upon the overall delivery of quality client services.

PHARMACY POLICIES AND PROCEDURES

Table of Contents and Overview

1. Consultation and Counseling

This document is designed to provide a formal outline of the procedures CARE Pharmacies Inc. shall follow in an effort to engage in patient consultation, counseling, education, and monitoring with regard to drug regimen adherence issues. This guideline aims to consider factors including, but not limited to, side effects, pill size or regimen difficulties, memory limitations, financial status, and motivational challenges; enhance communication by taking into consideration issues of education or lack thereof, literacy assistance, and language translation needs; allow for analysis and establishment of a patient-specific adherence program designed to include consultation frequency, healthcare provider communications and partnership(s), and resistance testing.

2. Drug Interaction, Reaction, or Incidents

This document is designed to provide a formal outline of the procedures CARE Pharmacies Inc shall follow in an effort to proactively avoid or minimize adverse drug interactions and/or reactions. This guideline aims to enhance overall evaluation of medication use; provide a monitoring mechanism for all reported potential serious or unexpected adverse drug interaction(s); allow for a trending mechanism with regard to tendencies or progression of adverse drug interaction(s) potential.

3. Prescription Fill and Refill

This document is designed to provide a formal outline of the procedures CARE Pharmacies Inc shall follow in an effort to ensure that pharmacy personnel will meet, greet, and provide the patient with his or her prescriptions within a timely, efficient, and acceptable time frame. Encompasses refill reminders, monitoring of late refills, and chronic abusers.

4. Inventory Storage and Handling

The storage and handling of inventory policy serves to establish a procedure that maintains adequate active stock, engages in proper storage, rotation, and safety (with regard to expiration dating or recalls), and speaks to diversion.

5. Pharmacy Responsibilities Including Ethical Conduct

The policy serves to establish guidelines with regard to ethical business conduct, job designations, specific assignments, and expectations of pharmacy personnel and his or her provision of services.

6. Training, Development, and Evaluation

The policy serves to establish a procedure that maintains provision of quality services via a properly credentialed staff; it provides a formal outline of the procedures CARE Pharmacies Inc shall follow in an effort to ensure that pharmacy personnel will receive adequate training coupled with competency evaluations by way of verbal, written, or practical mechanisms.

7. Health and Safety Including Emergency Equipment and Notifications

This policy serves to establish a procedure that documents emergency protocol which will maintain or improve upon response time and overall preparedness; this includes familiarization with safety rules, easy access to necessary emergency equipment, and updated contact lists.

8. Privacy and Information Security

This document is designed to provide a formal outline of the procedures CARE Pharmacies Inc shall follow to ensure compliance to the Health Insurance Portability and Accountability Act (HIPAA) regulations by protecting the patient's private health information and restricting access to same.

9. Pharmacy Inspection

This document is designed to provide a formal outline of the procedures CARE Pharmacies Inc shall follow to ensure that pharmacy inspectors and internal auditors will have the information required for an accurate and safe appraisal of the facility without compromising record confidentiality, and to ensure that the inspectors and auditors will follow any precautions that may be communicated to them. The intention is to also include blank inspection reports for each applicable state.

10. Data Management and Contingency Planning

This document is designed to provide an outline of the procedures CARE Pharmacies Inc shall follow in the event of a catastrophe, disaster, or other scenario that may cause a break or disruption in provision of services. Crisis preparedness serves to maintain continuity of care via agreements with contractors, vendors, or other affiliates, as well as provision of a process for pharmacy systems data recovery and restoration.

11. Quality Improvement Program

This document is designed to provide a formal outline of the procedures CARE Pharmacies Inc shall follow in an effort to analyze, measure, and improve upon the delivery of client services. In an ever changing, evolving marketplace and economy, continuous improvement undertakings will allow the pharmacy to meet or exceed customer wants and needs while continuing to maintain a competitive edge. Continuous improvement initiatives include, but are not limited to

the development, enhancement, and enforcement of written, documented standard operating procedures, processes, or policies; availability of continuing education and training across relevant disciplines; effective communication and feedback techniques; dedication to internal controls such as conducting compliance audits and implementing corrective and preventive actions (CAPA) when or if necessary or appropriate.

12. **INDEX**

This document is a compilation of terms used throughout the policy and procedures manual; it is designed as a quick reference guide.

13. **ATTACHMENTS**

This section includes sample inspection documents.

CARE Pharmacies, Inc.

Quality Assurance

Policy Manual

Consultation and Counseling

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POLICY NAME: **Pharmacy Consultation and Counseling**

POLICY NUMBER: QA01 ORIGINAL DATE OF ISSUE: 01/01/2009

REVISION NUMBER: Original REVISION DATE OF ISSUE: xx/xx/xxxx

PAGES: 6

AUTHORED BY: Carolyn Miller, Director of Quality Assurance & Pharmacy Operations

AUTHORIZED BY: Gerry Crocker, Chief Executive Officer

- 1) **INTRODUCTION:** The drug adherence policy serves to establish a procedure that identifies potential barriers to medication adherence, advocates mandatory counseling, and improves upon the patient's health care accountability and responsibility.
- 2) **RESPONSIBILITIES**
 - a) The Pharmacy Manager or Pharmacist-in-Charge (PIC) will oversee policy compliance for personnel under his or her supervision.
 - b) All CARE Pharmacies employees and contractors will adhere to the policies and SOPs in this manual.
 - c) The Quality Assurance department reserves the right to regularly perform audits, both on and off site.
- 3) **SCOPE:** This policy shall apply to all CARE Pharmacies pharmacy sites.

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- 4) PURPOSE: Patient counseling sessions aim to provide clarity with regard to introductory, adherence, and drug interaction concerns and/or confusions. This document is designed to provide a formal outline of the procedures CARE Pharmacies Inc shall follow in an effort to engage in patient consultation, counseling, education, and monitoring with regard to drug regimen adherence issues. This guideline aims to:**
- a) Consider factors including, but not limited to, side effects, pill size or regimen difficulties, memory limitations, financial status, and motivational challenges.**
 - b) Enhance communication by taking into consideration issues of education or lack thereof, literacy assistance, and language translation needs.**
 - c) Allow for analysis and establishment of a patient-specific adherence program designed to include consultation frequency, healthcare provider communications and partnership(s), and resistance testing.**
- 5) POLICY**
- a) The pharmacist shall offer and make every effort to provide counseling or consultation to every new patient, as well as to those patients who incur a prescription change or adjustment. Additionally, auxiliary stickers may be placed on prescription bags to tag, flag, and promote patient specific counseling needs.**
 - b) If the patient, or his or her designee, chooses to decline consultation the pharmacist shall make note of the refusal by way of patient signature. Form attached.**
 - c) The pharmacist shall always confer with the patient in a private manner, whether the consult occurs via phone or in person, so as to maintain patient confidentiality and in accordance with the health insurance portability and accountability act of 1996 (HIPAA).**
 - i) The pharmacy will have access to a confidential consultation area or engage in confidential consultation mechanisms whether in the form of an on- or off-site office area or via phone conversation.**
 - ii) If a pharmacy does not have a private room on site, a patient confer may occur in the pharmacy before or after store hours, or at a mutually agreed upon alternate location, or via phone.**
 - d) The pharmacist shall demonstrate opening and inspecting the drug container, as well as instruct on the importance of proper usage, adherence, storage, and potential side effects or drug interaction potential. Form attached.**

- e) Pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act, the pharmacist shall ensure that the patient is provided with and aware of the FDA's required side effects statement (SES) to read "Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088".
- f) The pharmacist shall be candid when educating the patient as to the consequences of non-adherence to treatment program management.
- g) The pharmacist shall pose questions to the patient in an effort to determine if pharmacy instructions were understood and if confusion was eliminated. Further, the pharmacist will utilize empathy, not sympathy, when inviting and answering questions from the patient or his or her designee.
- h) The pharmacist shall 'know his/her audience' and be cognizant to communicate in a manner most effective for the patient. Further, only the pharmacist or other authorized formally trained pharmacy personnel familiar with patient specific medication(s) shall offer counseling or guidance to a patient or his or her designee. Pharmacy communication and customer service techniques may include:
 - i) Avoidance of overly technical verbiage, rather, speak at an educational level similar to the patient's
 - ii) The allowance of an appropriate amount of time so as not to feel rushed
 - iii) Provision of large print or 'layman's terms' educational material
 - iv) Availability and provision of a translator when appropriate or necessary
 - v) Showing compassion rather than pity
- i) AIDS Drug Assistance Program (ADAP) participating pharmacies shall maintain access to specialized staff who are trained and experienced in the area of AIDS/HIV.
- j) Pharmacy staff shall remind ADAP patients of his or her entitlement to a complementary drug delivery service. A strong focus shall be directed toward ADAP patients who have a history of late refills or lack the understanding or motivation to remain compliant to adherence endeavors.
- k) The pharmacist or other authorized pharmacy personnel shall advise patients that they may have a financial entitlement to health insurance assistance via the ADAP program. Additional information may be obtained from the Department of Health at



http://dchealth.dc.gov/doh/cwp/view,A,1371,Q,598643,dohNav_GID,1802,dohNav,%7C33200%7C34259%7C,.asp

- l) The pharmacist working in conjunction with the patient and the physician is an important element in medication adherence. In the event a patient should experience difficulty with pill size or medicine regimen, the pharmacist shall confer with the prescribing physician in an effort to make the appropriate adjustments to the prescription. Modification assistance may include, but is not limited to, an adjustment from a pill form to liquid form, provision of a calendar or pill boxes to assist with organization, or dose adjustments which may alleviate undesirable side effects.**
- m) The pharmacist or other authorized pharmacy personnel shall encourage the patient to contact the pharmacy, or his or her personal physician, if the patient should have any questions or concerns regarding his or her condition or medication regimen.**



PATIENT CONSULTATION WAIVER

DATE	PATIENT SIGNATURE	PATIENT INTITALS	PHARMACIST INTIALS

PATIENT CONSULTATION AND EDUCATION

Patient participation in a pharmacy counseling session(s) aims to provide clarity with regard to introductory, adherence, and drug interaction concerns and/or confusions.

At a minimum, the pharmacist shall discuss and explain the following:

Handling

___ Inspection of drug container

___ Opening drug container

___ Storage of medication

Usage

___ Adherence

___ Treatment program management

___ Side effects or interactions

Other

___ Auxiliary stickers and package inserts

___ Insurance/payment options

___ HIPAA

___ Emergency numbers (physician, pharmacy, 911)

Contact Prescribing Physician

___ Medication modification assistance

Additional comments/concerns: _____

Date

Patient name (printed)

Pharmacist Signature

Patient Signature

CARE Pharmacies, Inc.

Quality Assurance

Policy Manual

Drug Interaction, Reaction, or Incident(s)

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POLICY NAME: **Drug Interaction, Reaction, or Incident(s)**

POLICY NUMBER: QA02 ORIGINAL DATE OF ISSUE: 01/01/2009

REVISION NUMBER: Original REVISION DATE OF ISSUE: xx/xx/xxxx

PAGES: 15

AUTHORED BY: Carolyn Miller, Director of Quality Assurance & Pharmacy Operations

AUTHORIZED BY: Gerry Crocker, Chief Executive Officer

1) INTRODUCTION: The adverse drug interaction, reaction, or incident policy serves to improve patient safety by outlining a procedure to identify, classify, and prevent potential instances of adverse drug interfaces.

- a) An adverse reaction is considered an unintended or harmful response to, or interaction with, a drug.
- b) A medication error is considered to be an error, a preventable harmful event, by way of inappropriate use of medication by the consumer or provider.
- c) A medication incident encompasses an adverse reaction or a medication error.

2) RESPONSIBILITIES

- a) The Pharmacy Manager or Pharmacist-in-Charge (PIC) will oversee policy compliance for personnel under his or her supervision.
- b) All CARE Pharmacies employees and contractors will adhere to the policies and SOPs in this manual.
- c) The Quality Assurance department reserves the right to regularly perform audits, both on and off site.

3) SCOPE: This policy shall apply to all CARE Pharmacies pharmacy sites.

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4) PURPOSE: This document is designed to provide a formal outline of the procedures CARE Pharmacies Inc shall follow in an effort to proactively avoid or minimize adverse drug interactions and/or reactions. This guideline aims to:

- a) Enhance overall accuracy and evaluation of medication fill and use.
- b) Provide a monitoring mechanism for all reported potential serious or unexpected adverse drug interaction(s).
- c) Allow for a trending mechanism with regard to tendencies or progression of adverse drug interaction(s) potential.
- d) Protect the interests of CARE Pharmacy staff with regard to conducting work with accuracy, efficiency, and professionalism.

5) POLICY

- a) In an effort to limit variances in care that may result in an unexpected occurrence or adverse outcome, pharmacy personnel shall make every attempt to validate prescription accuracy.
 - i) The pharmacist, or other authorized staff member as appropriate, who receives a verbal prescription shall repeat the information back to the prescribing entity to ensure accuracy.
 - ii) Inquiries or clarity with regard to any prescription requires the prescribing physician to be contacted. Inquiries may encompass potential drug interactions, appropriateness of therapy or dosage, or underlying health condition(s). Any adjustments made and authorized by the prescribing physician shall be documented on the attached Physician Inquiry form.
 - iii) In an effort to sustain a viable drug and health care management program, the pharmacist shall strongly encourage the patient to utilize a single source pharmacy for his or her medication needs and avoid indulging in multi-source pharmacy dispensing.
 - iv) Patient contact and identifying information shall be cross-checked to verify that the individual noted on the prescription corresponds with the information documented in computerized pharmacy system.
 - v) Upon verification of prescription and corresponding patient, the prescription data shall be entered into the computerized pharmacy system and the appropriate medication label will be printed.

- vi) Prior to medication dispensing, the technician and the pharmacist shall both review the original prescription then both shall review against the corresponding drug label.
 - vii) The pharmacist or pharmacy technician shall remove the product from inventory based upon the oral or written prescription.
 - viii) A visual inspection shall be performed to ensure that the drug dispensed is the actual drug requested.
 - ix) The prescription shall be filled into the appropriate bottle, vial, or other container to adequately accommodate the dispensed product. The remaining inventory shall be placed back into stock.
 - x) Prior to the drug being released to a patient, the national drug code (NDC) shall be verified by either or both the pharmacist and/or technician. The DEA and/or NPI number shall also be confirmed.
 - xi) Prior to the drug being released to a patient, pharmacy personnel shall reconfirm patient name and prescriber; the pharmacist shall confirm that the drug dispensed matches the container label as well as prescription request.
 - xii) Pharmacy personnel shall ensure that the directions for use are included in the pharmacy prescription bag. Further, pharmacy personnel shall ensure that the directions pertaining to the drug requested on the original prescription correspond with the drug actually dispensed and packaged for release.
 - xiii) Pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act, the pharmacist shall ensure that the patient is provided with and aware of the FDA's required side effects statement (SES) to read "Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088".
 - xiv) Upon releasing medication to a patient, pharmacy personnel will ask the patient if he or she has any questions. If the patient should have questions or concerns, the patient shall be directed to confer with the pharmacist; dialogue shall be conducted in a private setting such as a conference room, office, or other mutually acceptable venue conducive to maintaining patient confidentiality and compliance to Health Insurance Portability and Accountability Act (HIPAA) regulations.
- b) Pharmacy personnel shall utilize the tools within the computerized pharmacy system which has the capacity to monitor patient profiles as well as trend refill compliance, inventory control, and identify, inform and warn the pharmacist of potential adverse drug interactions, combinations, or allergy alerts. Samples attached.

- c) **The identification of trends and the detection of potential errors with respect to reported occurrences is an essential element of the quality enhancement initiative.**
 - i) **Trending has the capacity to track and monitor the performance of staff member's daily duties and highlight areas that may require improvement or correction.**
 - ii) **Trending has the capacity to track and monitor the effectiveness, or lack thereof, of particular products, services, and treatment regimens; trending highlights product and service problems, deficiencies, and/or malfunctions.**

- d) **An incident report shall be completed in the event of an adverse reaction or other notable unusual incident. An incident report is a record of an unintended event that describes the details of what is/was correct and what actually happened. Form attached.**
 - i) **The report shall identify the nature of the incident, involvement of the patient or pharmacy employee(s), witness accounts if applicable, a note advising if the physician was contacted, and resolution of the incident event.**
 - ii) **The report shall be submitted to the PIC within three (3) days of the incident.**
 - iii) **The Food and Drug Administration (FDA) must be notified within ten (10) days of any and all serious adverse event observations that are product related. Both the FDA and the manufacturer shall be notified within fifteen (15) days if the serious adverse event is a device-related death. The FDA can be reached via www.fda.gov/medwatch.org or at 1-800-FDA-1088 (1-800-332-1088) via phone, or via fax at 1-800-FDA-0178 (1-800-332-0178).**
 - iv) **The incident log shall be securely maintained and accessible to authorized pharmacy personnel only.**

ALLERGY ALERT SAMPLE 1

1 0022699 Name: PHARMACIES, CARE Sex:
2 Addr: 100 DAINGERFIELD RD, SUITE 400, ALEXANDRIA, VA 22314 Bd:
3 [PC/HC] PT: Disc: SC: LG: [Tel:]703-414-5430
4 Allg: PENICILLINS
5 Cvg: Pl: Gp: Id: L#:
6 C/H: Elig: Cpy: ExDt:
7 Rx#: Drg: AMOXICILLIN 250MG/5CC 55 Cst:

ALERT: ALLER-CHEK(TM)

The Patient is Allergic to: PENICILLINS

Possible ALLERGIC REACTION to: AMOXICILLIN 250MG/5CC

<ESC>, <CR> TO CONTINUE: .

ALLERGY ALERT SAMPLE 2

1 0022699 Name: PHARMACIES, CARE Sex:
2 Addr: 100 DAINGERFIELD RD, SUITE 400, ALEXANDRIA, VA 22314 Bd:
3 [PC/HC] PT: Disc: SC: LG: [Tel:]703-414-5430
4 Allg: PENICILLINS
5 Cvg: Pl: Gp: Id: L#:
6 C/H: Elig: Cpy: ExDt:
7 Rx#: Drg: AMOXICILLIN 250MG/5CC 55 Cst:

DOCUMENTATION UPDATE

1. RPh: CTS 2. Tech:

3. Type: Aller-Chek Alert

4. Documentation:

ALLERGY: PENICILLINS

POSSIBLE ALLERGIC REACTION TO

AMOXICILLIN 250MG/5CC

1-4, P(rint) <CR> or <ESC>: ..

DRUG DISEASE MONITORING SAMPLE

1 0022699 Name: PHARMACIES, CARE Sex:

2 Addr: 100 DAINGERFIELD RD, SUITE 400, ALEXANDRIA, VA 22314 Bd:

3 [PC/HC] PT: Disc: SC: LG: [Tel:]703-414-5430

4 Allg: PENICILLINS

5 Cvg: Pl: Gp: Id: L#:

6 C/H: Elig: Cpy: .00 ExDt:

7 Rx#: Drg: RETROVIR 100MG (AZT) 55 Cst:

DRUG-DISEASE MONITORING(TM)

- 1. HIV INFECTION
- 2. AIDS RELATED DISORDERS
- 3. AIDS-RELATED COMPLX (ARC)
- 4. AIDS

Enter ICD9 Code (XXX.XXX)

ENTER LINE# OR ICD9, <CR>:

DRUG INTERACTION ALERT SAMPLE

1 0022699 Name: PHARMACIES, CARE Sex:
2 Addr: 100 DAINGERFIELD RD, SUITE 400, ALEXANDRIA, VA 22314 Bd:
3 [PC/HC] PT: Disc: SC: LG: [Tel:]703-414-5430
4 Allg: PENICILLINS
5 Cvg: Pl: Gp: Id: L#:
6 C/H: Elig: Cpy: .00 ExDt:
7 Rx#: Drg: COUMADIN 1MG TAB 00056-0169-70 Cst:

DOCUMENTATION UPDATE

- 1. RPh: HBS 2. Tech:
- 3. Type: Drug Interaction Alert
- 4. Documentation:

COUMADIN 1MG TAB

AMOXICILLIN 250MG/5C

SEVERITY 2

REFILL ALERT SAMPLE

1 0022699 Name: PHARMACIES, CARE Sex:
2 Addr: 100 DAINGERFIELD RD, SUITE 400, ALEXANDRIA, VA 22314 Bd:
3 [PC/HC] PT: Disc: SC: LG: [Tel:]703-414-5430
4 Allg: PENICILLINS
5 Cvg: Pl: Gp: Id: L#:
6 C/H: Elig: Cpy: .00 ExDt:
7 Rx#: Drg: AMOXICILLIN 250MG/5CC 00781-6041-55 Cst:

REFILL TOO SOON

Latest Fill Date: 12-04-08 Rx: 00937534

Days Supply: 0001 % Utilized: 0

Actual Refill Date: 12-05-08 Allowable Refill Date: 12-05-08

Enter RD, <C>ontinue, <Esc> : ..

User: 0364 Rx System 8.5d (C)2000 HBS, Inc. CARE TRAINING MACHINE

Quality Assurance Station (Workflow)

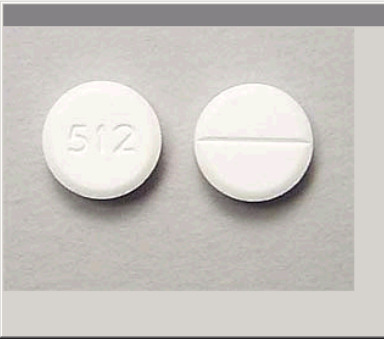
Rx#:121 11-01-2007 Bill:
Pat: PATIENT TEST
123 MAIN STREET
DOB: 01-01-1970
313-444-4444
Dr: TEST T.
Med#: 123456 Dea#: AC5634945

Drg: OXYCODONE-APAP 5MG/325MG TAB**
00406-0512-01 5-325MG
Qty: 60 Days: 15 Rfls Lft: 0

TAKE ONE TABLET BY MOUTH EVERY 6 HOURS WHEN NEEDED FOR PAIN

Scan Drug Label Bar Code: 30406051201 Matched Successfully.

BL, D, DOC, H, L, M, PD, S, SRX, RX, WFI, <F1>, <Esc>:



Workflow Information

Input: HBS Successful	QA: 10
QA Scan: CS UPC Scan Match	RC: 1
RPh Chk:	WC: 14
	PQ: 5

Start | HBS Support - r rx | User: 0364 Rx S... | Preview and Enhance - C... | 11:22 AM

User: 0363 Rx System 8.5d (C)2000 HBS, Inc. CARE TRAINING MACHINE

Field Pa	Documentation Module	Y/A/N:	Print, Y/N:
	1. Drug Interaction,	Y/A/N: Y	Print, Y/N:
	2. Allergy Alert,	Y/A/N: Y	Print, Y/N: Y
Optional Mod	1. W 3. Duplicate Therapy,	Y/A/N:	Print, Y/N:
	2. D 4. Drug-Disease Alert,	Y/A/N:	Print, Y/N:
	3. D 5. Dose-Chek Alert,	Y/A/N: Y	Print, Y/N: [Y]
	4. I 6. Refill Too Soon,	Y/A/N: N	Print, Y/N: N [Y]
	5. C 7. Non Formulary Alert,	Y/A/N:	Print, Y/N: [Y]
	6. D 8. House Stock Alert,	Y/A/N:	Print, Y/N: Y
	7. I 9. Price Override Alert,	Y/A/N:	Print, Y/N: [Y]
	8. W 10. ECS Cost LT Aq Cost,	Y/A/N: Y	Print, Y/N: Y [B]
	9. C 11. Desi Drug Alert,	Y/A/N:	Print, Y/N:
	10. P 12. Code 1 Drug Alert,	Y/A/N:	Print, Y/N:
	11. E 13. TAR Restriction,	Y/A/N:	Print, Y/N:
	12. B 14. New Refill Auth,	Y/A/N:	Print, Y/N:
	13. W 15. WorkFlow Scan,	Y/A/N:	Print, Y/N:
	16. Increase Refills,	Y/A/N:	Print, Y/N:
	17. Change Bill Code,	Y/A/N:	Print, Y/N:
	1-20 18. User Defined Codes,	Y/A/N:	Print, Y/N:

1-16, <ESC>: . .

Start User: 0362 Rx Sy... User: 0363 Rx S... Preview and Enhance - C... 10:19 AM


The screenshot displays a software window titled "CARE TRAINING MACHINE" with the following text and elements:

- Header: User: 0364 Rx System 8.5d (C)2000 HBS, Inc. CARE TRAINING MACHINE
- Form fields:
 - 1 0000014 Name: TEST, PATI
 - 2 Addr: 123 MAIN STREET, MI
 - 3 [PC/HC] PT: Dis
 - 4 Allg: **PENICILLINS**
 - 5 Cvg: P1: Gp:
 - 6 C/H:
 - 7 Rx#: 00000121 Drg: OXYC
 - 8 Qtyw: 00060 5-32
 - 9 Days: 015 Rf1: 00
 - 10 Bill: Rlt: Prc:
 - 11 Instr:
- Text: Last Refill: NONE
- Handwritten note (on a white background):
 - Patient Test
 - Perocet 5mg/325mg
 - 1T/PO/Q6h/Prn
 - Dr. Tom Test
- Bottom text: 1-15, DOC, PA#, CMT#, NR, RB#, ECS#, PQ#, FX, RX, <F1>, <ESC>: SRXC
- Taskbar: Start, HBS Support - r rx, User: 0364, Rx S..., Preview and Enhance - C..., 11:21 AM

User: 0363 Rx System 8.5d (C)2000 HBS, Inc. CARE TRAINING MACHINE

Drug #: 001343

1. Drug Name: LASIX 20MG TABS
2. Strength: 20MG
3. Form: TABS SIG Def: T
4. [Units] 100 Metric: .000
5. [NDC] 00039-0067-10
6. UPC #: 30039006710
7. Ident:
8. StF #:



PRICING

1. AWP:	28.8		
2. New AWP:	.0		
3. AqC:	23.02	Updated:	6-21-07
4. AAWP:	.00	12. Pr/100:	.00
5. HCFA:	5.63	13. Fee:	.00
6. WAC:	23.07	14. Tax:	
7. MC/AqC:	.00	15. Mark Up:	
8. PPO/AqC:		16. Price Table:	011
9. Contract:	.00	17. Unit Pack:	0
10. MAC Y/N:	.0000	18. Bucket Pricing	
11. Cost Basis:		19. Update AWP, Y/N:	
		20. Update ACQ, Y/N:	

9. Indicators
10. Label Info
11. Pricing
12. Brand/Generic
13. Sensitivities
14. Cautions
15. Manufacturer
16. Inventory
17. Utilization
18. Vendor
19. Compounds
20. Third Party
21. Nursing Home

1-21, D#, W#, DM, COPY, REQ, IMG, <F1>: |.....

Start | User: 0362 Rx Sy... | User: 0363 Rx S... | Preview and Enhance - C... | 11:01 AM

PHYSICIAN INQUIRY FORM

If clarity is needed with regard to any prescription, the prescribing physician shall be contacted. Inquiries may encompass potential drug interactions, appropriateness of therapy or dosage, or underlying health condition(s). Any adjustments made and authorized by the prescribing physician are to be documented and retained on file.

Patient Name: _____

Address: _____

Phone Number(s): _____

Date of Birth: _____ Age: _____ Weight: _____

Male Female

Predisposed clinical conditions: _____

Physician/Hospital Name: _____

Address: _____

Phone Number(s): _____

Current Drug Therapy (use back of sheet, or page 2, for multiple drugs)

Drug name: _____ Dose: _____

Administration route: _____ Frequency: _____

Additional therapy regimens: _____

Basis for Inquiry

- | | |
|--|---|
| <input type="checkbox"/> Allergy alert | <input type="checkbox"/> Drug modification assistance |
| <input type="checkbox"/> Contraindication | <input type="checkbox"/> Method of administration |
| <input type="checkbox"/> Dosage/therapy | <input type="checkbox"/> Frequency |
| <input type="checkbox"/> Supply/quantity | <input type="checkbox"/> Verbal or written instructions clarity |
| <input type="checkbox"/> Predisposed health condition(s) | <input type="checkbox"/> Recalled product |
| <input type="checkbox"/> Other _____ | |

PHYSICIAN INQUIRY FORM (continued)

Authorized adjustments: _____

Additional notes: _____

Inquiring pharmacy entity (print): _____

Reporting entity (signature): _____

Date: _____

INCIDENT FORM

Date Received: _____ Date of Initial Occurrence: _____

Time of Initial Occurrence (if known): _____ a.m. / p.m.

Name of Patient: _____

Address: _____

Phone Number(s): _____

Date of Birth: _____ Age: _____ Weight: _____

Male Female

Predisposed clinical conditions: _____

Current Drug Therapy (use back of sheet for multiple drugs)

Drug name: _____ Dose: _____

Administration route: _____ Frequency: _____

Prescribing Physician: _____

Additional therapy regimens: _____

Potential Types of Incident(s)/Reaction(s)

- | | |
|--|---|
| <input type="checkbox"/> Allergy | <input type="checkbox"/> Patient/medication mismatch |
| <input type="checkbox"/> Contraindication | <input type="checkbox"/> Recalled product |
| <input type="checkbox"/> Expired product | <input type="checkbox"/> Storage error |
| <input type="checkbox"/> Formulation error | <input type="checkbox"/> Supply quantity error |
| <input type="checkbox"/> Frequency error | <input type="checkbox"/> Wrong drug |
| <input type="checkbox"/> Incorrect patient information leaflet | <input type="checkbox"/> Wrong verbal instructions |
| <input type="checkbox"/> Label error or omission | <input type="checkbox"/> Wrong method of administration |

Other possible reason(s) that the error might have occurred: _____

INCIDENT FORM (continued)

Details of incident: _____

Did the incident result in a physician or hospital visit? Yes No

If yes, name of physician and/or hospital: _____

Contact info: _____

No medical attention was required.

Pharmacy personnel involvement: Yes No

If so, please explain: _____

Remediation Efforts

Corrective action(s) taken: _____

Recommendations for preventive actions: _____

Additional comments: _____

Reporting entity or investigator (print): _____

Reporting entity (signature): _____

Date: _____

CARE Pharmacies, Inc.

Quality Assurance

Policy Manual

Prescription Fill and Refill

NOTICE OF CONFIDENTIALITY

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POLICY NAME: **Prescription Fill and Refill**

POLICY NUMBER: QA03 ORIGINAL DATE OF ISSUE: 01/01/2009

REVISION NUMBER: Original REVISION DATE OF ISSUE: xx/xx/xxxx

PAGES: 4

AUTHORED BY: Carolyn Miller, Director of Quality Assurance and Pharmacy Operations

AUTHORIZED BY: Gerry Crocker, Chief Executive Officer

1) **INTRODUCTION:** The prescription refill policy serves to establish a procedure that maintains provision of prescription fill and refill services in an expeditious and knowledgeable manner.

2) **RESPONSIBILITIES**

- a) The Pharmacy Manager or Pharmacist-in-Charge (PIC) will oversee policy compliance for personnel under his or her supervision.
- b) All CARE Pharmacies employees and contractors will adhere to the policies and SOPs in this manual.
- c) The Quality Assurance department reserves the right to regularly perform audits, both on and off site.

3) **SCOPE:** This policy shall apply to all CARE Pharmacies pharmacy sites.

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- 4) PURPOSE:** This document is designed to provide a formal outline of the procedures CARE Pharmacies Inc shall follow in an effort to ensure that pharmacy personnel will meet, greet, and provide the patient with his or her prescriptions within a timely, efficient, and acceptable time frame.
- 5) POLICY**
- a) Every customer shall receive a greeting with professional courtesy.
 - b) Pharmacy personnel shall ask the customer/patient if he or she intends to wait for the prescription to be filled or if he or she will return to pick up the medication at a later date or time.
 - i) Pharmacy personnel shall be truthful regarding an estimated wait time. If the patient chooses to wait, the prescription shall be prioritized and marked to indicate 'customer waiting'.
 - ii) If the patient chooses to pick up at a later date or time, the prescription shall be ready upon the customer's anticipated return time frame.
 - c) The correct spelling of customer name, address, phone number, prescriber, and the like shall be verified in the computerized pharmacy system. If the customer is a new patient, the contact name, insurance information, and other identifying information shall be entered into the computerized pharmacy system.
 - d) Upon releasing medication to a patient, pharmacy personnel shall ask the patient if he or she has any questions. If the patient should have questions or concerns, the patient shall be directed to confer with the pharmacist; dialogue shall be conducted in a private setting such as a conference room, office, or other mutually acceptable venue conducive to maintaining patient confidentiality.
 - e) Pharmacy personnel shall always verify drug refill status and advise patient of such. The patient may receive this information verbally or in writing via "# refills remaining" data provided via the prescription container label.
 - f) Pharmacy personnel shall monitor the occurrence of chronically late refills. Refill compliance methods may include utilizing the computerized pharmacy system to produce refill due reports, automated and personal reminder phone calls, and patient enrolled reminder programs.

- i) Reminder phone calls shall be generated commencing at seven (7) days prior to refill due date.**
 - ii) Each patient notification effort shall be documented by pharmacy personnel.**
- g) Chronic abusers shall be counseled and/or provided with written educational material outlining the importance of adherence as well as the consequences associated with the lack thereof. Written documentation, by the patient or his or her designee, must be obtained if the patient chooses to decline said counseling.**
- h) The pharmacist shall notify the prescribing and attending physician(s) of chronic abusers and/or persistent occurrences of refill and/or pick up delinquency.**
- i) The pharmacist shall work in conjunction with the physician and the patient, especially if the patient's motivation or resistance to timely refills is efficacy related. For example:**
 - i) If non-adherence is due to difficulty with pill size or treatment regimen, the pharmacist shall confer with the prescribing physician in an effort to make the appropriate adjustments to the prescription such as an adjustment from a pill form to liquid form.**
 - ii) If confusion is a result of organizational issues, the provision of a calendar or pill boxes may prove helpful.**
- j) If prescriptions are mailed or delivered, the pharmacy shall charge for the medications prior to the drugs leaving the pharmacy. AIDS Drug Assistance Program (ADAP) patients are entitled to complementary drug delivery services and shall be reminded of such.**
 - i) All patients shall be asked to provide current contact information such as mailing address, phone number, e-mail, etc. This information shall be cross-checked via the computerized pharmacy system and adjustments shall be noted as necessary, prior to drug delivery.**
 - ii) Prior to delivery, pharmacy staff shall ask the patient if his or her health insurance has changed or if the health insurance carrier remains unchanged.**

REFILL ALERT SAMPLE (generated by pharmacy system)

1 0022699 Name: PHARMACIES, CARE Sex:

2 Addr: 100 DAINGERFIELD RD, SUITE 400, ALEXANDRIA, VA 22314 Bd:

3 [PC/HC] PT: Disc: SC: LG: [Tel:]703-414-5430

4 Allg: PENICILLINS

5 Cvg: Pl: Gp: Id: L#:

6 C/H: Elig: Cpy: .00 ExDt:

7 Rx#: Drg: AMOXICILLIN 250MG/5CC 00781-6041-55 Cst:

REFILL TOO SOON

Latest Fill Date: 12-04-08 Rx: 00937534

Days Supply: 0001 % Utilized: 0

Actual Refill Date: 12-05-08 Allowable Refill Date: 12-05-08

Enter RD, <C>ontinue, <Esc> : ..

CARE Pharmacies, Inc.

Quality Assurance

Policy Manual

Inventory Storage and Handling

NOTICE OF CONFIDENTIALITY

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POLICY NAME: **Inventory Storage and Handling**

POLICY NUMBER: QA04 ORIGINAL DATE OF ISSUE: 01/01/2009

REVISION NUMBER: Original REVISION DATE OF ISSUE: xx/xx/xxxx

PAGES: 4

AUTHORED BY: Carolyn Miller, Director of Quality Assurance and Pharmacy Operations

AUTHORIZED BY: Gerry Crocker, Chief Executive Officer

- 1) **INTRODUCTION:** The storage and handling of inventory policy serves to establish a procedure that maintains adequate active stock as well as engages in proper storage, rotation, and safety.
- 2) **RESPONSIBILITIES**
 - a) The Pharmacy Manager or Pharmacist-in-Charge (PIC) will oversee policy compliance for personnel under his or her supervision.
 - b) All CARE Pharmacies employees and contractors will adhere to the policies and SOPs in this manual.
 - c) The Quality Assurance department reserves the right to regularly perform audits, both on and off site.
- 3) **SCOPE:** This policy shall apply to all CARE Pharmacies pharmacy sites.

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- 4) PURPOSE:** This document is designed to provide a formal outline of the procedures CARE Pharmacies Inc shall follow in an effort to ensure that adequate stock inventory is maintained, inspected, and properly separated and/or identified.
- a) AIDS Drug Assistance Program (ADAP) participating pharmacies shall maintain sufficient on-hand inventory of antiretroviral medications to fill 95% of drug requests.
 - b) ADAP participating pharmacies, shall maintain ADAP product in an isolated location, or the product shall be clearly marked to identify 'ADAP-dispensing-only', rendering it inaccessible for the general population.
- 5) POLICY**
- a) Inventory items shall be stored in accordance with the manufacturer's specifications to include temperature, lighting, humidity, etc.
 - b) Upon receipt of inventory, products shall be reviewed for expiration date and rotated, if necessary, so that products with early expiration dates will be used first. Inventory without noted expiration dates shall be used as they come in, rather, first lot in is the first lot out.
 - c) Check expiration date prior to any dispensing.
 - d) Visually inspect inventory prior to use to ensure packaging and containers are free from defect(s).
 - e) Expired or defective inventory shall be removed from active stock and either destroyed or returned to the manufacturer. ADAP participating pharmacies shall return said inventory to the DOH warehouse.
 - f) Expired and/or defective inventory shall be removed from the pharmacy system's active inventory records. ADAP participating pharmacies should expect to receive immediate replacement product from the DOH warehouse.
 - g) In the event the pharmacy is notified of a product recall via the distributor, manufacturer, wholesaler, or similar, pharmacy staff shall scrutinize the current inventory to identify and remove product subject to said recall notice.
 - i) Pharmacy personnel shall review pharmacy records to determine if recalled product was dispensed to a patient. If so, both patient and physician shall be notified, provided with an explanation as to the recall and advised that the recalled product must be returned. The patient shall then receive an appropriate replacement medication/product. Sample letter attached.

- ii) A recall notation, for each affected patient, shall be placed and recorded in the computerized pharmacy system.
- iii) Inventory subject to recall shall be removed from active stock and either destroyed or returned to the manufacturer. ADAP participating pharmacies shall return said inventory to the DOH warehouse. Additionally, recalled product shall be removed from the pharmacy system's active inventory records.
- iv) Recall records shall be maintained for traceability.
- h) Inventory velocity reports shall be generated at the CARE corporate level on a monthly basis.
- i) Drugs differentiated, segregated, and identified as ADAP shall not be privy to customers other than ADAP patients. Conversely, ADAP patients shall receive product from ADAP inventory only. Intermingling or sharing of product is not an option.
- j) The pharmacy will dispense drugs from inventory as they were intended for legitimate use only and shall not engage in willful diversion. Diversion includes, but is not limited to, the sale of prescriptions to dealers or abusers, falsification or manipulation of records, deceptive billing practices, theft from inventory, short-fills, and similar.
- k) The pharmacy manager or owner shall utilize the U.S. Department of Health and Human Services Office of the Inspector General <http://www.oig.hhs.gov/> to search through the list of excluded individuals or entities (LEIE). Those individuals or entities noted on the exclusion list are implicated in convictions for program-related fraud and patient abuse, licensing board actions, default on health education assistance loans, or similar.
- l) Any employee found to be engaging in any type of unlawful practices will be subject to disciplinary action, up to and including termination of employment.

Sample Recall Letter to Patients

Date: _____

RE: Drug Recall
STATUS: Urgent

Dear Valued Customer:

Please be advised that CARE Pharmacies Inc. is voluntarily recalling the following product, (*insert product name*), due to (*insert reason, i.e., contamination, manufactures advisory, etc.*).

Product Description: _____
Manufacturer: _____
Packaging: _____
NDC Number: _____
Product Code: _____
Product Lot Number(s): _____

Our records indicate that you have received this product. Please examine your medication inventory immediately and determine if this product is in your possession. If so, please discontinue the use of said product and return it to the CARE pharmacy point of purchase.

You will receive full credit for any product returned and replacement product can be obtained at this time as well. If you have any questions concerning this recall, you may call the corporate office, toll free, at 1-866-227-3797, or contact your local CARE pharmacy at (*insert phone number*). You are, however, encouraged to speak with your CARE pharmacist for this and any other inquiries or concerns.

We appreciate your loyalty in purchasing your healthcare supplies from CARE Pharmacies and we deeply value the trust you have placed in us. We regret any inconvenience this product recall may have caused you.

Sincerely,

Representative Name
Title
CARE Pharmacies Inc.
Street Address
City/State/Zip
USA

CARE Pharmacies, Inc.

Quality Assurance

Policy Manual

Pharmacy Responsibilities

Including Ethical Conduct

NOTICE OF CONFIDENTIALITY

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POLICY NAME: **Pharmacy Responsibilities including Ethical Conduct**

POLICY NUMBER: QA05 ORIGINAL DATE OF ISSUE: 01/01/2009

REVISION NUMBER: Original REVISION DATE OF ISSUE: xx/xx/xxxx

PAGES: 4

AUTHORED BY: Carolyn Miller, Director Quality Assurance & Pharmacy Operations

AUTHORIZED BY: Gerry Crocker, Chief Executive Officer

- 1) **INTRODUCTION:** The pharmacy responsibilities policy serves to establish guidelines with regard to ethical business conduct, job designations, specific assignments, and expectations of pharmacy personnel and his or her provision of services.
- 2) **RESPONSIBILITIES**
 - a) The Pharmacy Manager or Pharmacist-in-Charge (PIC) will oversee policy compliance for personnel under his or her supervision.
 - b) All CARE Pharmacies employees and contractors will adhere to the policies and SOPs in this manual.
 - c) The Quality Assurance department reserves the right to regularly perform audits, both on and off site.
- 3) **SCOPE:** This policy shall apply to all CARE Pharmacies pharmacy sites.

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4) PURPOSE: This CARE Pharmacies Inc document is designed to provide a formal outline designed to maintain and enhance the reputation of CARE Pharmacies Inc. Built upon the principles of fair dealing(s) and ethical conduct guiding each CARE employee, CARE's reputation for integrity and excellence requires astute observance of applicable laws and regulations, as well as a scrupulous regard for the highest quality standards of performance and personal integrity.

5) POLICY

a) Ethical Business Conduct

- i) Pharmacy personnel have a duty to CARE Pharmacies and its customers to act in a way that will merit the continued trust and confidence of the public. Further, each employee shall refrain from any illegal, dishonest, or unethical conduct.**
- ii) CARE Pharmacies will comply with all applicable laws and regulations and expects its directors, officers, and employees to conduct business in accordance with the intent of said laws and regulations.**
- iii) If a situation should present itself and it becomes difficult to determine a proper course of action, the matter should be discussed openly utilizing the appropriate management chain up to and including, if necessary, the Chief Executive Officer for advice and consultation.**

b) Roles and Responsibilities

- i) The Pharmacy Owner/Manager or PIC shall maintain knowledge of local, state, and federal rules and regulations relative to pharmacy practices; handling and transport of sensitive material; and environmental health and safety. He or she shall implement measures to ensure staff compliance with the aforementioned requirements and shall advise of penalties or consequences for noncompliance. The Pharmacy Manager shall be fully versed of all company policies and standards and shall implement measures to ensure compliance with same. Further, the Pharmacy Manager is responsible to ensure that pharmacy and staff shall:
 - (1) Operate only when a licensed pharmacist is on site.**
 - (2) Uphold the pharmacy hours of operation which shall be clearly posted for customers to view. AIDS Drug Assistance Program (ADAP) participating pharmacies are required to maintain hours of operation from Monday through Saturday.**
 - (3) In the case of ADAP participating pharmacies, patients shall be advised of free delivery services of medication(s).****

- ii) In addition to accurately dispensing prescription drugs to individuals, the pharmacist shall counsel patients, and advise physicians, on the selection, dosages, interactions, and side effects of medications. He or she shall monitor the health and progress of patients to ensure the safe and effective use of medication. The pharmacist must check and verify accuracy of each filled prescription prior to its release to a patient. The pharmacist shall maintain knowledge of local, state, and federal rules and regulations relative to pharmacy practices.**
- iii) The pharmacy technician shall assist the pharmacist in provision of patient medication. He or she not only counts tablets or labels bottles, but may also answer phones, stock shelves, maintain patient profiles, prepare insurance forms, or act as cashier. It is the responsibility of the pharmacy tech to refer any questions regarding prescriptions, drug information, or health matters to a pharmacist, when appropriate.**
- iv) Drivers and couriers of the pharmacy are expected to handle, package, and deliver prescription medications in compliance with all regulations and company policies. Couriers will ensure that deliveries are accompanied by completed paperwork for outgoing customer products. He or she may also be asked to assist in inventory control by reviewing, documenting, and verbalizing stock needs to pharmacy personnel. Each pharmacy driver is expected to regularly inspect and coordinate routine maintenance of delivery vehicles.**
- v) The pharmacy employee is responsible for ensuring that the quality of his or her work produced meets all regulatory requirements and company standards.**
- vi) The pharmacy shall designate one member of the staff to be the pharmacy's First Responder or Safety Coordinator. The First Responder/Safety Coordinator is the primary resource for safety leadership. Additional responsibilities include surveillance of health and safety policies and procedures to include emergency notification postings, maintenance of clear emergency evacuation routes, as well as attending First Aid/CPR training.**
- vii) The Pharmacy Quality Assurance (QA) and Pharmacy Operations team will organize continuous improvement initiatives serving to improve upon the provision of services. The QA team will assist the pharmacy to meet and potentially exceed customer expectations; the QA team is expected to:**

 - (1) Evaluate operational and business functions and will implement policies and procedures, as appropriate, serving to maintain and improve upon pharmacy operations best practices.**

- (2) Conduct process audits, both internal and external in nature.**
- (3) Identify, expose, and analyze risk, develop a contingency plan when or if necessary, and monitor the resulting corrective and preventive action plan results.**

CARE Pharmacies, Inc.

Quality Assurance

Policy Manual

Training, Development, and Evaluation

NOTICE OF CONFIDENTIALITY

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POLICY NAME: **Personnel Training, Development, and Evaluation**

POLICY NUMBER: QA06 ORIGINAL DATE OF ISSUE: 01/01/2009

REVISION NUMBER: Original REVISION DATE OF ISSUE: xx/xx/xxxx

PAGES: 4

AUTHORED BY: Carolyn Miller, Director of Quality Assurance and Pharmacy Operations

AUTHORIZED BY: Gerry Crocker, Chief Executive Officer

1) **INTRODUCTION:** The personnel training and evaluation policy serves to establish a procedure that maintains provision of quality services via a properly credentialed staff.

2) **RESPONSIBILITIES**

- a) The Pharmacy Manager or Pharmacist-in-Charge (PIC) will oversee policy compliance for personnel under his or her supervision.
- b) All CARE Pharmacies employees and contractors will adhere to the policies and SOPs in this manual.
- c) The Quality Assurance department reserves the right to regularly perform audits, both on and off site.

3) **SCOPE:** This policy shall apply to all CARE Pharmacies pharmacy sites.

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4) PURPOSE: This document is designed to provide a formal outline of the procedures CARE Pharmacies Inc shall follow in an effort to ensure that pharmacy personnel will receive adequate training coupled with competency evaluations by way of verbal, written, or practical mechanisms.

5) POLICY

- a) All pharmacies, (and employees as dictated by Federal, State, Local, or District law), shall maintain proper licensure. Further, each CARE pharmacy owner shall ensure that every employee is competent to perform the duties assigned.
- b) Pharmacy personnel are required to monitor and maintain his or her professional credentials.
- c) In addition to all pharmacy personnel earning required CE credits necessary for proper credentialing, AIDS Drug Assistance Program (ADAP) participating pharmacy staff is required to attend DOH-HAA sponsored training that shall occur quarterly with a typical duration of approximately four (4) hours.
- d) ADAP participating pharmacies must have specialized staff available, trained and experienced in the area of AIDS/HIV.
- e) All pharmacies must have trained and experienced, or have timely access to, bi-lingual or multi-lingual capabilities necessary for appropriate translation and/or counseling activities.
- f) All pharmacy staff must participate in Health Insurance Portability and Accountability Act (HIPAA) training and understand the importance of secure and confidential patient information.
- g) All pharmacy personnel shall be trained on Medicare Part D compliance policies and procedures, with a specific focus on fraud, waste, and abuse detection. For more detailed information please refer to the U.S. Department of Health and Human Services Centers for Medicare and Medicaid Services <http://www.cms.hhs.gov/MDFraudAbuseGenInfo/>
- i) Pharmacy personnel shall understand that components of fraud, waste, and abuse include, but may not be limited to, inappropriate billing practices, improper coding, drug short-fills, bait and switch tactics, forged or altered prescriptions or other records, dispensing or sale of expired product, refill errors or manipulations, remuneration schemes, false claims, anti-kickback violations, theft from inventory, and similar diversion tactics.

- ii) **Consequences and penalties associated with fraud, waste, and abuse may include civil or criminal penalties (monetary or incarceration, respectively), placement on Medicare exclusion lists, loss of employment, and/or immediate contract termination.**

- h) **In accordance with federal law, specifically the Combat Methamphetamine Epidemic Act of 2005, training must be completed if the pharmacy intends to sell Scheduled Listed Chemical Products containing ephedrine, pseudoephedrine, or orphenylpropanolamine. To complete self certification, log on to <http://www.deadiversion.usdoj.gov/> .**

- i) **Pharmacy personnel shall engage in pharmacy systems computer training on proper data input, monitoring, inventory control, and report generation.**

- j) **Pharmacy personnel who have completed training segments shall sign a training log. An authorized reviewer, such as the pharmacy owner or PIC, shall sign the form as verification that the employee has completed the training.**

- k) **Training documentation shall be placed in the employee personnel file and maintained for adequate accessibility in the event of an audit.**

PHARMACY PERSONNEL TRAINING LOG			
<u>STAFF MEMBER NAME</u>	<u>TRAINING COURSE</u>	<u>BEGIN/END</u>	<u>AUTHORIZED BY</u>
<i>Joe Pharmacist</i>	<i>CPR Training</i>	<i>xx-xx-xx/xx-xx-xx</i>	<i>Management Name</i>

CARE Pharmacies, Inc.

Quality Assurance

Policy Manual

Health and Safety

Including Emergency Equipment and Notifications

NOTICE OF CONFIDENTIALITY

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POLICY NAME: **Health and Safety, including Emergency Equipment and Notifications**

POLICY NUMBER: QA07 ORIGINAL DATE OF ISSUE: 01/01/2009

REVISION NUMBER: Original REVISION DATE OF ISSUE: xx/xx/xxxx

PAGES: 10

AUTHORED BY: Carolyn Miller, Director of Quality Assurance and Pharmacy Operations

AUTHORIZED BY: Gerry Crocker, Chief Executive Officer

1) **INTRODUCTION:** The health and safety, including emergency equipment and notifications policy serves to establish a procedure that documents emergency protocol which will maintain or improve upon response time and overall preparedness.

2) **RESPONSIBILITIES**

- a) The Pharmacy Manager or Pharmacist-in-Charge (PIC) will oversee policy compliance for personnel under his or her supervision.
- b) All CARE Pharmacies employees and contractors will adhere to the policies and SOPs in this manual.
- c) The Quality Assurance department reserves the right to regularly perform audits, both on and off site.

3) **SCOPE:** This policy shall apply to all CARE Pharmacies pharmacy sites.

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- 4) PURPOSE:** This document is designed to provide a formal outline of the procedures CARE Pharmacies shall follow in an effort to ensure that pharmacy personnel are provided with familiarization with safety rules, easy access to necessary emergency equipment, and updated contact lists.
- 5) POLICY**
- a) CARE Pharmacies Inc shall provide information to employees about workplace safety and health issues via regular internal communication channels such as management-employee meetings, bulletin board postings, training sessions, memos, or other written communications. Additionally, CARE Pharmacies shall provide specialized job appropriate training upon request when, in the sole judgment of management, such training is deemed appropriate.
 - b) Employees with safety enhancement ideas, concerns, or suggestions for improved safety in the workplace are encouraged to raise them with his or her management. Reports and concerns about workplace safety issues may be made anonymously if the employee wishes and all reports can be made without fear of reprisal.
 - c) A personal commitment to health and safety preparedness is expected of each employee; pharmacy personnel shall exercise caution and alertness in all aspects of work activities.
 - i) Pharmacy personnel are expected to immediately report any unsafe condition(s) to pharmacy management. Workplace hazard form attached.
 - ii) Employees who violate safety standards, who cause hazardous or dangerous situations, or who fail to report and/or remedy such situations, may be subject to disciplinary action, up to and including termination of employment.
 - d) In the event of accidents that result in injury, regardless of how insignificant the injury may appear, the employee must notify his or her management in a timely manner. Workplace incident reports are necessary as they comply with laws as well as initiate insurance and workers' compensation benefits procedures. Form attached.
 - e) **General Safety Rules**
 - i) The pharmacy shall designate a First-Responder responsible for safety leadership. Form attached.
 - ii) All employees must be familiar with emergency procedures, equipment, and evacuation routes.

- iii) **Never block access to aisles, corridors, emergency exits, or equipment. Further, fire lanes and emergency access points shall not be obstructed.**
 - iv) **Treat every alarm as if it were an actual emergency.**
 - v) **Pharmacy staff shall immediately report all unsafe acts or conditions (to include leaks, spills, outages, odors, etc) to the first-responder, manager, or his or her designee.**
 - vi) **Smoking in the pharmacy is prohibited, further, CARE Pharmacies takes a firm stand against alcohol and drug abuse.**
 - vii) **Become familiar with all equipment prior to use and use extra caution when performing a task for the first time.**
 - viii) **When not in use, drugs shall be stored in their proper locations.**
- f) Emergency Equipment**
- i) **Smoke detectors and sprinkler systems shall be maintained and operational as required by local code of regulations.**
 - ii) **A fire extinguisher sign is required for each extinguisher location and posted in accordance with local code of regulations. All fire extinguishers must be mounted a minimum of three feet above floor level near an exit.**
 - iii) **Illuminated emergency exit signs must be secured over all exits and have the ability to remain visible during a power failure.**
 - iv) **The pharmacy must have a fully stocked first aid kit on hand. Each kit must meet ANSI standards to include, at a minimum, one (1) absorbent compress, sixteen (16) adhesive bandages, one (1) adhesive tape, ten (10) antiseptic applications, six (6) burn treatment applications, two (2) pair of medical exam gloves, four (4) sterile pads, and one (1) triangular bandage.**
 - (1) **If an employee requires a first aid product, the item must be logged on the posted or accessible sign out sheet. Form attached.**
 - (2) **Inventory shall be conducted to assure a fully stocked kit void of expired material.**
 - v) **The pharmacy shall have at least two heavy duty rechargeable flashlights on hand. Each flashlight must be mounted in an accessible location. Battery longevity shall be verified quarterly by the First-Responder or other pharmacy designee.**

- vi) **The pharmacy shall have a portable radio on hand to be able to collect information on weather or emergency situations in the area.**
 - vii) **Spare batteries shall be kept on hand to accommodate flashlights, radios, beepers, or similar.**
 - viii) **The First-Responder, safety coordinator, or other pharmacy designee shall routinely, quarterly at a minimum, verify equipment is in working order, and inspect for damage or defect(s). An emergency equipment check sheet is attached. Discoveries of damage or defect shall be documented on the attached damage or defect log.**
- g) Notifications**
- i) **The pharmacy shall have accessible a written call list that documents pharmacy employee phone numbers. Said list shall be used in the event of an emergency which may include coverage issues, technical or professional assistance, or for other unforeseen circumstances.**
 - ii) **The pharmacy shall post an emergency call list near the phone. The list of names and/or numbers as the case may be shall include, but may not be limited to:**
 - (1) Police Department**
 - (2) Fire Department**
 - (3) Hospital or other Emergency Care Facility**
 - (4) Pharmacy Manager and/or Owner**
 - (5) 911!**

NOTIFICATION OF [POTENTIAL] WORKPLACE HAZARD

Submitted by: _____ Date: _____

Nature of [potential] workplace hazard: _____

Did injury occur as a result of said unsafe condition or workplace hazard? Yes* No

**If injury occurred, be sure to also complete the Workplace Accident/Incident Form.*

In the event of injury, was the injured: Employee Customer

Type of injury: _____

Basics of incident: _____

Did injury require physician or hospital visit? Yes No Medical attention waived

Suggested corrective or preventive actions (CAPAs): _____

#####

ASSESSMENT

[Potential] Hazard Reviewed and Evaluated By _____ Date _____

CAPA Required? Yes No

CAPAs to be implemented and when: _____

#####

CAPAs Implemented? Yes No Closed

If no, explain: _____

Return this form to Safety Coordinator or First Responder upon discovery of unsafe work environment.

WORKPLACE ACCIDENT/INCIDENT FORM

Date Received: _____ Date of Initial Occurrence: _____

Time of Initial Occurrence: _____ a.m. / p.m.

Name of injured person: _____

Address: _____

Phone number(s): _____

Date of birth: _____ Male Female

Who was injured person: Employee Customer

Type of injury or incident: _____

Details of incident: _____

Did injury require physician or hospital visit? Yes No

Name of physician and/or hospital: _____

Address: _____

Physician and/or hospital phone number: _____

Signature of injured party _____ Date _____

No medical attention was desired and/or required.

Signature of injured party _____ Date _____

Return this form to Safety Coordinator or First Responder within 24 hours of incident.

FIRST RESPONDER DESIGNEE FORM

The pharmacy shall designate, at a minimum, one member of the staff to be the pharmacy's First Responder or Safety Coordinator. The First Responder/Safety Coordinator is the primary resource for safety leadership.

He or she is expected to act with proficiency in emergency response situations to include maintenance of and direction toward clear evacuation routes. He or she shall attend First Aid and/or CPR education or training sessions. The First Responder or Safety Coordinator shall ensure, via quarterly inspections at a minimum, that health and safety equipment is operational and appropriately maintained.

The First Responder or Safety Coordinator serves in an important pharmacy capacity. He or she shall be able to effectively coordinate an emergency response in the event of an accident or incident. Most valuable, the First Responder or Safety Coordinator will be able to prepare for, consider, and organize a plan for emergency actions, look for potential hazard(s), identify and evaluate preemptive necessities, and be a skilled communicator with regard to facilitating appropriate emergency preparedness and response(s).

First Responder or Safety Coordinator Nomination (print name):

First Responder or Safety Coordinator Designated or Authorized by:

Acceptance of First Responder or Safety Coordinator Role (signature):

(Date)

This form to be retained on site and in employee personnel file.

EMERGENCY EQUIPMENT INSPECTION CHECK SHEET – Performed Quarterly

Check if in working order	Note reason for failing inspection
<input type="checkbox"/> Batteries	_____
<input type="checkbox"/> Emergency exit lights	_____
<input type="checkbox"/> Evacuation routes (posted)	_____
<input type="checkbox"/> Fire extinguishers	_____
<input type="checkbox"/> First aid kit (fully stocked)	_____
<input type="checkbox"/> Flashlights	_____
<input type="checkbox"/> Radio	_____
<input type="checkbox"/> Smoke detectors	_____
<input type="checkbox"/> Sprinkler system	_____
<input type="checkbox"/> Other	_____

REMEDIATION (if necessary): _____

CORRECTIVE ACTION(S) TO BE COMPLETED BY: _____

INSPECTION CONDUCTED BY: _____
First Responder or Safety Coordinator (signature) Date

CORRECTIVE ACTIONS IMPLEMENTED _____
Pharmacy Designee Verification (signature) Date

IF CORRECTIVE ACTIONS HAVE NOT YET BEEN IMPLEMENTED (explain): _____

FIRST AID KIT PRODUCT SIGN OUT SHEET					
<u>DATE</u>	<u>NAME</u>	<u>ITEM REMOVED</u>	<u>QTY</u>	<u>REPLACED BY</u>	<u>REPLACED</u>
xx/xx/xx	Joe Schmoe	Adhesive Tape	1		
xx/xx/xx	Jane Doe	Gloves	1	P.M.	xx/xx/xx



INSPECTION FOR DAMAGE OR DEFECT LOG

<u>DATE</u>	<u>ITEM INSPECTED</u>	<u>PASS/FAIL</u>	<u>COMMENTS</u>	<u>INSPECTED BY</u>
xx/xx/xx	Fire extinguishers (2)	P		
xx/xx/xx	Exit signs (2)	1 P / 1F	One cracked; awaiting replacement	P.M.

CARE Pharmacies, Inc.

Quality Assurance

Policy Manual

Privacy and Information Security

NOTICE OF CONFIDENTIALITY

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POLICY NAME: **Privacy and Information Security (HIPAA)**

POLICY NUMBER: QA08 ORIGINAL DATE OF ISSUE: 01/01/2009

REVISION NUMBER: Original REVISION DATE OF ISSUE: xx/xx/xxxx

PAGES: 8

AUTHORED BY: Carolyn Miller, Director of Quality Assurance and Pharmacy Operations

AUTHORIZED BY: Gerry Crocker, Chief Executive Officer

1) INTRODUCTION: The privacy and information security policy, in conjunction with the health insurance portability and accountability act of 1996 (HIPAA), is meant to ensure the protection of private, identifying personal health information.

- a) Information to be considered patient identifiers include, but may not be limited to, patient name, social security number, address, phone number, medication, therapy or illness history.
- b) Insurance forms, prescriptions, and other confidential, identifiable, patient health records are referred to as protected health information (PHI). PHI includes all identifiable patient data that is retained or transmitted in any way, shape, or form such as electronic, paper files, or verbal communications.

2) RESPONSIBILITIES

- a) The Pharmacy Manager or Pharmacist-in-Charge (PIC) will oversee policy compliance for personnel under his or her supervision.
- b) All CARE Pharmacies employees and contractors will adhere to the policies and SOPs in this manual.
- c) The Quality Assurance department reserves the right to regularly perform audits, both on and off site.

3) SCOPE: This policy shall apply to all CARE Pharmacies pharmacy sites.

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4) PURPOSE: This document is designed to provide a formal outline of the procedures CARE Pharmacies Inc shall follow to ensure compliance to HIPAA regulations by protecting the patient's private health information and restricting access to same.

5) POLICY

- a) The pharmacy shall provide notification of its privacy practice to its patients and customers. The advisory shall explain how the pharmacy will use, disclose, and protect PHI. Further, the advisory will explain patient rights including a point of contact for potential complaints or perceived privacy violations.
 - i) The pharmacy manager shall be responsible for receiving inquiries or complaints with regard to the privacy policy. CARE Corporate as well as the department of Health and Human Services (HHS) are alternative points of contact with regard to the communication of any complaint, concern, or inquiry.
 - ii) Pharmacy management shall make a good faith effort to alleviate any potential harmful effects caused or incurred as a result of noncompliance to HIPAA guidelines.
 - iii) Documented privacy policies, procedures, complaints, confidentiality status reports, associated authorizations, and other PHI related data will be retained for six (6) years at a minimum following the latest publication, revision, or update.
- b) A reasonable effort must be made to obtain patient, or patient designee, acknowledgement of receipt of privacy practices. If the patient, or his or her designee, declines signature acknowledgement then the pharmacist must supplement the authorization form with the provision of a written explanation for said refusal. Form attached.
- c) All pharmacy employees will be trained in and adhere to HIPAA compliance initiatives. Every employee shall sign the attached form as acknowledgment that they have been properly trained, additionally, an authorizing agent, such as the pharmacy manager or other training entity, shall sign as verification of training completion.
- d) When collecting, storing, and exchanging or transmitting sensitive personal data, pharmacy personnel shall recognize and adhere to personal privacy laws and regulations.
 - i) The obtainment, retainment, and use of personal data shall be for legitimate business purposes only and in accordance with applicable laws.
 - ii) The pharmacy shall limit access to PHI and monitor the potential for unauthorized access or exploitation.

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- e) **Pharmacy personnel shall secure and mark any and all PHI as confidential. All PHI records in the pharmacy must be labeled as confidential and stored in a secured location, such as locked file cabinets or password protected electronic files.**
 - f) **Pharmacy staff shall not disclose any PHI, under any circumstance, without the prior approval of the pharmacy owner, manager, or CARE Corporate. Prior to information release, pharmacy personnel must obtain consent for PHI disclosure. Said notifications, consent forms, or other authorizations shall be retained on file as evidence and in the event of an audit. Consent to release and revocation of release forms are attached.**
 - i) **Upon written request, the pharmacy shall provide the patient, or his or her designee, access to their PHI. Further, the patient shall be advised in the event his or her personal information has been disclosed.**
 - ii) **The pharmacy shall obtain a written notification prior to the release of PHI required for judicial proceedings, FDA, OSHA, or HHS investigations, worker's compensation issues, victims of abuse or violence, or to avert serious threat to the health or safety of others.**
 - iii) **Other permitted PHI disclosures include provision of information to funeral directors, coroners and the like for identification of the deceased, or to facilitate organ or tissue donation from the deceased.**
 - iv) **Authorization, or the individual patient's written approval, is required prior to any disclosure of PHI with regard to pharmaceutical or medical device product marketing companies, potential employers regarding pre-employment lab tests, or the life insurance industry.**
 - g) **Pharmacy personnel shall de-identify, or omit, any and all PHI information prior to discarding the data. Data disposal shall include on-site shredding or other confidentiality secured means.**
 - h) **The patient, and/or his or her designee, is entitled to consultation(s) and/or counseling that is confidential in nature and communicated effectively, such as the consideration of language or literacy requirements. The pharmacy shall have an accessible mechanism in place to achieve, maintain, and adhere to the patient privacy rule. Such mechanisms may include, but may not be limited to, a private consult room or office in the pharmacy, privacy-protected phone conversation(s), or similar confers that may occur either on or off site.**
 - i) **No pharmacy employee, customer, patient, or his or her designee, shall be subject to intimidation or retaliation for exercising his or her privacy rights, or for engaging in the protection of privacy, or for opposing violations of the privacy rule.**
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- j) Pharmacy personnel must understand that the consequences associated with improper disclosure and overall failure to comply with the safeguard of private information is an offense that will result in civil or criminal penalties of monetary value, prison time, or both.**
 - i) Civil penalties may result in no more than one hundred dollars (\$100.00) per violation, in upwards up twenty five thousand (\$25,000.00) per person.**
 - ii) Criminal penalties may range from fifty thousand dollars (\$50,000.00) to two hundred fifty thousand dollars (\$250,000.00), and from one to ten years of incarceration.**
 - iii) Violators may be subject to disciplinary action, to include termination, for noncompliance of this policy or for failing to report any violation of this policy.**
 - iv) The following websites provide additional HIPAA related information.**
 - (1) <http://www.hhs.gov/ocr/hipaa/>**
 - (2) <http://www.cms.hhs.gov/hipaaGenInfo/>**

CARE PHARMACIES INC.

CERTIFICATION AND AGREEMENT OF COMPLIANCE WITH PRIVACY POLICIES AND PROCEDURES

I, as a CARE Pharmacies Inc employee, certify that:

1. I was offered an educational training session regarding compliance with CARE Pharmacies Inc privacy and information security policies and procedures including policies directly related to the Health Insurance Portability and Accountability Act of 1996 (HIPAA).
2. As an attendee of the training session, I was instructed as to the policies and procedures regarding the handling of patient information. I acknowledge that I was afforded an opportunity to ask questions regarding the privacy policy outlined by CARE Pharmacies and that all questions were answered to my satisfaction. I understand that if I should have additional questions or require further clarity I will contact the pharmacy manager, CARE Corporate or, if necessary, the Department of Health and Human Services.
3. I hereby agree to act in accordance with CARE Pharmacies Inc privacy and information security policy as well as in accordance with HIPAA regulations. Further, I have been advised and I understand the penalties, to include disciplinary action or termination, associated with failure to comply with or failure to report violations of said policy.

Signature _____

Printed Name _____

Position _____

Date _____

Authorizing Signature _____

Printed Name _____

Position _____

Date _____

Copy of training acknowledgement record is to be retained on file.

PHARMACY PRIVACY and INFORMATION SECURITY PRACTICES OVERVIEW

As a customer/patient of this CARE Pharmacy, I understand the following:

1. In conjunction with the health insurance portability and accountability act of 1996 (HIPAA), the pharmacy shall ensure the protection of private, identifying personal health information (PHI). Patient identifiers include, but may not be limited to, patient name, social security number, address, telephone number, and medication, therapy, or illness history.
2. When collecting, storing, exchanging, transmitting, and communicating sensitive personal data, pharmacy personnel will recognize and adhere to personal privacy laws and regulations. The obtainment of personal data shall be used for legitimate business purposes only and in accordance with applicable laws.
3. The pharmacy will provide the patient (or designee) with access to his or her PHI upon written request. In accordance with state and federal law, the pharmacy may disclose PHI in the event it is required for judicial proceedings, workers compensation issues, health and human services related investigations, or similar.
4. The pharmacy will not disclose any PHI to pharmaceutical or medical device product marketing companies, potential employers regarding pre-employment lab tests, or the life insurance industry without the expressed written consent of the patient.
5. Each patient (and his or her designee) is entitled to confidential consultation(s) communicated effectively and in accordance with language or literacy considerations.
6. The customer/patient/designee shall not be subject to intimidation or retaliation for exercising his or her privacy rights.

ACKNOWLEDGEMENT NOTICE OF RECEIPT

Customer/Patient Signature: _____ Date: _____

Comment(s): _____

CONSENT TO RELEASE CONFIDENTIAL HEALTH INFORMATION

Patient Name: _____

Provider Name: _____

Person, agency, or provider to whom disclosure is to be made: _____

Information or records allowed to be disclosed: _____

As the person signing this consent, I understand that I am giving permission to the above named person, agency, provider, or other named third party for disclosure of confidential health care records. I understand that I have the right to revoke this consent at any time but that my revocation is not effective until delivered, in writing, to the pharmacy in possession of my records. A copy of this consent and a notation concerning the persons or agencies that disclosure was made shall be included with my original records. The person(s) in receipt of the records to which this consent pertains may not re-disclose them to anyone else without my separate written consent, unless such recipient is a provider who makes a disclosure permitted by law.

This consent commences on (date): _____

This consent expires on (date): _____

Patient Signature: _____

Date Signed: _____

Copy of Consent to Release PHI form is to be retained on file.

REVOCATION OF AUTHORIZATION TO RELEASE PROTECTED HEALTH INFORMATION (PHI)

I, (patient name) _____,

born on _____,

do wish to revoke my authorization for release of PHI, which was dated on _____,

and due to expire on _____.

I do not hold the pharmacy liable for documentation or communications that the pharmacy may have already acted upon based on a previously prepared or delivered authorization form.

(Signature of Patient or His or Her Designee)

(Date Signed)

(Printed Name of Patient or His or Her Designee)

(Signer's Date of Birth)

If signed by the patient's personal representative or designee, the designee must explain his or her authority to act on behalf of the patient: _____

Copy of Revocation of PHI Release form is to be retained on file.

CARE Pharmacies, Inc.

Quality Assurance

Policy Manual

Pharmacy Inspection

NOTICE OF CONFIDENTIALITY

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POLICY NAME: **Pharmacy Inspection**

POLICY NUMBER: QA09 ORIGINAL DATE OF ISSUE: 01/01/2009

REVISION NUMBER: Original REVISION DATE OF ISSUE: xx/xx/xxxx

PAGES: 7

AUTHORED BY: Carolyn Miller, Director of Quality Assurance and Pharmacy Operations

AUTHORIZED BY: Gerry Crocker, Chief Executive Officer

- 1) **INTRODUCTION:** The pharmacy inspection policy serves to establish a procedure that allows for pharmacy inspection by authorized personnel only to comply with Federal, State, Local, or District code of regulations.
- 2) **RESPONSIBILITIES**
 - a) The Pharmacy Manager or Pharmacist-in-Charge (PIC) will oversee policy compliance for personnel under his or her supervision.
 - b) All CARE Pharmacies employees and contractors will adhere to the policies and SOPs in this manual.
 - c) The Quality Assurance department reserves the right to regularly perform audits, both on and off site.
- 3) **SCOPE:** This policy shall apply to all CARE Pharmacies pharmacy sites.

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4) PURPOSE: This document is designed to provide a formal outline of the procedures CARE Pharmacies Inc shall follow to ensure that pharmacy inspectors and internal auditors will have the information required for an accurate and safe appraisal of the facility without compromising record confidentiality, and to ensure that the inspectors and auditors will follow any precautions that may be communicated to them.

5) POLICY

a) Inspectors and Auditors

- i) Upon scheduling and arrival of an outside agency inspector, the owner/manager, PIC, or his or her designee, shall be immediately notified. CARE Corporate shall also be immediately notified.**
- ii) Both external inspector and internal auditor must provide valid identification. A badge or picture ID must be provided; a business card is an unacceptable means of identification. If the inspector fails to provide adequate credentials, pharmacy personnel shall phone the inspecting agency to verify and confirm.**
- iii) The inspector must sign the visitor registration form and attach/provide a business card as a secondary ID means and cross-reference.**
- iv) All pharmacy personnel will be informed that an inspection is in progress.**
- v) The pharmacy owner/manager, PIC, or his or her designee shall be deemed the primary contact and will accompany the inspector at all times. When accompaniment by the primary is not possible, a secondary contact will be designated for the interim. When possible, and if space allows, an area for record review or interviews will be provided to the inspector.**
- vi) In conjunction with the pharmacy owner, CARE Corporate must approve all photography, video recording, or photocopying of pharmacy documents.**
- vii) Documents of confidentiality shall not be shared with the inspector(s). Confidential documents include, but may not be limited to pricing, personnel profiles, customer profiles, and similar. Questions regarding confidentiality should be referred to the pharmacy owner as well as CARE Corporate.**
- viii) Inspectors must engage in an exit interview with the owner/manager, or his or her designee.**

- ix) The primary contact designated to accompany the outside inspector must complete an inspection synopsis immediately upon audit conclusion to allow for optimal recall. The synopsis shall be provided to both the pharmacy owner and to CARE Corporate.
- x) Inspectors must agree to adhere to the pharmacy inspection policy as outlined, as well as other pharmacy procedures as applicable, during the inspection.

b) Internal Audits

- i) The internal auditor will assist in the management of overall quality and compliance activities by ensuring operational adherence to corporate policies, industry standards, and applicable regulations.
- ii) All CARE Pharmacies and contracted CARE partner pharmacies are subject to audits and site visits; pharmacy audits may be conducted on-site as well as from the corporate office.
- iii) The selection of pharmacy audits will be at random and on a rotating schedule based upon the needs of the franchise. Audits may also be performed at a pharmacy that is perceived to require assistance with compliance criteria adherence.
- iv) The internal auditor shall notify the pharmacy to be inspected at least seventy two (72) hours prior to a site visit audit. The auditor may use his or her discretion in accommodating pharmacy scheduling requests however the pharmacy is not entitled to a postponement.
- v) The auditor shall engage in both an opening and closing meeting with the pharmacy owner, manager, or other designated pharmacy contact or escort.
- vi) The auditor shall research and investigate via electronic, paper, and/or personal interviews, a variety of data sources that may include but may not limited to, training records, inventory reports, voided prescriptions, credentials verification, past audit reports, customer satisfaction surveys, pharmacy complaints, physician inquiries, storage facilities, process control data, HIPAA compliance, and similar.
- vii) Upon completion of the audit, the auditor shall compile, review, and analyze his or her findings; the auditor shall identify strengths and areas for improvement and shall provide recommendations for corrective or preventive actions (CAPAs) as appropriate.
 - (1) A corrective action is defined as a measure take to correct, fix, repair, or eliminate an existing problem, defect, or non-conformity.

(2) A preventive action is defined as a measure taken to correct, fix, repair, or eliminate the occurrence of a potential problem, defect, or non-conformity.

viii) The auditor, in conjunction with executive management, is charged with determining if adequate measures for quality compliance are in place and being maintained at the pharmacy level. The auditor must review said report with appropriate management and shall receive authorization prior to audit report release.

ix) The auditor shall write and provide a written report to the pharmacy manager or owner as well as CARE Corporate in a timely manner, no more than thirty (30) days from completion of audit. If more than 30 days is required, communication shall be provided to auditee advising of such to include when the report is expected to be released.

x) The auditee shall have thirty (30) days of receipt of report to respond in writing. If CAPAs were recommended, the auditee shall address actions that were taken or will be taken to prevent recurrence.

xi) The auditor shall engage in follow up action as necessary.

6) ATTACHMENTS: Sample inspection reports.

a) Maryland Board of Pharmacy Community Pharmacy Inspection Form www.mdbop.org

b) Virginia Pharmacy Inspection Report

c) Virginia “Dirty Dozen” frequently cited pharmacy inspection deficiencies www.dhp.virginia.gov

d) Further Board of Pharmacy information can be obtained from [http://www.uspharmd.com/pharmacist/State Board of Pharmacy.html](http://www.uspharmd.com/pharmacist/State_Board_of_Pharmacy.html)

VISITOR REGISTRATION FORM

<u>DATE / TIME IN</u>	<u>NAME</u>	<u>AFFILIATION</u>	<u>PURPOSE</u>	<u>TIME OUT</u>
<i>xx/xx/xx 9:30 a.m.</i>	<i>Iris Inspector</i>	<i>CMS</i>	<i>Medicare Audit</i>	<i>6:15 p.m.</i>

PHARMACY PHOTOGRAPHY AND VIDEO AUTHORIZATION FORM

1. Identification of and access to pharmacy video, photographs, or photocopying
 - a. It is the policy of CARE Pharmacies Inc. that any individual or organization engaged in taking photos, video recordings, photocopies, or access to and/or removal of any pharmacy property, must obtain appropriate authorization from the pharmacy owner or CARE Pharmacies corporate prior to commencement of any such activities. The intended use of the photography must be stated explicitly in writing and submitted to the pharmacy owner and CARE Pharmacies Inc. corporate office. The statement of intended use must be presented with distinct detail and include the pharmacy product(s) or service(s) being filmed, the reason for filming/photography, any accompanying text or images, and how images of CARE pharmacy personnel, paperwork, and/or services will be used.
 - b. Photos, et.al. shall not be used beyond what is stated on the authorization form without the individual pharmacy's authorization. Authorization forms shall not be vague or ambiguous.
 - c. The photo(s) et.al. may be released by the individual or organization taking said images in the following cases: (1) in compliance with written/electronic authorization from CARE Pharmacies; (2) to comply with valid legal requests or orders to produce the photograph as approved by General Counsel; or (3) to otherwise comply with applicable federal, state or local laws or regulations.
2. Photo Consent and Authorization Form Guidelines
 - a. CARE Pharmacies executive management reserves the right to restrict or deny the use of photography and similar, in accordance with applicable laws and regulations and/or if such use might be harmful to the reputation of CARE or to its healthcare purposes.
 - b. Permission to photograph the pharmacy may commence only if the access control criteria have been satisfied. If permission is granted, the photographer or videographer shall advise an authorized CARE Pharmacies representative of the need for personnel, equipment, or other anticipated assistance. If the scope of photography changes significantly from the original request, permission to copy or film may be withdrawn.
3. A valid photo and video authorization and consent form will contain all of the following information:
 - a. Thorough description of the photo or video use, including exactly:
 - i. Who will be taking the photo
 - ii. What will be photographed or videoed
 - iii. Why photo or video is required
 - iv. When photo or video will occur
 - v. Where filming will occur
 - vi. How filming will proceed
 - b. A statement from the photographer or videographer that indicates: "Pharmacy photograph(s), video, and/or photocopies will not be used for any other purpose without the express permission of CARE Pharmacies Inc."
 - c. Written authorization from CARE Pharmacies for video or photography
 - d. Individual's printed name, signature, affiliation, and date

I (video or photographer) certify that I have read and understand the above statement of policy, and agree to its terms and stipulations. Yes No

PHARMACY PHOTOGRAPHY AND VIDEO AUTHORIZATION FORM (continued)

VIDEO OR PHOTOGRAPHING ENTITY

In accordance with section 3A, details of the photo and video request are as follows:

I hereby confirm that CARE pharmacy photograph(s), video, or photocopies will not be used for any other purpose than that stated, without the express permission of CARE Pharmacies Inc. Further, video or photography of CARE Pharmacy staff, files, and other overall pharmacy products and services shall remain compliant with confidentiality and privacy laws and other local, state, and federal regulations. _____ (please initial).

Signature: _____ Date _____

Printed Name: _____

Title: _____

Organization: _____

#####

CARE PHARMACIES INC.

CARE Pharmacies Inc. hereby approves said request to: Photocopy Photograph Videotape

Applicable Conditions: _____

CARE Pharmacies Inc. hereby denies said request to: Photocopy Photograph Videotape

Reason for Denial: _____

Signature: _____ Date _____

Printed Name: _____

Title: _____

CARE Pharmacy Location: _____

CARE Pharmacies, Inc.

Quality Assurance

Policy Manual

Data Management and Contingency Planning

NOTICE OF CONFIDENTIALITY

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POLICY NAME: **Data Management and Contingency Planning**

POLICY NUMBER: QA10 ORIGINAL DATE OF ISSUE: 01/01/2009

REVISION NUMBER: Original REVISION DATE OF ISSUE: xx/xx/xxxx

PAGES: 3

AUTHORED BY: Carolyn Miller, Director of Quality Assurance & Pharmacy Operations

AUTHORIZED BY: Gerry Crocker, Chief Executive Officer

- 1) **INTRODUCTION: The data management and contingency policy aims to enhance preparedness and limit vulnerability in the event of an emergency. Crisis preparedness serves to maintain continuity of care via agreements with contractors, vendors, or other affiliates, as well as provision of a process for pharmacy systems data recovery and restoration.**
- 2) **RESPONSIBILITIES**
 - a) **The Pharmacy Manager or Pharmacist-in-Charge (PIC) will oversee policy compliance for personnel under his or her supervision.**
 - b) **All CARE Pharmacies employees and contractors will adhere to the policies and SOPs in this manual.**
 - c) **The Quality Assurance department reserves the right to regularly perform audits, both on and off site.**
- 3) **SCOPE: This policy shall apply to all CARE Pharmacies pharmacy sites.**

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- 4) **PURPOSE:** In an effort to resume pharmacy operations as expeditiously as possible, this document serves to provide an outline of the procedures CARE Pharmacies Inc shall follow in the event of a catastrophe, disaster, or other scenario that may cause a disruption of service(s) due to events that occur naturally, accidentally, or intentionally.
- 5) **POLICY**
- a) Although the pharmacy owner may designate an on-site systems administrator or similar, the pharmacy owner has the ultimate responsibility for the handling and execution of all aspects of pharmacy data management to include daily computer system backups, access to current technical support services contact(s), seven year record retention, and documentation destruction methods which do not to breach confidentiality standards.
 - b) Every CARE Pharmacies site shall utilize anti-virus, sonic wall, or fire wall protection mechanisms which shall be maintained and updated accordingly.
 - c) Every CARE Pharmacies site shall engage in daily facility backups via automatic main server E-vaulting, or via the utilization of tapes or CDs. Daily facility backups are essential to the recovery and restoration efforts of patient and other pharmacy information.
 - i) Pharmacies that use the same computer system as that of CARE corporate shall subscribe to the system's E-vaulting offer to provide daily facility backups.
 - (1) E-vaulting is an automatic process conducted by the main server entity and does not require pharmacy manpower or man hours.
 - (2) The process of E-vaulting shall occur during non business hours and does not require pharmacy manpower or man hours.
 - ii) Pharmacies that do not use the same computer system as that of CARE corporate or are unable to utilize E-vaulting services shall use tapes or CDs that are not re-writeable; that is to say, one disc/tape for each day the backup is performed.
 - iii) CARE corporate as well as the pharmacies shall maintain files for seven years prior to destruction eligibility. These files may be kept on site or an approved off site data repository that is easily accessible when, if, and as necessary.
 - d) The pharmacy shall have current Tech Support contact information easily accessible.
 - i) Pharmacies that use the same computer system as that of CARE corporate may contact the HBS Interactive Support Specialist with issues related to the pharmacy system. HBS can be reached at 1-800-444-1427, extension 9122, or option 1.

- (1) Pharmacies that are unable to process claims, have a printer malfunction, system crash, or other debilitating operational issues during regular business hours (8 a.m. to 5 p.m.) shall utilize the *System Down* line at 1-800-444-1427. For immediate assistance and to have a team member paged, dial 0. For a down system, dial extension 9588.**
 - (2) Pharmacies that are unable to process claims, or experience a printer malfunction, system crash, or other debilitating operational issue before or after regular business hours shall utilize the *Emergency After Hours* line at 1-800-444-1427, option 1, then option 2. Pharmacy staff shall leave a voice mail message with the expectation that HBS will return the call within a ten (10) minute span.**
 - (3) Per contractual vendor obligations, if HBS is contacted due to debilitating computer operations, the vendor is responsible for discovery and provision of an appropriate resolution. With the exception of holidays, and between the hours of 8:00 a.m. and 8:00 p.m. Monday through Friday, HBS will respond within four (4) hours of a logged service request. If the issue entails part replacement, the vendor shall make every reasonable effort to provide a substitute component by no later than 10:00 a.m. the following business day.**
 - (4) Pharmacies performing their own backups shall communicate with HBS then send the backup disc or tape to HBS at 738 Louis Drive, Warminster, PA 18974 via overnight mail. HBS will then recover and upload pharmacy data as recent as daily facility backups have captured.**
- ii) Pharmacies that do not use the same computer system as that of CARE corporate shall contact their selected software vendor with problems or other computer related issues.**
 - iii) The Director of Technical Services, 703-414-5434, is the designated CARE Pharmacies corporate contact and liaison for technical and information support issues.**
 - iv) In the event of data loss or security breach, pharmacies shall immediately contact their respective software vendor(s) as well as CARE's Director of Technical Services.**

CARE Pharmacies, Inc.

Quality Assurance

Policy Manual

Quality Improvement Program

NOTICE OF CONFIDENTIALITY

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POLICY NAME: **Quality Improvement Program**

POLICY NUMBER: QA11 ORIGINAL DATE OF ISSUE: 01/01/2009

REVISION NUMBER: Original REVISION DATE OF ISSUE: xx/xx/xxxx

PAGES: 11

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- 1) **INTRODUCTION:** The quality improvement program policy serves to establish a pharmacy procedure that is dedicated to continuous improvement endeavors and thereby strives to meet and exceed customer expectations via safe, reliable, timely, and effective deliverables.
- 2) **RESPONSIBILITIES**
 - a) The Pharmacy Manager or Pharmacist-in-Charge (PIC) will oversee policy compliance and conformance for personnel under his or her supervision.
 - b) All CARE Pharmacies employees and contractors will adhere to the policies and SOPs in this manual.
 - c) The Quality Assurance department reserves the right to regularly perform audits, both on and off site.
- 3) **SCOPE:** This policy shall apply to all CARE Pharmacies pharmacy sites.

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- 4) PURPOSE:** This document is designed to provide a formal outline of the procedures CARE Pharmacies Inc shall follow in an effort to analyze, measure, and improve upon the delivery of client services. In an ever changing, evolving marketplace and economy, continuous improvement undertakings will allow the pharmacy to meet or exceed customer wants and needs while continuing to maintain a competitive edge. Continuous improvement initiatives include, but are not limited to:
- a) Development, enhancement, and enforcement of written, documented standard operating procedures, processes, or policies
 - b) Availability of continuing education and training across relevant disciplines
 - c) Provision of a performance management and process improvement mechanism via utilization of valuable communication and constructive feedback techniques
 - d) Clarity of rights and responsibilities with regard to patient v provider
 - e) Resolution of all [potential] complaints amicably, effectively, safely, and in a timely manner
 - f) Dedication to internal controls such as conducting compliance audits and implementing corrective and preventive actions (CAPA) when or if necessary or appropriate
- 5) POLICY**
- a) The CARE Quality Assurance (QA) and Pharmacy Operations team, with the support of executive management, aims to ensure that each CARE pharmacy operates within acceptable standards of practice and in accordance with the CARE Pharmacies QA policy and procedures manual.
 - i) CARE Corporate shall take accountability for and ownership of the development and administration of an up-to-date, documented, company-wide QA policy and procedure and improvement program manual. Compliance and conformance shall be monitored by the QA team working in conjunction with the pharmacy manager and/or owner.
 - ii) The pharmacy owner or manager shall ensure that the facility and employee is properly and legally licensed and credentialed.
 - b) Continuing education (CE) is an investment in one's future; therefore, schooling, technical programs, or attendance at other training seminars or professional credentialing courses shall be expected of all pharmacy personnel.

- i) Each and every new employee shall receive on-site training followed by practical evaluation or review. Introductory training may include, but is not limited to, processes associated with privacy rules, sensitivity training, computer usage, prescription refill compliance, comprehension of government standards, and similar. All training sessions shall be documented noting attendance, course description, and other relevant CE material.**

- ii) Pharmacy personnel shall engage in continuing education (CE) with regard to changes and updates to applicable and evolving laws and regulations relevant to his or her business operations functionality. Pharmacists and/or technicians shall earn the applicable amount of CE credits in accordance with her or her State Board of Pharmacy requirements. Additionally, pharmacy personnel shall be made aware of and be versed in any restructured employment standards.**

- iii) AIDS Drug Assistance Program (ADAP) participating pharmacy staff will attend ongoing DOH-HAA sponsored training that shall occur quarterly with an expected typical duration of approximately four (4) hours.**

- c) Two way communication and acceptance of constructive criticism or feedback shall be welcomed by pharmacy personnel as well as by CARE Corporate. Open communication channels are an essential element for optimum customer service.**
 - i) Communication assists the overall quality improvement program gain support both internally and externally.**
 - (1) Pharmacy staff is encouraged to speak with, and listen to, customers with regard to customer perception(s) of pharmacy health care delivery. Ask open ended questions, seek ideas or suggestions, and determine how the pharmacy might compare to its competition.**
 - (a) Written patient satisfaction surveys shall be used to engage customers to offer constructive criticism and provide feedback as it relates to the provision of pharmacy services. Surveys shall be given out one month per quarter, or for thirty consecutive days four times per year.**
 - (b) A written customer survey shall be placed in every prescription bag of all AIDS Drug Assistance Program (ADAP) patients to include both new and returning customers.**
 - (c) Results of pharmacy customer satisfaction feedback shall be shared with CARE Corporate and the Board of Directors as deemed appropriate.**

- (2) Management is encouraged to speak with, and listen to, his or her employees with regard to perceived performance. Refer to the Human Resources manual for a detailed performance management form. Seek ideas or suggestions; determine how the pharmacy and its management might compare to its competition.**
 - (a) Pharmacy employees are encouraged to open dialogue with the pharmacy manager, owner, PIC, or alternatively, the employee is invited to contact CARE Corporate or his or her Ombudsman in the event of a complaint, a notable violation, or to receive clarification on company policy.**
 - (b) No pharmacy employee shall be subject to intimidation or retaliation. While his or her confidentiality shall be respected, contact information is an important element in the obtainment and validation of clear, concise, complete, and correct description of evidence, events, and/or concerns. Identification is also necessary if a follow-up status report notification is desired or requested.**
- ii) Feedback received in any way, shape, or form, written or verbal, shall be noted and trended so that recommendations for corrective and/or preventive actions may be sufficiently set forth.**
- d) The pharmacy has an obligation to protect and promote the rights of its customers. Both customers and pharmacy staff have the right to be treated with dignity and respect. Customers have a right to confidentiality, and the pharmacy has a right to refuse certain service(s) within legitimate boundaries. The patient is responsible for his or her own contact information and condition accuracy while the pharmacy is responsible for provision of effective communications. Patient rights and responsibilities page attached.**
- e) A complaint is a written or verbal communication that expresses dissatisfaction concerning any aspect of provision of services. Provision of services shall encompass the actions, or lack thereof, of CARE Pharmacies personnel. Anyone who has used or seeks to use the services rendered by CARE Pharmacies or any representative of such may communicate a complaint.**
 - i) Each staff member maintains the responsibility of ownership once he or she is made aware of an issue of discontent. If the issue cannot be corrected immediately, and if the customer remains dissatisfied, the complaint shall be escalated to the PIC. Further escalation, such as the individual pharmacy owner or intervention by CARE Corporate for example, may occasionally be required.**
 - ii) All complaints, formal or informal, must be recorded and dealt with in a timely manner. A sample complaint form is attached.**

- iii) **Pharmacy staff shall confidentially interview the customer with regard to the complaint to commence the investigative process.**
 - iv) **Whenever possible, the customer should put the complaint in writing. The customer shall be encouraged to provide as much detail as possible without the fear of retaliation of any kind.**
 - v) **If an immediate fix is not plausible, the pharmacy shall keep the customer informed, in the same manner in which the complaint was provided, as to the progress of complaint resolution. Notice shall be provided no later than fifteen (15) days upon receipt of complaint.**
 - vi) **The final stage of the complaint process entails notification to the patient/customer which outlines the complaint, research conducted, and the corrective and preventive measure(s) implemented as the case warrants. All records of such must be documented and retained; the complaint is then closed.**
- f) **Internal controls, via the utilization of quality tools and techniques, shall be governed by CARE Pharmacies on a corporate level.**
- i) **Monitoring mechanisms include generation of pharmacy system reports, real-time-on-site observation, internal process and procedural audits, as well as customer feedback via surveys or on-site visitation, etc. Data collected shall include both quantitative data (measurable by count) and qualitative data (obtained by observation).**
 - ii) **The QA and pharmacy operations team shall engage in impartial on and off site compliance audits geared toward driving improvement(s); the auditing entity will gather information, investigate potential process deviations or suspected noncompliance or nonconformance issues, evaluate controls for adequacy and effectiveness, and issue CAPAs intended to protect the pharmacy from risk or liability.**
 - (1) **Risk reduction and management endeavors include a constant and continuous assessment, review, or appraisal of suspected or potential hazards or threats, followed by the identification of risk tradeoffs, and, ultimately, taking the necessary steps to manage said risk(s) with the intended result of enhanced quality outcomes. Risk management serves to preserve the pharmacy's wealth, well-being, and reputation, while eradicating negative publicity, loss of customer loyalty, and/or legal implications.**
 - (2) **Audits serve to verify that agreed upon criteria has been met and determine if business goals are being addressed; they identify areas of opportunity or cost-savings,**

strengths and weaknesses associated with training effectiveness, and discover potential regulatory or contractual deficiencies. Further, audit results assist management in making educated decisions with regard to business performance, business development, and strategic planning ventures. Overall, audits serve to build credibility.

- (3) The QA team shall engage in root cause analysis which is valuable in the prevention of recurring problems or incidents.
 - (4) Pharmacy staff shall be cognizant of lean principles, such as the 5S theory (sort, straighten, sweep/shine, standardize, sustain), designed to minimize waste. Poor performance indicators such as redoing work, delays or backlogs, wasted time, non value adding work responsibilities, complicated facility or work station layout(s), are symptoms of ineffectiveness and inefficiency and must be improved upon.
- iii) The QA team shall take a proactive approach to continuous improvement by monitoring and comparing the price of conformance and compliance to the price of nonconformance and noncompliance or, measuring the costs associated with ensuring an adequate and realistic level of quality services against losses sustained for failing to achieve it.
 - iv) Pharmacy personnel shall adhere to company policies and procedures as outlined in the QA manual. Further, pharmacy personnel shall be advised of disciplinary actions associated with violations of the law or other intentional or unintentional noncompliance activities.
 - (1) Consequences associated with noncompliance may result in civil or criminal penalties of monetary value, prison time, or both, depending on the nature of the offense.
 - (2) Violators may be subject to disciplinary action, to include written or verbal warnings, suspension, or termination for lack of compliance or conformance to this policy or for failing to report any witnessed or known violation of this policy.

Customer Satisfaction and Opinion Survey

CARE’s culture of quality and integrity aims to ensure success via the provision of consistently safe and reliable care. Our desire is to meet and to exceed your expectations...let your voice be heard!

Please rate each item on a scale from one (1), strongly disagree (👎 poor) to five (5), strongly agree (👍 excellent) with N/A being not applicable.

1. The pharmacy staff was courteous and polite.

👎	1	2	3	4	5	👍	N/A
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2. Your item(s) were ready within the promised time frame.

👎	1	2	3	4	5	👍	N/A
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3. Your order was complete upon receipt.

👎	1	2	3	4	5	👍	N/A
---	---	---	---	---	---	---	-----

4. The pharmacy delivery personnel were respectful of your time.

👎	1	2	3	4	5	👍	N/A
---	---	---	---	---	---	---	-----

5. The pharmacy was able to supply all of the products/services you required.

👎	1	2	3	4	5	👍	N/A
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6. Pharmacy personnel offered you clear instructions on how to use meds or equipment.

👎	1	2	3	4	5	👍	N/A
---	---	---	---	---	---	---	-----

7. You are aware of all of the products and services the pharmacy is able to provide to you.

👎	1	2	3	4	5	👍	N/A
---	---	---	---	---	---	---	-----

8. You would refer this pharmacy to your family or friends.

👎	1	2	3	4	5	👍	N/A
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If you have any additional comments or concerns you would like to share, we welcome your feedback.

Customer Service and Satisfaction Survey

CARE Pharmacies is dedicated to the delivery and provision of high quality services and we strive to be proactive in meeting and maintaining customer needs and wants. The CARE network of pharmacies is passionate about safe, consistent, and reliable performance provided via a comfortable, confidential, welcoming environment.

Your opinion is important to us. CARE is serious about its rendering of quality services, and the driving force behind our commitment to excellence is you, our customer. Taking a moment to complete our customer service satisfaction survey would be greatly appreciated.

1. Pharmacy name and location: _____
2. Date/Timeframe of service or visit: (year) _____

Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----
3. Approximately how long was your pharmacy wait time? _____ hrs _____ min
4. Were you aware of the pharmacy's complementary drug delivery service? Yes No
5. Was your medication in inventory and readily available for pickup/delivery? Yes No
 - a. Was the refill picked up and/or delivered on time? Yes No
 - b. If not, why? _____

6. Is this pharmacy your dedicated source for medication or do you utilize multi-sources? _____
 - a. If you use multiple pharmacies, why? _____

7. Were you offered counseling (introductory, adherence, drug interactions)? Yes No
 - a. Did you accept counseling? Yes No
 - b. If you declined counseling, why? _____

8. Was educational printed material available and/or provided to you? Yes No
9. Does staff communicate effectively (language, knowledge, willingness to be helpful)? Yes No
 - a. If not, please elaborate. _____

10. Are you comfortable engaging in discussion(s) with your pharmacist(s)? Yes No
 - a. If not, why? _____

11. Additional Comments? _____

12. Overall, how would you rate this pharmacy with 1 being poor and 10 being excellent? _____

Thank you for your time; any and all feedback is welcome. The CARE network of pharmacies will make every effort to maintain and/or enhance the quality of services provided to you. Your voice, your satisfaction, matters.

Patient Rights and Responsibilities

CARE Pharmacies staff has an obligation to protect and promote the rights of our clients.

As the patient/caregiver, you have the RIGHT to:

- Be treated with dignity, respect, and nondiscrimination
- Confidentiality and privacy of patient records and information pertaining to patient care
- Provision of equipment, medication, supplies, and service in a timely manner
- Be provided with accurate and clear information about your health and health care provider
- Be informed of providers and plans reimbursement criteria, as well as be notified of financial responsibility for products or services not fully reimbursed by health care insurers to include Medicare and Medicaid
- Express grievances without fear of reprisal or discrimination
- Have a manufacturer's warranty honored if product was purchased from this pharmacy
- Be informed of company ownership

As the pharmacy/provider, we have the RIGHT to:

- Refuse service to a patient when or if his or her behavior warrants such action, as in the case of uncontrollable or unmanageable conduct
- Express and address grievances without fear of reprisal or discrimination
- Refuse honoring a warranty if the item was misused or not purchased from this store

As the patient/caregiver, you are RESPONSIBLE for:

- Notifying the provider of any changes to address, phone number(s), email, or insurance status
- Notifying the provider of any change in condition, physician orders, or physician designation
- Participation in the treatment decision making process
- Taking accountability for your own actions if you do not follow your plan of care properly

PHARMACY COMPLAINT FORM

A complaint is a communication that expresses dissatisfaction concerning any aspect of provision of pharmacy services. Provision of services encompasses the actions, or lack thereof, of pharmacy personnel. Please provide as much detail as possible.

THE COMPLAINANT

Submitted by: _____ Date: _____

Nature of complaint: _____

Did injury occur? Yes* No

**If injury occurred, be sure to also complete the Workplace Accident/Incident Form.*

Did injury require physician or hospital visit? Yes No Waived N/A

Ideas for corrective or preventive actions (CAPAs) are welcomed but not necessary: _____

#####

PHARMACY RECEIPT OF COMPLAINT

Complaint Received by _____ Date _____

Additional notes or comments that may be helpful to the investigation: _____

#####

PHARMACY COMPLAINT FORM (Continued)

PHARMACY ASSESSMENT

Complaint Reviewed and Evaluated By _____ Date _____

Escalation Required? Yes No

If yes, note to whom: _____

Reason for escalation: _____

Brief description of complaint: _____

CAPA Required? Yes No

If yes, CAPAs to be implemented and when: _____

#####

RESOLUTION

CAPAs Implemented? Yes No Closed

If no, explain: _____

Was customer notified of status? Yes, date _____, via (circle) mail, phone, personally

No

If no, explain: _____

Complaint Closed by: _____ Date: _____

Notes: _____

This form shall be retained on file, and in adherence with applicable privacy rules and regulations.

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<u>Index Term</u>	<u>Policy Section</u>
ADAP	Pharmacy Consultation and Counseling Inventory Storage and Handling Pharmacy Responsibilities Prescription Fill and Refill Personnel Training, Development, & Evaluation Quality Improvement Program
Adherence	Pharmacy Consultation and Counseling
Adverse Reaction	Drug Interaction, Reaction, or Incident(s)
AIDS Drug Assistance Program (ADAP)	Pharmacy Consultation and Counseling Inventory Storage and Handling Pharmacy Responsibilities Prescription Fill and Refill Personnel Training, Development, & Evaluation Quality Improvement Program
Allergy	Drug Interaction, Reaction, or Incident(s)
Audits	Pharmacy Responsibilities Privacy and Information Security Quality Improvement Program
Auxiliary Stickers	Pharmacy Consultation and Counseling
Complaint	Quality Improvement Program
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Consultation	Pharmacy Consultation and Counseling Privacy and Information Security
Contingency Plan	Pharmacy Responsibilities
Corrective and Preventive Actions (CAPA)	Quality Improvement Program



Counseling	Pharmacy Responsibilities Prescription Fill and Refill
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Health Insurance Portability and Accountability Act (HIPAA)	Drug Interaction, Reaction, or Incident(s) Privacy and Information Security Personnel Training, Development, & Evaluation



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NDC	Drug Interaction, Reaction, or Incident(s)
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