Standard Operating Procedures

March 2024

[Address Redacted] [Address Redacted] At Pure Pharmacy our goal is to provide the best possible care to our patients. In order for us to do that, we must all work together and be on the same page. Let's begin...

What are Standard Operating Procedures?

Standard Operating Procedures or SOPs are a set of rules by which we must all act by and comply with in order to safeguard the practice of pharmacy and the trust our patients have in us.

How often are Standard Operating Procedures Updated?

Standard Operating Procedures (SOPs) are updated continually. It is your obligation to stay current with the policies and procedures of our practice. If you have any questions, please let us know.

STANDARD OPERATING PROCEDURES

PROCEDURES GOVERNING THE PRACTICE

Policy Purpose:

These policies and procedures are continually maintained and updated by pharmacy management. Documents list dates the standard operating procedure was created, amended, or deemed no longer applicable. While the contents here may not cover all situations, their goal is to establish a mutual understanding amongst all pharmacy staff on fundamental aspects that govern the practice.

This standard operating manual is being provided to all employees as a general source of information about the policies, practices, and procedures at PURE PHARMACY. We request that all employees familiarize themselves with its contents and direct any questions to the Director.

This employee manual supersedes all previous employee manuals, regulations, work rules, and procedures. The policies summarized within apply to all employees of PURE PHARMACY and are subject to change or elimination by the company in some cases without notice, with the exception of the at-will employment provision set forth in the disclaimer below.

DISCLAIMER

THE POLICIES IN THIS MANUAL DO NOT CONSTITUTE AN AGREEMENT OTHER THAN EMPLOYMENT AT WILL. THE EMPLOYEE OR THE FIRM MAY TERMINATE THE EMPLOYMENT RELATIONSHIP AT ANY TIME WITH OR WITHOUT NOTICE AND FOR NO REASON OR ANY REASON. NO AGREEMENT TO THE CONTRARY WILL BE VALID UNLESS SUCH AGREEMENT IS IN WRITING AND SIGNED BY EACH OF THE OWNERS.

PURE PHARMACY

[Address Redacted] [Address Redacted] [Phone Redacted]

STANDARD OPERATING PROCEDURES

These documents set forth the operating agreements governing this practice.

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Medical Billing Terminology

ACA - Affordable Care Act. Also referred to as "ObamaCare". A Federal law enacted in 2010 intended to increase healthcare coverage and make it more affordable. It also expands Medicaid eligibility and guarantees coverage without regard to pre-existing medical conditions.

Accept Assignment - When a healthcare provider accepts as full payment the amount paid on a claim by the insurance company. This excludes patient responsible amounts such as coinsurance or copay.

Adjusted Claim - When a claim is corrected which results in credit or payment to the provider.

Allowed Amount - The reimbursement amount an insurance company will pay for a healthcare procedure. This amount varies depending on the patient's insurance plan. For 80/20 insurance, the provider accepts 80% of the allowed amount and the patient pays the remaining 20%.

AMA - American Medical Association. The AMA is the largest association of doctors in the United States. They publish the Journal of American Medical Association which is one of the most widely circulated medical journals in the world.

Aging - One of the medical billing terms referring to unpaid insurance claims or patient balances that are due past 30 days. Most medical billing software's have the ability to generate a separate report for insurance aging and patient aging. These reports typically list balances by 30, 60, 90, and 120-day increments.

Ancillary Services - These are typically services that a patient requires in a hospital setting that are in addition to room and board accommodation - such as surgery, lab tests, counseling, therapy, etc.

Appeal - When an insurance plan does not pay for treatment, an appeal (either by the provider or patient) is the process of objecting to this decision. The insurer may require documentation when processing an appeal and typically has a formal policy or process established for submitting an appeal. Many times, the process and associated forms can be found on the insurance providers web site.

Applied to Deductible (ATD) - You typically see these medical billing terms on the patient statement. This is the amount of the charges, determined by the patient's insurance plan, the patient owes the provider. Many plans have a maximum annual deductible that once met is then covered by the insurance provider.

Assignment of Benefits (AOB) - Insurance payments that are paid directly to the doctor or hospital for a patient's treatment. This is designated in Box 27 of the CMS-1500 claim form.

ASP - Application Service Provider. This is a computer-based service over a network for an application. Sometimes referred to as SaaS (Software as a Service). Their

application service providers that offer Medical Billing. The appeal of an ASP is it frees a business of the need to purchase, maintain, and backup software and servers.

Authorization - When a patient requires permission (or authorization) from the insurance company before receiving certain treatments or services.

Beneficiary - Person or persons covered by the health insurance plan and eligible to receive benefits.

Blue Cross Blue Shield (BCBS) - An organization of affiliated insurance companies (approximately 450), independent of the association (and each other), that offer insurance plans within local regions under one or both of the association's brands (Blue Cross or Blue Shield). Many local BCBS associations are non- profit BCBS sometimes acts as administrators of Medicare in many states or regions.

Capitation - A fixed payment paid per patient enrolled over a defined period of time, paid to a health plan or provider. This covers the costs associated with the patients' health care services. This payment is not affected by the type or number of services provided.

Carrier - Simply the insurance company or "carrier" the patient has a contract with to provide health insurance.

Category I Codes - Codes for medical procedures or services identified by the 5 digit CPT Code.

Category II Codes - Optional performance measurement tracking codes which are numeric with a letter as the last digit (example: 9763B).

Category III Codes - Temporary codes assigned for collecting data which are numeric followed by a letter in the last digit (example: 5467U).

CHAMPUS - Civilian Health and Medical Program of the Uniformed Services. Recently renamed TRICARE. This is federal health insurance for active duty military, National Guard and Reserve, retirees, their families, and survivors.

Charity Care - When medical care is provided at no cost or at reduced cost to a patient that cannot afford to pay.

Clean Claim - Medical billing term for a complete submitted insurance claim that has all the necessary correct information without any omissions or mistakes that allows it to be processed and paid promptly.

Clearinghouse - This is a service that transmits claims to insurance carriers. Prior to submitting claims, the clearinghouse scrubs claim and checks for errors. This minimizes the amount of rejected claims as most errors can be easily corrected. Clearinghouses electronically transmit claim information that is compliant with the strict HIPPA standards (this is one of the medical billing terms we see a lot more of lately).

CMS - Centers for Medicaid and Medicare Services. Federal agency which administers Medicare, Medicaid, HIPPA, and other health programs. Formerly known as the HCFA (Health Care Financing Administration). You'll notice that CMS it the source of a lot of medical billing terms.

CMS 1500 - Medical claim form established by CMS to submit paper claims to Medicare and Medicaid. Most commercial insurance carriers also require paper claims be submitted on CMS-1500's. The form is distinguished by its red ink.

Coding - Medical Billing Coding involves taking the doctors notes from a patient visit and translating them into the proper diagnosis (ICD-9 or ICD-10 code) and treatment medical billing codes such as CPT codes. This is for the purpose of reimbursing the provider and classifying diseases and treatments.

COBRA Insurance - This is health insurance coverage available to an individual and their dependents after becoming unemployed - either voluntary or involuntary termination of employment for reasons other than gross misconduct. Because it does not typically receive company matching, it's typically more expensive than insurance the cost when employed but does benefit from the savings of being part of a group plan. Employers must extend COBRA coverage to employees dismissed for a. COBRA stands for Consolidated Omnibus Budget Reconciliation Act which was passed by Congress in 1986.

COBRA coverage typically lasts up to 18 months after becoming unemployed and under certain conditions extend up to 36 months.

Co-Insurance - Percentage or amount defined in the insurance plan for which the patient is responsible. Most plans have a ratio of 90/10 or 80/20, 70/30, etc. For example, the insurance carrier pays 80% and the patient pays 20%.

Collection Ratio - This is in reference to the providers accounts receivable. It's the ratio of the payments received to the total amount of money owed on the providers accounts.

Contractual Adjustment - The amount of charges a provider or hospital agrees to write off and not charge the patient per the contract terms with the insurance company.

Coordination of Benefits (COB) - When a patient is covered by more than one insurance plan. One insurance carrier is designated as the primary carrier and the other as secondary.

Co-Pay - Amount paid by patient at each visit as defined by the insured plan.

CPT Code - Current Procedural Terminology. This is a 5-digit code assigned for reporting a procedure performed by the physician. The CPT has a corresponding ICD-9 diagnosis code. Established by the American Medical Association. This is one of the medical billing terms we use a lot.

Credentialing - This is an application process for a provider to participate with an insurance carrier. Many carriers now request credentialing through CAQH. The CAQH credentialing process is a universal system now accepted by insurance company networks.

Credit Balance - The balance that's shown in the "Balance" or "Amount Due" column of your account statement with a minus sign after the amount (for example \$50-). It may also be shown in parenthesis; (\$50). The provider may owe the patient a refund.

Crossover claim - When claim information is automatically sent from Medicare the secondary insurance such as Medicaid.

Date of Service (DOS) - Date that health care services were provided.

Day Sheet - Summary of daily patient treatments, charges, and payments received.

Deductible - amount patient must pay before insurance coverage begins. For example, a patient could have a \$1000 deductible per year before their health insurance will begin paying. This could take several doctor's visits or prescriptions to reach the deductible.

Demographics - Physical characteristics of a patient such as age, sex, address, etc. necessary for filing a claim.

DME - Durable Medical Equipment - Medical supplies such as wheelchairs, oxygen, catheter, glucose monitors, crutches, walkers, etc.

DOB - Abbreviation for Date of Birth

Down coding - When the insurance company reduces the code (and corresponding amount) of a claim when there is no documentation to support the level of service submitted by the provider. The insurers computer processing system converts the code submitted down to the closest code in use which usually reduces the payment.

Duplicate Coverage Inquiry (DCI) - Request by an insurance company or group medical plan by another insurance company or medical plan to determine if other coverage exists.

Dx - Abbreviation for diagnosis code (ICD-9 or ICD-10 code).

Electronic Claim - Claim information is sent electronically from the billing software to the clearinghouse or directly to the insurance carrier. The claim file must be in a standard electronic format as defined by the receiver.

Electronic Funds Transfer (EFT) - An electronic paperless means of transferring money. This allows funds to be transferred, credited, or debited to a bank account and eliminates the need for paper checks.

E/M - Medical billing terms for the Evaluation and Management section of the CPT codes. These are the CPT codes 99201 thru 99499 most used by physicians to access (or evaluate) a patient's treatment needs.

EMR - Electronic Medical Records. Also referred to as EHR (Electronic Health Records). This is a medical record in digital format of a patient's hospital or provider treatment. An EMR is the patient's medical record managed at the providers location. The EHR is a comprehensive collection of the patient's medical records created and stored at several locations.

Encryption - Conversion of data into a form that cannot be easily seen by someone who is not authorized. Encrypted emails may be used when sending patient info to comply with HIPAA requirements for protection of patient information.

Enrollee - Individual covered by health insurance

EOB - Explanation of Benefits. One of the medical billing terms for the statement that comes with the insurance company payment to the provider explaining payment details, covered charges, write offs, and patient responsibilities and deductibles.

ERA - Electronic Remittance Advice. This is an electronic version of an insurance EOB that provides details of insurance claim payments. These are formatted in according to the HIPAA X12N 835 standard.

ERISA - Employee Retirement Income Security Act of 1974. This law established the reporting, disclosure of grievances, and appeals requirements and financial standards for group life and health. Self- insured plans are regulated by this law.

Errors and Omissions Insurance - Liability insurance for professionals to cover mistakes which may cause financial harm to another part.

Fair Credit Reporting Act - Federal law that regulates the collection and use of consumer credit information.

Fair Debt Collection Practices Act (FDCPA) - Federal law that regulates creditor or collection agency practices when trying to collect on past due accounts.

Fee for Service - Insurance where the provider is paid for each service or procedure provided. Typically allows patient to choose provider and hospital. Some policies require the patient to pay provider directly for services and submit a claim to the carrier for reimbursement. The trade-off for this flexibility is usually higher deductibles.

Fee Schedule - Cost associated with each CPT treatment billing code for a provider's treatment or services.

Financial Responsibility - The portion of the charges that are the responsibility of the patient or insured. Fiscal Intermediary (FI) - A Medicare representative who processes

Medicare claims.

Formulary - A list of prescription drug costs which an insurance company will provide reimbursement for.

Fraud - When a provider receives payment, or a patient obtains services by deliberate, dishonest, or misleading means.

GPH - Group Health Plan. A means for one or more employer who provide health benefits or medical care for their employees (or former employees).

Group Number - Number assigned by insurance company to identify the group under which a patient is insured.

Guarantor - A responsible party and/or insured party who is not a patient.

HCFA - Health Care Financing Administration. Now known as CMS (see above in Medical Billing Terms).

HCPCS - Health Care Financing Administration Common Procedure Coding System. (pronounced "hick- picks"). Three level system of codes. CPT is Level I. A standardized medical coding system used to describe specific items or services provided when delivering health services. May also be referred to as a procedure code in the medical billing glossary.

Health Savings Account - Also called Flexible Spending Account. A tax-exempt account provided by an employer from which an employee can pay health care related expenses. The current limit is \$2500 per year.

Healthcare Insurance - Insurance coverage to cover the cost of medical care necessary as a result of illness or injury. May be an individual policy or family policy which covers the beneficiary's family members. May include coverage for disability or accidental death or dismemberment.

Healthcare Provider - Typically a physician, hospital, nursing facility, or laboratory that provides medical care services. Not to be confused with insurance providers or the organization that provides insurance coverage.

Health Care Reform Act - Health care legislation championed by President Obama in 2010 to provide improved individual health care insurance or national health care insurance for Americans. Also referred to as the Health Care Reform Bill or the Obama Health Care Plan.

HIC - Health Insurance Claim. This is a number assigned by the Social Security Administration to a person to identify them as a Medicare beneficiary. This unique number is used when processing Medicare claims.

HIPAA - Health Insurance Portability and Accountability Act. Several federal regulations intended to improve the efficiency and effectiveness of health care and establish privacy and security laws for medical records. HIPAA has introduced a lot of new medical billing terms into our vocabulary lately.

HMO - Health Maintenance Organization. A type of health care plan that places restrictions on treatments.

Hospice - Inpatient, outpatient, or home healthcare for terminally ill patients.

ICD-9 Code - Also known as ICD-9-CM. International Classification of Diseases classification system used to assign codes to patient diagnosis. This is a 3 to 5-digit number.

ICD 10 Code - 10th revision of the International Classification of Diseases. Uses 3 to 7 digit. Includes additional digits to allow more available codes. The U.S. Department of Health and Human Services has set an implementation deadline of October 2013 for ICD-10.

Incremental Nursing Charge - Charges for hospital nursing services in addition to basic room and board.

Indemnity - Also referred to as fee-for-service. This is a type of commercial insurance were the patient can use any provider or hospital

In-Network (or Participating) - An insurance plan in which a provider signs a contract to participate in. The provider agrees to accept a discounted rate for procedures.

Inpatient - Hospital stay of more than one day (24 hours).

IPA - Independent Practice Association. An organization of physicians that are contracted with a HMO plan.

Intensive Care - Hospital care unit providing care for patients who need more than the typical general medical or surgical area of the hospital can provide. May be extremely ill or seriously injured and require closer observation and/or frequent medical attention.

MAC - Medicare Administrative Contractor.

Managed Care Plan - Insurance plan requiring patient to see doctors and hospitals that are contracted with the managed care insurance company. Medical emergencies or urgent care are exceptions when out of the managed care plan service area.

Maximum Out of Pocket - The maximum amount the insured is responsible for paying for eligible health plan expenses. When this maximum limit is reached, the insurance typically then pays 100% of eligible expenses

Meaningful Use - A provision of the 2009 HITECH act that provides stimulus money to providers who implement Electronic Health Records (EHR). Providers who implement EHR must show "Meaningful Use" and meet certain requirements defined in the act. The incentive is \$63,750 over 6 years for Medicaid and \$44,000 over 5 years for Medicare. Providers who do not implement EHR by 2015 are penalized 1% of Medicare payments increasing to 3% over 3 years.

Medical Assistant - A health care worker who performs administrative and clinical duties in support of a licensed health care provider such as a physician, physician's assistant, nurse, nurse practitioner, etc.

Medical Coder - Analyzes patient charts and assigns the appropriate code. These codes are derived from ICD-9 codes (soon to be ICD-10) and corresponding CPT treatment codes and any related CPT modifiers.

Medical Billing Specialist - Processes insurance claims for payment of services performed by a physician or other health care provider. Ensures patient medical billing codes, diagnosis, and insurance information are entered correctly and submitted to insurance payer. Enters insurance payment information and processes patient statements and payments. Performs tasks vital to the financial operation of a practice. Knowledgeable in medical billing terminology.

Medical Necessity - Medical service or procedure that is performed on for treatment of an illness or injury that is not considered investigational, cosmetic, or experimental.

Medical Record Number - A unique number assigned by the provider or health care facility to identify the patient medical record.

PURE PHARMACY - Medicare Secondary Payer.

Medical Savings Account - Tax exempt account for paying medical expenses administered by a third party to reimburse a patient for eligible health care expenses. Typically provided by employer where the employee contributes regularly to the account before taxes and submits claims or receipts for reimbursement. Sometimes also referred to in medical billing terminology as a Medical Spending Account.

Medical Transcription - The conversion of voice recorded, or hand written medical information dictated by health care professionals (such as physicians) into text format records. These records can be either electronic or paper.

Medicare - Insurance provided by federal government for people over 65 or people under 65 with certain restrictions. There are 2 parts:

- Medicare Part A Hospital coverage
- Medicare Part B Physicians visits and outpatient procedures
- Medicare Part D Medicare insurance for prescription drug costs for anyone enrolled in Medicare Part A or B.

Medicare Coinsurance Days - Medical billing terminology for inpatient hospital coverage from day 61 to day 90 of a continuous hospitalization. The patient is responsible for paying for part of the costs during those days. After the 90th day, the patient enters "Lifetime Reserve Days."

Medicare Donut Hole - The gap or difference between the initial limits of insurance and the catastrophic Medicare Part D coverage limits for prescription drugs.

Medicaid - Insurance coverage for low income patients. Funded by Federal and state government and administered by states

Medicap - Medicare supplemental health insurance for Medicare beneficiaries which may include payment of Medicare deductibles, co-insurance and balance bills, or other services not covered by Medicare.

Modifier - Modifier to a CPT treatment code that provide additional information to insurance payers for procedures or services that have been altered or "modified" in some way. Modifiers are important to explain additional procedures and obtain reimbursement for them.

N/C - Non-Covered Charge. A procedure not covered by the patients' health insurance plan.

NEC - Not Elsewhere Classifiable. Medical billing terminology used in ICD when information needed to code the term in a more specific category is not available.

Network Provider - Health care provider who is contracted with an insurance provider to provide care at a negotiated cost.

Nonparticipation - When a healthcare provider chooses not to accept Medicareapproved payment amounts as payment in full.

NOS - Not Otherwise Specified. Used in ICD for unspecified diagnosis.

NPI Number - National Provider Identifier. A unique 10-digit identification number required by HIPAA and assigned through the National Plan and Provider Enumeration System (NPPES).

OIG - Office of Inspector General - Part of department of Health and Human Services. Establish compliance requirements to combat healthcare fraud and abuse. Has

guidelines for billing services and individual and small group physician practices.

Out-of Network (or Non-Participating) - A provider that does not have a contract with the insurance carrier. Patients usually responsible for a greater portion of the charges or may have to pay all the charges for using an out-of network provider.

Out-Of-Pocket Maximum - The maximum amount the patient has to pay under their insurance policy. Anything above this limit is the insurers obligation. These Out-of-pocket maximums can apply to all coverage or to a specific benefit category such as prescriptions.

Outpatient - Typically treatment in a physician's office, clinic, or day surgery facility lasting less than one day.

Palmetto GBA - An administrator of Medicare health insurance for the Centers for Medicare & Medicaid Services (CMS) in the US and its territories. A wholly owned subsidiary of BlueCross BlueShield of South Carolina based in Columbia, South Carolina.

Patient Responsibility - The amount a patient is responsible for paying that is not covered by the insurance plan.

PCP - Primary Care Physician - Usually the physician who provides initial care and coordinates additional care if necessary.

POS - Point-of-Service plan. Medical billing terminology for a flexible type of HMO (Health Maintenance Organization) plan where patients have the freedom to use (or self-refer to) non-HMO network providers. When a non-HMO specialist is seen without referral from the Primary Care Physician (self-referral), they have to pay a higher deductible and a percentage of the coinsurance.

POS (Used on Claims) - Place of Service. Medical billing terminology used on medical insurance claims - such as the CMS 1500 block 24B. A two-digit code which defines where the procedure was performed.

For example, 11 is for the doctor's office, 12 is for home, 21 is for inpatient hospital, etc.

PPO - Preferred Provider Organization. Commercial insurance plan where the patient can use any doctor or hospital within the network. Similar to an HMO.

Practice Management Software - software used for the daily operations of a provider's office. Typically used for appointment scheduling and billing.

Preauthorization - Requirement of insurance plan for primary care doctor to notify the patient insurance carrier of certain medical procedures (such as outpatient surgery) for those procedures to be considered a covered expense.

Pre-Certification - Sometimes required by the patient's insurance company to determine medical necessity for the services proposed or rendered. This doesn't guarantee the benefits will be paid.

Predetermination - Maximum payment insurance will pay towards surgery, consultation, or other medical care - determined before treatment.

Pre-existing Condition (PEC) - A medical condition that has been diagnosed or treated within a certain specified period of time just before the patient's effective date of coverage. A Pre-existing condition may not be covered for a determined amount of time as defined in the insurance terms of coverage (typically 6 to 12 months).

Pre-existing Condition Exclusion - When insurance coverage is denied for the insured when a pre-existing medical condition existed when the health plan coverage became effective.

Premium - The amount the insured or their employer pays (usually monthly) to the health insurance company for coverage.

Privacy Rule - The HIPAA privacy standard establishes requirements for disclosing what the HIPAA privacy law calls Protected Health Information (PHI). PHI is any information on a patient about the status of their health, treatment, or payments.

Protected Health Information (PHI) - An individual's identifying information such as name, address, birth date, Social Security Number, telephone numbers, insurance ID numbers, or information pertaining to healthcare diagnosis or treatment.

Provider - Physician or medical care facility (hospital) who provides health

care services. PTAN - Provider Transaction Access Number. Also known as

the legacy Medicare number.

Referral - When one provider (usually a family doctor) refers a patient to another provider (typically a specialist).

Remittance Advice (R/A) - A document supplied by the insurance payer with information on claims submitted for payment. Contains explanations for rejected or denied claims. Also referred to as an EOB (Explanation of Benefits).

Responsible Party - The person responsible for paying a patient's medical bill. Also referred to as the guarantor.

Revenue Code - Medical billing terminology for a 3-digit number used on hospital bills to tell the insurer where the patient was when they received treatment, or what type of item a patient received.

RVU - Relative Value Amount. This is the average amount Medicare will pay a provider or hospital for a procedure (CPT-4). This amount varies depending on geographic location.

Scrubbing - Process of checking an insurance claim for errors in the health insurance claim software prior to submitting to the payer.

Self-Referral - When a patient sees a specialist without a primary

physician referral. Self-Pay - Payment made at the time of service by

the patient.

Secondary Insurance Claim - claim for insurance coverage paid after the primary insurance makes payment. Secondary insurance is typically used to cover gaps in

insurance coverage.

Secondary Procedure - When a second CPT procedure is performed during the same physician visit as the primary procedure

Security Standard- Provides guidance for developing and implementing policies and procedures to guard and mitigate compromises to security. The HIPAA security standard is kind of a sub-set or compliment to the HIPAA privacy standard. Where the HIPAA policy privacy requirements apply to all patient Protected Health Information (PHI), HIPAA policy security laws apply more specifically to electronic PHI.

Skilled Nursing Facility - A nursing home or facility for convalescence. Provides a high level of specialized care for long-term or acutely ill patients. A Skilled Nursing Facility is an alternative to an extended hospital stay or home nursing care.

SOF - Signature on File.

Software As A Service (SAAS) - One of the medical billing terms for a software application that is hosted on a server and accessible over the Internet. SAAS relieves the user of software maintenance and support and the need to install and run an application on an individual local PC or server. Many medical billing applications are available as SAAS.

Specialist - Physician who specializes in a specific area of medicine, such as urology, cardiology, orthopedics, oncology, etc. Some healthcare plans require beneficiaries to obtain a referral from their primary care doctor before making an appointment to see a Specialist.

Subscriber - Medical billing term to describe the employee for group policies. For individual policies the subscriber describes the policyholder.

Superbill - One of the medical billing terms for the form the provider uses to document the treatment and diagnosis for a patient visit. Typically includes several commonly used ICD-9 diagnosis and CPT procedural codes. One of the most frequently used medical billing terms.

Supplemental Insurance - Additional insurance policy that covers claims for deductibles and coinsurance. Frequently used to cover these expenses not covered by Medicare.

TAR - Treatment Authorization Request. An authorization number given by insurance companies prior to treatment in order to receive payment for services rendered.

Taxonomy Code - Specialty standard codes used to indicate a provider's specialty sometimes required to process a claim.

Term Date - Date the insurance contract expired or the date a subscriber or dependent ceases to be eligible.

Tertiary Insurance Claim - Claim for insurance coverage paid in addition to primary and secondary insurance. Tertiary insurance covers gaps in coverage the primary and secondary insurance may not cover.

Third Party Administrator (TPA) - An independent corporate entity or person (third party) who administers group benefits, claims and administration for a self-insured company or group.

TIN - Tax Identification Number. Also known as Employer Identification Number (EIN).

TOP - Triple Option Plan. An insurance plan which offers the enrolled a choice of a more traditional plan, an HMO, or a PPO. This is also commonly referred to as a

cafeteria plan.

TOS - Type of Service. Description of the category of service performed.

TRICARE - This is federal health insurance for active duty military, National Guard and Reserve, retirees, their families, and survivors. Formerly known as CHAMPUS.

UB04 - Claim form for hospitals, clinics, or any provider billing for facility fees similar to CMS 1500. Replaces the UB92 form.

Unbundling - Submitting several CPT treatment codes when only one code is necessary.

Untimely Submission - Medical claim submitted after the time frame allowed by the insurance payer. Claims submitted after this date are denied.

Upcoding - An illegal practice of assigning an ICD-9 diagnosis code that does not agree with the patient records for the purpose of increasing the reimbursement from the insurance payor.

UPIN - Unique Physician Identification Number. 6-digit physician identification number created by CMS. Discontinued in 2007 and replaced by NPI number.

Usual Customary & Reasonable(UCR) - The allowable coverage limits (fee schedule) determined by the patient's insurance company to limit the maximum amount they will pay for a given service or item as defined in the contract with the patient.

Utilization Limit - The limits that Medicare sets on how many times certain services can be provided within a year. The patients claim can be denied if the services exceed this limit.

Utilization Review (UR) - Review or audit conducted to reduce unnecessary inpatient or outpatient medical services or procedures.

v-Codes - ICD-9-CM coding classification to identify health care for reasons other than injury or illness. Workers Comp - Insurance claim that results from a work-related injury or illness.

Write-off - Typically reference to the difference between what the physician charges and what the insurance plan contractually allows, and the patient is not responsible for. May also be referred to as "not covered" in some glossary of billing terms.

Basic Medical Term Glossary

Abduction: Movement of a body part such as a limb away from the mid-line axis or center of the human body (e.g. muscles that pull arms or legs away from the body are called "Abductors."

Abscess: A localized collection of white blood cells (pus) indicating an infection.

Adduction: In essence, the opposite of Abduction (i.e. the movement of body parts towards the center of the body) with "Adductors" being the muscles that perform this function.

Artery: Vessel that carries blood away from the heart.

Arthroplasty: Surgical construction of movable joint parts

Arthroscope: An optical tube that is inserted into an incision in the body and used to examine potentially damages tissue, usually in joints.

Articulation: A place where two or more bones come together.

Atrophy: A decrease in the size of organ or muscle tissue due to lower blood flow or non-use.

Blood Pressure: The pressure of blood flowing from the heart as measured by the exertion against veins and arteries (Measured in two parts: Systolic: pressure when the heart is contracting; and Diastolic: the pressure when the heart rests between heartbeats).

Brain Scan: The brain is usually scanned to detect damage in one of two ways: CT or CAT Scan or MRI. This can be "with or without contrast" meaning with or without a dye substance being injected into the brain tissue.

Bursa: A gel-like filled sac located in areas of the body where friction could develop such as between joints.

C-Spine Series: A series of x-rays of the upper (neck) portion of the spine including x-ray views from the front, side and diagonally – This is usually ordered after any type of major trauma to the cervical spine such as in an auto accident.

Carotid Artery: Large artery located on the side of the neck next to the Adam's Apple. This is often used as a point to check a patient's pulse.

Carpal Tunnel Syndrome: A condition caused by pressure on the median nerve running through the wrist resulting in pain, numbness and other symptoms, most often caused by repetitive motion injuries but, also can be due to trauma.

Cephalgia: Pain in the head (headache)

Coccyx: The lowest portion of the spine (commonly called the "tailbone").

Comminuted Fracture: A bone that has been crushed or splintered.

Compound Fracture: Fracture where the bone is protruding through the skin.

Concussion: Condition caused when the head or body is shocked or jarred resulting in the brain being jostled inside the skull (for more information, see our brain injury page).

Contusion: Bruising

Cyst: Sac containing liquid or semi-solid material.

Discectomy: A surgery to remove all or a portion of an intravertebral disk (a disk between two individual vertebrae in the spine)

Effusion: Escape of bodily fluids into a portion of a body part or tissue.

Embolism: A portion of air, fat, blood clot, plague or other mass that blocks the flow of blood through an artery.

Epidural: The space inside the spinal column between the "dura" (membrane that covers the spinal cord) and the vertebral canal. Most often used in association with a procedure called "Epidural Injections" where this area is injected with anti-inflammatory drugs to shrink the disk material that is causing pressure on a nerve and causing pain, numbness or other symptoms.

Fistula: Abnormal drainage of fluid between two organs or between organs and the outer skin layer. The fluid is most often associated with drainage of pus from an abscess.

Flexion: The ability to bend all or a portion of

the body. Fracture: A break or rupture in a

bone.

Hematoma: A collection of blood in a localized area.

Hernia: A protrusion of an organ through a tear or abnormal opening in the wall of tissue. In personal injury claims, this is often used in association with "herniated discs" which are vertebral disks that are protruding abnormally due to a trauma.

Herniated Nucleus Pulposis (HNP): Condition in which the center of an intervertebral disk has protruded outside of the tissue that connects the adjacent vertebrae.

Hypertension: High blood pressure.

Hypotension: Low blood pressure.

Hypoxia: Lack of oxygen.

Infarction: Area of dead tissue resulting from a lack of sufficient

blood flow. Intervertebral: Between vertebrae (the small bones that

form the human spine).

Ischemia: Lack of adequate blood flow due to a rupture, blockage or constriction of a blood vessel.

Laparotomy: A surgical incision in the abdomen.

Lesion: Often used to describe any type of abnormality in organ tissue.

Lordosis: The curvature of the spine. Often used to describe an abnormal curvature due to some type of spinal trauma.

Meninges: The three membranes that surround the brain and spinal

cord. Myelogram: An x-ray film taken of the spinal canal after injection

of a dye material. Necrosis: Dead cells.

Neuralgia: Pain along the path of a

nerve. Occipital: The back portion of

the head.

Open Reduction: Repair of a fracture by re-positioning the bone pieces after surgical incision.

Orthopedics: The branch of medical specialty that deals with the diagnosis and treatment of the skeletal system and associated structures.

Osteoarthritis: So, called "degenerative" breakdown of the cartilage in the joint surfaces and the enlargement of surrounding bone tissue.

Osteomyelitis: Inflammation of the bone including the

marrow. Paravertebral: The area on the sides and

surrounding the vertebrae.

Paraplegia: Loss of the use of one the lower part of the human body including the legs due to paralysis Peritoneal Cavity: Abdominal cavity where containing many of the body's

internal organs.

Phalanges: Bones in the fingers and toes.

Plasma: The liquid portion of the blood after all blood cells have been removed.

Psychiatrist: Medical doctor who specializes in the diagnosis and treatment of mental or emotional illnesses. Able to prescribe medications.

Psychologist: Health care professional (non-medical doctor but, usually holds a PhD in Psychology) who diagnoses cares and treats persons suffering from disturbances in their emotional health.

Quadriplegia: Paralysis of both the arms and legs

Radiculopathy: Injury to the spinal nerve root, which causes pain or numbness to radiate along the path of the nerve (A common example would be impingement of the sciatic nerve root causing pain down the buttocks and leg).

Range of Motion: The ability of a body part such as a limb to move around an axis (measured in degrees). Limited range of motion is a common condition following trauma

Reduction: Sometimes also referred to as an "open reduction". This is a surgical technique to repair a fracture or dislocation of a bone or joint.

Reflex Sympathetic Dystrophy: Trauma to the sympathetic nervous system caused by damaged blood vessels or nerves and can result in swelling, pain, numbness and changes in skin color to the affected area.

Resection: Surgical removal of a portion of a body organ.

Sacrum: Triangular group of small bones at the lowest portion of the spine to which the tailbone is attached.

Skull Series: A series of x-rays of the human skull from multiple angles including frontal, side and oblique. Usually ordered following a head trauma and sometimes in conjunction with a head CT scan or MRI.

Spondylitis: Inflammation of the spinal vertebrae.

Stenosis: Narrowing of a body passage such as a blood vessel (artery or vein).

Thoracic Spine: The 12 vertebrae of the mid back starting at the bottom of the neck (bottom of the cervical spine) and going to the mid-abdomen (the top of the lumbar spine).

Vein: A blood vessel that carries blood back to the heart.

Whiplash: <u>Trauma to the cervical spine</u> due to a sudden back and forth movement (most commonly associated with rear end collision auto accidents).

Workers Compensation Terminology

Administrative Conference-A meeting where a staff member of the Office of Administrative Hearings will help the employee, employer, and insurer discuss the issues and resolve differences.

Apportionment-Apportionment refers to dividing the costs related to your injury among two or more employers or insurers. In certain circumstances, apportionment may also reduce your benefits because of a pre-existing injury.

Compensable Injury-A compensable injury is an injury that an employer is responsible to pay for under applicable state laws. Sometimes there is a dispute about whether or not an employer should really be responsible for paying for an injury.

Consequential Injury-A consequential injury is a secondary injury that is related to and stems from your original work injury. For example, you injure your right leg at work, and as a result, you tend to put more weight on your left leg. Later, you need a knee replacement in your *left* knee because of the extra strain and use.

Date of Injury ("DOI")-A date of injury or DOI is usually straight forward: it is the date you were injured. However, special rules may apply to determine your date of injury for legal purposes if you have certain kinds of injuries.

Deposition-A deposition is out-of-court testimony usually held at an attorney's office. The individual being deposed will be asked to answer questions about his or her injury in the presence of the attorneys and a court reporter.

Discovery-Discovery is a phase where the parties can formally obtain information from each other. There are multiple ways parties can obtain information, such as requesting documents from the other party or deposing a witness.

Gillette Injuries-A Gillette injury is an injury that has no single, identifiable incident that caused your injury. A Gillette injury usually occurs when you do a repetitive action so frequently that over time it causes an injury. Carpal tunnel syndrome is an example of this kind of injury.

Idiopathic Injuries-An idiopathic injury is an injury that is spontaneous, doesn't have a clear cause, or is caused by a personal health condition.

Independent Medical Examination ("IME")-An independent medical examination is a medical exam requested by a party to the case that you see a doctor of their choosing. This allows that party's doctor to evaluate your injury.

Medical Benefits-Medical benefits are benefits available to you under workers' compensation if you are injured and require medical care. This refers to payment of medical costs, such as doctor's visits or therapy.

Occupational Disease-Occupational diseases develop as the result of your employment. To be a work- related disease, your workplace conditions must put you at greater risk of contracting the illness than those who are in the general public.

Office of Administrative Hearings ("OAH")-The Office of Administrative Hearings ("OAH") is an independent tribunal under the executive branch of government.

Permanency Rating-Employees who are permanently injured may be assigned a "permanency rating." This is a percent given that represents the loss of a bodily function. The more severe your permanent injury, the higher your permanency rating. The rating is then used to calculate the amount of money you are entitled to because of your permanent loss.

Qualitative Rehabilitation Consultant ("QRC")-A qualified rehabilitation consultant is a counselor whose job it is to help you get back to work and earning a pay check again as well as facilitate communications between employers and doctors.

Settlement-A settlement is a voluntary agreement between the parties to not pursue the claim in court in exchange for the agreed upon settlement terms.

Statute of Limitations-In work comp, a statute of limitation sets a time limit on how long injured employees have to initiate a workers' compensation claim.

Expectations of New Hires

For the first **90 days**, all new hires are under a probationary period. During these **90 days**, you miss scheduled shifts up to 3 times. If you miss more than 3 times, your employment with Pure Pharmacy will be terminated immediately.

Pure Pharmacy realizes things happen, all we ask is that you notify [Personnel Redacted], Diretor of Pharmacy by 8:00am an hour before your start time 9:00 am. Failure to give proper notification will result in immediate termination of your position. [Personnel Redacted] may be reached by (cell) at [Phone Redacted].

New Hire Signature:	Date:	
PIC Signature:	Date [.]	

SOP 0.1 EXPECTATIONS OF NEW HIRES 38 | P a g e

[Address Redacted] [Address Redacted] [Phone Redacted]

Dress Code

Purpose

Maintaining professionalism and wearing appropriate attire in the pharmacy.

Responsibility

This SOP is maintained by the Pharmacist in Charge.
Pharmacy technicians and Pharmacists are responsible for this SOP

Policy

Professional attire shall be worn at all times in the pharmacy. Business casual attire is acceptable along with medical scrubs.

Procedure

- 1. Professional attire shall be worn at all times in the pharmacy. Business casual attire is acceptable along with medical scrubs.
- 2. Pharmacy personnel must wear their ID badges, displayed clearly, at all times.
- 3. Open toed shoes are not accepted in the pharmacy.
- 4. In the event that an employee of the pharmacy comes to work in dress that does not meet aforementioned standard, the employee shall be sent to change clothing into something that meets requirements.
- 5. Repeated disregard for pharmacy dress code shall be grounds for discipline.

SOP Created: March 2	024 [Personnel Redacted], PharmD, PIC
	Signature

DRESS CODE SOP



Dress Code Supplement

Section 1. **General Rule.** Employees' personal appearance and hygiene are important both to Employees and PURE PHARMACY-PURE PHARMACY. Employees are expected to maintain a good personal appearance and to give consideration to neatness and cleanliness. Employees should always dress in a manner befitting the job, with due consideration to the needs of PURE PHARMACY, other Employees, and safety, particulary when compounding or handling bulk chemicals.

Section 2. <u>Clothing Requirements.</u> An Employee's clothing should always be in keeping with customary acceptable attire for the [*workplace, *an office, *work, *and meeting with customers, clients, and the public.] <u>Clothing that is NOT allowed to be worn by Employees while working includes, but is not limited to, the following:</u>

- Shirts with language or graphics that are vulgar, sexually explicit, or may otherwise be offensive
- Attire that is revealing or provocative and or has skin susceptible to chemical exposure
- Sweat suits/Hoodies
- Skirts or clothing that reveals bare skin susceptible chemical exposure
- See-through blouses or shirts
- Sports bras, halter tops, or similar attire
- Clothing that allows bare midriffs
- Open toed shoes
- Proper protective equipment and protection must be worn at all times while doing non- sterile compounding including but not limited to cap, gown, hand protection, eye protection, and respiratory protection

Section 3. **Accommodation.** In the event that the above policy causes religious concerns or concerns based upon any other legally protected class, please contact PURE PHARMACY Management to discuss an appropriate religious accommodation.



Dress Code Sign Off

I hereby acknowledge receipt of the PURE PHARMACY dress code. I understand that it is my continuing responsibility to read and know its contents.

I hereby acknowledge that I have read the PURE PHARMACY Dress Code Policy in full and that I understand the policies and procedure regarding the dress code in full.

Signature			_
Print Name _			
Date			

PURE PHARMACY

[Address Redacted] [Address Redacted] [Phone Redacted]

Punctual Arrival/Departure to Shift

Purpose

Maintaining professionalism and arriving and leaving punctually with scheduled shifts.

Responsibility

This SOP is maintained by the Pharmacist in Charge.

Pharmacy technicians and Pharmacists are responsible for this SOP

Policy

Employees shall report and depart for ALL scheduled shifts/ work day in a timely manner.

Procedure

- 1. All employees shall report to scheduled shifts/ work day in a timely manner.
- 2. All employees shall not leave earlier than scheduled shift unless approved by pharmacy management.
- 3. Arriving late to scheduled shift or leaving early shall be grounds for discipline.
- 4. Late arrival to scheduled shift shall be defined as 5 minutes past time of beginning of scheduled shift.
- 5. Early departure to scheduled shift shall be defined as 5 minutes prior to end of scheduled shift..
- 6. Employee shall notify Pharmacy Management of an imminent late arrival or early departure, either in- person, via phone call, or through a voicemail on the pharmacy telephone system before he/she is due for start of shift.
- 7. Not notifying management of imminent late arrival or early departure, either in-person, via phone call, or through a voicemail on the pharmacy telephone system before he/she is due for start of shift shall be grounds for discipline.

SOP Created: March 2024 [Personnel Redacted], PharmD, PIC			
_			
	Signature		

PURE PHARMACY

[Address Redacted] [Address Redacted] [Phone Redacted]

Discipline and Dismissal

Purpose

To define the process of disciplining pharmacy employees and grounds for dismissal.

Responsibility

This SOP is maintained by the Pharmacist in Charge.

The Pharmacist in Charge and Pharmacists are responsible for this SOP

Policy

- 1. Discipline shall be enforced by the Pharmacist in Charge and Pharmacy Managers.
- 2. Discipline incidents shall be tracked, documented, and discussed with the employee being disciplined.
- 3. Three reported discipline incidents within one year shall be grounds for dismissal.
- 4. Disregard/ Non-Compliance for state and federal laws governing the practice of pharmacy shall be grounds for dismissal.
- 5. Disregard/ Non-Compliance with the Controlled Substance Act shall be grounds for dismissal.
- 6. Substance Abuse shall be grounds for dismissal.

SOP Created: March 20	024 [Personnel Redacted], PharmD, PIC
<u>-</u>	
	Signature



Employee Discipline Form

Employee Name: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	Date: XXXXXXXXXXX

The purpose of this written warning is to bring to your attention ongoing deficiencies in your conduct and/or performance. The intent is to define for you the seriousness of the situation so that you may take immediate corrective action. This written warning will be placed in your personnel file.

This warning is the 1st time you have been warned on this issue.

REASON(S) FOR WARNING:

(Enter Here)

CORRECTIVE ACTION(S) REQUIRED:

(Enter Here)

The above has been discussed with me by my supervisor. I understand the contents and acknowledge and understand the corrective action required. I also acknowledge and understand the potential consequences of noncompliance.

I understand that I have ___days to rectify this behavior.

Signatures:	
Employee:	Date:
Supervisor:	Date:



LAST CHANCE AGGREEMENT

DATE: [XXXXXXXX]

EMPLOYEE: [XXXXXXXX]

This letter, effective on today's date, is to detail circumstances for continuing employment with PURE PHARMACY. To avoid termination, the conditions of this agreement must be met. The employee is being considered for dismissal due to the following behaviors:

REASONS:

Multiple warnings from managers have not solved the problem that has been ongoing the past months. The employee agrees to reach and maintain these goals by (ENTER DATE).

The employee understands that not demonstrating a change in behavior will result in immediate termination.

STIPULATIONS OF CONTINUED EMPLOYMENT:

The employee understands that during the probation period there will be increased monitoring of her behavior and a manager will always be on duty to supervise her interactions with coworkers.

However, this agreement does not guarantee future employment for any amount of time. The employee understands that by signing this agreement she is agreeing to its terms. He/She understands if she fails to meet the conditions in this agreement she will be terminated immediately, and all benefits stopped.

Signatures:	
Employee:	Date:
Supervisor:	Date:

PURE PHARMACY

[Address Redacted] [Address Redacted] [Phone Redacted]

Compliance of State and Federal Laws

Purpose

To stay compliant with all applicable state of federal laws governing the practice of pharmacy.

Responsibility

This SOP is maintained by the Pharmacist in Charge. Pharmacy technicians and Pharmacists are responsible for this SOP.

Policy

Disregard for state and federal laws governing the practice of pharmacy shall be grounds for discipline and dismissal.

SOP Created: March 2	024 [Personnel Redacted], PharmD, PIC
	Signature



HIPAA Privacy and Security Policy and Procedures

I. Assignment of HIPAA Privacy/Security Officer

[Personnel Redacted], PharmD has been designated as our HIPAA Officer by PURE PHARMACY LLC and has authority to establish, implement, and enforce these policies and procedures for the security and privacy of our patients protected health information (PHI).

II. Risk Assessment

[Personnel Redacted] is responsible for conducting annual HIPAA privacy and security risk assessment. The assessment will be completed with the assistance of at least two other employees.

Additional risk assessments may be necessary each time (1) new software or hardware is acquired and placed in service; (2) when a new service or procedure is initiated; (3) when there is a significant change in an existing service or procedure; or (4) when there is a change or addition to the physical layout of our office.

[Personnel Redacted] will periodically but at least quarterly review the DHHS's HIPAA website to determine if there have been any changes in the HIPAA rules and regulations and to determine if any changes or modifications to this policy and procedure is necessary due to changes in HIPAA rules, regulations or regulatory interpretations.

[See Addendum IV for sample risk assessment form]

III. Policy regarding physical access to building

(The main door is locked each evening, the only individuals with keys are [Personnel Redacted] and Mehwash Masood.)

Employees access our office via main entrance or employee entrance. Main entrance is locked after hours and is unlocked each morning at 8:00. The Pharmacist on duty has the key to both entrances and is responsible for unlocking main entrance each AM. Only pharmacists have access to the premises.

IV. Policy regarding confidentiality of all forms of PHI

All PHI regardless of its form, mechanism of transmission, or storage is to be kept confidential. Only individuals with a business need to know are allowed to view, read, or discuss any part of a patient's PHI. During initial new hire orientation and at annual HIPAA training employees are reminded that any viewing, reading, or discussions of PHI that is not for business purposes is prohibited. An employee who violates this confidentiality policy will be subject to sanctions up to immediate termination. All employees are required to verify in writing that they have read and will comply with our policy regarding confidentiality of all forms of PHI.

V. Policy regarding security of electronic PHI (e-PHI)

Employees whose job functions require access to our computer system will be given a secure, unique password to access the system. Passwords will consist of at least five characters, upper and lower case, alpha numeric and shall be changed at least every 90 days.

Access will be immediately terminated for employees who leave our employment.

All PHI transmitted to third parties will be transmitted on secured lines. The security of transmission lines will be verified via contract with third party responsible for transmitting our patient's PHI.

No digitally stored PHI shall leave this facility without being first encrypted; this includes laptops, flash drive devices, CDs, and e-mail.

VI. Patient request for accounting of all disclosures made by (PURE PHARMACY)

Patients have a right to request an accounting of all disclosures of their PHI made by (PURE PHARMACY). When a patient makes such a request, ([Personnel Redacted]) will be notified. The patient will be told when the

information will be available and given the option of waiting or returning to pickup the data.

VII. Patient request for restriction of PHI paid for "out of pocket"

Patients who pay for a procedure, test, or service out of pocket (fully paid for by patient with no reimbursement or additional payment by a third party), have a right to have all information regarding such procedure/test held confidentially and not released to third parties. To exercise this right the patient must (1) pay for test/procedure and (2) make known to (name of your facility) their desire to have information regarding the procedure/test held in confidence and not released to third parties. Any employee who receives such a request must immediately inform (name of responsible party in your facility) who will flag the information as being restricted. HIPAA allows for the release of restricted PHI (1) in compliance to a subpoena; (2) in compliance to statutory reporting requirement; or (3) upon receiving an unrestricted, HIPAA compliant authorization for release of medical records from the patient, patient's legal representative, or executor of deceased patient's estate.

VIII. Policy regarding charges for e-copies of medical records

The Privacy Rule permits the Covered Entity (a healthcare provider) to impose reasonable, cost-based fees for paper copies (See Addendum I, page 5).

According to HITECH the covered entity may charge for the labor cost of making the e-copy. This does not include the cost for searching the data base to find appropriate medical record(s). Currently (October 1, 2010) there is no guidance regarding whether the covered entity is allowed to charge for the cost of the media on which the e-copy is provided to the patient - i.e., CD, flash drive, etc.

IX. Business continuity

¹ This contemplates development and implementation of appropriate software programming with your electronic medical records (EMR) vendor.

X. HIPAA Incident/Breach Investigation

Any incident in which the privacy/security of a patient's PHI may have been compromised will be immediately reported to ([Personnel Redacted]). An incident investigation will be initiated without unreasonable delay. [Personnel Redacted] will establish an Incident Response Team (IRT) to investigate incidents and determine if the incident rises to the level of a breach. Refer to definition of IRT in Addendum II, page 7. The procedure for conducting HIPAA incident/breach investigation is located in Addendum II, pages 10-12.

XI. Sanction Policy

All employees will receive training regarding (<u>PURE PHARMACY</u>) policy for sanctioning employees who violate our HIPAA privacy/security policy. Employees shall receive training prior to assuming work duties and annually thereafter.² (<u>PURE PHARMACY</u>) HIPAA sanction policy is located in Addendum III, pages 15-16.

XII. Document Retention Policy

a. All HIPAA documentation such as policy and procedures, risk assessment, incident investigation, breach notification, and training records will be maintained for at least six years³ in the HIPAA records and documentation section of this policy beginning on page [create a section in your HIPAA policy/procedure manual/file labeled Misc. Documents].

² Note: HIPAA requires "periodic" training but does not specify the time frame—annually is recommended by most HIPAA Officers.

³ Standard (Documentation) (Time Limit) Sec. 164.316(b)(2)(i)

Addendum I

HIPAA FAQs

>www.hhs.gov/ocr/privacy/hipaa/fag<

If patients request copies of their medical records as permitted by the Privacy Rule, are they required to pay for the copies?

Answer:

The Privacy Rule permits the covered entity to impose reasonable, cost-based fees. The fee may include only the cost of copying (including supplies and labor) and postage, if the patient requests that the copy be mailed. If the patient has agreed to receive a summary or explanation of his or her protected health information, the covered entity may also charge a fee for preparation of the summary or explanation. The fee may not include costs associated with searching for and retrieving the requested information. See 45 CFR 164.524.

Addendum II

[PURE PHARMACY]

HIPAA Incident/Breach Investigation Procedure

I. Purpose

To distinguish between (1) cases in which our HIPAA policy was not correctly followed but such violation did not result in the unauthorized release of protected health information (PHI) (referred to as a HIPAA incident) and (2) cases involving the unauthorized release of PHI and said release resulted in or is reasonably expected to result in financial, reputational or other harm to the patient. This investigation procedure outlines the process for contacting the patient and identifying risk management measures to mitigate identified risks.

II. Definitions

<u>Breach</u> is the unauthorized acquisition, access, use or disclosure of PHI in a manner not permitted by HIPAA regulations which compromises the security or privacy of the PHI and poses a significant risk of financial, reputational, or other harm to the patient except where an unauthorized person to whom such information is disclosed would not reasonably have been able to retain such information. (Also see definition of incident and reportable breach).

<u>Breach Notification</u> is a HIPAA requirement in which the Covered Entity (CE) that has experienced a breach must notify the patient that the privacy or security of their PHI has been compromised.

<u>Business Associate (BA)</u> is a business organization but not an employee of the CE that performs or assists in the performance of activity involving the use or disclosure of individually identifiable health information; for example, claims processing or administration, data analysis, utilization review, quality assurance, billing, benefit management or practice management.

<u>Commercial Supplier</u> (CS) is a business organization that provides services to a CE. While said services do not require CS to directly handle or impact PHI, their presence in the CE's facility may cause or allow them to come in contact with PHI. A janitorial service is an example of a commercial supplier.

<u>Commercial Supplier agreement</u> is a signed contract or memo of understanding between the CE and commercial supplier explaining the CS's duty to avoid PHI and

provides assurances that the CS will instruct their employees regarding their duty to avoid viewing, reading, copying or otherwise obtaining information relating to patients PHI.

<u>Covered Entity (CE)</u> is a healthcare provider, a health plan, or a healthcare clearinghouse.

<u>e-PHI</u> is individually identifiable patient healthcare information created, stored or transmitted in electronic format.

<u>Health Information</u> is any information, whether oral or recorded in any form or medium, that: (1) is created or received by a healthcare provider, health plan, public health authority, employer, and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of healthcare to an individual; or the past, present, or future payment for the provision of healthcare to an individual.

[Personnel Redacted] is the individual formally assigned the duty to establish, implement, and monitor the CE's HIPAA policy and procedures. In small CEs both the Privacy and Security regulations could be handled by one individual, whereas in a large CE one individual may be assigned as the CE's HIPAA Privacy Officer and a second individual assigned as the CE's HIPAA Security Officer.

<u>Incident</u> is an actual or suspected unauthorized release, loss, or destruction of PHI but upon complete investigation it is determined by the Incident Response Team that the incident does not represent a significant risk of financial, reputational, or other harm to the individual.

Incident Response Team (IRT) is composed of members of the CE's staff including at least one key individual with decision making authority. The team is responsible for investigating the actual or suspected unauthorized access, release, or destruction of PHI; making the determination as to whether or not (1) the incident did in fact occur, (2) whether or not the incident rises to the level of a breach, (3) identifying appropriate Risk Management interventions to prevent similar re-occurrence, (4) assuring appropriate individuals are notified, and (5) assuring appropriate reports are made to Department of Health and Human Services (DHHS) when breach occurs.

<u>Individually Identifiable Health Information</u> any protected health information about an individual that can possibly be used to identify that individual and connect him/her to the health information.

<u>Notification</u> the contacting of individual(s) (or if deceased-next of kin or executor of estate) who is the subject of the unauthorized disclosure, release, loss or destruction of

their PHI. Notification is required when the incident is determined to rise to the level of a breach.

Office of Civil Rights (OCR) is the Federal agency authorized by DHHS to investigate claims of HIPAA Privacy or Security breaches.

<u>Protected Health Information (PHI)</u> individually identifiable health information created, transmitted or maintained by CE or BA that (1) identifies the individual or offers a reasonable basis for reconstructing said identity, (2) is created, received, maintained or transmitted by the CE or BA, and (3) refers to a past, present or future physical or mental condition, healthcare treatment, or payment for healthcare.

Reportable Breach is a HIPAA incident that rises to the level of a breach. A HIPAA breach requires the CE to notify the patient, log the breach and report all such breaches to DHHS annually—If 500 or more individuals are involved in a given breach then special notification/reporting requirements apply.

Risk Analysis is the process by which the CE attempts to (1) identify all ways in which an unauthorized release, loss, access, or destruction of PHI could occur; (2) determine what risk management protections are currently in place to minimize the likelihood of the identified risk occurring; (3) assess the current level of risk management protections for each identified risk; (4) recommend additional privacy or security safeguards as needed; (5) review DHHS's website for breach events at other CEs that might suggest weaknesses in CE's privacy/security safeguards; and (6) assess adequacy of HIPAA training for CE's staff.

<u>Sanction Policy</u> is CE's written employee disciplinary policy that outlines the consequences of an employee's violation of the CE's HIPAA Privacy and Security policy and procedures. The sanction policy clearly states that the CE retains the right to immediately terminate an employee for what the CE determines to be an egregious violation of the CE's HIPAA Privacy or Security policy/procedures.

<u>Unsecured PHI</u> is PHI that is not secured through the use of a technology or methodology specified by HIPAA/HITECH rules or regulations. Generally, it would be e-PHI not secured by encryption, paper or other media containing PHI that has not been shredded or destroyed in a manner that would prevent it from being reassembled.

III. Acquiring Knowledge of Actual or Suspected Breach:

There are many ways in which we may become aware of an actual or suspected breach.

- Employee training is a major key to the early discovery of a suspected or actual breach. Early detection will often prevent an incident from becoming a reportable/notifiable breach. As part of employee HIPAA training all employees will be instructed to report any actual or suspected breach to [Personnel Redacted] as soon as it is discovered or suspected.
- 2. Business Associate may cause or become aware of a breach and informus.
- 3. Another CE may become aware of an actual or suspected breach and inform us.
- 4. The patient may become aware of an actual or suspected breach and inform us.
- 5. We may discover an actual or suspected breach while performing an audit of our HIPAA privacy/security policy and procedures.
- 6. We may be informed by the Office of Civil Rights that a complaint has been filed against us.

PURE PHARMACY will investigate all incidents we become aware of to determine if a breach did in fact occur; to determine steps necessary to mitigate possible damage to patient; to determine risk management interventions necessary to prevent such incidents from reoccurring; and, to provide appropriate notification to patient and report to Department of Health and Human Services (DHHS).

IV. Unsecured PHI—Exceptions & Safe Harbors

HIPAA allows for two **exceptions** and three **safe harbors** for the unauthorized release of PHI in which breach notification is not required. The following **exceptions** are allowed:

- (1) when unauthorized access or use of PHI is unintentional and is made by an employee working within the scope of their job in which they would normally be expected to access or use PHI and such access is not continued, enlarged or disclosed by said employee; and
- (2) an unintended or accidental disclosure is caused by an employee who is authorized to access, use or disclose PHI at the facility in which they work (our employee) who sends or causes to be sent PHI to another individual in another healthcare facility who is also authorized to access, acquire or use PHI at their facility (an employee of another healthcare facility or other CE) provided the second employee agrees to return or destroy PHI and agrees not to disclose or further access PHI.

The three safe harbors are:

- (1) The unauthorized release of e-PHI but the e-PHI is protected by encryption;
- (2) The media on which the PHI was stored has been destroyed: (a) paper, film or hard copy media destroyed via shredding, incineration or, for digital/video media, destroyed in such a manner that the PHI cannot be reconstructed (For example; cutting CD into small parts), (b) electronic media destroyed or rendered un-retrievable in a manner consistent with NIST Special Publication 800-88, Guide to Media Sanitization; or,
- (3) The unauthorized release consisted of health information that was completely deidentified—removal of all names, addresses down to zip code, social security numbers, date of birth, phone numbers, case numbers or any other data that might be used to trace back and identify the individual.

Unauthorized releases that fall under these exceptions or safe harbors are not considered as a breach and do not require notification of patient or reporting to DHHS.

V. Incident Response Team (IRT):

[PURE PHARMACY] has established an Incident Response Team and charged it with the responsibility of investigating HIPAA incidents. The team is composed of at least one key decision maker, i.e., an individual who is authorized by the organization to make key decisions relative to organizational policy and expenditure of organizational funds, and at least two employees one of whom has line (as opposed to management) responsibility. The following individuals are members of [replace with name of your organization] the Incident Response Team:

- 1. Marc Strongin [Key Decision Maker]
- 2. [Personnel Redacted] [HIPAA Officer]

VI. Procedure

Distinguish between a HIPAA incident and a breach. Breaches of PHI would require notification of patient and inclusion in the annual report to DHHS. If breach involves 500 or more individual patients then DHHS must be immediately notified and public news media must be advised.

- First determine if the incident/breach falls within one of the exceptions or safe harbors allowed by HIPAA
 - i. If Yes, document and close file
 - ii. If No, move to #2.

- 2. Second determine if there has been an impermissible use or disclosure of PHI under HIPAA rules.
 - i. If No (there has not been an impermissible use or disclosure of PHI), document rationale and close file. For example, the incident falls under the "Oops!" category or a case in which the individual would not reasonably be able to retain the PHI, such as a visitor glancing at a computer screen containing PHI.
 - Documentation should include date, time and names of Incident Response Team members as well as a brief description of the incident and the reason it was determined the incident was not an impermissible use or disclosure of PHI under HIPAA rules. Include any FAQ from DHHS's website that was used to support final decision as well as citation to any HIPAA rules or regulations used to make the determination.
 - 2. Refer to XI, page 14, Note Regarding Determination of Incident vs. Breach
 - ii. If Yes, move to 3.
- 3. Third, determine if the impermissible use or disclosure compromises the security or privacy of the PHI, i.e., there is a significant risk of financial, reputational, or other harm to the individual.
 - If No (this was an incident that did not rise to the level of a breach), document your rationale, record this as a HIPAA incident, and close file.
 - Documentation should include date, time and names of Incident Response Team members as well as a brief description of the incident and the reason it was determined the incident was not an impermissible use or disclosure of PHI under HIPAA rules. Include any FAQ from DHHS's website that was used to support final decision as well as citation to any HIPAA rules or regulations used to make the determination.
 - 2. Determine and document why our policy, procedures, or training failed to prevent this incident and what risk

- management intervention(s) was taken to prevent similar occurrences.
- 3. Include this incident in our annual risk assessment for ongoing review and monitoring.
- 4. If changes were made to office policies or procedures as part of risk management intervention subsequent to incident, train all employees, owners, and business associates as needed and document training.
- 5. Refer to IX, page 14, Note Regarding Determination of Incident vs. Breach
- ii. If Yes (Breach did occur)
 - 1. Complete investigation as soon as possible
 - Determine cause of breach—why our HIPAA policy and procedures failed to prevent the breach from occurring, <u>not</u> just who caused the breach. For example: Breach occurred due to failure to follow procedure arising from failure to train employee before assigning her to job; failure of BA to follow BA agreement; or failure of computer firewall due to outdated technology.
 - 3. Identify corrective action(s) (risk management interventions) to be taken to address failure(s) including sanction for employee(s) if appropriate.
 - 4. Notify patient as per VII below
 - 5. Log breach for end of year reporting to DHHS
 - 6. Include failure in annual risk assessment

VII. Notification of Patient

When the Incident Response Team determines that there has been an unauthorized disclosure of a patient's PHI, and it rises to the level of a breach, then the patient must be notified. Notification will be made as soon as the determination of an unauthorized disclosure is made and appropriate investigation has been completed, but no later than 60 days from discovery. It is expected that the notification will be completed as soon as possible - once discovery and appropriate investigation is completed the notification will be made at that time without waiting for the running of the sixty-day maximum limit. In

addition, if the situation is deemed urgent by the Incident Response Team, notification to the patient will be made immediately without waiting for full investigation. Urgent notification will be made, if possible, via phone. Non-urgent notification will be provided as follows:

- Written notification provided via first class mail with copy of letter placed in patient's medical record. Said notification mailed to last known address. If patient has given prior approval for communication via e-mail, then notification may be made via e-mail. Additional mailings may be required as additional information is obtained.
- 2. If individual is deceased, then notification will be mailed to next of kin or executor of estate.

VIII. Business Associate Notification

If a Business Associate (BA) becomes aware of a breach caused by the BA, our written BA agreement requires the BA to notify us immediately. Our Incident Response Team will conduct the investigation to determine if impermissible disclosure occurred, how to notify the patient, and what steps should be taken to prevent similar incident/breach from reoccurring.

IX. Delay of Notification Requested by Law Enforcement

Notification may be delayed if law enforcement official determine that notification would impede a criminal investigation or endanger national security. The delay request must be in written form and identifies the law enforcement official making the request. The delay can be for no more than 30 days unless a written request for a specific extension is made within the initial 30-day extension by a law enforcement official.

X. Elements of the Written Notification

The patient's written notification of a breach involving their PHI will contain:

- 1. A short description of how the breach occurred; when it occurred; when we discovered the breach
- An explanation of the type of PHI involved in the breach such as patient name (full or partial), diagnosis, treatment, lab/test results, social security number, date of birth, patient's address, account or case number and/or financial data such as credit card numbers
- Our recommendation(s) to the patient as to the steps he/she should take to
 protect themselves from identity theft or the unauthorized use of their medical
 insurance accounts

- 4. An explanation of what we are doing to prevent re-occurrence of such breaches
- 5. Information the patient may use to contact us if they have further questions

XI. Note Regarding Determination of Incident vs. Breach

If, after an appropriate investigation has been conducted, it is determined that the incident did not rise to the level of a breach, we have the burden of proof, i.e., we must be able, if required at a later time, to demonstrate to DHHS or OCR that the impermissible use or disclosure did not constitute a breach, and therefore we were not required to notify the patient and include incident in our annual report of breaches to DHHS. Appropriate documentation of the investigation and the rationale used to make our non-breach (incident) determination will be maintained for at least six years after the initial non-breach finding. To demonstrate due diligence regarding our desire to comply with HIPAA requirement, we will document all changes in policies/procedures and/or additional staff training that resulted from our investigation into the incident. We will also include the incident in our annual risk assessment.

Addendum III

(PURE PHARMACY) HIPAA Privacy

and Security SANCTION GUIDELINE

Legal and Ethical Duty

Healthcare providers, employees, consultants, business associates and others who have a business reason to create, maintain, view, or transmit confidential data relative to patient's medical care have a legal and ethical duty to maintain the privacy, security, and confidentiality of such medical information. Violation of this duty will result in sanctions being imposed on the responsible party.

Federal Privacy and Security Legal Requirements

(PURE PHARMACY) requires all employees, as a condition of employment, to receive training regarding their responsibility relative to HIPAA privacy and security standards. All employees must follow established privacy and security policies to ensure the confidentiality, integrity, and availability of all protected health information. All individuals having access to protected health information (PHI) are required to read, sign, and comply with this organization's privacy and security policy. By signing the privacy and security policy employee acknowledges that both (PURE PHARMACY) and the employee have a legal duty to comply to the best of their ability with the privacy and security policy.

Sanctions for Breach of Privacy and Security Policy

An employee(s) who, without a business "need to know," unintentionally or carelessly views or accesses PHI is subject to an initial verbal warning. This warning is given with an additional warning that repeat of this or similar offense will result in further disciplinary action not to exclude suspension without pay or immediate termination of employment.

An employee(s) who, without a business "need to know," unintentionally or carelessly views or accesses PHI and then relates portions of the PHI to another individual is subject to an initial written warning. This warning is given with an additional warning that repeat of this or similar offense will result in further disciplinary action not to exclude suspension without pay or immediate termination of employment.

An employee(s) who, without a business need to know, intentionally views or accesses PHI to satisfy personal desire to learn details regarding a patients PHI is subject to immediate termination of employment.

An employee(s) who views or access PHI with malicious intent or desire for personal gain is subject to immediate termination of employment.

Non Retaliation Policy

An employee who, in good faith and belief that a privacy or security policy has been violated, reports such concern to (PURE PHARMACY) Karolina Maculewicz shall not be subject to retaliation, harassment, or intimidation as a result of such communication to HIPAA officer. Should such an employee believe he/she is being harassed by the individual serving as the HIPAA Officer, the employee should report situation to (HIPAA Officer's immediate

Date Policy Created/Approved	March 2024
Date Policy Reviewed/Revised	

Addendum IV:

Risk Assessment Form (Example)

Scoring:

- 0 = Probability possible, but not likely
- 1 = Probability could happen
- 2 = Probability likely to happen, but not guaranteed to happen

	Risk	Probability of Occurrence
1	Lost laptop (MD takes unencrypted laptop home)	1
2	Lost paper medical record (Nurse puts lab reports in pocket and waits until end of day to file reports)	2
3	Hacker getting into our system and obtaining e-PHI	1
4	Lost CD or flash drive (MD takes unencrypted flash drives home)	2
5	Break-in and patient records stolen (Facility specializes in pain management and is located in a high crime area)	2
6	Patient's HIV prescription accidentally broadcast to dozens of fax numbers in the system	0

- 1. Begin with blank spreadsheet or flip chart and have Risk Assessment Team brainstorm all the possible ways in which the confidentiality of PHI might be breached.
- List each risk under the risk column, and then as a group assign the probability of the risk occurring at our facility. The brainstorming session should be freeflowing, no bad ideas, be careful that an authority figure does not repress the free flowing of ideas.
- 3. Take all the "2s" and develop risk interventions that will eliminate or reduce the possibility of the risk occurring. For example; under risk number 2 a policy could be established that all lab reports are filed as soon as they are received; risk number 4 could be reduced to a "0" with the adoption of encryption technology for CDs and flash drives used in the facility; and, risk number 5 could be lowered to a "1" with the addition of better lighting and a monitored security service.

- 4. Risk number 6 was scored a "0" because the Office Manager had the broadcast function removed prior to putting the software into service.
- 5. Keep documentation of the meeting to use as a beginning point for next years session; check DHHS's HIPAA web site to determine if other facilities have had breaches that might occur in our facility; perform risk assessment each time new or updated electronic medical records software/hardware is adopted; perform risk assessment any time a new procedure or new clinical technology is adopted; and maintain documentation for at least six years.
- 6. Keep in mind that the purpose of Risk Assessment is to (1) identify potential risk to PHI, (2) set the priority for addressing identified risks, (3) establish risk management interventions to minimize or eliminate identified risks, (4) test our current risk management interventions to make sure they are still appropriate, and (5) gauge the effectiveness of our HIPAA training.



HIPAA Policy Receipt

I hereby acknowledge receipt of the PURE PHARMACY HIPAA Policy. I understand that it is my continuing responsibility to read and know its contents.

I have read, understand and agree to all the above. I have also read and understand the PURE PHARMACY HIPAA Policy.

Signature		
Print Name _		
Date		

PURE PHARMACY

[Address Redacted] [Address Redacted] [Phone Redacted]

Verification/ Dispensing

Purpose

To ensure all prescriptions are accurately dispensed with correct product identification and quantity.

Responsibility

This SOP is maintained by the Pharmacist in Charge.
Pharmacy technicians and Pharmacists are responsible for this SOP

Policy

Pharmacist shall review all prescriptions and ensure every medication is correctly dispensed according to a physician's order.

Procedure

Dispensing/ Verification of Legend Drugs

- 1. After a Technician picks an order in its entirety, it is given to a Pharmacist to verify.
- The Pharmacist will verify each medication for correct product identification and quantity, date, signature, address, patient, and number of refills.

Note: Any picking error will be given back to the Technician to correct. After the error is corrected, the Technician will return it to the Pharmacist to re-check.

- 3. After a medication (s) reviewed, the Pharmacist will use his fingerprint identifier to electronically log the pharmacists final check of that prescription.
- 4. Pharmacist gives completed order to Pack/Ship Technician to prepare for shipment or counsels patient at pharmacy/ dispenses medication(s).

- 5. Pharmacist or Technician captures patient's signature as proof that the patient has received the prescription.
- 6. The pharmacist must counsel on all prescriptions.
- 7. Failure to ensure safe dispensing of prescriptions drugs or making repeated dispensing errors shall be grounds for discipline.

DISPENSING AND PHARMACIST VERIFICATION

SOP

Dispensing/ Verification of Controlled Drugs

- 1. After a Technician picks an order in its entirety, it is given to a Pharmacist to verify.
- The Pharmacist will verify each medication for correct product identification and quantity, date, signature, address, patient, and number of refills and DEA Number.

Note: Any picking error will be given back to the Technician to correct. After the error is corrected, the Technician will return it to the Pharmacist to re-check.

- 3. A prescription for a controlled substance shall be counted twice, by fives, on a tablet tray or applicable manual device. An automatic counting device or automatic means of counting tablets is NOT acceptable.
- 4. Schedule 2 substances shall be stored and maintained by the pharmacist. A prescription for schedule 2 substance shall be counted twice, by fives, on a tablet tray or applicable manual device by a pharmacist. Technicians may not count schedule II controlled substances.
- 5. After a medication (s) reviewed, the Pharmacist will use his fingerprint identifier to electronically log the pharmacist's final check of that prescription. Prescriptions do not need to be signed on the hard copy, as the fingerprint verification / biometrics serves as a unique identifies/ signature.
- 6. Pharmacist gives completed order to Pack/Ship Technician to prepare for shipment or counsels patient at pharmacy/ dispenses medication(s). (see sop: shipping of controlled substances)
- 7. At the point of check out, the pharmacist or technician, must verify the date of birth AND address of the patient or patient's agent,
- 8. Pharmacist or Technician captures patient's signature as proof that the patient has received the prescription.
- 9. The pharmacist must counsel on all prescriptions.
- 10. In the event that a patient is on the premises (nearby location/ inside building), but unable to come to the pharmacy counter to pick a controlled substance prescription due to mobility issues, a pharmacist may bring the patient his or her prescription with confirmation of signature. A technician may NOT bring the controlled substance prescription to the patient. Additionally, the pharmacist may not bring the controlled substance prescription to the provider or the provider's agent.
- 11. Failure to ensure safe dispensing of controlled substances or making repeated dispensing errors shall be grounds for discipline.

SOP Created: March 2024 [Personnel Redacted], PharmD, PIC

Signature

PURE PHARMACY

[Address Redacted] [Address Redacted] [Phone Redacted]

Auto Refill Policy

Purpose

To define and establish procedures governing prescriptions auto-refill services.

Responsibility

This SOP is maintained by the Pharmacist in Charge.

The Pharmacist in Charge and Pharmacists are responsible for this SOP.

Policy

All prescriptions are eligible for auto-refill at the patient's approval. This includes maintenance medications, as well as medications for acute and chronic conditions.

Procedure

- 1. At the time of initial dispensing of prescription/ patient pick up the patient shall be notified of auto-refill services.
- 2. Auto-Refill service agreement shall be approved and signed by the patient. Address verified in its entirety.
- The acceptance of auto-refill shall be documented and signed for by the patient and kept on file indefinitely in the patient's prescription profile indefinitely.
- 4. The patient may cancel auto-refill services on all or some of his/her prescriptions at any time.

SOP Created: March 2	024 [Personnel Redacted], PharmD, PIC
•	Signature

PURE PHARMACY

[Address Redacted] [Address Redacted] [Phone Redacted]

Shipping of Medications

Purpose

To establish policies and procedures for shipping of medications to a patient or patient's agent.

Responsibility

This SOP is maintained by the Pharmacist in Charge.

Pharmacy technicians and Pharmacists are responsible for this SOP.

Policy

Pharmacists and Employees are to ensure safe shipping of medications to the patient and patient's agent.

Procedure

- 1. Medications may be shipped to the patient or the patient's agent.
- 2. Medications may be shipped by a common carrier (USPS, FedEx, UPS)
- 3. Confirmation of delivery shall be kept on file, electronically, in the prescription profile indefinitely.
- 4. When shipping legend drugs, the shipping container or shipping packaging, shall ensure safety of contents.
- 5. When shipping legend drugs, the shipping container or shipping packaging, shall clearly identify the recipient.
- 6. When shipping legend drugs, the shipping container or shipping packaging, may NOT have any information that may identify the contents of the package, including but not limited to the word pharmacy, or patient information protected by the Health Insurance Portability and Accountability Act (HIPAA).
- 7. Not following the procedures set forth in this policy shall be grounds for discipline.

SOP Created: March 20	024 [Personnel Redacted], PharmD, PIC
- -	Signature

[Address Redacted] [Address Redacted] [Phone Redacted]

Shipping of Controlled Substances

Purpose

To establish policies and procedures for shipping of controlled substances to a patient or patient's agent.

Responsibility

This SOP is maintained by the Pharmacist in Charge. Pharmacy technicians and Pharmacists are responsible for this SOP.

Policy

Pharmacists and Employees are to ensure safe shipping and handling of controlled substances to the patient and patient's agent.

Procedure

- 1. Medications may be shipped to the patient or the patient's agent.
- 2. Medications may be shipped by a common carrier (USPS, FedEx, UPS) with signature confirmation to the address provided by the patient at the time of shipping.
- 3. Confirmation of delivery and confirmation of signature shall be kept on file, electronically, in the prescription profile indefinitely.
- 4. When shipping controlled substances, the shipping container or shipping packaging, shall ensure safety of contents and tampering of packaging.
- 5. When shipping controlled substances, the shipping container or shipping packaging, shall clearly identify the recipient by name and address.
- When shipping controlled substances, the shipping container or shipping packaging, may NOT have any information that may identify the contents of the package, including but not limited to the word pharmacy, or patient information protected by the Health Insurance Portability and Accountability Act (HIPAA).

- 7. A call shall be placed to the patient or patient's agent by the dispensing pharmacist on all narcotic prescriptions that need to be shipped. The call shall verify that the recipient patient or patient's agent will be home at time of scheduled delivery to sign for prescription and the patient's address. The dispensing pharmacist may delegate this duty to a technician.
- 8. Failure to comply with policies of shipping of controlled substances shall be grounds for discipline.

SOP Created: March 20	U24 [Personnel Redacted], PharmD, PIC
-	Signature

[Address Redacted] [Address Redacted] [Phone Redacted]

Returning Undeliverable Prescriptions

Purpose

To define and establish procedures governing prescriptions returned to the pharmacy by common carriers (FedEx. UPS, USPS)

Responsibility

This SOP is maintained by the Pharmacist in Charge.

The Pharmacist in Charge and Pharmacists are responsible for this SOP.

Policy

Prescriptions returned to the pharmacy must be sent back or the patient or patient's agent or returned and the prescription fill canceled. Prescription returned must have stock adjusted accordingly and may NOT be redispensed in any way.

Procedure

- 1. When a common carrier returns a package as undeliverable, a pharmacy staff member must sign for the package as proof of return.
- 2. Upon receipt of package, the patient to whom it was addressed must be contacted to see why the package could not be delivered.
- 3. If the package could not be delivered due to an error, address change, or any other reason pertaining to the shipping and/or delivery of the package, the package can be sent back out.
- 4. If the patient to whom the package was scheduled to be delivered to is unreachable, no longer wishes to receive the package, or is no longer taking the medications the prescriptions must be returned, insurance reversed, and stock adjusted.
- 5. Medications returned to pharmacy after shipping to patient or patient's agent may not be redispensed and must be reverse distributed.
- 6. Returned Schedule II through Schedule V Controlled Substances must be reverse distributed and their contents held kept under lock inside of the narcotic cabinet while pending destruction.

SOP Created: March 2024 [Personnel Redacted], PharmD, PIC

Signature	

[Address Redacted] [Address Redacted] [Phone Redacted]

Controlled Substance Counts

Purpose

Routine cycle counts and physical inventories will be performed to ensure inventory accuracy and loss prevention of Controlled Substances.

Responsibility

This SOP is maintained by the Pharmacist in Charge.
Pharmacy technicians and Pharmacists are responsible for this SOP

Policy

Cycle counts and physical inventories for both controlled and non-controlled inventory will be performed per standard operating procedures to maintain adequate inventory control.

Procedure

- 1. A full narcotic controlled substance inventory will be performed monthly. By a pharmacist or pharmacist in Charge.
- 2. A full inventory of schedule 3 through 5 medications will be performed twice yearly.
- Cycle counts of both controlled and non-controlled medications will be performed periodically based on random locations assigned by the manager.
- 4. Only the established inventory count sheets should be used. This will contain the location, product name, NDC, and quantity on hand for each medication. This will be printed after the production workflow has been cleared at either the beginning of the day or at the end of the day.
- 5. Picking in specific location of cycle count will cease until physical counts are completed.
- 6. Any discrepancies found between the physical and system quantities will be investigated. Adjustments will be made to correct the inventory by a pharmacist/ pharmacist in charge.

- 7. The Pharmacist in Charge will be informed of any discrepancy that cannot be reconciled.
- 8. Only authorized inventory associates are permitted to participate in controlled substance cycle counts. Narcotic controlled substances must be inventoried by a pharmacist.
- 9. All CII drugs must be counted via the pill tray. CIIs are counted twice by RPh.
- 10. Recounts will be performed once discrepancies have been identified after the initial counts. Recount of a medication cannot be done by the same inventory associate who performed the initial count.
- 11. Each Rph/ PIC should sign an acknowledgement form after counts have been completed.
- 12. All inventory counts shall be kept on hand in the pharmacy for 5 years.
- 13. Failure to maintain controlled substances counts and follow these procedures shall be grounds for discipline.

SOP Created: March 2	024 [Personnel Redacted], PharmD, PIC
•	Signature

[Address Redacted] [Address Redacted] [Phone Redacted]

Quality Assurance/ Incident Report

Date of Incident: Patient Name: ID#: Order #: Rx#: Drug Name(s):		
Error Type: 1.[] Incorrect patient		
2. [] Incorrect drug		
3. [] Incorrect strength		
4. [] Incorrect directions		
5. [] Drug interaction		
6. [] Other, please explain:		
Did patient ingest medication? [] Yes , how much?	[] No	
Summary of events:.		
Actions taken to improve or resolve		
error: Manager/employee comments:		
Employee (printed)		Employee Signature
Manager (printed)		Manager Signature
PIC (printed)		PIC Signature

Staff Pharmacist Duties and Competencies General ☐ Pharmacist has read through and complies with the standard operating procedures. ☐ Pharmacist complies with HIPAA Privacy and Security Policy and Procedures as stated in the standard operating procedures. ☐ Pharmacist understands all duties of the Pharmacy Technician, Pharmacist, and Pharmacist-In-Charge (PIC). Any concern is delegated to the PIC. Processing and Filling Medication Orders ☐ Pharmacist can process electronic data entry through PioneerRx of all written, electronic, faxed, medications correctly with appropriate medication selection, sig code, refills, etc. as allowed by Illinois Law. ☐ Pharmacist appropriately checks Prescription online Monitoring Program before processing all prescriptions for Controlled Substances. ☐ Pharmacist can select and fill the appropriate medication from stock to fill the prescription. This may be delegated to the pharmacy technician. ☐ Pharmacist checks and verifies all filled orders before dispensing to public **Dispensing Medications** Pharmacist sells medications after verification of prescription, and selects correct method of sale (signature on tablet, paper receipt, delivery hold, etc.) and specifies the name of patient or patient's agent at pick up ☐ Pharmacist appropriately verifies the patient's name, date of birth, and address before handing off

medications.

Pharmacist offers to counsel on all medication fills, to include name and dose of medication, directions of use, number of refills, side effects, monitoring parameters, storage.

	Pharmacist performs a medication reconciliation on initial evaluation of patient and enters any additional home medications into the patient's chart on PioneerRx.
	For delivery orders, pharmacist sets aside all orders to be packaged for Delivery using FedEx Manager. All patient with controlled substances being sent out must be called by the pharmacist before being sent out to the patient.
	Pharmacist delivers medications to surgery patients in the recovery room of the PACU.
	Pharmacist understands and complies with standard operating procedures for the shipping of medications, emergent medication fills, lost or stolen medications.
Disner	sing Errors and Incident Reporting
	Pharmacist understands and complies with the internal process for medication error reporting as described in the standard operating procedures. Please see the standard operating procedure.
	Pharmacist reports all side effects to medications to appropriate outlet (i.e. MedWatch), makes note of event within patient's chart, and sends notification of event to pharmacist in charge.
Patien	t Profile Entry
_	Pharmacist can access and pull data from Medisoft and Database. When this is not available, the pharmacist appropriately calls and interviews the patient to gather information.
	Pharmacist can appropriately create a new profile and A/R

Account for a patient in PioneerRX. Correct address, date of birth, date of injury, ICD 10, attorney, allergies, and medications will be entered at initial creation of the profile prior to filling medication orders

	for said patient.
Invento	ory Management
	Pharmacist submits orders to distributors to restock medications at the end of each day. Electronic orders may be placed to distributors (Auburn before 4 PM, PAR Med before 9 PM).
	Scheduled II medications are submitted by the Pharmacist-in-Charge (PIC) or by pharmacist with specified power-of-attorney to do so.
	Pharmacist documents and stores invoices for all controlled substances in the appropriate bins provided in the pharmacy. Discrepancies will be noted and immediately reported to the PIC
	Pharmacist removes from stock any product that has been tampered, expired, adulterated, or otherwise damaged in any way. This is reported to the PIC
Precep	oting Duties
	Pharmacist role-models for any student on rotation at the site.
	Pharmacist participates and facilitates learning activities for the student.
	Pharmacist allows student to fill medications and counsel patients only under his or her direct supervision.

Pharmacy Technician Duties and Competencies

	Competencies
Data e	ntry and Filling prescription orders
	Technician can search for the correct patient for the corresponding script within PioneerRX, Medisoft, or Database using name or date of birth.
	Technician can create a new patient profile and A/R Account for new patients with all appropriate information (name, DOB, address, phone, DOI, ICD 10, Account number)
	Technician completely and accurately enters data from a new prescription order with correct pharmacy sig codes, medication, dose, quantity, provider, days supply, etc.
	Technician appropriately selects the correct medication from stock, and scans all medication bar codes with each fill of new and refilled medications.
	Technician appropriately affixes labels to medication vial to include necessary auxiliary labels and patient education.
Shippir	ng of Medication
	Pharmacy Technician understands standard operating procedures for Shipping of Medication.
	Technician sends medications requiring direct or indirect signature when necessary for controlled substances.
	Technicians call on all controlled substance prescriptions to coordinate delivery day/confirm someone will be home for signature
	Technician may contact FedEx to inquire on the status of a pending delivery. Technician understands standard operating procedure for lost and stolen medications.

Patien	nt Care	
	Pharmacy Technician answers phone and helps patients with medication issues to the best of his or her abilities, and defers all medication related	

questions to the pharmacist as appropriate Pharmacy technician does NOT counsel medications, but can provide an offer to counsel by the pharmacist. He or she may translate for the pharmacist as needed. Technician understands the HIPAA Privacy and Security Policy and Procedures as stated in the PURE PHARMACY standard operating procedure manual. Pharmacy Technician may NOT dispense a medication without the permission and presence of the pharmacist on duty Temperature Log and Stock Technician logs the temperature of the pharmacy refrigerator twice daily, once at opening and once at closing Technician notifies pharmacist when stock is low for certain medications so that the medication may be restocked Technician checks in orders delivered form distributors and reports any discrepancies to pharmacist. Technician provides all controlled substances to pharmacist for inventory and storage Technician examines and removes from stock any expired products, torn packaging, or otherwise damaged products, and alerts pharmacist that medication need to be re-ordered or returned		
 □ Pharmacy technician does NOT counsel medications, but can provide an offer to counsel by the pharmacist. He or she may translate for the pharmacist as needed. □ Technician understands the HIPAA Privacy and Security Policy and Procedures as stated in the PURE PHARMACY standard operating procedure manual. □ Pharmacy Technician may NOT dispense a medication without the permission and presence of the pharmacist on duty Temperature Log and Stock □ Technician logs the temperature of the pharmacy refrigerator twice daily, once at opening and once at closing □ Technician notifies pharmacist when stock is low for certain medications so that the medication may be restocked □ Technician checks in orders delivered form distributors and reports any discrepancies to pharmacist. Technician provides all controlled substances to pharmacist for inventory and storage □ Technician examines and removes from stock any expired products, torn packaging, or otherwise damaged products, and alerts pharmacist that medication need to be re-ordered or 		
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Shipping of Medications

Purpose

To establish policies and procedures for shipping of medications to a patient or patient's agent.

Responsibility

This SOP is maintained by the Pharmacist in Charge. Pharmacy technicians and Pharmacists are responsible for this SOP

Policy

Pharmacists and Employees are to ensure safe shipping of medications to the patient and patient's agent.

Procedure

- 1. Medications may be shipped to the patient or the patient's agent.
- 2. Medications may be shipped by a common carrier (USPS, FedEx, UPS)
 - All controlled substances while require signature. Schedule II products will require direct signature. Schedule III-V may be sent with indirect signature at the discretion of the pharmacist
 - A patient may waive signature, however this must be documented in the patient chart critical comments.
- 3. Confirmation of delivery shall be kept on file, electronically, in the prescription profile indefinitely.
- 4. When shipping all drugs, the shipping container or shipping packaging, shall ensure safety of contents.
- 5. When shipping legend drugs, the shipping container or shipping packaging, shall clearly identify the

recipient.

 When shipping drugs, the <u>OUTERMOST</u> shipping container or shipping packaging, MAY NOT have any

information that may identify the contents of the package, including but not limited to the word pharmacy,

or patient information pr	rotected by the Health		

Insurance Portability and Accountability Act (HIPAA).

- 7. The <u>INNERMOST</u> shipping container WILL have a PURE PHARMACY Sticker, with the address and contact information for the pharmacy. This will not be visible on the outside of the shipping container.
- 8. A call shall be placed to the patient or patient's agent by the dispensing pharmacist on all new medications and controlled substance prescriptions that need to be shipped.
 - a. The call shall verify that the recipient patient or patient's agent will be home at time of scheduled delivery to sign for prescription and the patient's address. The dispensing pharmacist may delegate this duty to a technician.
 - b. An offer to counsel will be made for all medications. Pharmacists will counsel over the phone as needed. Pharmacy technicians may not counsel patients on medications.
- 9. Failure to comply with policies of shipping of controlled substances shall be grounds for discipline.

Emergent

Medication Fills

Purpose

To establish policies and procedures for the filling and deliver

Responsibility

This SOP is maintained by the Pharmacist in Charge. Pharmacy technicians and Pharmacists are responsible for this SOP

Policy

Pharmacists and Employees are to ensure appropriate transfer of medications to the patient's preferred secondary pharmacy

Procedure

- If the patient is having an acute emergency requiring immediate medical attention, the patient will be instructed to call 911or report to the nearest medical facility for treatment.
- If the patient is out of a necessary medication one of the following will occur:
 - a. If the medication is readily available in the pharmacy and is able to be filled, the pharmacy staff will process, fill, dispense and send the medication to the patient. Medications will be sent via FedEx Standard or Priority Overnight as needed. Courier services are available for patients in the Chicagoland area only.
 - b. If the medication is not available in stock and the patient cannot wait for the pharmacy to restock this medication, then the remaining medication fills will be transferred to the pharmacy of the patient's choice for his or her convenience

c. For medications that may not be transferred, the pharmacy staff will call the prescriber to instruct them to send the prescription to another location that is more convenient for the patient

- 3. If the patient does NOT have refills remaining, an attempt will be made to contact the prescribing physician to authorize new refills or to send a new prescription to a secondary pharmacy
- 4. Transfer of medication refills shall be carried out by the pharmacist.

 Pharmacist will provide original Rx number, name of medication, instructions for use, quantity to dispense per fill, original number of fills and fills remaining, date written, provider's information (name, NPI, phone number, DEA number, etc), and any additional information requested by the secondary pharmacy.
- Transfers shall be notated within PioneerRx with the correct store location, phone number, and receiving pharmacist's first name and last initial.
- Failure to comply with policies of shipping of controlled substances shall be grounds for discipline.

Lost or Stolen Medications

Purpos

е

To establish policies and procedures for filling and delivering lost or missing medications.

Responsibility

This SOP is maintained by the Pharmacist in Charge. Pharmacy technicians and Pharmacists are responsible for this SOP

Policy

Pharmacists and Employees are to ensure safe shipping, tracking, of medications to the patient and patient's agent.

Procedure

- Confirmation of delivery shall be kept on file, electronically, in the prescription profile indefinitely.
- Pharmacists shall responsible for the monitoring all pending "Out for Delivery" orders in PioneerRx system. This will entail checking on delivery status, tracking number, and follow-up with FedEx and the patient if medications have yet to be delivered.
- If a medication has been pending delivery for equal to or greater than 5 business days, the pharmacy staff will contact both FedEx and the patient to investigate the delay in delivery. The following will be verified:
 - a. The location of the package (if known)
 - b. The correct address and phone number of the patient
 - c. The estimated time of arrival for the package
- Should the medication be found to be lost or stolen, the patient shall be sent a replacement fill of his or her medication. The insurance will NOT be charged additionally for the replacement fill.
- 5. IF THE LOST MEDICATION IS A CONTROLLED SUBSTANCE, THE APPROPRIATE FORMS MUST BE FILED AND SENT TO THE APPORPRIATE GOVERNING BODIES

WITHIN 48 HOURS OF NOTICE. This includes DEA 106 forms and incident reports. Forms and incident reports shall be kept on the premises for 2 years.

- Lost or stolen medications shall also be recorded on the patient's chart. For all future fills, the patient will be called to coordinate appropriate delivery.
- 7. Re-sent medication orders will be sent requiring direct signature to prevent theft or additional loss of medication.
- 8. Should medications return to the pharmacy after an additional replacement fill was sent, the medication will be returned to stock and placed in the bin for destruction. Returned medications may not be redispensed.
- Pharmacy staff will consult and comply to "Shipping of Medications" Standard Operating Procedure.
- 10. When shipping legend drugs, the shipping container or shipping packaging, may NOT have any information that may identify the contents of the package, including but not limited to the word pharmacy,
 - or patient information protected by the Health Insurance Portability and Accountability Act (HIPAA).
- 11. Failure to comply with policies of shipping of controlled substances shall be grounds for discipline.

Dispening Errors and Incident Reporting

Purpose

To establish policies and procedures for documentation of Dispensing errors and Incident Reports

Responsibility

This SOP is maintained by the Pharmacist in Charge. Pharmacy technicians and Pharmacists are responsible for this SOP.

Policy

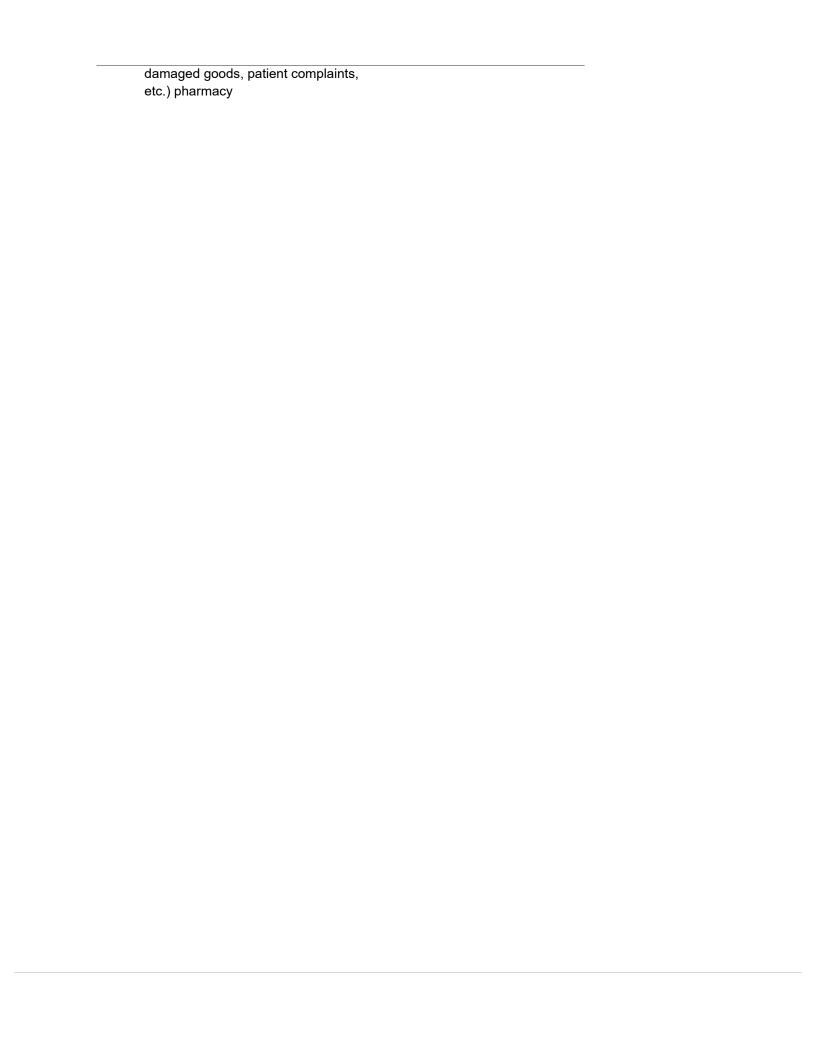
Pharmacists and Employees are to ensure proper filling and dispensing of medications. Should a mistake be caught by pharmacy staff, fill shall be corrected and reported as stated below.

Procedure

- Upon discovery of a dispensing error, pharmacy staff will inform Pharmacistin- charge in the form of email.
- If the patient has received the incorrect medication, they will be called and informed of any changes in medication with regard to the mis-fill. The correct medication will be sent to the patient accordingly. Patient will be counseled on new medication and instructed to discard the previous medication fill.
- 3. An incident report for dispensing errors will be drafted for the event, stating the following information:
 - a. Patient name and date of birth
 - b. Original Rx Number
 - c. Date of fill
 - d. Date of discovery of error
 - e. Medication filled and medication prescribed
 - f. Quantity and Directions of prescription
 - g. Summary of event with all Pharmacy staff involved
 - h. Plan for resolution and prevention of error
 - i. Signature of pharmacy staff

A template for incident reports will be made available in the Standard Operating Procedures.

4. For incidents not related to dispensing errors (delivery errors, inventory issues,



staff will consult Pharmacist in Charge and write a brief summary of the event. Only the appropriate information need be recorded on the incident report.

- 5. Incident report will be labeled and stored in pharmacy compliance binder.
- 6. Incident reports will be reviewed at quarterly Quality Assurance meeting.
- 7. [Personnel Redacted], PharmD

Implemented 12/16/2019

DEA Inspection Procedure

Purpose

To establish policies and procedures for inspection of pharmacy by DEA inspectors

Responsibility

This SOP is maintained by the Pharmacist in Charge.

Pharmacy technicians and Pharmacists are responsible for this SOP

Policy

Pharmacists and Employees are to ensure safety of pharmacy staff and stock, and comply with DEA inspection as stated and supervised by the Pharmacist in Charge

Procedure

- 1. Upon arrival of officials from the DEA, immediately contact the pharmacist-in- charge prior to allowing the inspectors into the pharmacy. Do NOT let the inspectors in prior to informing the PIC of their arrival.
- Upon arrival of officials from the DEA, review and verify identity and credentials of inspectors, and ask for their contact information (business card). If this is not provided to your, you may request that the inspectors return with a warrant.

Note: DEA inspectors will usually come in pairs, and will not carry firearms.

- The inspectors will provide a DEA 82 form for a Notice of Inspection. Signature on this form will consent to inspection. Consent may be removed at any time.
 - a. The PIC or delegated agent

will sign the form to provide consent to inspection
b. If the DEA 82 form is not signed (i.e. consent is refused),

- the inspectors may not inspect the pharmacy without a warrant.
- If a warrant is provided, read the warrant thoroughly for the actions authorized, and retain a copy for your records.
- 4. Upon request, provide any of the following information:
 - a. State of Illinois
 Pharmacy Licenses
 (for pharmacy,
 pharmacists, and staff)
 - b. State of Illinois Controlled Substance license and DEA certificate (located on poster in pharmacy)
 - c. Policies and Procedures
 - d. Invoices and Receipts
 - e. Incident Reports
 - f. DEA 222 Forms
 - g. Original prescription records (print and electronic)
 - h. Prescription Labels and Patient Charts
 - i. Lost or Stolen medication reports (DEA Form 106)
 - j. Wasted or destroyed medication (Reverse Distributor Reports, DEA Form 41)
 - k. Inventory records
 - Pharmacy Self-Inspection Records
 - m. Quality Assurance Records
- Upon request, provide access to the controlled substance safe.
 DEA Inspectors may specify a medication they would like to count. Verify physical count with electronic records.
- If the DEA inspectors request to take original records or controlled substances <u>off-site</u>, they must provide a DEA 12 Form

7. Be respectful and civil to agents. If they ask a question that you may not know the answer to, do NOT speculate. You may say "I am not sure, let me direct you to the person with the answer", and direct the inspector to the Pharmacist in

Charge.

- 8. Pharmacist will take note of all recommendations and findings of the DEA officials. Pharmacist will ask for follow-up on investigation findings so corrective actions may be made.
- Should the DEA Inspectors find a violation, they may press civil and criminal charges against the pharmacy registrant/license holder at that time. Non-compliance violations can result in increasing levels of penalty, including:
 - a. Letter of Admonition
 - b. \$10,000 fine to the licensee/registrant for each violation
 - Suspension or revocation of a controlled substance practitioner and/or research registration
 - d. Prison sentence

[Personnel

Implemented

Redacted], PharmD

10/13/2019

Emergency Preparedness Plan Fire and Natural Disasters

Purpose

To establish policies and procedures for Emergency situations in the pharmacy

Responsibility

This SOP is maintained by the Pharmacist in Charge. Pharmacy technicians and Pharmacists are responsible for this SOP.

Policy

Pharmacy staff are to ensure safety of staff and pharmacy stock. In cases of emergency, safety of the pharmacy staff is first priority.

Procedures

- Should there be a fire or natural disaster, facility will immediately call 911 and evacuate to the designated area.
 - a. Fire/Gas Leak: Outside the facility
 - b. Tornado: Basement floor, away from windows
- Pharmacy staff is to immediately, but calmly, proceed to the nearest exit.
 Pharmacy windows should be closed if safe to do so.
- Pharmacy staff will inform other members of staff via phone call that there is an emergency at the pharmacy.
- Only if absolutely necessary, a fire extinguisher may be used to put out the flames. Remember P-A-S-S:
 - a. Pull the pin to break the tamper seal
 - b. Aim low and point the nozzle of the extinguisher
 - c. Squeeze the handle to release the extinguishing agent inside.
 - d. Sweep from side to side at the

base of the fire.

 Pharmacy personnel will abide by the instructions of emergency personnel and will not return to the pharmacy or building until it is deemed to be safe.

- 6. Following the incident:
 - a. Conduct a damage
 assessment of the building,
 including medication stock,
 supplies and utilities.
 - b. Send incident/situation reports to relevant organizations (State of Illinois, DEA, local Division Office, Insurance etc.)
 - Monitor the initial and ongoing welfare of staff.
- 7. If the stock has received any direct damage related to this incident (high temperature exposure, chemical exposure, smoke damage, water damage, etc.) then the entire stock must be destroyed and replaced.

 Damaged stock will not be dispensed.
 - a. Pharmacists will fill out appropriate DEA Forms (DEA 106 for complete loss for controlled substances, DEA 41 for disposal of controlled substances)
- 8. Repairs to the pharmacy will be initiated as soon as possible, if needed. If not able to dispense medications from pharmacy during repair, patients will be contacted and medications will be transferred out to secondary pharmacies specified by the patient.

[Personnel

Redacted], PharmD

March 2024

Implemente	d			

Power of Attorney for Controlled Substance Ordering

Purpose

To establish policies and procedures for which individuals may and may not order controlled substances.

Responsibility

This SOP is maintained by the Pharmacist in Charge. Pharmacy technicians and Pharmacists are responsible for this SOP.

Policy

Currently no power of attorney exists for the ordering of schedule 2 controlled substances. Schedule 3-5 controlled substances may be ordered by Pharmacists other than the Pharmacist in Charge. EDI files shall be received from wholesalers and controlled substances orders through the CSOS system

Procedures

- Pharmacist in charge shall order all schedule II medications through CSOS system.
- 2. Staff Pharmacists shall receive schedule II controlled substances.
- At time of receipt the staff pharmacist shall verify that all C2-C5 medications have been received and sign and date all invoices.
- 4. All controlled substance invoices shall be retained on site for 5 years.



Standard Operating Procedure Sign Off

I hereby acknowledge receipt of the PURE PHARMACY Standard Operating Procedures (All Current Sections) and I understand that it is my continuing responsibility to read and know its contents. I also understand and agree that the Standard Operating Procedure is not an employment contract for any specific period of employment or for continuing or long-term employment. I have the right to resign from my employment with PURE PHARMACY at any time with or without notice and with or without cause, and that PURE PHARMACY has the right to terminate my employment at any time with or without notice and with or without cause.

I have read, understand and agree to all the above. I have also read and understand the I PURE PHARMACY.

Signature	
Print Name	
Date	
	=