Overview of Service

The purpose of this Pharmacorr Operations Manual is to familiarize correctional medical provider teams with the general operations of Pharmacorr and our delivery services in the correctional facility environment. Pharmacorr has 25+ years of proven history partnering in correctional care by providing effective pharmacy services in the correctional industry. This document will orient field staff to the workflow and processes associated with this type of pharmacy delivery system in order to help ensure that our partnership with your team is as efficient as possible.

Pharmacorr, LLC is independently owned and operates out of a centralized pharmacy distribution center located in Oklahoma City, Oklahoma. The pharmacy services from Pharmacorr are provided via mail order format through receipt of faxed or electronically transmitted orders from correctional medical facilities. The distributive and clinical pharmacy functions are usually performed in the same day that the order is placed (as long as the order is received prior to "cutoff" times which are designated by the correctional facility's time zone) and will be received via shipping carrier on the next business day.

Depending on the licensure of your Correctional Facility (CF), medications may be sent from Pharmacorr to CF sites under the site Administrator, Director of Nursing (licensee), or site Medical Director who assumes control of and authority over the medications. You may contact Pharmacorr to assist you in determining your appropriate licensure. These responsibilities are shared and require site specific policies and procedures. Everyone in leadership positions within the CF medical services unit must provide control over medications to comply with laws and company policy. This operations manual is not meant to take the place of those site-specific policies. The purpose and intent of these policies should be to provide:

Appropriate physical control of all pharmaceutical products and related supplies.

- Adequate inventory and accountability of all pharmaceutical products and related supplies.
- Appropriate storage conditions of all pharmaceutical products and related supplies.
- Appropriate training and applicable licensure of all staff.
- Maintenance of documentation for administration of pharmaceuticals and other required documentation.
- Adequate record keeping to reconcile all Controlled Substances in accordance with DEA and state regulation.

Pharmacorr History

Pharmacorr is one of the largest correctional pharmacy programs in the country, servicing the corrections industry as a central focus.

Notable facts about our company:

- Founded in Oklahoma with corporate headquarters and operations center in Oklahoma City.
- Licensed pharmacy in 45 states, with services provided in 24 states.
- Centralized prescription processing to more than 1,500 correctional facilities.
- Impacted more than two million patient lives.
- Filled more than 75 million prescriptions, 20,000 filled per day.
- Manage over \$100 million of inventory annually.
- Currently provide centralized prescription processing for 93 correctional facilities.

Our new, state-of-the art facility was built in Oklahoma City in early 2020, providing a highly automated dispensing system ensuring a same-day fill rate of 99.5% and an accuracy rate of 99.98%. We have maintained an impeccable record with all state Boards of Pharmacy.

Pharmacorr's corporate office and pharmacy are located as follows:

Pharmacorr 7400 Plaza Mayor Blvd., Suite 100 Oklahoma City, OK 73149

Toll-Free Phone: (888) 321-7774

Fax: (888) 200-7774

Direct Office Fax: (405) 634-5607

Pharmaceutical Packaging

Medications are packaged for dispensing from Pharmacorr in several different ways, depending upon the needs of the site, the availability of the product, federal and state pharmacy regulations, and cost considerations.

 Blister (or bubble) card is the primary method of packaging medications at Pharmacorr. The majority of cards are packaged by our automated dispensing processes within Pharmacorr or are purchased from manufacturers in cards of thirty dosage units.

The automated methods to package these dosage forms (or purchase them from the manufacturer in pre-packaged form) provides a great deal of cost efficiency to the medication delivery program. Coordination of site ordering to maximize 30-unit cards will further enhance cost efficiency.

- Patient specific medications are dispensed by Pharmacorr to a Correctional Facility pursuant to orders of authorized prescribers. These medications are to be administered to the patient dose-by-dose or as keep-on-person (selfadministered) medications.
- Stock prescription medications are to be administered to the patient on a dose-by-dose basis pursuant to the order of an authorized prescriber. This process may include controlled substances, injectables, and emergency drugs as approved by P&T Committee. Site stock prescription medication inventory (Maximum Inventory Levels) should be established and maintained to enable the site to initiate medications that cannot wait until the patient specific card arrives from Pharmacorr. The Maximum Inventory Level program is discussed in greater detail later in this document.

Stock medications may be dispensed by Pharmacorr and administered by site personnel in packaged cards or in bulk manufacturer's bottles, depending on the State Board of Pharmacy regulations of your particular CF. This regulation will vary from state to state. Discuss options with Pharmacorr management staff or your State Board of Pharmacy.

Stock medications cannot be used as KOP medication.

Patient-specific medication cannot be used as stock medication.

- Stock over the counter medications are supplied by Pharmacorr as bulk items (e.g., boxes of unit-dose acetaminophen or tubes of tolnaftate cream, etc.).
- Protocol over-the-counter medications are available from Pharmacorr from manufacturers in prepackaged boxes (or packets) with specific instructions included in the packaging to be given to the patient utilizing nursing protocol guidelines.

A clear distinction is made between the process of <u>dispensing</u> and the process of <u>administering</u> medication. Only pharmacies or individuals licensed to prescribe medication may dispense. **Dispensing** is defined as the labeling and issuance of multiple dosage units to a patient for multiple administrations of the drug. **Administration** is the process of providing one dosage of medication to one patient for one-time consumption.

<u>Sending Orders and Delivery of Medication</u> Electronic Order Transmission

Pharmacorr has the capability of receiving electronically transmitted orders from the Correctional Facilities that utilize certain Electronic Health Records (eHR), Electronic Medication Administration Records (eMAR), or Electronic Web-Based Order Entry (eWOE). Depending on the configuration of the electronic media transmitting the order, Pharmacorr's Operating System, FrameWorks LTC, may or may not accept the transmission via software interface. In the event that FrameWorks LTC does not have an interface with the transmitting media, Pharmacorr will arrange for the order to be printed in the pharmacy for immediate input or will ask the CF to print and fax the order to us.

Orders may be transmitted to Pharmacorr twenty-four hours per day, subject to standardized "cutoff" times. These "cutoff" times are in place to provide for the timely delivery of medication to the CF. The common carrier utilized by Pharmacorr to pick-up and deliver medication to the CF will be departing the Pharmacorr facility with each day's shipments no later than 8:00 p.m. CST (Central Standard Time) to ensure next day delivery. Adherence to the cut off times will allow Pharmacorr adequate time to process orders for pick up. Adherence to these deadlines should ensure next day delivery.

New orders and refills (all time zones) received on Saturday by Noon CST, the time zone where the pharmacy is located, will be in the following Monday delivery (unless that Monday is a federal holiday). Refrigerated medications will not be sent out on Saturday or holidays.

Refills of existing patient specific medications:

Based on daily prescription order volume, all refill orders received by the pharmacy cut off time will be filled for delivery to the CF on the next delivery day.

- Time frames must be considered when planning orders for refills of keep-onperson medications and dose-by-dose medications.
- Refrigerated items or products with special storage requirements will only be shipped on Monday, Tuesday, Wednesday, or Thursday so they can be immediately opened and stored properly. If the CF has Saturday delivery the refrigerated medications will be sent. The CF must ensure these packages are opened and refrigerated medications are stored properly.

Stock medication orders:

Stock orders received by cutoff time are processed, filled, and sent to the site usually the next day that the CF has delivery. Reordering of stock medications should be considered when deliveries are made to the CF to assure adequate supplies of needed medications.

A clear understanding of your patient-specific and stock inventory levels is necessary to ensure that no interruption of patient therapy occurs. It is important to note that more advanced notification may be required during holiday periods.

Saturday delivery may not be available to all sites, depending on location. If your site requires Saturday delivery, and if Saturday delivery is available to your site, this can be arranged by calling the pharmacy.

Sites must provide written authorization from the site administrator for routine Saturday delivery.

A properly completed fax cover page must be used when faxing to Pharmacorr.

Faxes must include:

- Facility name and cost center number.
- Specific unit location at the facility.
- Number of pages being faxed (Pharmacorr checks to verify that all pages are received).
- Name and telephone number of the person sending the fax.

Pharmacorr will provide site specific special forms with bar codes and blocks that are used with a fax server to sort orders when faxed.

The confirmation notice of transmittal should be attached to your faxed order; this serves as confirmation that your order was transmitted. Pharmacorr can provide fax cover pages for your site which can be used to make copies for future use.

A Pharmacorr pharmacist is available to accept phone orders for emergency prescriptions after the standard cut-off times for new orders. Logistically these late, new orders will be processed, and the pharmacy can determine if it will make the courier pick up time. It is important to note that this service is available ONLY for late, urgent prescriptions that must be received the next day.

Physician Data Records

Pharmacorr is required to maintain a record of the individuals at each site who may prescribe medications (e.g., physicians, dentists, mid-level practitioners). Each of these individuals should complete the top section of the Physician Data Record form. A copy of the form should be retained by the CF staff who routinely transcribe orders for the pharmacy as a reference.

The following information must be received by Pharmacorr prior to processing of orders:

- A completed physician data form (including National Provider Identification number).
- A copy of the individual practitioner license, DEA License, and State Controlled Substance license.

Each time you have a change in practitioners at your site, this process must be updated.

Orders from a practitioner who does not have this information on file with Pharmacorr may be delayed or denied.

Patient Specific Medications

Patient specific medications are dispensed by Pharmacorr upon receiving an order from an authorized prescriber. These medications are administered to the patient dose-by-dose (pill pass) or as a keep-on-person (self-administration) medication. These prescription medications are usually sent in a blister card or in manufacturer packaging.

Short-term therapy medications that are dispensed from floor stock, provided for by the practitioner card program, from back up pharmacy, or protocol OTC orders, should be plainly marked as "profile only" or "do not send – dispensed from stock." All other requests will be packaged as ordered by the prescriber. It is important to note that all orders should be sent to Pharmacorr to ensure appropriate clinical screening.

Pharmacorr packages all blister cards in counts of 30. Medications should be ordered as full cards for increased efficiency and cost containment.

Long-term therapy (chronic medications) will be packaged in thirty dose blister packs and will be shipped in thirty-day supplies unless an exception is specifically requested by the facility. Examples: BID antihypertensive - two cards will be sent for one month of therapy or for once daily antihypertensive - one card will be sent for one month of therapy.

- Jails will often request only one card per medication to eliminate waste.
- Multiple cards of the same prescription will be sent as 30 of 60, 30 of 90 etc...
- HIV medications will be routinely sent as a full 30-day supply or in the manufacturer's original packaging when applicable.

New Patient Specific Medication Orders

A new patient specific medication order may be obtained by transmitting electronically or by faxing the original order form. Orders may also be transcribed from the patient's medical record to a Pharmacorr New Order Form.

- If the order is transcribed:
 - Please write legibly and put one order per line.
 - Please provide Pharmacorr with the patient's full name, I.D. number, allergies, and any other necessary information.
 - o The person transcribing the orders must sign the page.
 - The New Order Form must include the CF name, cost center number, date, as well as phone and fax numbers.
 - The physician is not required to sign each New Order Form (depending on state requirements) unless a controlled substance (Schedule III, IV, V) is included on the page of orders.
 - The prescriber's signature must be on the form for Pharmacorr to fill any new order for a controlled substance.
- New medication orders should be written for a specific number of days or doses.
- Any limitations to the amount of medication required should be indicated, if applicable.
- All medication orders that do not indicate a specific stop date will be assigned a
 default stop date of 30 days, unless an antibiotic or a controlled substance
 (duration or number of doses is required).
- Orders sent to Pharmacorr without the required signatures will be returned to the site for completion.
- High dollar injectable medications, including IV antibiotics, are dispensed as a 10-day supply with a sufficient number of refills added.

PRN Orders

- All orders for medications which include "prn" (as needed) as part of the instructions will be routinely filled with a ten-day supply or a card of 30 doses to avoid waste.
- If a facility requires an amount greater than 30 doses to be dispensed, even though the medication is intended only "as needed," the larger amount required should be included in the order.
- If a topical medication covering a large body surface is needed, please indicate in the order to send a large tube or number of tubes needed.

Refills for Long-Term Medications

Chronic medications are ordered for a duration longer than the thirty-day supply that will be sent from the pharmacy. Long term therapy medications should be ordered in a 30, 60, 90, 120, or 180 day supply to accommodate the 30 dosage unit blister card system.

A system will be needed to alert the medical room staff that chronic medications need refilled.

- The medroom procedure "L" card system.
- This system can be established even in a keep-on-person system when the patient has the "responsibility" to initiate the refill of medications.

Continuation of Medication Orders

Renewal of an existing medication order is required prior to the expiration or stop date of the previous order. A new medication order from the prescriber is required.

Often, chronic medication orders are renewed before the current order has expired and medication remains available for the patient. If a renewal medication order is submitted for a continuation of therapy and the pharmacy has dispensed a 30-day supply of the medication within the last 20 days, Pharmacorr will profile the new order with the new stop date. The pharmacy will not dispense any medication. The facility can utilize the patient's remaining medication, then reorder that medication when necessary.

Stop Date

The stop date printed on the actual medication label is not considered a requirement for a legal prescription. It is the legal length that the medication order may remain active. It is also a requirement of most CFs. If a patient has a prescription with an expired stop date on the label, but has a new, current, and valid order for that medication in medical record and MAR, a licensed member of the medical staff may manually change the stop date on the card of medication to reflect the current stop date in the MAR and patient profile. The patient may then continue to use that medication card until it is gone. Any change in the medication strength or administration instruction would require a new prescription label.

Refill Tickler File System

For Sites Not Using "L" Card System

When long-term medications arrive from Pharmacorr and have been appropriately checked into the site, the peel-off section of the label(s) from the card(s) should be removed. One peel-off label should be affixed to a Refill Order Form that corresponds to the date that the order should be transmitted for refills. This process has demonstrated time savings and increased efficiency in the medication room.

Refills can be routinely submitted/scanned via MedRoom and can also, in extenuating circumstances, be faxed to the pharmacy by affixing refill labels to a Refill Order form.

Reminder: Pharmacorr's common carriers never deliver on Sundays and Holidays. Often, they do not deliver to certain locations on Saturday. Provide yourself with enough time to receive refill orders for continuity of care.

A second file should be kept holding all orders transmitted to the pharmacy, this includes floor stock orders, new orders, and patient specific refill orders.

- Upon verification of the receipt of the medication order, these "active" orders should be placed in an "inactive" file for a period of one month. Controlled substance records should be kept with the administration record for a period of five years.
- Any order not received should be maintained in the active file until reconciled.
- Pharmacorr will indicate a reason on the manifest for any order not dispensed from the pharmacy (backordered, refill too soon, duplicate order, need new order, non-formulary, etc.). It is especially important that the sites monitor and respond to the information provided from the pharmacy. This process will allow the site to avoid unnecessary interruptions and delays in receipt of medication.
- If the order has expired (i.e., the stop date has passed, or the approved quantity of medication has already been dispensed) a new order must be obtained from the prescriber. The new order should be transmitted to Pharmacorr.
- Refill orders submitted to Pharmacorr with 5 or less days left until stop date expiration will not be filled and will require a new order.
- Refill orders marked as "Refill Too Soon" by the pharmacy will need to be reinserted in the tickler file on the appropriate date for reorder.
- Some sites and/or state systems are utilizing other methods to transmit orders to Pharmacorr. Follow site specific directions in these instances.

Regularly monitoring and maintaining the Tickler and Verification files will greatly enhance the ordering process.

REMEMBER TO COPY ANY TICKLER FILE ORDER FORM WITH LABELS BEFORE FAXING TO PREVENT JAMMING YOUR FAX MACHINE.

COMPLETENESS AND LEGIBILITY ARE CRITICAL FACTORS. IF THE INFORMATION ON THE FORM IS NOT CLEAR, A DELAY IN RECEIVING SHIPMENTS COULD OCCUR WHILE CLARIFICATION IS SOUGHT. PLEASE WRITE/PRINT CAREFULLY.

Clinic Stock Prescription Medications And Maximum Inventory Levels

Clinic stock prescription medications, in limited quantities, are maintained at most sites to allow for the immediate initiation of a therapy when ordered by the practitioner. In some instances, it is most practical to provide medications from a stock system. This is especially relevant with behavioral health medications where dosages are altered frequently during acute phases and in jails with high occupancy turnover rates.

The type and quantity of clinic stock prescription medications is variable according to the size and complexity of the site, regulation of the Board of Pharmacy and/or Board of Nursing, the prescribing habits of the physician, and acuity of the patient population. The medical director, administrator, and director of nursing along with the P&T committee, and/or the consultant pharmacist should establish Maximum Inventory Levels based on approved inventory and reorder forms for stock medications including orals, injectables, intravenous, and behavioral health medications. Stock may be ordered electronically from MedRoom. If MedRoom is unavailable, or the item is not listed, paper request forms may be used. Forms have been developed based on the CF formulary to assist the site in developing an appropriate stock inventory.

NON-FORMULARY ITEMS MUST BE ORDERED PATIENT SPECIFIC USING AN APPROVED NON-FORMULARY REQUEST

***NON-FORMULARY ITEMS ARE NOT TO BE KEPT IN CLINIC STOCK UNLESS APPROVED BY THE AUTHORIZING NON-FORMULARY PHYSICIAN ***

Stock should be inventoried weekly to ensure adequate control of the medications. Individual administration of stock medications is made upon the order of a practitioner and is documented in the patient's Medication Administration Record (MAR). When the clinic stock is used only in emergencies or as a starter dosing, no other documentation is required unless site specific policies and procedures so state.

When clinic stock is used as the primary source of medications (i.e., the patient receives all doses from the blister card stock), the documentation for use must include entry of the initiation and discontinuation date of therapy on the Accountability Sheet as well as the documentation of each dosage on the MAR.

Clinic stock is a company asset. The responsibility for maintaining adequate levels of stock as well as safeguarding that asset rests with the CF Medical Director, Site Administrator, and Director of Nursing.

Clinic stock of all non-controlled products is accounted for in a similar manner:

- Only approved floor stock meds (which indicate Maximum Inventory Levels) may be used as stock medications.
- No more than a two-week supply of any given medication should be in inventory at one time.
- Re-order quantities should be what are necessary to bring stock levels back up to a two-week supply. Maximum Inventory Levels should be established for each inventory item to determine a two-week supply.
- Floor stock order forms must contain all inventory information required on the form to be processed (including dual signature).
- Orders are dispensed, packaged, and shipped by the pharmacy as they are requested in MedRoom or on the transmitted order form.
- A site must submit orders for specific units or wings as separate orders so that Pharmacorr can ship to the appropriate location.
 - Pharmacorr cannot separate units transmitted/ordered on the same form.
- The turnaround time for stock medications, in most cases, is one business day.
- Floor stock orders are considered "Refill" orders regarding cut off times.

Floor Stock OTC Medications And Maximum Inventory Levels

Floor stock OTC medications are provided in quantities to be administered to the patient on a dose-by-dose basis. If the medication is given by the nursing staff, it should be noted that nursing protocol guidelines were used. In instances when the patient receives a tube or the entire quantity of the medication, a notation must be made in the medical record. If the patient must receive the medication on a dose-by-dose basis the order must be transcribed onto the patient's MAR to ensure appropriate dosing.

Large quantities of medications should not be transferred to small containers. The medications should remain in the labeled bottle or cards.

Obtaining Floor stock OTC Medication

The Floor Stock OTC Medication Reorder Form serves as the mechanism to maintain inventory control and to reorder the packages. The site administrator ensures that a maximum quantity is developed for the inventory list. On a designated date, an assigned person will inventory the stock and prepare the order. This process should be done once weekly. The completed form is transmitted directly to Pharmacorr or used to re-order in MedRoom. This form must be signed and dated by the ordering person and the individual validating the order. When ordering stock medications, please allow enough time to receive orders for continuity of care, taking into consideration weekends and holidays.

Prepackaged OTC Protocol Medication

Frequently used OTC medications are available by Pharmacorr from manufacturers in prepackaged quantities that have warnings, dosing recommendations, and other information. These medications are intended to be used during sick call either by the nursing staff utilizing Nursing Protocol Guidelines or by a practitioner. The patient must also be able to keep OTC medications in his/her possession or notation on the MAR must trigger dose-by-dose administration.

When the patient is given a Prepackaged OTC Medication the following steps must occur:

- Nursing documentation for using the medication based on Nursing Protocol must appear in the P part of the SOAP notes. Practitioners will make the usual notation.
- A label with the patient's name, identification number, and time frame that the
 patient may keep the medication in his possession (e.g., start/stop dates) must
 be placed on the container. This should be done in a manner that does not cover
 up important directions for the patient. This label is for identification purposes
 and does not constitute any part of dispensing medications.
- A notation must appear in the medical record that the patient was given the package and instructions.

The site must develop specific policies if other documentation is required.

Controlled Substances

Controlled substances (CS) are medications which have been placed under federal control (by schedule designation) by the Drug Enforcement Administration (DEA) consistent with federal regulations or are designated as CS by state agency in exception to federal regulations. The schedules referenced below are designed to indicate the relative addictive potential of each medication controlled by the DEA. There are five schedules of CS:

Schedule I Addictive drugs having no medical use (e.g., heroin)
Schedule II Drugs like morphine and meperidine
Schedule III Drugs like potent pain killers (Tylenol with Codeine)
Schedule IV Benzodiazepines fall in this category (e.g., diazepam, clonazepam)
Schedule V Some cough preparations fall into this category

Many CFs keep a limited supply of Schedule III-V CS in floor stock inventory to manage acute pain, withdrawal, and other urgent needs of the patient. Due to the extreme control placed over these medications, their addictive potential, and their value as contraband, it is in the best interest of the CF to keep a limited supply of these products.

A valid order signed by an approved licensed DEA prescriber must be received before a controlled medication can be administered. The prescriber must be on staff at the site. Orders written by an outside provider must be approved and authorized by the site physician. Copies of current DEA licenses and State controlled substance licenses must be maintained by the site administrator and on file at Pharmacorr.

Each site is responsible for the security, documentation of usage, maintenance of records, and compliance with regulations. Controlled drugs must be secured under double locks, access limited to authorized individuals only, and inventories verified.

Key control is a primary issue relating to security and documentation of Controlled Substances. The individual responsible for the CS key on any shift MUST be clearly designated and is responsible for those CS products throughout the shift.

Each site must establish a Maximum Quantity for each stock controlled substance. This quantity must appear on the Inventory and Reorder Form for the site.

How to Obtain Controlled Substances Schedule III, IV & V Medications

Patient Specific Medication

Patient specific prescriptions for schedule III, IV, and V controlled substances may be obtained from Pharmacorr and should be limited to products that are not available as floor stock or for sites where floor stock is not allowed. As per DEA regulations, patient specific medication will only be issued pursuant to a Signed or Verbal Prescription issued by a DEA registered provider. Signed orders should be transmitted to the pharmacy. In states that use electronic order entry systems certified by the DEA to transmit CDS orders, a signed or verbal verification is not required. Signatures are not required for a "profile only" patient record, where medications will be taken from stock.

Stock Medication

Formulary medications may be maintained as stock controlled medications if the Medical Director has obtained a DEA license at the facility address or the on-site medication room has a DEA license and/or state controlled substance license.

The prescribing physician's actual signature or 2 signatures with 1 being a nurse, DON, or HSA is required when requesting any CS floor stock from PharmaCorr. When signing orders for CS you are acting as an agent under the DEA license.

The CS Stock Medication Order Form is required to order controlled medications and has a place for two signatures when ordering. Orders for stock controlled medications cannot be refilled; therefore, it is necessary to order a specific quantity to be shipped from Pharmacorr.

Controlled medications that do not appear on the CS Stock Medication Order Form must be ordered patient specific or if non-formulary utilizing a non-formulary request form. All CS stock will be dispensed in manufacturer's packaging (e.g., unit dose, prefilled card, injections, bulk bottles) as per DEA guidelines.

Schedule II Controlled Substances

Schedule II CS are typically not allowed to floor stock and require an original, patient specific, written prescription to be shipped overnight to Pharmacorr prior to the pharmacy filling the order. Schedule II orders may have only one drug per prescription blank. In circumstances where Schedule II is stocked, a DEA 222 Form is required and should be overnighted to Pharmacorr by the CF. If a mistake is made the order must be rewritten. Do not mark through or cross out anything. Since these medications are usually needed immediately and are usually for short-term therapy, the local back-up pharmacy may be the most practical method to meet the patient's need.

Schedule II medications that are needed immediately should be obtained from the local backup pharmacy. The facility should obtain at least a 72 hour supply of the required medication from the backup pharmacy and submit a second new prescription order (original copy) to Pharmacorr for any additional quantity required.

Receipt and Maintenance of CS

Appropriate documentation for CS entails three to four requirements:

- A record that a controlled medication has arrived at the site (e.g., an invoice).
- A record that the medication is counted and controlled until administration to a patient.
- A dose-by-dose accounting of each medication administered to a patient.
- A record of final destruction (if needing to destroy) of each dosage of drug (destruction by sending to a reverse distributor).

These activities, together, represent a true perpetual inventory system. You may refer to the Controlled Substance [Blue] Book: Training and Implementation section for useful information regarding setup and maintenance of an acceptable CS system.

Records of controlled substance receipt, administration, and transfer/destruction are to be kept by the DEA Certificate holder (physician or facility) on site for a period of 5 years or longer if regulated by other policy.

CS medications require very rigid and specific control. The minimal competencies for maintaining CS inventory are summarized below:

- Maintaining security of controlled drugs in the medication rooms and medication carts at CF sites is the responsibility of licensed (RN and LPN) staff members.
- Controlled drugs must be double locked at all times. Medication carts that
 contain controlled drugs must have a lockable box within a lockable drawer. A
 lockable cabinet affixed to a surface within a lockable medication area is also
 acceptable. It is not acceptable to have controlled substances on a medication
 cart that does not have a lockable box within a lockable drawer.

- Shift-to-shift counting of controlled drugs has two purposes:
 - Validation that all controlled drugs are accounted for
 - Relinquish responsibility and accountability from the off-going responsible nurse to the on-coming responsible nurse
- The nurses' signatures that are recorded on the shift-to-shift count sheet are the
 designated nurses responsible for the safety and security of all controlled drugs
 that are represented on the count sheet. The count may be for all the controlled
 drugs within the unit or may be for controlled drugs within a medication cart.
- The on-coming nurse who performs the count and verifies that controlled drugs are correct assumes responsibility for the counted drugs until another count and verification is performed and another nurse assumes responsibility.
- The responsible nurse must:
 - Maintain control and possession of the key to the controlled drug cabinet and/or medication cart and lockable box until a count is performed and another nurse has assumed responsibility for the controlled drugs.
 - Not allow another nurse or pharmacy technician to enter the controlled drug cabinet and/or medication cart for any reason.
 - Lock any drawer, cart, and/or cabinet that contains controlled drugs unless physically using the cart or cabinet.
- Controlled drugs are not to be out of the nurse's physical control from the time a
 dose is prepared for administration until the dose is administered to the patient
 and consumption by the patient is confirmed.
- At shift change count, the incoming nurse counts the available quantity of each controlled drug and the off going nurse verifies this number in the Controlled Substance Book. Both nurses should visually verify all counts by opening boxes and looking that each bubble in blister card has medication in it.
- The nurse responsible for the controlled drugs is responsible for adding newly arrived drugs to the count and completing required paperwork. Another licensed person must sign the documentation.
- Each nurse administering controlled drugs is responsible for completing the required documentation for the drug.

Each dispensation of stock controlled medications will arrive from Pharmacorr with a prescription number. It is the responsibility of the site to track medication using these identification numbers from arrival to completion of administration or destruction of the medications. The perpetual inventory log and the individual usage sheets must refer to this number. Floor stock controlled substance shipping/receipt documentation should be kept separate from the other non-controlled drug records. All controlled substance receipts should be kept for a minimum of 5 years per guidelines, longer if individual state law requires or per company guidelines.

Key control is a primary issue relating to security and documentation of Controlled Substances. The individual responsible for the CS key on any shift MUST be clearly designated and is responsible for those CS products throughout the shift.

PHARMACCRR

If discrepancies occur in any part of the process of accounting for controlled medications, the nurse(s) discovering the situation should at minimum:

- Contact the shift nursing supervisor for assistance.
- Make a reasonable attempt to problem-solve the situation.
- Contact Pharmacorr by phone if the pharmacy is involved.
- Follow site specific directions if the situation cannot be resolved and provide written documentation of the situation.

When working supplies of controlled medications are kept in more than one location (i.e., more than one medication cart), a central perpetual inventory log should be established and maintained by one designated responsible individual. This individual has the only access to the main supply of controlled medications and is responsible for maintaining accurate counts and documentation.

When controlled medications are maintained in only one location at a site, two individuals (one must be the shift CS nurse) should verify the arrival of the medication, add the received medication to the appropriate perpetual inventory sheet, and secure the medication in the locked area.

It is necessary to know when a controlled drug arrives at the facility, when it was administered, by whom, and that the controlled substance counts were verified each shift.

Verification of controlled medications is maintained each shift by an on-coming and offgoing nurse. The system used to count the controlled medications should account for the entire number of pills/vials of each specific medication.

When a controlled substance is removed from the card or vial and not used in its entirety (e.g., half a vial or half a tablet remaining), the nurse must have a witness to the waste of the residual medication. Wasted products may be placed in a designated biohazard container or other container for disposition according to state specific regulations. Both the nurse and the staff witness should sign on the usage sheet with a brief explanation of what occurred. Each site should have a written site-specific procedure for steps to follow if the controlled substance count is not correct. You may contact your consultant pharmacist for assistance with regulatory compliance issues.

Expired controlled substances that remain in the narcotics box must be counted at every shift change. Expired controlled substances can be removed from the daily count if they are locked in another secured area. Again, key control of this expired inventory is critical to the security of controlled substances. The following is a recommended process to move expired CS from active inventory:

- 1) Two (2) licensed medical professionals must remove the CS from the Perpetual Inventory Count Sheet, and both must sign the sheet.
- 2) Two (2) licensed medical professionals must indicate on the Controlled Substance Administration Record that the remaining drug is expired and is being removed from the count and awaiting disposal. These two parties MUST sign

PHARMAC CRR

and date that the count is correct. Clearly indicate in writing where the medication is to be secured.

- 3) Make a copy of the Controlled Substance Administration Record. Leave a copy in the Controlled Substance Book under the specific drug name. A copy must stay with the medication until disposal of the drug. The two licensed professionals must witness the disposal of the expired CS and must sign and date the original Controlled Substance Administration Record.
- 4) Any destruction of a controlled substance must be done by two licensed professionals. At no time may a single person destroy controlled substances.

All Schedule II medications must be ordered patient-specific with the original prescription signed by the physician and sent to Pharmacorr or the local pharmacy before the order can be filled

Destruction of CS

Controlled drugs must be destroyed locally where provided for by law. Pharmacorr has set up contracts with reverse distributors that will process and destroy CS. Please contact Pharmacorr for directions with setting up an account with a reverse distributor. This process allows for accountability for all persons involved with destroying CS. Any controlled drug shipped to Pharmacorr will be returned to the site for destruction locally. Immediately notify the pharmacy of any CS dispensing or shipping issues.

Transfer or Release of Patients on Medication

PATIENT TRANSFERS:

Site specific policy and procedures should be developed when medications are to be transferred with the patient. The specific issues that should be addressed include:

- Security of the medication during transportation.
- What medications may not be transferred.
- Where medications may be transferred and the circumstances under which medications may be transferred.

Pharmacorr must be informed of all patient transfers/releases, whether or not medications are being sent with the patient. Use the Patient Release/Transfer Form if the order cannot be entered electronically.

PATIENT RELEASE:

Site specific policies and procedures should be developed if medications are to be provided to the patient upon release/parole. When release dates are known in advance, Pharmacorr will assist in providing contractually required medications. The Patient Release/Transfer Form may be utilized to obtain medication for the patient's release, or the release order may be submitted electronically. Please be sure to include the patient's release date on the form or change the start date of the order to the release date if using electronic orders.

- Any medication given to the patient upon parole or release from the patient's existing stock must be documented in the MAR.
- Blister cards are not considered child resistant. Therefore, the patient must sign
 the non-child proof packaging section of the release form when sending blister
 cards. Special instructions for the medications should also be documented.

Non-Formulary Drug Requests

Non-Formulary medications are dispensed only after appropriate authorization has been obtained from the Regional Medical Director or designee following review for clinical justification. Unless special authorization has been received, the Regional or State Medical Director is responsible for approving any non-formulary request. The practitioner requesting the non-formulary medication is responsible for initiating a Non-Formulary Request and forwarding it to the Regional or State Medical Director, according to site policy. Pharmacorr keeps a list of designated practitioners allowed to approve non-formulary medication requests for each site.

Each member of the staff should be aware of the formulary and take an active role in the appropriate use of the non-formulary request. If the approval does not accompany the non-formulary order to Pharmacorr, there may be a delay in the site receiving the medication and the patient initiating or continuing therapy.

All non-formulary medications are for patient specific prescriptions only. No stock non-formulary medications may be dispensed by Pharmacorr unless approved by non-formulary request procedure.

Pharmacorr's clinical pharmacists are available via email at OKC-NF@pharmacorr.com or by phone 888-321-7774 ext 7885 if you have any questions related to a non-formulary order.

Medication Receipt Verification

It is important that the site verify and follow-up on any problems with medication orders daily. If possible, this should be the responsibility of one or two individuals. A file should be available for orders that need to be transmitted, orders that have been transmitted and are awaiting receipt, orders that are complete, and orders that have issues for follow-up.

Procedure for verifying medication received

- Once medications arrive, check medications received against the manifest report enclosed by Pharmacorr. The automated system will generate one manifest document per box of medication.
- The manifest report will show what products should be received in the order. The manifest will list reasons why a medication was not received (e.g., backorder, refill too soon, manufacturer backorder, etc.).
- Check contents of order against items ordered on transmitted order forms. Make sure all items are present.

After medications are received, verified, and checked in, contact Pharmacorr about any problems or discrepancies not addressed in the manifest explanations. Any missing medications must be reported within 72 hours. After that, a Missing Medication Form must be filled out and signed by the nursing supervisor and transmitted to Pharmacorr.

Maintain medication order forms and verification on file in the medical unit. 1–2-month retention of records of these orders should be sufficient.

Shipping Errors

Pharmacorr has implemented several safeguards to ensure that the proper shipment goes to the proper location. Even in the best of automation efforts, shipping errors will occur.

If you receive medication not intended for your facility (a single medication or a whole box of medications not for your facility): **IMMEDIATELY** call Pharmacorr and report this shipping error. The Pharmacorr representative will instruct your site on the appropriate way to return or re-route the shipment which will be the most efficient and cost-effective.

Patient Profiles & Medication Administration Records (MAR)

Pharmacorr must be notified of all medication orders that should appear on the patient profile and be listed on the MAR (Medication Administration Record). In order to receive a monthly preprinted, accurate MAR, Pharmacorr must have the following information in a timely manner:

- Patient transfers
- Patient releases
- Discontinued orders
- New orders

MARs will be sent to the sites for the following month during the last few days of the current month. The site must verify the information and make any changes that are required.

Site specific policies should address:

- How to complete the MAR.
- How to document dose-by-dose administration.
- How to document keep-on-person distribution and other pertinent topics.

Discontinued Orders

CF should appropriately document when an order is discontinued, or therapy changed to ensure that current information is available in the patient profile. This information may be documented via the electronic order entry system.

Sites should have specific procedures for noting discontinued orders on the MAR.

Monthly pre-printed MARs are generated from patient-profile data. Failure to notify Pharmacorr of discontinued medications and therapy changes will result in inaccurate MAR data.

Return of Medication to Pharmacorr

DO NOT RETURN CONTROLLED SUBSTANCE MEDICATIONS TO PHARMACORR

Medications should be removed from medication carts and other working areas when the patient for whom the card is labeled is no longer receiving the medication or when the medication has expired.

It is vital that sites return legend and OTC medications to Pharmacorr for possible re-use and credit to the site. Pharmacorr credits directly back to cost centers almost \$6,000,000 in drug returns annually.

Medications issued to a patient are not appropriate for credit and should be returned to Pharmacorr for destruction. Be sure to return the KOP (dirty) medication in a separate, properly labeled box.

All medication cards should be returned to Pharmacorr on an as needed basis after the medication is entered on the Medication Return to Pharmacy form or by electronic means using MedRoom. The site should maintain a copy of the log and return the medications to Pharmacorr using ground service. Facilities should NOT use Overnight service for medication returns except for refrigerated medications. Refrigerated returns should be sent back to Pharmacorr via next day delivery service. The item must be properly packaged with adequate ice packs, place drug in plastic bag, insert plastic bag in insulated package, and the outside of the box requires a refrigeration label. Never send refrigerated returns on a Friday or Saturday.

Returns to Pharmacorr should be done as needed to ensure that the working area remains current and uncluttered. Usually, one or two times per month is adequate. The return of medications should be supervised by the director of nursing, the administrator or designee. UPS return labels may be printed via our website and placed on each box. Boxes are then given to the driver at the next pickup.

The following are general guidelines to determine whether or not medications may be returned to Pharmacorr:

- Do not return contaminated drugs (e.g., blood, bodily fluids, etc.).
- Do not return Floor Stock Medications without the written approval of your site administrator
- Partial packages will be evaluated based on reusability.
- Clearly mark used inhalers and unsealed products so that they may be properly destroyed.
- Return all cards.
- Return all partial cards.

RETURN VIA GROUND SERVICE. DO NOT USE OVERNIGHT SERVICES UNLESS AUTHORIZED BY PHARMACORR FOR RETURN OF EXPENSIVE SPECIAL STORAGE ITEMS (E.G. REFRIGERATED ITEMS).

PHARMAC CRR

Notify Pharmacorr when returning expensive, special storage items so we will watch for delivery. Temperature sensitive medications returned to Pharmacorr inappropriately will not be credited.

PROCEDURE FOR USING GROUND SERVICE

- UPS labels may be generated on the Pharmacorr SharePoint page.
- · Pack items in a sturdy box.
- Remove or black out any old shipping labels.
- Place one label on each box to be returned and give it to the mail room for pick up by the service provider.

SPECIAL CONSIDERATIONS FOR RETURN OF MEDICATION

Any card or bulk product that has not been issued to a patient and is still intact may be returned to Pharmacorr for possible credit. If medications are marked on, bent out of shape, or in any other way damaged, they will not be credited.

Removal of Controlled Substances from Inventory

When it is verified that a patient specific control medication is no longer needed or that a control medication has expired, the medication may be removed from the active count by the DON or designee. Controlled substances should be stored in a secured double locked area pending destruction. If a separate, limited access box is not available, the medication must remain on the shift-to-shift count. The laws governing the destruction of controlled substances are regulated by the DEA and State Boards of Pharmacy.

Drug Recalls

Pharmacorr will comply with any communications from pharmaceutical manufacturers regarding recalled products. Pharmacorr will review product recalls and immediately notify facilities if the recall requires any specific action to be taken. If a recall requires facilities to pull a specific product from stock, Pharmacorr will notify each facility of the product's name and lot number(s) and provide specific information regarding the action to be taken to remove the product.

Back-Up Pharmacy Utilization

Each site should find a local pharmacy that will fill prescriptions that are needed on an emergency basis and for Schedule II medications. Attempts should be made to find a pharmacy that will deliver and has 24 hour and weekend service.

A supply of no more than 3 days from the back-up pharmacy should be adequate to maintain the facility until the remainder of the medication order can be obtained from Pharmacorr.

The local backup pharmacy should be utilized for any Schedule II Controlled Substance that is needed for immediate use at the facility.

The site administrator should establish site specific policies regarding who may use the back-up pharmacy, when to use, and documentation required.

Pharmacorr has set up a process with Employer Health Options (EHO) that will allow for processing and payment to the pharmacy for medications that are needed. Please contact Pharmacorr for a copy of the processing form and procedures for using this option.

Do not use the backup Pharmacy to obtain non-formulary medications or parole medications without the approval of the site administrator

Problem Intervention

Pharmacorr has intervention pharmacists on duty during regular working hours. Pharmacists will intervene and attempt to resolve problems with prescription orders. The following are common issues:

- <u>Non-formulary prescriptions</u>: The pharmacist is available to discuss alternative formulary therapy with the physician and offer therapeutically sound substitutions.
- <u>Unclear/illegible orders</u>: The pharmacist may contact the ordering site for clarification, fax the order back to the facility, or the order will be noted on the shipping manifest and placed in the next day shipment for clarification.
- Contraindications: If allergies, adverse drug interactions, or other potentially adverse effects of drug therapy are noted, the pharmacist may contact the ordering physician or site to recommend resolutions. Pharmacorr may elect to fill the order and return it to the site with a message about the allergy or adverse reaction. In serious clinical situations where Pharmacorr personnel have not been able to contact the site for resolution, Pharmacorr may elect not to fill an order until response is received from the prescribing practitioner.
- **Expired orders**: If a refill is submitted for a medication with no remaining refills, the site will be notified that a new order must be obtained.

Error Reporting and Continuous Quality Improvement (CQI) Activity

If a problem or error is noted by the site that requires follow-up and investigation by Pharmacorr as part of the Quality Control/Quality Improvement (QC/QI) program, the following steps should be taken:

- Complete the Pharmacy Error/Incident Form in CorTrack or fill out an Incident Form.
- Photocopy the blister pack or bottle with the label attached. Make sure the initials of who filled the order appear on the photocopy.
- Submit to Pharmacorr for investigation by the QC/QI pharmacist.
- A facility may contact Pharmacorr if there are any questions regarding an incident report.

Incomplete/incorrect labeling and concerns regarding appropriateness of medications are examples of issues that should be addressed using the incident report form.

Other suggestions and requests that would improve service may be handled in a variety of ways:

- Formally between the administrator and Pharmacorr director.
- Informally on an occurrence basis between the medication nurse and the designated pharmacist for the site.
- Formally at the P and T Committee.

Pharmacy and Therapeutics Committee

The number of drugs available and the complexities surrounding their safe and effective use make it necessary for health care systems to have an organized, sound program for maximizing rational drug use. The Pharmacy and Therapeutics Committee is the organizational keystone of this program.

The Pharmacy and Therapeutics Committee is an advisory group of medical, nursing, and pharmacy staff members who serve as the organizational line of communication between the medical staff and the organization. This committee is composed of physicians, pharmacists, and other health care professionals selected with the guidance of the medical staff. It is a policy-recommending body of the medical staff and the health care systems administration on matters related to the therapeutic use of drugs.

A. PURPOSE:

1. Advisory: The committee recommends the adoption of, or assists in the formulation of,

policies regarding evaluation, selection, and therapeutic use of drugs in health

care systems.

2. Educational: The committee recommends or assists in the formulation of programs designed

to meet the needs of the professional staff (e.g., physicians, nurses, pharmacists, and other health care practitioners) for complete current knowledge on matters

related to drugs and drug use.

B. ORGANIZATION AND OPERATION:

Pharmacy and Therapeutics Committee should meet regularly, at least once quarterly and more often when necessary. The Committee should invite people to attend meetings who can contribute specialized or unique knowledge, skills and recommendations. An agenda and supplementary materials (including minutes of the previous meeting) should be prepared by the secretary and submitted to committee members in sufficient time prior to the next meeting. Minutes of committee meeting to be maintained in a permanent record.

While the composition and operation of the pharmacy and therapeutics committee might vary, the following will apply:

- The Pharmacy and Therapeutics Committee should be composed of at least three physicians, a pharmacist, nurse, and an administrator. Committee members are appointed by a governing unit or elected official of the organized medical staff.
- 2. A major purpose of the committee is to develop a formulary of drugs accepted for use in the health care system and provide for its applicable revision. The selection of items to be included in the formulary will be based on objective evaluation of their relative therapeutic merits, safety, and cost. The committee should minimize duplication of the same basic drug type, drug entity, or drug product.
- 3. To establish programs and procedures that help ensure cost-effective therapy.
- 4. To establish or plan suitable educational programs for the medical staff on matters related to drug use.

PHARMACERR

- 5. To participate in continuous quality improvement/assurance activities related to distribution, administration, and use of medications.
- 6. To initiate and/or direct drug use review programs and studies and review the results of such activities.

Pharmacy Reports

Many reports may be generated on the Pharmacorr SharePoint page. There are several different self-generated reports available, for example:

- Patient Profile Report what medication a specific patient has been prescribed.
- Medication Specific which patients are prescribed a specific medication; can be run for multiple medicines.
- Drug Profile Report the Drug Profile Report can be run for Primary Drug categories (including HIV, Cardiovascular, Psychiatric, GI, and General medicine), Drug Classification and specific drugs (of which multiple can be chosen for the same report).
- Stop Date Report what prescription has a stop date in between two set dates.
- Dispensing Report which medication was sent within a given time period; can be run for medication specific or patient specific.

If you need assistance in generating a report or navigating the system, please call Pharmacorr administration 1-888-321-7774 or email the clinical department at OKC-NF@pharmacorr.com

Reference Material

There are many reference material documents on the Pharmacorr website.

The information available includes:

MicroMedex
Poison Control Guide/Poison Control Center Contact Information
Do Not Crush list
Conversion Tables
Guides for Medication Use for Nursing/Patients
Alcohol Free Products
Sulfite Containing Products
Drugs that May Cause Photosensitivity
Lactose and Galactose Free Products
Official USP/FDA Storage Definitions

The reference material and information guides listed may not be an all encompassing list and are subject to change at anytime.