NURSING CARE CENTER PHARMACY

Policy and Procedure Manual

January 2026

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PharMerica®

Nursing Care Center Pharmacy Policy & Procedure Manual

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Pharmacy Information

Site location: _____

Address: _____

Telephone: _____

Fax: _____

Hours of Operation:

- **Sunday**
- **Monday**
- **Tuesday**
- **Wednesday**
- **Thursday**
- **Friday**
- **Saturday**

After hours / emergency contact: _____

Contact instructions for on-call pharmacist: _____

_____

Delivery schedule: _____

_____

Stat orders shall be delivered within ____ hour(s) during regular business hours and within _____ hours after hours / emergency times.

Pharmacy Manager (General Manager/Pharmacist in Charge): _____

Consultant Pharmacist: _____

Pharmacy Business Office Manager: _____

Medical Records Technician: _____

Poison Information Telephone: _____

INTRODUCTION

PharMerica Corporation specializes in long-term care pharmacy, providing medications, consulting programs, regulatory assistance and related services to long-term care residents in skilled nursing, sub-acute and assisted living settings nationwide. PharMerica's comprehensive pharmacy strategy is built on customer service and patient care providing a continuum of full-service. Our services include accurate dispensing of medications, delivery, pharmacist consulting, medication compliance monitoring, infusion therapy, Medicare Part B and D products/billing, medical records, training and education and nurse consultants.

PharMerica Corporation pledges to provide accurate medication in the most cost-effective timely manner possible resulting in optimal outcomes, documented savings and reduced risk to our customers.

PharMerica Corporation has compiled this collection of policies and procedures as a basic practice guideline for pharmaceutical services for the professional nurse in a long-term care setting. The policies and procedures were written broad in scope to allow them to be followed in concept. The intention being, the policies and procedures must be reviewed by your healthcare professionals and may need to be modified as necessary to meet unique standards of practice within your nursing care center. It is not to be construed as a substitute for the professional judgment of health care professionals. This manual may serve as an orientation for all new nursing care center licensed employees who will be involved with medication handling, storage and administration.

PharMerica Corporation has made every effort to ensure accuracy and completeness of information presented in this manual. Pharmacy policies and procedures are constantly evolving due to regulatory and best practice changes and clinical experience. PharMerica Corporation, along with the writers, editors, and reviewers of these policies and procedures cannot be held responsible for the continued currency of information, for any errors or omissions and for any consequences arising from these policies and procedures. The responsibility for ensuring the accuracy of any provision and updating of the procedures for compliance within your nursing care center remains with you.

Correspondence should be sent to:

PharMerica Corporation
805 N. Whittington Pkwy
Louisville, KY 40222

PHARMACY POLICIES AND PROCEDURES ANNUAL AUTHORIZATION

For

_____

(Name of Nursing Care Center)

The nursing care center's Pharmacy Services Subcommittee / Pharmaceutical Services Committee / Quality Assessment and Assurance Committee / or its equivalent, on this, the _____ day of the _____ (month), _____ (year) hereby approve and adopt the following policies and procedures as amended by the nursing care center in accordance with nursing care center standards and state and federal regulations. All medical, nursing and pharmacy staff shall be inserviced on and have access to this manual.

Represented by:

_____
Administrator

_____
Director of Nursing

_____
Medical Director (or physician designee)

_____
Consultant Pharmacist

Organizational Aspects

1.0 ORGANIZATIONAL ASPECTS

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1.1 PHARMACEUTICAL SERVICES COMMITTEE

POLICY

The Pharmaceutical Services Committee, or its equivalent, oversees and evaluates pharmaceutical services and recommends policies and procedures related to medication use to the Quality Assessment and Assurance Committee. The Quality Assessment and Assurance (QA&A) Committee carry out these functions in the absence of a Pharmaceutical Services Committee. For purposes of this manual, the term Pharmaceutical Services Committee will be utilized.

PROCEDURES

The Pharmaceutical Services Committee shall be composed of the administrator, director of nursing, consultant pharmacist and/or a pharmacist from the provider pharmacy, and a physician.

1. The committee meets at least quarterly. Meetings may be held in conjunction with the Quality Assessment and Assurance meeting. In addition, any member may schedule special meetings.

2. Minutes of each meeting are recorded and includes:

    a. Names of members present

    b. Date and time of the meeting

    c. Discussion topics

    d. Actions taken

    e. Recommendations to the Quality Assessment and Assurance Committee

3. The committee:

    a. Reviews pharmaceutical policies and procedures and their implementation as often as deemed necessary by the chairperson or upon recommendation of the consultant pharmacist or provider pharmacy and at least annually;

    b. Reviews information on new medication delivery systems as appropriate regarding their use with the nursing care center and as policy changes are necessary, defer to the pharmacy's policy and procedure manual committee for recommendations;

c. Reviews and analyzes data, including data collected under the QAPI program and data resulting from drug regimen reviews, and acts on available data to make improvements.

4. Each agenda item is reviewed and an action plan is developed for improvement, if deemed necessary by the committee. The plan is submitted to the Quality Assessment and Assurance committee for approval of implementation.

1.2 PROVIDER PHARMACY REQUIREMENTS

POLICY

Regular and reliable pharmaceutical service is available to provide residents with prescription and non-prescription medications, services, and related equipment and supplies. A written agreement/contract with a provider pharmacy stipulates financial arrangements and the terms of the services provided.

PROCEDURES

1. The nursing care center maintains a written agreement/contract with the provider pharmacy, which has been signed by both the administrator, or authorized representative, and an authorized representative of the provider pharmacy. The obligations of the pharmacy provider are set forth in that written agreement/contract. Any additional or different or specifically enumerated obligations set forth in this manual are aspirational in nature and the obligations of the pharmacy are solely those set forth in the written agreement/contract.

2. The provider pharmacy maintains all current pharmacy licenses and registrations required by state and federal law, and adequate professional liability insurance, and may provide proof of same to the nursing care center at each renewal period or when requested. Current pharmacy staff licenses are on file at the pharmacy.

3. The provider pharmacy is responsible for rendering the required service in accordance with local, state, and federal laws and regulations, nursing care center policies and procedures, community standards of practice and professional standards of practice.

4. The provider pharmacy agrees to perform the following pharmaceutical services, including but not limited to:

    a. Assisting the nursing care center, as necessary, in determining the appropriate acquisition, receipt, dispensing and administration of all medications and biologicals to meet the medication needs of the residents and the nursing care center.

    b. Accurately dispensing prescriptions based on authorized prescriber orders.

    c. Providing medications packaged in accordance with the nursing care center’s needs and equipment requirements.

d. Supplying only FDA-approved medications, biologicals, and supplies approved by the United States Pharmacopeia (USP) and the National Formulary (NF), other than extemporaneously compounded medications or investigational medications.

e. Labeling all prescription medications to comply with all state and federal regulations. (See Section 3.7 – Medications and Medication Labels)

f. When the nursing care center is the responsible payer for a resident's maintenance medication therapy, then the provider pharmacy will dispense branded maintenance medications as determined by the provider pharmacy's standard packaging and dispensing practices and as per contract with the nursing care center. The provider pharmacy will dispense all other maintenance medication orders for the residents in thirty day supplies. The provider pharmacy will dispense all non-maintenance medications in such quantities so ordered by the resident's physician.

g. Providing routine and timely pharmacy service per contractual agreement and emergency pharmacy service 24 hours per day, seven days per week.

h. Maintaining a medication profile on residents for whom medications are dispensed. This includes all medications dispensed and nursing care center-provided information such as resident's age, diagnoses, medication allergies, and any other pertinent information.

i. Screening each new medication order for medication/drug interactions with other medications ordered for the resident; for duplication of therapy with other medications in the same therapeutic class ordered for the resident; and for appropriate medication dose, dosing interval, and route of administration, based on resident and other pertinent variables. Clinically significant medication issues or any irregularities that could result in a significant negative outcome are reported to the nursing care center and/or the prescriber immediately. Facility staff should follow up for resolution with prescriber by midnight the next calendar day and report to MDS for documentation in Section N, as appropriate.

j. Providing medication information and consultation to the nursing care center's nursing staff upon request.

k. Providing, maintaining, and replenishing in a timely manner an emergency medication supply in a properly labeled container per state requirements.

l. Where appropriate, assisting the prescriber in documenting the need for a "non-covered" or non-formulary medication ordered for a resident otherwise eligible for medication benefits through Medicaid, Medicare Part D or other third-party programs.

1.3 CONSULTANT PHARMACIST SERVICES PROVIDER REQUIREMENTS

POLICY

Regular and reliable consultant pharmacist services are provided to residents. The consultant pharmacist written agreement stipulates financial agreements and the terms of the services provided to the nursing care center.

PROCEDURES

1. The nursing care center maintains the consultant pharmacist written agreement, which is signed by the administrator, or nursing care center designee, and an authorized consultant pharmacist representative.

2. The consultant pharmacist maintains current licensure and adequate professional liability insurance and may provide proof of same to the nursing care center at each renewal period or as requested.

3. The consultant pharmacist agrees to render the required service in accordance with local, state, and federal laws, regulations, and guidelines; nursing care center policies and procedures; community standards of practice; and professional standards of practice.

4. The consultant pharmacist, or designee, provides pharmaceutical care services, including but not limited to the following:

    a. Notify the nursing care center's administrative staff of next visit prior to visit.

    b. Notify the nursing care center's administrative staff of the current visit upon arrival.

    c. Review and follow-up to previous month's pharmacy recommendations with the nursing care center staff.

    d. Medication Regimen Reviews (MRR) for each Skilled Nursing (SNF) resident at least monthly, or more frequently under certain conditions, incorporating the federally mandated standards of care in addition to other applicable professional standards.

    e. Communicate to the responsible prescriber, the facility's medical director and the director of nursing potential or actual problems detected and other findings related to medication therapy orders at least monthly. Communicate recommendations for changes in medication therapy and the monitoring of medication therapy.

f. Quality assurance (random) inspections of medication storage areas, carts and rooms at appropriate intervals to check for proper storage, cleanliness and dating of medications. This is a random check for oversight of systems in place for medication storage, not a three-way audit, nor a complete check of all medications at the nursing care center. This includes checking of the emergency medication supplies (kits) to ascertain that they are properly maintained, and that the contents are not outdated. Recommendations from these inspections are included in the consultant's reports.

g. Submit a monthly summary report to the nursing care center outlining specific findings based on the consultant pharmacist's Medication Regimen Review following the completion of the review. (Refer to Section 8.1 – Medication Regimen Review and Reporting)

h. Assist in the identification and evaluation of medication-related issues, including prevention and reporting of medication errors as well as suspected adverse medication consequences.

i. Observe and/or review medication administration pass observations as outlined in contract in order to assist in the assessment and improvement in nursing staff medication administration and submit a report to nursing administration.

j. Provide in-service educational programs to nursing staff on a medication-related topic at least annually, or as outlined in the contract.

k. Respond and aid in the investigation of potential medication diversion at the nursing care center as requested.

l. Assist the nursing care center staff on development, implementation, evaluation and revision of pharmaceutical service procedures that address resident needs and follow the current standards of practice.

m. Provide information on medication delivery systems and packaging as necessary.

n. Assist the provider pharmacy to establish a system of records of receipt and disposition of all controlled substances that produces an accurate reconciliation and account of use on a periodic basis. Assist in the accounting, destruction and reconciliation of unused controlled substances and non-controlled substances as required by state and federal law.

o. Aid in resolving problems with pharmacy providers/suppliers at the request of the nursing care center's administrator or director of nursing.

p. Participate and provide a report to the nursing care center's Quality Assessment and Assurance Committee's quarterly meeting. Assist the administrator and/or other nursing care center representatives in setting standards and developing, implementing, and monitoring policies and procedures for the safe and effective distribution, control and use of medications and related equipment and services in the nursing care center.

q. As requested, provides support for facility antibiotic stewardship program. Or as required by federal or state regulations.

r. As requested, provide recommendations to the nursing care center administration and the Pharmaceutical Services Committee or Quality Assessment and Assurance Committee:

- Recommend Quality Assurance and Continuous Quality Improvement (CQI) activities regarding the medication use process; and the prescribing, dispensing, storing, administration and monitoring of medications in the nursing care center;
- Review required CQI data and provide analysis and feedback to the medical and nursing staffs of the nursing care center;
- Review medication incident reports.

s. Participate in other nursing care center committees and activities as requested by the administrator or director of nursing and approved by the management or as agreeable to both parties. Examples of appropriate committees include Psychoactive Medication Review, Falls, Weight Management, Interdisciplinary Team, and Infection Control.

t. Assist in the coordination of pharmaceutical services when multiple providers are utilized. This may include provider pharmacies, infusion service providers, hospice and prescription drug plans (PDPs).

u. Identify one or more current medication references to assist in the identification of medications and information on indications/diagnoses, precautions, contraindications, possible adverse effects, and recommended dosages.

v. Assist nursing care center staff in outlining medication administration schedules to maximize effectiveness and to avoid potential interactions.

w. Maintain a record of time spent in the nursing care center and document activities performed and services provided on behalf of the residents and the nursing care center. This information is provided in the monthly consultant pharmacist report or electronically to comply with payroll based journal reporting.

x. Exit with the nursing care center's director of nursing, administrator or designee.

y. Provide a report of activities, findings and recommendations to the administrator and the director of nursing on a monthly basis. A copy of the monthly report will also be maintained by the pharmacy for reference. Individual resident recommendations are provided to prescribers, the facility's medical director and director of nursing upon completion or following MRR. (Refer to Section 8.1 – Medication Regimen Review and Reporting)

1.4 INFUSION THERAPY PRODUCTS PROVIDER

POLICY

The nursing care center maintains an agreement with a pharmacy provider qualified in infusion therapy preparation and distribution for infusion therapy products, and for consultation on the use of such products. Infusion therapy products include solutions with no additives, solutions with additives, and supplies for administering solutions and for preparation of emergency or mixed solutions with short expirations.

PROCEDURES

1. The infusion therapy provider furnishes the infusion therapy products on a timely basis.

2. The infusion therapy provider maintains a medication profile for each resident for whom infusion therapy products are provided and reviews the profile prior to dispensing any infusion therapy products.

3. Qualified personnel perform infusion therapy product preparation in a laminar flow clean air center.

4. Stringent infection control procedures are followed during preparation and distribution of infusion therapy products, and the provider has a quality assurance program for determining sterility of completed solutions.

5. The infusion therapy product provider contacts the nursing care center as appropriate to obtain updates on resident infusion therapy product needs prior to delivery to the nursing care center.

6. A pharmacist is available 24 hours a day for consultation on infusion therapy product compatibility, dosing, and other information.

7. Refer to the Intravenous Therapy Policy and Procedure Manual for specifics.

1.5 ARRANGEMENTS WITH NON-CONTRACT PHARMACY

POLICY

A resident or family member/responsible party may obtain medications from the pharmacy of their choice, if required by State law. The non-contract pharmacy must abide with the federal and state regulations and the policies and procedures of the care center, including, but not limited to having a written pharmacy services agreement on file. It is widely recognized that the use of multiple pharmacies within a nursing home center can lead to medication errors. Nursing Home Staff may not recommend a Non-Contract Pharmacy to a resident, family member/responsible party or insurance provider.

PROCEDURES

1. The nursing care center's business office representative provides the Non-Contract Provider Agreement to residents or responsible parties who wish to purchase medications from a non-contract pharmacy. A second copy of this agreement is mailed to the designated pharmacy. Specific items requiring Non-Contract pharmacy compliance shall be listed in the agreement.

2. The person distributing these copies, documents this activity and signs and dates the entry in the resident's business office record. Notification of agreement by the non-contract pharmacy to strictly adhere to the nursing care center's policies and procedures for pharmacy services as listed in the agreement is also documented.

3. The provider pharmacy is informed about the arrangement with the non-contract pharmacy. The nursing home center shall require and obtain from the Non-Contract Pharmacy a signed and written indemnification agreement indemnifying and holding harmless the nursing home center and the contract pharmacy and from all liability in the event the contract pharmacy supplies any medication to the resident served by the Non-Contract Pharmacy.

4. To inform nursing staff, a note is displayed prominently on the resident's medical record and Medication Administration Record (MAR) of the name of the pharmacy that the resident is using, which is different than the provider pharmacy.

5. The non-contract pharmacy is responsible for rendering the required service in accordance with local, state, and federal laws and regulations, nursing care center policies and procedures, community standards of practice and professional standards of practice.

6. If an insurance provider requests that the nursing home center assist it in obtaining a Non-Contract pharmacy for a resident in the nursing home center, the nursing home

center shall inform the insurance company that the contract pharmacy is the preferred pharmacy of the nursing home care center and the nursing home center shall promptly notify the contract pharmacy of the request made by the insurance company. The nursing home center shall assist the resident in making an informed decision to select an alternate insurance provider that can provide appropriate insurance for the resident which will cover the medications supplied by the contract pharmacy.

7. The Non-Contract pharmacy agrees to perform the following pharmaceutical services, including but not limited to:

    a. Assisting the nursing care center, as necessary, in determining the appropriate acquisition, receipt, dispensing and administration of all medications and biologicals to meet the medication needs of the residents and the nursing care center.

    b. Accurately dispensing prescriptions based on authorized prescriber orders.

    c. Providing medications packaged in accordance with the nursing care center's needs and equipment requirements.

    d. Supplying only FDA-approved medications, biologicals, and supplies approved by the United States Pharmacopeia (USP) and the National Formulary (NF), other than extemporaneously compounded medications or investigational medications.

    e. Labeling all prescription medications to comply with all state and federal regulations. (See Section 3.7 – Medications and Medication Labels)

    f. When the nursing care center is the responsible payer for a resident's maintenance medication therapy then the non-contract pharmacy will dispense branded maintenance medications in fourteen or fifteen day supplies as determined by the Non-Contract pharmacy's standard packaging and dispensing practices. The Non-Contract pharmacy will dispense all other maintenance medication orders for the residents in thirty day supplies. The Non-Contract pharmacy will dispense all non-maintenance medications in such quantities so ordered by the resident's physician.

    g. Providing routine and timely pharmacy service per contractual agreement and emergency pharmacy service 24 hours per day, seven days per week. The contract pharmacy shall have no obligation to provide STAT medication to residents being served by the Non-Contract Pharmacy. In the event that the Contract Pharmacy is requested to provide a Stat Order, the Non-Contract pharmacy shall pay the contract pharmacy its usual and customary Stat Order charges for Non-Contract pharmacies.

h. Maintaining a medication profile on residents for whom medications are dispensed. This includes all medications dispensed and nursing care center-provided information such as resident's age, diagnoses, medication allergies, and any other pertinent information.

i. Screening each new medication order for an appropriate indication or diagnosis; for medication/drug interactions with other medications ordered for the resident; for duplication of therapy with other medications in the same therapeutic class ordered for the resident; and for appropriate medication dose, dosing interval, and route of administration, based on resident and other pertinent variables. Any irregularities that could result in a significant negative outcome are reported to the nursing care center and/or the prescriber. If diagnosis or indication is not available, notifying the nursing staff of the need to obtain the information from the prescriber.

j. Providing medication information and consultation to the nursing care center's nursing staff upon request.

k. Providing, maintaining, and replenishing in a timely manner an emergency medication supply in a properly labeled container per state requirements. The emergency supply medication of the contract pharmacy shall not be used by residents being served by a Non-Contract Pharmacy.

l. Where appropriate, assisting the prescriber in documenting the need for a "non-covered" or non-formulary medication ordered for a resident otherwise eligible for medication benefits through Medicaid, Medicare Part D or other third-party programs.

1.6 PHARMACIST/PHYSICIAN COLLABORATIVE CARE AGREEMENT

POLICY

A licensed pharmacist and licensed physician may enter into a collaborative care agreement for residents of the long-term nursing care center, if approved by the nursing care center, as permitted by state law. The collaborative care agreement is reviewed and approved by the Pharmaceutical Services Committee and/or the Quality Assessment and Assurance Committee as well as the State Board of Pharmacy, if required by regulation.

PROCEDURES

The collaborative care agreement includes a written protocol authorizing the pharmacist to perform specific activities as permitted by state regulations. The protocol includes, but may not be limited to:

1. A statement identifying the licensed physician and the licensed pharmacist who are parties to the agreement.

2. A statement of the activities the pharmacist will/may undertake in the course of exercising the authority granted under the collaborative care agreement, which may include but not be limited to a statement of the types of diseases to be managed, medications or medication categories involved, and procedures, decision criteria or plan the pharmacist is to follow when operating under the collaborative care agreement.

3. A statement that describes how the pharmacist's activities will be documented and communicated to the physician.

4. The scope of the agreement is within the scope of the physician's current practice.

5. The agreement is both pharmacist and physician specific and must be updated to reflect changes in personnel, as indicated.

6. A current copy of the agreement signed by both practitioners is kept on file by the nursing care center and the provider pharmacy.

7. This agreement will terminate when either party notifies the other in writing of withdrawal from the agreement.

1.7 PHARMACY EMERGENCY PREPAREDNESS PLAN

POLICY

The Emergency Preparedness Plan establishes guidelines to provide effective response during communication and information failures, and environmental disasters or emergencies. The plan encompasses both the safety and welfare of residents and employees as well as providing for the uninterrupted delivery of pharmaceutical care to our nursing care centers and residents.

PROCEDURES

1. The Pharmacy Emergency Preparedness Plan includes procedures for the following:
   a. Acts of terrorism
   b. Bomb threats
   c. Civil disorders
   d. Earthquakes, hurricanes, tornadoes, flood and other acts of nature
   e. Fire
   f. Loss of utilities
   g. Unforeseen events that result in temporary or permanent closure of the provider pharmacy (e.g., flu or other epidemic situations, power outage, structural damage to facility)
2. Assignments of Responsibility:
   a. During any emergency situation, the pharmacy manager, or in her/his absence, the pharmacist in charge or the most senior pharmacist present will assign responsibilities and tasks based on assessed need, and ability and availability of personnel.
   b. These responsibilities will always include notifying any nursing care center whose medication delivery may be affected, the appropriate PharMerica officers, Corporate Office and appropriate external authorities (e.g., police, fire, etc.).
3. Communications of changes or issues at the nursing care center would be initiated by calling the pharmacy manager or pharmacist in charge. In the event that there is an evacuation of the pharmacy or landline telephone outage, the communication route will be established by the pharmacy manager or pharmacist in charge and communicated to the nursing care center administration.
4. Alternate Pharmacy Providers
   a. Situations that will require utilization of alternate pharmacy providers include those that pose a threat to employee safety or an inability to maintain the security of the pharmacy.

b. If an emergency requires the closure of the pharmacy for greater than four (4) hours, new orders will be sent from

_____
(customize to local pharmacy, address, telephone number).

c. Any medications not available from this location will be sent from

_____
(customize to local hospital pharmacy, address, telephone number).

d. If the pharmacy is closed for greater than three (3) days, medications will be sent from _____
(customize to pharmacy used, telephone number).

5. Skilled Nursing Facility (SNF)/Nursing Care Center Evacuation

In collaboration with the nursing care center, the following guidelines will be followed by the pharmacy staff in the event of a SNF evacuation:

a. A pharmacist, the director of nursing, or designee, will direct nurses to secure the medication carts and remove them from the nursing care center along with resident charts, the emergency medications/supplies/kits, and necessary infusion pumps to their designated emergency meeting spot. Nursing care center staff will be reminded of the need to maintain security of medication and record storage.

b. The pharmacy staff will maintain continuity with pharmacy services and meet resident needs by ensuring delivery of medications to an alternate site when required.

c. Nursing care center staff will be educated to the pharmacy plan for medication distribution in the event of an emergency.

d. The nursing care center staff will communicate pertinent aspects of their emergency/disaster plan to the pharmacy.

6. Assessment of Plan
The emergency preparedness plans are reviewed and revised at least annually. In order to monitor effectiveness of the plan, the following sources of data may be utilized:

a. Serious Event Reports (security risks, vandalism, fire safety, thefts, spills).

b. Biomedical equipment reports on preventative maintenance, equipment failure, and safety testing.

c. Product recall notices.

d. Annual safety evaluations.

1.8 RESIDENT CENSUS INFORMATION REQUIREMENTS

POLICY

The provider pharmacy's ability to accurately charge the responsible party for the payment of products and services is dependent on the nursing care center's timely and accurate report of Resident Census Information.

PROCEDURES

1. The nursing care center agrees to provide the following information (the "Resident Census Information"), including but not limited to:

    a. Resident Last Name

    b. Resident First Name

    c. Resident Middle Initial

    d. Gender

    e. Resident Date of Birth

    f. Resident Social Security Number

    g. Date of Resident Admission

    h. Time of Resident Admission

    i. Resident Admitting Physician

    j. Resident Medicare Number

    k. Resident Medicaid Number (if applicable)

    l. Resident Admission Pay Source

    m. Additional Payer Information (ID Number, Group Number, etc.)

    n. Responsible Party Name

    o. Responsible Party Address

p. Responsible Party Telephone Number

q. Responsible Party Relationship to Resident

r. Resident Nursing Station

s. Resident Room Number

t. Resident Bed Number/Name

u. Allergies

2. For new residents, the nursing care center shall provide complete and accurate Resident Census Information to provider pharmacy within forty-eight (48) hours of the resident's admission to the nursing care center.

3. For existing residents, the nursing care center shall provide changes to Resident Census Information within forty-eight (48) hours of such changes becoming known to the nursing care center.

4. For new and readmitted residents where the admission occurs after the provider pharmacy's normal business hours, the provider pharmacy may record the date of admission as the next business day.

1.9 AUTOMATED DISPENSING MACHINE FOR FIRST DOSE AND EMERGENCY MEDICATIONS

POLICY

The facility may use automated dispensing machines (e.g., Pyxis™, Omnicell™, Talyst Insyte, MedDispense, Automed, TCGRx, RxNow™, others) for first dose and emergency medications, where permitted by regulation or law.

PROCEDURES

1. Automated dispensing machines (ADM) may be used by authorized facility staff to access first dose and emergency medications, per regulation and applicable law. Contents are property of the pharmacy, require a valid order and/or prescription on file at the pharmacy and may require authorization prior to medication removal.
2. The facility's Pharmacy and Therapeutic Committee should determine the content of an ADM in conjunction with Pharmacy and in accordance with regulation or applicable law.
   a. Controlled substances may be stored in the ADM per regulation and applicable law.
   b. Changes to the content of the ADM should be approved by the facility's Pharmacy and Therapeutic Committee and the pharmacy.
3. Only authorized licensed facility personnel who have received training, have access to medications in the ADM.
   a. The director of nursing or designee authorizes staff and administers user names and passwords for access to the dispensing machine.
   b. User names and passwords are removed immediately when staff leave employment of the facility.
4. Complete policies and procedures for security, access, physician orders, electronic maintenance and proper use of the packaging provided in the ADM are available and kept up-to-date current.
5. Facility staff should follow dispensing machine manufacturer's instructions for log-in and patient information when removing and returning medications from the system.
6. Upon receipt of a new medication order, facility staff should obtain the total number of doses necessary to cover the period of time from the administration of the first dose until it is expected to become available from the pharmacy.
7. Facility staff may return medications removed from the dispensing machine if permitted by regulation or applicable law.
8. A witness who is a licensed professional should observe the removal and return of a controlled substance to the dispensing machine.

9. Facility staff should destroy any medications that cannot be returned to the dispensing machine, in accordance with facility policy.
10. Facilities utilizing automated dispensing systems should send census to pharmacy daily.
11. Replenishment of medications in the ADM is scheduled so that no medication supply is exhausted.
12. Upon delivery of the replenishment medications, authorized facility staff or an authorized pharmacy representative should place each medication into the proper compartment of the dispensing machine in accordance with the instructions for the ADM.
    a. Authorized staff should not place any medications with expiration dates less than 60 days in the dispensing machine.
13. In the event of a system malfunction or failure, facility should:
    a. Refer to the machine's user manual;
    b. Contact the pharmacy during pharmacy's normal hours of operation; and
    c. If the system failure occurs after regular pharmacy hours, contact the Pharmacist on Call through the Afterhours pharmacy department at the regular pharmacy phone number.
14. In the event of a sustained power outage:
    a. Facility should contact the pharmacy to arrange for manufacturer's service.
    b. Authorized facility staff may access the dispensing machine manually using keys until power is restored. Facility staff should manually document any activity (removals and returns) during the power failure, recording:
        1) Medication name;
        2) Resident name;
        3) Date and time removed;
        4) Quantity removed;
        5) Name of facility personnel removing medication; and
        6) Waste (if a full dose of a controlled substance was not given).
15. The pharmacy will provide routine (e.g., weekly, semi-monthly, monthly) inspections to evaluate:
    a. Machine condition.
    b. Need for minor maintenance.
    c. Medication quantities.
    d. Medication placement in compartment.
    e. Appropriate quantities of medications.
    f. Condition and expiration dates of medications stored in the dispensing machine.

Medication Orders

2.0 MEDICATION ORDERS

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2.1 NON-CONTROLLED MEDICATION ORDERS

POLICY

Medications are administered only upon the receipt of a clear, complete and signed order by a person lawfully authorized to prescribe. Medication orders from physician assistants, nurse practitioners, clinical nurse specialists, pharmacists and other appropriately licensed personnel are accepted if they comply with the requirements listed below, are in accordance with state law, and comply with applicable formularies or prescribing protocols that have been provided to the nursing care center by the responsible physician.

PROCEDURES

ELEMENTS OF THE MEDICATION ORDER:

1. Medication orders include the following specifics:
    a. Resident's Name
    b. Date
    c. Name of medication
    d. Strength of medication, where indicated
    e. Dose and dosage form
    f. Time or frequency of administration
    g. Route of administration
    h. Quantity or duration (length) of therapy, when applicable. If not specified by prescriber on a new order, the duration may be limited by automatic stop order policy.
    i. Indication for use if ordered PRN or as needed
    j. Any other state or federal requirements
2. Any dose or order that appears inappropriate, considering the resident's age, condition, allergies or diagnosis, is verified by nursing with the prescriber.

3. PRN (as-needed) orders shall specify the condition for which they are being administered, for example, “as needed for pain”. The dose must also be specified, for example, “1 tablet for mild pain or 2 tablets for moderate pain”.

4. The prescriber shall be contacted by nursing for direction when delivery of a medication will be delayed or the medication is not available. (Refer to Section 3.12 – Medication Shortages)

DOCUMENTATION OF THE MEDICATION ORDER

1. Care should be taken to avoid errors or misinterpretation of handwritten information. Particular attention must be given to how medication names and strengths are expressed when writing medication orders.

2. Each medication order is documented in the resident’s medical record with the date, time, and signature of the person receiving the order. The order is recorded on the Physician Order Sheet (POS) / Telephone Order Sheet (TO) if it is a verbal order, and on the Medication Administration Record (MAR) or Treatment Administration Record (TAR).

    a. New orders (handwritten by prescriber or verbal orders)

        - Order is written by the prescriber while present in the nursing care center; or may be received verbally by the nurse on duty for transcription. If verbally received, the nurse writes down the complete order and then reads the information back to the prescriber for confirmation.

        - Order is transcribed onto the Physician’s Order Sheet or Telephone Order Sheet.

        - Order is noted by the nurse receiving the order (i.e., “Noted 3 p.m., 05/17/12, M. Jones, RN).

        - Order is recorded on the MAR or TAR.

        - Send the appropriate copy of the telephone order form to the prescriber for signing in a timely manner (unless signed by the prescriber in the nursing care center).

        - Transmit the appropriate copy of the order to the pharmacy for dispensing.

        - Place the signed copy of the order on the designated page in the resident’s medical record.

b. Written transfer orders (sent with a resident from a hospital or other health care facility)

- Implement a transfer order without further validation if it is signed and dated by the resident's current attending physician, unless the order is unclear or incomplete or the date signed is different from the date of admission.

- If the order is unsigned or signed by another prescriber or the date is other than the date of admission, the receiving nurse verifies the order with the current attending prescriber before medications are administered. The nurse documents verification on the admission order record by entering the time, date, and signature. Example: "Order verified by phone with Dr. Smith / M. Jones, RN".

- The nurse who transcribes the orders to the physician order sheet and/or MAR documents on the admission form the date, the time and by whom the orders were noted, as follows: ("Noted 3 p.m., 5/17/12, M. Jones, RN").

- Orders are transmitted to the pharmacy with any additional information required for new admission.

c. Renewed or recapitulated ("recapped") orders (to continue a medication therapy beyond a previous order with limited duration)

- The attending physician or authorized prescriber renews the order either by repeating the entire order process or with a statement providing a specific end date such as "continue medication for ten days." The attending physician or authorized prescriber writes a new order for continued therapies that require a change in directions, dosage form, or strength.

- A designated nurse reviews the order summary for any necessary corrections.

- This is done on a routine basis per regulation.

d. Orders faxed from the prescriber's office

- The nurse on duty at the time the faxed order is received notes the order and enters it into the medical record or transcribes it on a telephone order sheet if appropriate.

- Order is recorded on the MAR or TAR.

- Orders are transmitted to the pharmacy for dispensing.

3. Complete documentation by clarifying orders as necessary.

4. Scheduling new medication orders on the Medication Administration Record (MAR)/Treatment Administration Record (TAR):

    a. Non-emergency medication orders: The first dose of medication is scheduled to be given after the next regularly scheduled pharmacy delivery to the nursing care center.

    b. Emergency/STAT medication orders when medication is available in the emergency kit/RxNow: From the emergency kit, remove the appropriate number of doses to be administered prior to the regularly scheduled pharmacy delivery. Thereafter, doses are scheduled according to nursing care center policy on medication administration. (Refer to Section 3.4 – Emergency Pharmacy Service and Emergency Kits (E-Kits))

    c. Emergency/STAT medication order when medication is not available in the emergency kit/RxNow: An emergency/STAT order is placed with the provider pharmacy and the medication is scheduled to be given as soon as received. Subsequent doses are timed according to nursing care center policy on medication administration schedule. (Refer to Section 3.4 – Emergency Pharmacy Service and Emergency Kits (E-Kits))

2.2 CONTROLLED SUBSTANCE MEDICATION ORDERS

POLICY

Before a controlled substance medication can be dispensed, the pharmacy must be in receipt of a clear, complete, valid prescription from a person lawfully authorized to prescribe them.

The pharmacy can dispense a Schedule II controlled substance medication only after the receipt of a practitioner signed valid Schedule II prescription (original, FAX or electronically prescribed (EPCS)) OR in the case of an emergency, the practitioner may speak directly to the pharmacist providing an emergency authorization for the pharmacy to supply a small quantity of the Schedule II medication until the practitioner can provide a valid signed prescription.

The pharmacy can dispense a Schedule III-V controlled substance medication after the receipt of a practitioner signed valid Schedule III-V prescription (original, FAX or electronically prescribed (EPCS)) or the practitioner (or his agent) speaks directly to the pharmacist providing a verbal authorized controlled substance prescription.

PROCEDURES

Written valid prescriptions for a controlled substance medication may be faxed to the pharmacy from the facility for dispensing and the original hard copy is then sent to the pharmacy following state and federal regulations.

ELEMENTS OF A VALID CONTROLLED SUBSTANCE PRESCRIPTION

1. Medication orders include the following:
    a. Date the prescription is issued
    b. Resident’s name and address of the resident, including street address of the facility
    c. Name of medication
    d. Strength of medication*
    e. Dosage form*
    f. Route of administration
    g. Time and frequency of administration
    h. Authorized quantity (written both numerically and expanded form) and for Schedule III-V the number of refills (for CIII-Vs)
    i. Diagnosis or indication for use

j. Manual signature of prescriber*

k. Printed name, address, and DEA registration number of prescriber

l. PRN (as needed) orders clearly delineate the condition for which they are being administered, for example, "as needed for severe pain (pain scale 7-10)," or "as needed for sleep"

* These are components of a CII prescription deemed "essential elements" according to the Drug Enforcement Administration (DEA) that may not be modified by a pharmacist upon oral directions from a prescriber[1]

The prescriber can FAX the valid signed controlled substance prescription (or order from the chart if ALL valid elements are noted) to the pharmacy for dispensing.[1]

The pharmacist can receive a phone order for a Schedule III-V controlled substance from the prescriber (or his agent), commit the information to writing and create the valid controlled substance prescription. [2]

The pharmacist can receive a verbal emergency authorization for Schedule II controlled medications if communicated directly to the pharmacist by the prescriber.[3] If a verbal authorization is received by the pharmacist, the pharmacist will contact the facility nurse. If the controlled substance is needed as an emergency, the pharmacist may provide authorization to the nurse to access the controlled substance from the emergency supply located in the facility.

Incomplete prescriptions and verbal orders for controlled substances may not be edited or changed by facility nursing staff. Controlled substance medication prescriptions from physician assistants and nurse practitioners, who are authorized to prescribe controlled drugs, are valid if they comply with the requirements listed above, are in accordance with state law, and comply with applicable formularies or prescribing protocols that have been provided to the facility by the responsible physician.

2. The prescriber may need to be contacted to verify or clarify a prescription when needed (e.g., when the resident has allergies to the medication, contraindications to the medication, administration directions are not clear; the prescription does not contain all valid elements). If changes to a controlled substance prescription are necessary, the prescriber (or prescriber's agent) must communicate the new order to the facility nursing

[1] If acceptable practice in state, prescriber may need to follow up with mailing the original signed and dated prescription to the pharmacy.
[2] If acceptable practice in state, prescriber may need to follow up with mailing the original signed and dated prescription to the pharmacy.
[3] Not acceptable practice in State of Kentucky.

staff for documentation in the chart and communicate or transmit the new prescription to the pharmacy prior to dispensing.

DOCUMENTATION OF THE CONTROLLED SUBSTANCE ORDERS

Each controlled substance medication order is documented in the resident's medical record with the date, time, and signature of the person receiving the prescription. The medication order is recorded on the physician order sheet (POS) or the telephone order sheet (TO) and recorded on the Medication Administration Record (MAR).

1. If a valid controlled substance medication prescription is written by the prescriber while present in the facility or sent with the resident from an office visit, emergency room visit, or upon hospital discharge, the prescriber is encouraged to document on separate paperwork the fact that a prescription has been provided to ensure accountability on the receiving end.

   For written valid controlled substance prescriptions received by the facility:

   a. The prescription is faxed to the pharmacy by the prescriber or prescriber's agent.

      - If this is not possible, the facility nurse on duty faxes the prescription to the pharmacy with a notation of his/her name and the facility name on the cover sheet or order as the sender. After faxing to the pharmacy, the nurse on duty should deface the written prescription to prevent diversion by writing "Faxed to pharmacy" with the date, time and his/her initials. A copy of the defaced prescription should also be placed in the resident's medical record for future reference.

      - The pharmacy prepares the medications based on the faxed copy of the prescription and the pharmacy representative may request to pick up the original, written prescription (with the nurse's notation above) prior to handing off the dispensed controlled substance.

   b. Written transfer orders for controlled substance medications can only be accepted by the pharmacy for dispensing if all components of a legal, complete prescription as outlined above (including prescriber signature) is completed and if the transfer orders are transmitted to the pharmacy by the prescriber or authorized prescriber's agent.

2. New orders for controlled substance medications originating in the facility should be handled as follows:

a. If the prescriber is present in the facility, all new orders for controlled substance medications must be written, contain all required elements and be signed by the prescriber before leaving the facility.

b. New orders for controlled substance medications communicated to the nurse verbally by the prescriber via telephone are entered onto the physician order sheet /telephone order sheet and noted as follows: "T.O. noted 3:00 p.m. 5/17/12, M. Jones, R.N.". To ensure the pharmacy has a complete, valid prescription from which to dispense the medication, the facility requests that:

- the prescriber or prescriber's agent prepares a written prescription and faxes the complete prescription (containing all required elements) to the pharmacist directly, OR

- if unable to provide the written prescription in an emergency situation, the prescriber verbally communicates the order directly to the pharmacist for a limited quantity.

3. When accessing controlled substance medications from the facility's emergency kit, refer to Section 3.4 Emergency Pharmacy Service and Emergency Kits. NOTE: ALL CONTROLLED SUBSTANCE MEDICATION REMOVALS REQUIRE AN AUTHORIZATION CODE FROM THE PHARMACIST PRIOR TO OBTAINING THE MEDICATION FROM AN EMERGENCY DRUG KIT OR AUTOMATED DISPENSING MACHINE.

4. Scheduling orders for new controlled substance prescriptions on the Medication Administration Record (MAR).

a. Non-Emergency Medication Order

- The first dose of the medication is scheduled to be given after the next regularly scheduled pharmacy delivery to the facility.

b. Emergency/STAT Medication Order (Medication contained in Emergency Supply)

- Schedule the appropriate number of doses to be administered after notification is received from the pharmacy that the prescription has been received and prior to the regularly scheduled pharmacy delivery. Thereafter, doses are scheduled according to facility policy. (Refer to Section 7.1 Medication Administration – General Guidelines)

c. Emergency/STAT Medication Order (Medication not contained in Emergency Medication Supply)

- An emergency/STAT order is called into the provider pharmacy and the medication is scheduled to be given as soon as received. Subsequent doses are scheduled according to facility policy. (Refer to Section 7.1 Medication Administration – General Guidelines)

5. Receipt of Orders from Nurse Practitioners, Physician Assistants, Clinical Nurse Specialists, and Pharmacists

   a. Orders may be accepted from non-physician personnel licensed to work with the resident's physician, if state law permits and the practitioner has their own DEA registration number.

   b. The orders must comply with all the legal requirements for a controlled substance medication prescription.

   c. The responsible physician countersigns the orders.

   d. Applicable formularies, protocols, or prescribing guidelines are kept on file in the facility and are followed closely.

2.3 STANDING ORDERS (OPTIONAL)

POLICY

Certain self-limited conditions are often amenable to treatment with nonprescription medications (and a limited number of prescription medications, if allowed by state law), using good nursing judgment. To facilitate prompt treatment of such conditions, and to avoid unnecessary telephone calls to those prescribers, who approve, standing orders are used.

PROCEDURES

1. The Pharmaceutical Services Committee approves a list of standing orders and situations for which they may be used. These become the nursing care center's standing orders.

2. Each standing order contains the following:

    a. Applicable medications

    b. Indications or diagnosis for use

    c. Dose, frequency, and route of administration

    d. Limitation placed on the number of doses, or duration the order may be used

    e. Any necessary vital signs or laboratory test orders associated with the administration of the specified medication

    f. Any other information required in order to meet state and federal guidelines

3. A copy of these standing orders, signed by the attending physician, is retained in each medical record for each resident for whom the physician approves said orders.

4. Only licensed nurses implement standing orders. Professional judgment is used in the initiation and administration of standing orders.

5. The order is written following the procedure for verbal prescriber orders, as detailed in Section 2 – Medication Orders. In indicating the source of the order, the abbreviation "s.o." is used to indicate a standing order.

6. Documentation of the situation requiring the use of the standing order is placed in the nursing notes section of the resident's medical record prior to initiation of the order.

7. The authorized prescriber countersigns all standing orders.

8. The corresponding automatic stop order listed for each condition and treatment is used when initiating a standing order.

9. Standing orders are not renewable. If the condition persists after the stop order deadline, or sooner if professional judgment warrants it, the primary care provider is contacted.

This policy is optional. It may be removed if standing orders are not allowed by the individual state law or nursing care center.

Medication Ordering and Receiving from Pharmacy Provider

3.0 MEDICATION ORDERING AND RECEIVING FROM PHARMACY PROVIDER

Table of Contents

3.1 PHARMACY HOURS AND DELIVERY SCHEDULE

POLICY

A schedule of pharmacy hours, order instructions, order cut-off times, delivery times and after hours procedures is established and available to the nursing care center.

PROCEDURES

1. The provider pharmacy establishes a daily delivery and pick-up schedule for medications and supplies.

2. The schedule will list the pharmacy's regular business hours and on call or after hours procedures, applicable telephone numbers, approximate routine delivery times, and other pertinent information.

3. Refer to the "General Information Poster" in the front of the manual for pharmacy specific information.

3.2 ORDERING AND RECEIVING NON-CONTROLLED MEDICATIONS

POLICY

Medications and related products are received from the provider pharmacy on a timely basis. The nursing care center maintains accurate records of medication order and receipt.

PROCEDURES

1. Ordering medications from provider pharmacy:

    a. All new medication orders are transmitted to the pharmacy. The prescriber's medication order includes all required elements. (Refer to Section 2 – Medication Orders)

    b. If utilizing a "cycle fill" or "anniversary fill" system, all routinely used dosage forms are provided by "automatic" dispensing and no reorder is required of these medications. For remaining routine and PRN orders, repeat medications (refills for a new supply), the orders can be transmitted by the following methods:

        1) Electronic Health Record
        2) Write the medication name and prescription number and faxing to the pharmacy
        3) Apply the peel-off bar coded label from the prescription label on the reorder sheet and faxing the order to the pharmacy

    c. If not utilizing "cycle fill" or "anniversary fill" system, all medications shall be reordered in advance by writing the medication name and prescription number, or applying the peel-off bar coded label from the prescription label on the reorder sheet and faxing or otherwise transmitting the order to the pharmacy.

    d. All medication order changes or discontinuations must be communicated to the pharmacy, timely, in order to provide the correct quantities and accurate labeling when doses or administration frequencies are modified.

    e. New medications, except for emergency or "stat" medications, are ordered as follows:

        - If the first dose of medication is scheduled to be given before the next regularly scheduled pharmacy delivery, please telephone or transmit the medication orders to the pharmacy immediately upon receipt. Inform the pharmacy of the need for prompt delivery.

- Timely delivery of new orders is required so that medication administration is not delayed. If available, the emergency kit is used when the resident needs a non-controlled medication prior to pharmacy delivery.

f. "Stat" and emergency medications*; except for* Controlled Substances are ordered as follows:

- During regular pharmacy hours, the emergency or "stat" order is transmitted to the pharmacy immediately upon receipt. Such medications are delivered and administered in a timely manner.

- Emergency/STAT medication orders: when medication is available in the emergency kit remove the emergency/STAT dose needed for administration prior to the next pharmacy delivery. Thereafter, doses are scheduled according to nursing care center policy on medication administration. (Refer to Section 3.4 Emergency Pharmacy Service and Emergency Kits (E-Kits))

- Emergency/STAT medication order when medication is not available in the emergency kit: An emergency/STAT order is placed with the provider pharmacy and the pharmacy is called by nursing staff to request the STAT. The requested medication(s) will be delivered in a timely manner. Subsequent doses are scheduled according to nursing care center policy on medication administration. (Refer to Section 3.4 Emergency Pharmacy Service and Emergency Kits (E-Kits))

g. New admission orders:

- When transmitting medication orders for a newly admitted resident, the pharmacy should be given date of birth, Social Security Number, attending physician, medication allergies, diagnoses, all ancillary orders, and pay status information to facilitate generation of a resident profile and permit initial medication use assessment.

- Changes in dosage, directions for use, discontinuation, etc., of current medications may be transmitted to the pharmacy via Electronic Health Records or a medication order form faxed to the pharmacy.

2. Receiving medications from the pharmacy:

a. A licensed nurse or appropriate personnel as required by law:

- Receives medications delivered to the nursing care center from the pharmacy and documents delivery on the medication delivery receipt/manifest.
- Verifies medications received with the prescriber orders.

- Promptly reports discrepancies and omissions to the issuing pharmacy and the charge nurse/supervisor.

- Returns a signed copy of the delivery receipt/manifest to the pharmacy via driver, fax or other method, as defined by the pharmacy provider.

- Retains a copy of the delivery receipt for an appropriate time to reconcile any ordering issues.

3.3 ORDERING AND RECEIVING CONTROLLED MEDICATIONS

POLICY

Medications included in the Drug Enforcement Administration (DEA) classification as controlled substances, and medications classified as controlled substances by state law, are subject to special ordering, receipt, and record keeping requirements in the nursing care center, in accordance with federal and state laws and regulations. The nursing care center obtains and keeps current and on file any permits required by state agencies.

PROCEDURES

1. The director of nursing and the consultant pharmacist monitors for compliance with federal and state laws and regulations in the handling of controlled medications. Only authorized, licensed nursing and pharmacy personnel have access to controlled medications.

2. Medications listed in Schedules II, III, IV and V are dispensed by the pharmacy in readily accountable quantities and containers designed for easy counting of contents. When possible, injectable controlled substance medications are dispensed in ampules or vials of the smallest available dosage unit. (Note: Refer to state regulations, as particular states do not require Schedule V medications to be dispensed in accountable quantities and containers.)

3. The pharmacy or the nursing care center prepares an individual resident controlled substance record/receipt/log for each controlled substance medication prescribed for a resident as applicable per state law. This log is placed in the MAR or narcotic book to be counted every shift. The nursing care center may designate a particular medication, which is not mandated as a controlled substance by state or federal laws and subject to abuse or diversion, to be handled under these procedures for controlled medications. (Note: Refer to state regulations, as particular states do not require this documentation for Schedule V medications.) The following information is completed:

    a. Name of resident

    b. Prescription number

    c. Medication name

    d. Medication strength (if designated)

    e. Dosage form of medication

f. Date received

g. Quantity received

h. Name of person receiving the medication supply

4. The Drug Enforcement Agency (DEA) requires that a pharmacy must have a valid prescriber signed prescription in order to dispense controlled substances. A valid written prescription requires patient name, drug name and strength, quantity to dispense, directions for use, date and signature of the prescriber. (Refer to Section 2.2 –Controlled Substance Medication Orders). In an emergency situation, verbal authorization may be given by the prescriber to the pharmacist for a new order as described by state law. (Refer to Section 3.4 Emergency Pharmacy Service and Emergency Kits (E-Kits))

5. Refill Requests for CIII-CV, and Partial Fill Requests for CII

   a. If one or more refills (CIII-Vs) or a partial fill quantity (CIIs) remains:

      - Written on a medication order form or ordered by peeling the top label from the label and placing it in the appropriate area on the order form provided by the pharmacy for that purpose, and requested from the pharmacy a minimum of 3 days in advance of need to assure an adequate supply is on hand.

      - If only one refill remains (CIII-Vs) or only a partial fill quantity remains (CII), the pharmacy will simultaneously dispense the remaining fill, and, if necessary proactively seek out a new, complete prescription from the prescriber for future use. The facility may be asked to contact the prescriber for a new prescription upon request for a medication with no remaining fills available.

3.4 EMERGENCY PHARMACY SERVICE AND EMERGENCY KITS (E-KITS)

POLICY

Emergency pharmaceutical service is available on a 24-hour basis. Emergency needs for medication are met by using the nursing care center's approved emergency medication supply or by special order from the provider pharmacy. Emergency medications and supplies are provided by the pharmacy in compliance with applicable state and federal regulations.

PROCEDURES

1. Contact information for emergency pharmacy service is posted at each nursing station. This includes the telephone and fax numbers of the provider pharmacy and after-hours ("on call") telephone numbers.

2. The provider pharmacy is contacted if an emergency arises requiring immediate pharmacist consultation regarding medications ordered and needed prior to the next scheduled pharmacy delivery.

3. The provider pharmacy supplies emergency or "stat" medications/items according to the provider pharmacy agreement. Emergency medications and supplies are kept secure, checked periodically for integrity and dating and stored in accordance with State Board of Pharmacy and federal regulations.

4. Prescribers are notified of the availability of emergency medications and supplies in the nursing care center.

5. Medications are not borrowed from other residents. The ordered medication is obtained either from the emergency kit or from the provider pharmacy.

6. The emergency kit, along with the list of contents posted on the outside of the kit, is maintained at a designated locked area that is easily accessible in an emergency.

7. When an emergency or stat medication is needed, the nurse first verifies and reviews the prescriber's orders for appropriateness, checks the resident's allergies, and removes the required non-controlled medication from the emergency kit. Emergency medications are only administered with a valid prescriber's order.

    - See specific procedures for removal of controlled medications at the end of this policy. These medications may NOT be removed from the emergency kit for new orders or refills for current orders.

8. Upon removal of any medication or supply item from the emergency kit, the nurse will document the medication or item used on an emergency kit log. One copy of this information should be placed within the resealed emergency kit until it is scheduled for exchange. This process will be defined by the provider pharmacy. The hard copy will be retained in the nursing care center. Items to be documented on the log include:

    a. Resident's name

    b. Medication name, strength and quantity

    c. Date and time of medication removal

    d. Prescriber's name

    e. Date and time pharmacy notified

    f. Signature of nurse removing and administering dose

9. Use of the emergency medication is noted on the resident's current medication administration record (MAR) including:

    a. Resident's name

    b. Medication name and dose administered

    c. Prescriber's name

    d. Date and time of administration

    e. Nurse's initials/signature

10. Emergency Kits will be replaced on a routine schedule per pharmacy and facility policy, and any applicable state and federal regulations regarding replacement/exchange of emergency kits.

11. Before reporting off duty, the charge nurse indicates the "opened" or "sealed" status of the emergency kit at the shift change report, and transfers the new medication orders to oncoming staff.

12. When the replacement kit arrives, the receiving nurse gives the used kit to the pharmacy personnel for return to the pharmacy. In states that allow replacing used doses of

medication, the nurse replaces the medication in the appropriate area of the kit within 24 hours of opening or next scheduled delivery, or as required by state regulation. If applicable per state law, a new seal is placed on the kit after the replacement medication has been added.

13. The nursing staff, consultant pharmacist and provider pharmacy designee checks the emergency kits regularly for expiration dating of the contents. The date of expiration is noted on the outside of the kit.

14. The emergency medication kit may contain controlled substances in Schedules II – V as allowed by state regulation.

    a. Schedule II medications that are part of the emergency medication supply must be double locked and shall be stored in a locked cabinet or locked drawer separate from non-controlled medications.

    b. Contact the pharmacy immediately if a new order for a controlled medication is needed from the E-Kit and follow the procedures outlined below. An authorization code from the pharmacist is required prior to entering the controlled E-Kit.

    c. When only part of a controlled medication ampule or vial is needed, the amount remaining shall be destroyed according to state requirements. This shall be documented on the emergency kit log or on the controlled inventory log. A second licensed nurse shall sign as witness to the destruction. (Refer to Section 5.5 – Disposal of Medications)

    d. The provider pharmacy may require additional forms or procedures to aid in controlled substance accountability as appropriate per state regulation.

15. Infusion therapy products are prepared and delivered by the infusion therapy product provider except in emergencies or when product instability precludes preparation away from the nursing care center. Infusion therapy products are prepared in the nursing care center only by a qualified nurse who follows infection control measures.

    a. Refer to the Intravenous Therapy Policy and Procedure Manual.

    b. The infusion therapy product provider notifies the charge nurse about any transfer instability of an infusion therapy product.

    c. Such notification is documented and the need for a nurse to prepare the admixture is indicated on the infusion therapy record and on the MAR.

d. When a required medication additive is stocked in the emergency medication supply and the prepared admixture is needed before the infusion therapy product provider can deliver it, the emergency admixture is prepared only after verifying dose and compatibility with the infusion therapy product provider.

e. Preparation of the infusion therapy product is documented in the resident's medical record.

f. Infusion therapy products are prepared and labeled in accordance with infection control standards and with equipment and medication manufacturer's recommendations.

g. The area in which infusion therapy products are prepared and the supplies used for preparation are stored is kept clean and free of clutter.

16. Removal of controlled substances from Emergency Kit.

Emergency verbal Schedule II-V authorizations for dispensing must conform to the following requirements:

- The prescribing practitioner determines (42 CFR 1306. 11.):
    - That immediate administration of the controlled substance is necessary, for the proper treatment of the intended ultimate user, and
    - That no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance; and
    - That it is not reasonably possible for the practitioner to provide a written prescription to be presented to the person dispensing the substance, prior to the dispensing.

The prescriber must determine if the situation does meet the requirements of being deemed an "Emergency".

Procedure to communicate emergency verbal authorization for removal of controlled medications from emergency kit:

Once the prescriber has determined that the order meets the definition of "Emergency Situation", the nurse must contact the pharmacist for an authorization to access the E-kit.

The valid prescription requirement can be met in 2 ways:

1. An emergency verbal order communicated directly from the authorizing prescriber to the PharMerica Pharmacist.

2. A hard copy prescriber signed prescription is faxed by prescriber or agent of prescriber or transmitted to the pharmacy.

If an emergency verbal order is required the Pharmacist/Prescriber contact can occur either:

1. By the Facility nurse contacting the pharmacy to notify there is a need to withdraw a controlled medication from the emergency kit (EDK) and provides prescriber contact information so that the pharmacist can contact the prescriber directly.

2. By the Facility nurse requesting prescriber contact pharmacy directly to give verbal emergency order and provide prescriber with pharmacy contact information.

Once the pharmacist receives the valid emergency verbal authorization, the pharmacist will contact facility to notify Facility nurse of:

- Authorization to access emergency kit
- Specific prescription details
- Number of authorized entries to E-kit
- Number of doses per entry to E-kit

If hard copy Prescriber signed prescription is available:

1. Nurse will contact pharmacist to communicate need to access E-kit.

2. Nurse will fax hard copy prescription to the pharmacist.

3. Once the pharmacist confirms receipt of a valid prescription, the pharmacist will contact facility nurse to communicate:
   - Authorization to access emergency kit
   - Specific prescription details
   - Number of authorized entries to E-kit
   - Number of doses per entry to E-kit

4. Nurse will send hard copy to pharmacy with the next pharmacy delivery.

Process for removal of controlled medications from emergency kits:

Initial removal:
Upon notification of a valid verbal authorization by the pharmacist, the nurse will document the following detail on the emergency kit withdrawal log:

- Patient Name
- Prescriber Name
- Medication Name
- Medication Strength
- Date/time of Pharmacist authorization
- Number doses authorized to pull
- Doses withdrawn
- Authorized doses remaining
- Date/time accessing kit
- Nurse's Signature/title
- Second licensed nurse signature is suggested
- Pharmacist authorization code

The nurse will remove the top copy of completed withdrawal log and place in the kit for pharmacy record. Process defined by the provider pharmacy. The master, back copy of withdrawal log, is to remain in facility.

Subsequent removal of authorized doses:
Prior to accessing the emergency kit for subsequent removal, the nurse will review the emergency kit withdrawal log to determine # of authorized doses remaining for the resident.

If zero authorized doses remain, the nurse is prohibited from accessing the emergency kit medication.

If additional authorized doses remain, the nurse will document the following detail on the emergency kit withdrawal log:

- Patient Name
- Prescriber Name
- Medication Name
- Medication Strength
- Indicate “see above” for date/time of Pharmacist authorization
- Indicate number doses authorized to pull based on the most recent entry
- Doses withdrawn
- Calculate any authorized doses remaining
- Date/time accessing kit
- Nurse’s Signature/title
- Second licensed nurse signature is suggested
- Pharmacist authorization code

The nurse will remove the top copy of completed withdrawal log and place in the kit for pharmacy record. The master, back copy of withdrawal log is to remain in facility.

Refer to Section 1.9 – Automated Dispensing Machine for First Dose and Emergency Medications if withdrawing emergency medications from an Automated Dispensing Machine.

3.5 HOUSE SUPPLIED (FLOOR STOCK) MEDICATIONS

POLICY

The nursing care center may maintain a supply of commonly used over-the-counter (OTC) medications considered as floor stock or house medications as allowed by state regulations.

PROCEDURES

1. The Pharmaceutical Services Committee establishes a list of non-legend medications to be utilized as floor stock.

2. The floor stock medication list is available to the nursing care center and the provider pharmacy.

3. Floor stock medications kept in the original manufacturer's container must have expiration date and lot numbers clearly visible. Unless otherwise specified, the expiration date is limited to the expiration date on the original container.

4. The manufacturer's or pharmacy's label shall include the following elements:

    a. Medication name

    b. Medication strength

    c. Quantity

    d. Accessory information

    e. Lot number

    f. Expiration date

5. Floor stock items are not to be administered without a current order from the resident's prescriber.

NURSING CARE CENTER-SPECIFIC HOUSE SUPPLIED FLOOR STOCK MEDICATION LIST
(Insert list)

3.6 MEDICATION INFORMATION RESOURCES

POLICY

The licensed nursing staff has access to reference and safety materials that include current information on medication effects, cautions, available strengths, dosage forms, recommended doses, and nomenclature.

PROCEDURES

1. Pharmacists recommend current resources to help nursing staff identify medications and information on contraindications, adverse effects, appropriate dosages and other pertinent medication information.

2. A copy of a current medication reference is kept at each nursing station.

3. When information about a medication is not available, the provider pharmacy or the consultant pharmacist is available to the nursing care center nurses.

4. Reference materials or the pharmacist shall be consulted before administering an unfamiliar medication.

5. Medication guides or Patient Package Inserts (PPIs) may be requested from the dispensing pharmacy. If no medication guide or PPI is available, the information may be obtained from the manufacturer or a reference text. The information in a medication guide or PPI explains the benefits and risks associated with use of a medication or medication class.

   Note: Nursing care center residents are generally considered exempt from the FDA's medication guide requirement as the guidance applies primarily to human prescription medication products used on an outpatient basis without direct supervision by a health professional. [Reference the Codified Federal Register (CFR) Title 21, Chapter I, Subchapter C, Part 208, Subpart A, the Scope and Purpose of Section 208.1.]

6. The Material Safety Data Sheet (MSDS) on each hazardous medication as defined by the Occupational Safety and Health Administration (OSHA) is available from the dispensing pharmacy. Medications considered hazardous include:

The manufacturers of the following medications recommend that they be handled as hazardous drugs. Therefore, NIOSH considers these drugs to be included in the Table 1 of the NIOSH list of hazardous drugs.

- Trabectedin (Yondelis®)
- Inotuzumab ozogamicin (Besponsa™)
- Polatuzumab vedotin (Polivy™)
- Enfortumab vedotin (Padcev™)
- Trastuzumab deruxtecan (Enhertu®)
- Sacituzumab govitecan (Trodelvy™)
- Loncastuximab tesirine (Zynlonta™)
- Melphalan flufenamide (Pepaxto®)
- Belantamab mafodotin (Blenrep)
- Tisotumab vedotin-tftv (Tivdak™)
- Lurbinectedin (Zepzelca®)
- Mirvetuximab soravtansine (Elahere™)

NIOSH Group	Generic Drug Name	AHFS Classification
2	abacavir	8:18.08.20 nucleoside and reverse transcriptase inhibitors
2	abiraterone	10:00 antineoplastic agents
2	acitretin	84:92 skin and mucous membrane agents, miscellaneous
1	ado-trastuzumab emtansine	10:00 antineoplastic agents
2	afatinib	10:00 antineoplastic agents
2	alefacept	84:92 skin and mucous membrane agents, miscellaneous
2	alitretinoin	84:92 skin and mucous membrane agents, miscellaneous
1	altretamine	10:00 antineoplastic agents
2	ambrisentan	48:48 vasodilating agents
1	amsacrine	10:00 antineoplastic agents
2	anastrozole	68:16.08 antiestrogens
2	apomorphine	28:36.20.08 nonergot derivative dopamine receptor agonists
1	arsenic trioxide	10:00 antineoplastic agents
2	axitinib	10:00 antineoplastic agents
1	azacitidine	10:00 antineoplastic agents
1	azathioprine	92:44 immunosuppressive agents
1	belantamab mafodotin	10:00 antineoplastic agents
1	belinostat	10:00 antineoplastic agents
1	bendamustine	10:00 antineoplastic agents
2	bexarotene	10:00 antineoplastic agents
2	bicalutamide	10:00 antineoplastic agents
1	bleomycin	10:00 antineoplastic agents
2	blinatumomab	10:00 antineoplastic agents
1	bortezomib	10:00 antineoplastic agents
2	bosentan	48:48 vasodilating agents
2	bosutinib	10:00 antineoplastic agents
1	brentuximab vedotin	10:00 antineoplastic agents
1	busulfan	10:00 antineoplastic agents
1	cabazitaxel	10:00 antineoplastic agents
2	cabergoline	28:36.20.04 ergot-derivative dopamine receptor agonists
2	cabozantinib	10:00 antineoplastic agents
1	capecitabine	10:00 antineoplastic agents
2	carbamazepine	28:12.92 anticonvulsants
1	carboplatin	10:00 antineoplastic agents
2	carflizomib	10:00 antineoplastic agents
1	carmustine	10:00 antineoplastic agents
2	ceritinib	10:00 antineoplastic agents
2	cetrorelix	68:18.04 antigonadotropins
1	chlorambucil	10:00 antineoplastic agents
1	chloramphenicol	8:12.08 chloramphenicol
2	choriogonadotropin	68:18.08 gonadotropins
1	cidofovir	8:18.32 nucleosides and nucleotides
1	cisplatin	10:00 antineoplastic agents
1	cladribine	10:00 antineoplastic agents
2	clobazam	28:12.08 benzodiazepines
1	clofarabine	10:00 antineoplastic agents
2	clomiphene	68:16.12 estrogen agonist antagonists
2	clonazepam	28:12.08 benzodiazepines
2	cobimetinib	10:00 antineoplastic agents
2	colchicine	92:16 antigout agents
2	crizotinib	10:00 antineoplastic agents
1	cyclophosphamide	10:00 antineoplastic agents
1	cyclosporine	52:08.92 anti-infammatory agents
1	cytarabine	10:00 antineoplastic agents
2	dabrafenib	10:00 antineoplastic agents
1	dacarbazine	10:00 antineoplastic agents
1	dactinomycin	10:00 antineoplastic agents
1	dasatinib	10:00 antineoplastic agents
1	datopotamab deruxtecan	10:00 antineoplastic agents
1	daunorubicin	10:00 antineoplastic agents
1	decitabine	10:00 antineoplastic agents

NIOSH Group	Generic Drug Name	AHFS Classification
2	deferiprone	64:00 heavy metal antagonists
2	degarelix	68:18.04 antigonadotropins
1	dexrazoxane	92:56 protective agents
1	diethylstilbestrol	NA
2	dihydroergotamine	12:16.04.04 non-selective alpha-adrenergic blocking agents
2	dinoprostone	76:00 oxytocics
2	divalproex	28:12.92 anticonvulsants
1	docetaxel	10:00 antineoplastic agents
1	doxorubicin	10:00 antineoplastic agents
2	dronedarone	24:04.04.20 Class III antiarrhythmics
2	dutasteride	92:08 5-alpha reductase inhibitors
1	enfortumab vedotin	10:00 antineoplastic agents
2	entecavir	8:18.32 nucleosides and nucleotides
2	enzalutamide	10:00 antineoplastic agents
1	epirubicin	10:00 antineoplastic agents
1	eribulin mesylate	10:00 antineoplastic agents
2	erlotinib	10:00 antineoplastic agents
2	eslicarbazepine	28:12.92 anticonvulsants, miscellaneous
2	estradiol	68:16.04 estrogens
1	estramustine	10:00 antineoplastic agents
1	estrogen/ progesterone combinations	68:12 contraceptives; 68.16.04 estrogens; 68:32 progestins
1	estrogens, conjugated	68:16.04 estrogens; 92.24 bone resorption inhibitors
1	estrogens, esterifed	68:16.04 estrogens; 92.24 bone resorption inhibitors
2	estropipate	68:16.04 estrogens
1	etoposide	10:00 antineoplastic agents
1	everolimus	10:00 antineoplastic agents; 92.44 immunosuppressive agent
2	exemestane	68.16.08 antiestrogens
2	exenatide	68:20.06 incretin mimetics
1	fam-trastuzumab deruxtecan	10:00 antineoplastic agents
2	fluconazole	8:14.08 azoles
1	fludarabine	10:00 antineoplastic agents
1	fluorouracil	10:00 antineoplastic agents; 84.92 skin and mucus membrane agents
2	fluoxymesterone	10:00 antineoplastic agents
2	flutamide	10:00 antineoplastic agents
2	fnasteride	84:92 skin and mucous membrane agents, miscellaneous
2	fngolimod	92:20 immunomodulatory agents
2	fosphenytoin	28:12.12 hydantoins
1	foxuridine	10:00 antineoplastic agents
2	fulvestrant	10:00 antineoplastic agents
1	ganciclovir	8:18.32 nucleosides and nucleotides; 52.04.02 antivirals
2	ganirelix	68:18.04 antigonadotropins
1	gemcitabine	10:00 antineoplastic agents
1	gemtuzumab ozogamicin	10:00 antineoplastic agents
2	gonadotropin, chorionic	68:18.08 gonadotropins
2	goserelin	68:18.08 gonadotropins
2	histrelin	68:18.08 gonadotropins
1	hydroxyurea	10:00 antineoplastic agents
2	icatibant	92:32 complement inhibitors
1	idarubicin	10:00 antineoplastic agents
1	ifosfamide	10:00 antineoplastic agents
1	imatinib	10:00 antineoplastic agents
1	inotuzumab ozogamicin	10:00 antineoplastic agents
1	irinotecan	10:00 antineoplastic agents
2	isotretinoin	84:92 skin and mucous membrane agents, miscellaneous
2	ivabradine	24:04.92 cardiac drugs, miscellaneous
1	ixabepilone	10:00 antineoplastic agents
1	ixazomib	10:00 antineoplastic agents
2	lefunomide	92:36 disease-modifying antirheumatic agents
1	lenalidomide	10:00 antineoplastic agents; 92.20 immunomodulatory agents
2	lenvatinib	10:00 antineoplastic agents
2	letrozole	68.16.08 antiestrogens

NIOSH Group	Generic Drug Name	AHFS Classification
2	leuprolide	68:18.08 gonadotropins
2	lomitapide	24:06.92 antilipemic agents, miscellaneous
1	lomustine	10:00 antineoplastic agents
1	loncastuximab tesirine	10:00 antineoplastic agents
1	lurbinectedin	10:00 antineoplastic agents
2	macitentan	48:48 vasodilating agents
1	mechlorethamine	10:00 antineoplastic agents; 84:92 skin and mucus membrane agents
2	medroxyprogesterone	68:32 progestins
2	megestrol	68:32 progestins
1	melphalan	10:00 antineoplastic agents
1	melphalan fufenamide	10:00 antineoplastic agents
2	menotropins	NA
1	mercaptopurine	10:00 antineoplastic agents; 92:44 immunosuppresive agents
2	methimazole	68:36.08 antithyroid agents
1	methotrexate	10:00 antineoplastic agents
2	methylergonovine	76:00 oxytocics
2	methyltestosterone	68:08 androgens
2	mifepristone	76:00 oxytocics
2	miltefosine	8:30.92 miscellaneous antiprotozoals
2	mipomersen	24:06.92 antilipemic agents, miscellaneous
1	mirvetuximab soravtansine	10:00 antineoplastic agents
2	misoprostol	56:28.28 prostaglandins
1	mitomycin	10:00 antineoplastic agents
1	mitotane	10:00 antineoplastic agents
1	mitoxantrone	10:00 antineoplastic agents
1	mycophenolate mofetil	92:44 immunosuppressive agents
2	mycophenolic acid	92:44 immunosuppressive agents
2	nafarelin	68:18.08 gonadotropins
1	nelarabine	10:00 antineoplastic agents
2	nevirapine	8:18.08.16 HIV nonnucleoside reverse transcriptase inhibitors
2	nilotinib	10:00 antineoplastic agents
2	olaparib	10:00 antineoplastic agents
1	omacetaxine	10:00 antineoplastic agents
2	ospemifene	68:16.12 estrogen agonist-antagonists
1	oxaliplatin	10:00 antineoplastic agents
2	oxcarbazepine	28:12.92 anticonvulsants, miscellaneous
2	oxytocin	76:00 oxytocics
1	paclitaxel	10:00 antineoplastic agents
2	palifermin	84:16 cell stimulants and proliferants
2	pamidronate	92:24 bone resorption inhibitors
1	panobinostat	10:00 antineoplastic agents
2	paroxetine	28:16.04.20 selective serotonin uptake inhibitors
2	pasireotide	68:29.04 somatostatin agonists
2	pazopanib	10:00 antineoplastic agents
2	peginesatide	20:16 hematopoietic
1	pemetrexed	10:00 antineoplastic agents
2	pentetate calcium trisodium	NA
1	pentostatin	10:00 antineoplastic agents
2	phenoxybenzamine	12:16.04.04 non-selective No No alpha-adrenergic blocking agents
2	phenytoin	28:12.12 hydantoins
2	pipobroman	NA
2	plerixafor	20:16 hematopoietic agents
1	polatuzumab vedotin	10:00 antineoplastic agents
1	pomalidomide	10:00 antineoplastic agents
2	ponatinib	10:00 antineoplastic agents
1	pralatrexate	10:00 antineoplastic agents
1	procarbazine	10:00 antineoplastic agents
2	progesterone	68:32 progestins
2	progestins	68:32 progestins
2	propylthiouracil	68:36.08 antithyroid agents
2	raloxifene	68:16.12 estrogen agonists-antagonists

NIOSH Group	Generic Drug Name	AHFS Classification
2	rasagiline	28:36 antiparkinsonian agents
2	regorafenib	10:00 antineoplastic agents
2	ribavirin	8:18.32 nucleosides and nucleotides
2	riociguat	48:48 vasodilating agents
1	romidepsin	10:00 antineoplastic agents
1	sacituzumab govitecan	10:00 antineoplastic agents
2	sirolimus	92:44 immunosuppressive agents
2	sonidegib	10:00 antineoplastic agents
2	sorafenib	10:00 antineoplastic agents
2	spironolactone	24:32.20 mineralocorticoid (aldosterone) receptor antagonists
1	streptozocin	10:00 antineoplastic agents
2	sunitib	10:00 antineoplastic agents
2	tacrolimus	84:92 skin and mucous membrane agents
1	tamoxifen	10:00 antineoplastic agents
1	telisotuzumab vedotin	10:00 antineoplastic agents
2	temazepam	28:24.08 benzodiazepines
1	temozolomide	10:00 antineoplastic agents
1	temsirolimus	10:00 antineoplastic agents
1	teniposide	10:00 antineoplastic agents
2	terifunomide	92:20 immunomodulatory agents
2	testosterone	68:08 androgens
1	thalidomide	92:20 immunomodulatory agents
1	thioguanine	10:00 antineoplastic agents
1	thiotepa	10:00 antineoplastic agents
1	tisotumab-vedotin	10:00 antineoplastic agents
2	tofacitinib	92:36 disease-modifying antirheumatic drugs
2	topiramate	28:12.92 anticonvulsants, miscellaneous
1	topotecan	10:00 antineoplastic agents
2	toremifene	68.16.12 estrogen agonist-antagonist
1	trabectedin	10:00 antineoplastic agents
2	trametinib	10:00 antineoplastic agents
1	trastuzumab dereuxtecan	10:00 antineoplastic agents
1	treosulfan	10:00 antineoplastic agents
2	tretinoin	84:16 cell stimulants and proliferants
1	trifuridine	10:00 antineoplastic agents
2	triptorelin	68:18.08 gonadotropins
2	ulipristal	68:12 contraceptives
1	uracil mustard	NA
2	urofollitropin	NA
1	valganciclovir	8:18.32 nucleosides and nucleotides
2	valproate/valproic acid	28:12.92 anticonvulsants, miscellaneous
1	valrubicin	10:00 antineoplastic agents
1	vandetanib	10:00 antineoplastic agents
2	vemurafenib	10:00 antineoplastic agents
2	vigabatrin	28:12.92 anticonvulsants, miscellaneous
1	vinblastine	10:00 antineoplastic agents
1	vincristine	10:00 antineoplastic agents
1	vinorelbine	10:00 antineoplastic agents
2	vismodegib	10:00 antineoplastic agents
2	voriconazole	8:14.08 azoles
1	vorinostat	10:00 antineoplastic agents
2	warfarin	20:12.04.08 coumarinderivatives
2	zidovudine	8:18.08.20 HIV nucleoside and nucleotide reverse transcriptase inhibitors
2	ziprasidone	28:16.08.04 atypical antipsychotics
2	ziv-afibercept	10:00 antineoplastic agents
2	zoledronic acid	92:24 bone resorption inhibitors
2	zonisamide	28:12.92 anticonvulsants, miscellaneous

*These lists of hazardous drugs were used with the permission of the institutions that provided them and were adapted for use by NIOSH. The sample lists are intended to guide health care providers in diverse practice settings and should not be construed as complete representations of all of the hazardous drugs used at the referenced institutions. Some drugs defined as hazardous may not pose a significant risk of direct occupational exposure because of their dosage formulation (for example, intact medications such as coated tablets or capsules that are administered to patients without modifying the formulation). However, they may pose a risk if solid drug formulations are altered outside a ventilated cabinet (for example, if tablets are crushed or dissolved, or if capsules are pierced or opened).

3.7 MEDICATIONS AND MEDICATION LABELS

POLICY

The pharmacy will use sound professional judgment and acceptable industry practices for establishing pharmacy's formulary. Medications are labeled in accordance with currently accepted professional principles including appropriate auxiliary and cautionary instructions to promote safe medication use following state and federal laws. Only the dispensing pharmacy can modify or change prescription labels.

PROCEDURES

1. Each prescription medication will be labeled to include:
    a. Resident's name
    b. Specific directions for use, including route of administration
    c. Medication name
        - Generic medication products dispensed in place of brand products are labeled with the generic medication name and the manufacturer's name or an acceptable abbreviation as allowed per state regulation.
        - If medication ordered by brand name and substituted with a generic product, an explanatory statement is included on the label (e.g., "ordered as," "used for," or "replaces" preceding the brand name). Example: Furosemide used for Lasix®
            - Explanatory statement of substitution may not include the phrase "same as." Example: Pantoprazole same as Protonix.
        - Medication product definitions:
            - Pharmaceutically Equivalent Medication Products: Medication products that contain the same active ingredient(s), in identical amounts, in identical dosage forms, administered by the same route of administration and that meet existing standards in the United States Pharmacopeia (USP). The products may differ in characteristics such as color; flavor; shape; packaging, inert ingredients; and the method of manufacture.
            - Bioequivalent Medication Products: Pharmaceutically equivalent medication products that when administered under similar conditions produce comparable bioavailability. The rate and extent of absorption of the active ingredients do not show a significant difference from that of the reference product; or if the rate is different, it does not affect the medication concentration in a clinically significant manner.

- Therapeutically Equivalent Medication Products: Equivalent medication products that when administered under similar conditions provide the same therapeutic effect as measured by control of a symptom or disease.
- Multiple Source Medication Products: Pharmaceutically equivalent medication products that are marketed by different pharmaceutical companies.
- Brand Drug: A drug so reported by First Databank (FDB) or Medi-Span; or as otherwise determined by the pharmacy.
- Generic Drug: A drug, whether identified by its chemical, proprietary, or non-proprietary name, that (a) is substitutable for a drug under state law; or (b) if not addressed by state law, is accepted by the U.S. Food and Drug Administration as interchangeable with drugs having an identical amount of the same active ingredient; and (c) is readily available to pharmacy for dispensing from three or more of the non-affiliated top ten national manufacturers.

d. Strength of medication
   - Injectables: strength per mL and the amount to be given in mL equivalent on label.
     - Example: When furosemide 40 mg is ordered and the pharmacy supplies it in an ampule containing 40 mg/4mL, the directions read "Inject 40 mg (4 mL)."
   - Liquids: strength per mL. Directions for use are expressed in mLs.
     - Example: "Phenytoin 250 mg (give 10 mLs) po every bedtime."

e. Prescriber's name

f. Date medication is dispensed

g. Quantity dispensed

h. Expiration or end-of-use date, if not dispensed in original manufacturer packaging
   - End-of-use dating, which only includes the month and year (01/2017), falls to the last day of that month (expires 1/31/2017).

i. Name, address, and telephone number of dispensing pharmacy

j. Prescription number

k. Accessory/precautionary labels indicating storage requirements and special procedures

- Example: “Shake well”, “Take on empty stomach, one hour before or 2 hours after meals,” “Do not crush”.

l. Lot number of medication dispensed, if not dispensed in original manufacturer packaging, where required by state law

m. Any other information required by state and federal regulations

2. Multi-dose vials shall be labeled to assure product integrity, considering the manufacturers’ specifications. (Example: Modified expiration dates upon opening the multi-dose vial.). Nursing staff should document the date opened on multi-dose vials on the attached auxiliary label.

3. Improperly or inaccurately labeled medications are refused and returned to the dispensing pharmacy.

4. The provider pharmacy permanently affixes label to the outside of prescription containers. Medication labels are not inserted into vials, bags or other containers. For medications designed for multiple administration, (for example, inhalers or eye drops), a label is affixed to product to assure proper resident identification.

5. Non-prescription medications not labeled by the pharmacy are kept in the manufacturer’s original container. Nursing care center personnel may write the resident’s name on the container or label as long as the required information is not covered, if applicable by state regulations.

6. Medication labels are not altered, modified, or marked in any way by nursing personnel. Contents are not transferred from one container to another. Under no circumstances are unattached labels requested or accepted from the pharmacy. Only the pharmacy may place a label on the medication container.

   a. If the prescriber's directions for use change or the label is inaccurate, the nurse may place a “direction change”, “change of order-check chart” or similar label on the container indicating there is a change in directions for use, taking care not to cover important label information.

   b. When such a direction change label appears on the container, the medication nurse checks the resident’s medication administration record (MAR) or the prescriber’s order for current information.

7. If directions for use change, the provider pharmacy is informed prior to the next refill of the prescription so the new container will show an accurate label.

8. Medication containers having soiled, damaged, incomplete, illegible, or makeshift labels are returned to the dispensing pharmacy for re-labeling or destroyed in accordance with the medication destruction policy. (Refer to Section 5 – Disposal of Medications, Syringes and Needles)

9. Medications ordered for use/storage at bedside or for self-administration shall be labeled as such, in addition to the instructions for use.

10. Floor stock medications kept in the original manufacturer's container must have the expiration date and lot numbers clearly evident. The manufacturer's or pharmacy's label shall include the following:
    a. Medication name
    b. Medication strength
    c. Quantity
    d. Accessory information
    e. Lot number
    f. Expiration date

11. The label of physician-dispensed medications, as well as those dispensed from a non-provider pharmacy, shall conform to the above labeling requirements.

12. Prescribers may indicate refusal of product substitutes when ordering medications. According to state and federal requirements, the prescriber complies with the required paperwork to document the necessity of a particular brand of medication, as follows:

    a. The prescriber must certify in his or her own handwriting that a specific brand is "medically necessary" or "dispense as written" for a particular recipient as required by state laws. The handwritten phrase "brand necessary", "brand medically necessary" or "dispense as written" must appear on the face of the prescription.

    b. The above prescriber certification must be made on each order written for which substitution is not permitted. A cover letter or blanket order for "brand medically necessary" is not sufficient to cover individual residents or individual medications.

13. Labels from automated dispensing units placed in the facility must comply with State Board of Pharmacy requirements. At a minimum, the package labeling from the automated device must contain the following:
    a. Name of resident
    b. Name of medication ordered
    c. Expiration date
    d. Dose
    e. Quantity

3.8 MEDICATION PACKAGING

POLICY

Medications are provided in packaging to facilitate proper storage and administration of the medication.

PROCEDURES

1. Solid oral medication forms (tablets and capsules) are supplied by the provider pharmacy using the agreed upon distribution system. (This may take the form of unit-dose packaging, punch cards, cassettes or other packaging.)

    a. All unit dose medications contain a lot number, expiration date, product name, strength and any other information required by state or federal regulations.

    b. All unit dose medication packaged by the provider pharmacy are done so in accordance with USP standards and state and federal guidelines.

2. Medications which may require special packaging other than unit dose include:

    a. Medications requiring refrigeration

    b. Schedule II controlled substances

    c. Liquid medications

    d. Injectable medications

    e. Externally applied medications, e.g., ointments, sprays, and other treatment medications

    f. Oversized or irregularly shaped medications or containers

    g. Heat-labile medications

3. Any problems noted with packaging of a medication are reported immediately to the provider pharmacy.

3.9 ORDERING AND RECEIVING MEDICATIONS FROM NON-CONTRACT PHARMACIES

POLICY

A resident, or responsible party, may request purchase of medications from a pharmacy other than the provider pharmacy. Such non-contract pharmacies will adhere to nursing care center medication policies and procedures and assure delivery on a timely basis, as detailed in the policy and procedures on arrangements with non-contract pharmacy. This and other relevant policy and procedures are provided to the non-contract pharmacy provider.

PROCEDURES

1. The business office representative notifies the charge nurse of the resident's choice of a non-contract pharmacy after the non-contract pharmacy has agreed to the terms of the "Arrangement With Non-Contract Pharmacy" (See Section 1.5 – Arrangements with Non-Contract Pharmacy).

2. The name of the selected pharmacy is identified in the resident's record.

3. The nursing care center ensures that the selected pharmacy has received and signed the Non-Contract Pharmacy Agreement, which includes policies and procedures for ordering and receiving medications.

4. A licensed nurse or appropriate nursing care center staff receives all medications and related supplies delivered from the non-contract pharmacy. Delivery of prescription or non-prescription medications directly to a resident's bedside is prohibited.

5. If non-contract pharmacy is unable to provide ordered medications, the provider pharmacy may be contacted to supply the ordered medications.

3.10 MEDICATIONS BROUGHT TO NURSING CARE CENTER BY RESIDENT OR RESPONSIBLE PARTY

POLICY

Medications brought into the nursing care center by a resident or responsible party are accepted only with a current order by the resident's prescriber, after the contents are verified by the nurse, and if the packaging meets the state, federal and pharmacy's guidelines. Other unauthorized medications are not accepted by the nursing care center.

PROCEDURES

1. Use of medications brought to the nursing care center by a resident or responsible party is allowed only when the following conditions are met and as allowed per state regulation:

    a. The medication name, dosage form, and strength have been verified by the nurse accepting the medication by:

    - Consulting a tablet identification reference (e.g., Lexicomp's On-line Drug-ID)

    – or –

    - Calling the dispensing pharmacy, Drug Information Center or Poison Control Center for a physical description of the medication.

    b. The medication container is clearly labeled and packaged in accordance with pharmacy procedures for medication labeling and packaging in a manner consistent with pharmacy guidelines for medications and within all state and federal regulations.

    c. The nursing care center may use medications transferred from other licensed health facilities or those medications dispensed or obtained after admission from any licensed or governmental pharmacy and may accept the delivery of those medications by any agent of the resident or pharmacy without the necessity of identification by a nurse, physician or pharmacist.

2. Medications not ordered by the resident's prescriber, or unacceptable for other reasons (such as questions of the identity, improper packaging or labeling of the medication), are returned to the family or responsible party. If unclaimed, the medications are disposed of in accordance with nursing care center's medication destruction/disposal procedures.

3.11 MEDICATIONS WITH BOXED WARNING

POLICY

Many medications used by residents may carry an FDA issued warning. The boxed warning is the most serious type of warning the FDA can require on medication labeling and is important to the health and safety of the patient. Nursing staff, prescribers and pharmacists must be familiar with boxed warnings for any medication used by a resident and assure that these medications are used appropriately.

PROCEDURES

1. All licensed nurses, attending physicians, prescribers and pharmacists must be familiar with the medications used by the residents that carry a boxed warning relevant to the resident. Nursing Staff shall refer to Boxed Warning Monitoring Guidelines and appropriate references for specific health risk and signs and symptoms for monitoring.

2. The attending physician must determine whether the use of such medications provides a benefit to the resident and outweighs the potential risk by conducting a risk-benefit determination. The frequency and duration of monitoring needed to identify therapeutic effectiveness and adverse consequences will depend on factors such as clinical standards of practice, facility policies and procedures, manufacturer's specifications, and the resident's clinical condition. Monitoring involves three aspects:
    - Periodic planned evaluation of progress toward the therapeutic goals;
    - Continued vigilance for adverse consequences; and
    - Evaluation of identified adverse consequences.

3. Nursing Staff shall include the appropriate monitoring parameters on the resident specific Care Plan as appropriate. Monitoring for adverse consequences involves ongoing vigilance and may periodically involve objective evaluation (e.g., assessing vital signs may be indicated if a medication is known to affect blood pressure, pulse rate and rhythm, or temperature). Using quantitative and qualitative monitoring parameters facilitates consistent and objective collection of information by the facility.
    - Quantitative monitoring parameters may include collection of serum drug levels to assess safety and efficacy of the specific medication. Frequency of collection is to be determined by either the prescribing physician or pharmacist.

4. Nursing staff must be informed of their responsibilities and educated/inserviced on monitoring parameters, observations of signs and symptoms in the progress notes and need for care planning if appropriate.

3.12 MEDICATION SHORTAGES

POLICY

On occasion, a medication ordered for a resident in the nursing facility may be unavailable for dispensing from the pharmacy. This may result from the pharmacy being temporarily out of stock of a particular product, a drug recall, manufacturer's shortage of a drug, or the situation may be permanent because the drug is no longer being manufactured.

The facility nurse must make every effort to ensure that a medication ordered for the resident is available to meet their needs.

PROCEDURES

1. The pharmacy staff shall:

    a. Call and/or provide written notification to the nursing staff that the physician ordered product(s) is/are unavailable.

    b. Provide nursing with the date that it is anticipated that the drug(s) will become available.

    c. Suggest alternative, comparable drug(s) and dosage of drug(s) that is/are available, which is covered by the resident's insurance.

        - The consultant pharmacist may assist in recommending an alternative therapy during routine visits when appropriate.

2. Nursing staff shall, if the shortage will impact the patient's immediate need of the ordered product:

    a. Notify the attending physician of the situation, explain the circumstances, expected availability and optional therapy(ies) that are available.

    b. Obtain a new order and cancel/discontinue the order for the non-available medication.

    c. Notify the pharmacy of the replacement order.

3.13 REFILL TOO SOON

POLICY

PharMerica will make a commercially reasonable effort to dispense and deliver prescriptions ordered before the last dose of the previous dispense is administered. A refill for a new supply of the prescription should be requested only once from PharMerica. Refills will be fulfilled and delivered when eligible from the payor.

PROCEDURES

1. The "Order After" date located on the prescription label is the indicator for the nurse to request a refill. If a request to refill prior to this date is needed due to a change in the prescription dosage, please contact the pharmacy.

2. If utilizing electronic records or e-prescribing, please follow procedures as directed by vendor, facility and pharmacy, otherwise, peel off the reorder sticker on the prescription label, on or after the "Order After" date, and affix it in the designated area on the *Prescription Reorder* sheet pad.

3. If communication to the pharmacy specifying a quantity is necessary, write it in the box to the right of the sticker. Any changes to the medication order itself should be communicated via a new telephone or physician's order, signed and dated by a nurse.

4. Prior to faxing, the nurse will date and write his/her name on the top of the reorder sheet and then fax the *Prescription Reorder* sheet to the pharmacy.

5. Record the prescription request in the facility reorder book.

6. PharMerica will communicate any refills that do not meet the refill or payer criteria as "Refill Too Soon" via daily communications to each requesting client's nursing station or facility fax number.

7. PharMerica will also communicate those refills that are too soon via its client web portal, ViewMasteRx, please refer to instructions for obtaining the "Refill Too Soon" report in the ViewMasteRx training guide.

8. Nursing should review the "Refill Too Soon" and "Refill Reminder" reports daily.

Medication Storage

4.0 MEDICATION STORAGE

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4.1 STORAGE OF MEDICATION

POLICY

Medications and biologicals are stored properly, following manufacturer's or provider pharmacy recommendations, to keep their integrity and to support safe, effective drug administration. The medication supply shall be accessible only to licensed nursing personnel, pharmacy personnel, or staff members lawfully authorized to administer medications.

PROCEDURES

1. The provider pharmacy dispenses medications in containers that meet state and federal labeling requirements, including those established by the United States Pharmacopeia (USP). Medications are to remain in these containers and stored in a controlled environment. This may include such containers as medication carts, medication rooms, medication cabinets, or other suitable containers.

2. Controlled medications should be stored separately from non-controlled medications (see state regulations for Schedules III-V). The access system (key, security codes) used to lock scheduled medications, cannot be the same access system used to obtain the non-scheduled medications. Schedule II medications and preparations must be stored in a separately locked permanently affixed compartment. Controlled substances stored in refrigerator should be secured in a separately locked, permanently affixed compartment. (See Section 4.2 – Controlled Medication Storage)

3. In order to limit access to prescription medications, only licensed nurses, pharmacy staff, and those lawfully authorized to administer medications (such as medication aides) are allowed access to medication carts. Medication rooms, cabinets and medication supplies should remain locked when not in use or attended to by persons with authorized access.

4. Medications should be stored so that various routes of administration are separated. Internally administered medications are stored separately from medications used externally such as lotions, creams, ointments, and suppositories.

5. Intravenously administered medications are stored separately from orally administered medications, under appropriate temperature and sterility conditions, and following the manufacturer's recommendations.

6. Eye medications are stored separately from ear medications and inhalers, etc. See manufacturer guidance.

7. Medications for oral inhalation are stored in the dispensed containers following manufacturer guidelines for positioning and priming.

8. Medications for nasal inhalation are stored in the dispensed containers following manufacturer guidelines for positioning and priming. The following information is provided as general guidelines for proper storage of specific nasal inhaler products and is not meant to be all-inclusive.
   a. Calcitonin (Fortical® and Miacalcin®) nasal spray should be stored in the refrigerator until opened. Once opened, the bottle should be stored in the upright position in the medication cart.

9. Potentially harmful substances (such as urine test reagent tablets, household poisons, cleaning supplies, disinfectants) are clearly identified and stored in an area separate from medications.

10. Medications requiring storage at "room temperature" are kept at temperatures ranging from 15°C (59°F) to 25°C (77°F). "Controlled room temperature" is defined as 20°C (68°F) to 25°C (77°F). Excursions between 15°C (59°F) to 30°C (86°F) are allowed, with transient spikes to 40°C (104°F) as long as they don't exceed 24 hours.

11. Medications requiring "refrigeration" or "temperatures between 2°C (36°F) and 8°C (46°F)" are kept in a refrigerator with a thermometer to allow temperature monitoring. Medications requiring storage "in a cool place" may be refrigerated unless otherwise directed on the label as "cool" temperatures are those between 8°C (46°F) and l5°C (59°F). A temperature log or tracking mechanism is maintained to verify that temperature has remained within accepted limits. The temperature of any refrigerator that stores vaccines should be monitored and recorded twice daily. If using a temperature monitoring device (TMD; digital data logger recommended) that records min/ max temps (I.e., the highest and lowest temps recorded in a specific time period), document current and min/max once each work day preferably in the morning. If using TMD that does not record min/max temps, document current temps twice, at beginning and end of each work day. If no vaccines are stored in the refrigerator, document temperature checks at least once daily. CMS Guidance-Maintain temperatures in accordance with manufacturer specifications and monitor according to national guidelines (e.g., see CDC vaccine storage and handling).

12. Insulin products should be stored in the refrigerator until opened. Note the date on the label for insulin vials and pens when first used. The opened insulin vial may be stored in refrigerator or at room temperature. Opened insulin pens should be stored at room temperature (Refer to specific product labeling for additional detail). Do not freeze insulin. If insulin has been frozen, do not use. (Refer to Section 9.7 – Abridged List of Medications with Shortened Expiration Dates)

13. Refrigerated medications should be kept in closed and labeled containers, with internal medications separated from external medications and all medications segregated from fruit juices, applesauce, and other foods used in administering medications. Any other foods such as employee lunches and activity department refreshments should not be stored in this refrigerator. The refrigerator should be kept clean and frost-free. To protect refrigerated medications from freezing, store them away from the freezer section.

14. Outdated, contaminated, discontinued or deteriorated medications and those in containers that are cracked, soiled, or without secure closures are immediately removed from stock, disposed of according to procedures for medication disposal (Refer to Section 5 - Disposal of Medications, Syringes and Needles), and reordered from the pharmacy (Refer to Section 3.2 - Ordering and Receiving Non-Controlled Medications), if a current order exists.

15. Medications awaiting destruction that cannot be disposed of immediately should be recorded on a log to include the name of the individual(s) storing the medication, resident name, the prescription number if applicable, the quantity of the medication, the strength of the medication and the date of disposition. These medications should be stored in a secured area separate from active orders. Controlled drugs awaiting disposition will need stored in a separately locked permanently affixed compartment. These medications should be reconciled at the time of final disposition.

16. Medication storage areas should be kept clean, well lit, organized and free of clutter.

17. Medication storage conditions are monitored on a regular basis as a random quality assurance ("QA") check. As problems are identified, recommendations are made for corrective action to be taken.

4.2 CONTROLLED MEDICATION STORAGE

POLICY

Medications included in the Drug Enforcement Administration (DEA) or state classification as controlled substances are subject to special handling, storage, disposal and record keeping in the nursing care center in accordance with federal, state and other applicable laws and regulations.

PROCEDURES

1. The director of nursing and the consultant pharmacist monitor for compliance with federal and state laws and regulations in the handling of controlled medications. Schedule II-V medications must be maintained in separately locked permanently affixed compartments. The access system (e.g. key, security codes) used to lock Schedule II-V medications and other medications subject to abuse, cannot be the same access system used to obtain the non-scheduled medications. The facility must have a system to limit who has security access and when access is used.
   Exception: Controlled medications and those medications subject to abuse may be stored with non-controlled medications as part of a single unit package medication distribution system, if the supply of the medication(s) is minimal and a shortage is readily detected.
2. Only authorized licensed nursing and pharmacy personnel have access to controlled medications. The medication nurse on duty maintains possession of the key to controlled medication storage areas. The director of nursing shall keep back-up keys to all medication storage areas, including those for controlled medications.
3. The access system (key, security codes) used to lock controlled medications and other medications subject to abuse cannot be the same access system used to obtain the non-scheduled medications. The facility must have a system to limit who has security access and when access is used.
4. Controlled medications requiring refrigeration are stored within a separately locked, permanently affixed box within the refrigerator. (§483.45(h)(2) The facility must provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.)
5. A controlled medication accountability record is prepared when receiving inventory of any controlled substance to establish a record of receipt and disposition in sufficient detail to enable accurate reconciliation. The following information is completed:
   a. Name of resident
   b. Prescription number
   c. Name, strength (if designated), and dosage form of medication
   d. Date received
   e. Quantity received
   f. Name of person receiving medication

6. At each shift change or when keys are surrendered, a physical inventory of all controlled substances, including refrigerated items, is conducted by two licensed nurses or approved individuals per state regulation and is documented on the controlled substances accountability record or verification of controlled substances count report.

   Any discrepancy in controlled substance medication counts is reported to the director of nursing immediately. The director of nursing or designee investigates and makes every reasonable effort to reconcile all reported discrepancies while nurses remain on duty. The director of nursing, in a report to the administrator, documents irreconcilable discrepancies.

   a. If a major discrepancy or a pattern of discrepancies occurs or if there is apparent criminal activity, the director of nursing notifies the administrator, pharmacy manager, and consultant pharmacist immediately.

   b. If diversion is discovered and substantiated, timely notifications must be made to appropriate agencies, which may include local law enforcement, Drug Enforcement

   Administration, State Board of Nursing, State Board of Pharmacy, the state Medicaid Fraud Control Unit, and possibly the State Licensure Board for Nursing Home Administrators. Current controlled medication accountability records are kept in MAR or narcotic book. When completed, accountability records are submitted to the director of nursing and maintained on file at the nursing care center. Refer to specific state regulations for the required time period for records retention.

7. Controlled medications are not surrendered to anyone, including the resident's prescriber, other than releasing controlled medications for a resident on pass or therapeutic leave, to a resident or responsible party upon discharge from the nursing care center, or to the DEA or other law enforcement officials functioning in a professional capacity in exchange for a receipt documenting the transaction. (Refer to Section 5.2 - Discharge Medications and Section 6.1 - Out-on-Pass (Leave of Absence) Medications)

   Controlled medications remaining in the nursing care center after the order has been discontinued are retained in the nursing care center in a securely double locked area with restricted access until destroyed as outlined by state regulation. (Refer to section 5.5 - Disposal of Medications)

8. The consultant pharmacist, or pharmacy designee, routinely reviews a sampling audit of controlled medication storage, records and expiration dates during the medication storage inspections.

9. Safety of nursing care center personnel and residents is to be assured in the event of entry to the nursing care center for the purpose of stealing controlled medications. This may necessitate surrendering controlled medications if bodily harm is threatened. The local public safety agency, the administrator, and the director of nursing are immediately notified.

10. Non-controlled medications that have been identified by the nursing care center as having the potential for abuse may also be stored with controlled substances.

11. The nursing care center may store some controlled medications in an emergency medications supply in accordance with state requirements.

4.3 BEDSIDE MEDICATION STORAGE

POLICY

Bedside medication storage is permitted for residents who are able to self-administer medications, upon the written order of the prescriber and when it is deemed appropriate in the judgment of the nursing care center's interdisciplinary resident assessment team.

PROCEDURES

1. The interdisciplinary team (IDT) will review and approve resident competencies and understanding prior to permission of bedside storage of medications as established in the nursing care centers policies and procedures.

2. A written order for the bedside storage of medication is present in the resident's medical record.

3. Bedside storage of medications is indicated on the resident medication administration record (MAR) for the appropriate medications. (See state regulations as some states restrict types of medications that may be kept at the resident's bedside.)

4. Bedside medication storage is permitted only when it does not present a risk to confused residents who wander into the rooms of, or room with, residents who self-administer. The following conditions are met for bedside storage to occur:
   a. The manner of storage prevents access by other residents. Lockable drawers or cabinets are required (unless otherwise specified by state regulation).
   b. The medications provided to the resident for bedside storage are kept in the containers dispensed by the provider pharmacy (or in the original container if a nonprescription medication).

5. All nurses and nursing aides are required to report to the charge nurse on duty any medications found at the bedside not authorized for bedside storage and to give unauthorized medications to the charge nurse for return to the family or responsible party. Families or responsible parties are reminded of this procedure and related policy when necessary.

6. Medications stored at the bedside are reordered in the same manner as other medications. The nursing staff is responsible for proper rotation of bedside stock and removal of expired medications.

7. The nurse will oversee storage security and accountability of bedside medications. Under- and over-utilization of medications will be identified and brought to the attention to the director of nursing for reassessment by the IDT.

8. Candy, cough drops, mouthwashes, aftershave lotions, colognes and perfumes, hair sprays, dentifrices, deodorants, lotions, dry skin creams and personal hygiene products not considered medications may be stored at the bedside in small quantities in accordance with the nursing care center's policy and procedures for personal items and are not included in the provisions of this policy and procedure.

9. The nurse inquires of the resident regarding routine medication; and the resident must inform the nurse of PRN use of medications so that documentation may be completed.

Refer to section 7.3, Medication Administration, Self-Administration by Resident.

4.4 SYRINGE AND NEEDLE INVENTORY (OPTIONAL)

POLICY

The facility documents the use of all syringes and needles as required by applicable state law.

PROCEDURES

1. An inventory control sheet is prepared at the time needles and syringes are received from the supplier.
2. Syringes and needles are stored in a locked supply cabinet, with access limited to those with authorization.
3. Syringes and needles placed into service on the nursing unit are logged onto the inventory control sheet at that unit.
4. Syringes and needles are inventoried at least daily.
   a. The off-going nurse unlocks the medication cart' s syringe drawer in the presence of the on-coming nurse.
   b. The on-coming nurse counts the remaining syringes and needles, along with used syringes and needle wrappers and plastic caps.
   c. The off-going nurse records the amount remaining and the amount used on the inventory control sheet.
   d. Both nurses sign the inventory control sheet to verify the count.
   e. Any used wrappers and caps are discarded.
   f. The off-going nurse surrenders the keys to the oncoming nurse who then locks the syringe and needle storage drawer. Inventory control sheets are kept in (a separate notebook in the locked medication room).
5. Used syringes and needles are sent to the (director of nursing) office when the sharps container is approximately two-thirds full.
6. The inventory sheet is signed by the nurse surrendering the used syringes, and the (director of nursing), and the number of syringes and needles is documented on the inventory control sheet.

Disposal of Medications, Syringes and Needles

5.0 DISPOSAL OF MEDICATIONS, SYRINGES AND NEEDLES

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5.1 DISCONTINUED MEDICATIONS

POLICY

When medications are discontinued by prescriber order, a resident is transferred or discharged and does not take medications with him/her, or in the event of resident's death, the medications are marked as "discontinued" and destroyed or returned to the issuing pharmacy, if applicable per state regulations.

PROCEDURES

1. If a prescriber discontinues a medication, the medication container is removed from the medication cartas soon as practicable according to state/federal regulations in a timely manner.

2. Medications awaiting disposal or return are stored in a locked secure area designated for that purpose and separate from active orders until destroyed or picked up by pharmacy staff. Medications awaiting destruction that cannot be disposed of immediately should be recorded on a log to include the name of the individual(s) storing the medication, resident name, the prescription number if applicable, the quantity of the medication, the strength of the medication and the date of disposition. Controlled drugs awaiting disposition will need stored in a separately locked permanently affixed compartment.

3. Medications subject to return are to be picked up by the pharmacy staff along with proper paperwork within a timely manner to avoid inadvertent administration.

4. Discontinued medications that are unopened (such as unit-dose packages, sealed containers) may be returned to the pharmacy in accordance with the medication return policy and procedure, as allowed per state regulation. Discontinued medications not returned to the pharmacy are destroyed in accordance with the destruction policy and procedure (See Sections 5.4- Returning Medications to the Pharmacy and Section 5.5 - Disposal of Medications). Discontinued controlled substances cannot be returned to the pharmacy unless refused by facility at time of delivery.

5.2 DISCHARGE MEDICATIONS

POLICY

Medications are sent with the resident upon discharge only under conditions that protect the resident and assure compliance with applicable state laws.

PROCEDURES

1. Medications, including controlled substances, may be sent with the resident upon discharge if the prescriber has authorized this, it is allowed per payor source and permitted by state law.

2. The labels of discharge medications are verified for completeness and accuracy by checking them against the most recent prescriber' s orders.

3. Directions for use are reviewed with the resident or responsible party. If current directions for use are not the same as those on a prescription label, the medication name, strength, and the correct directions for use are written on a separate piece of paper. The correct directions are given to the resident or responsible party, not affixed to the container.

4. If the discharging nurse is unable to answer a question about these medications, the provider pharmacy is called for the information before releasing the medications and/or patient information sheets will be provided by the dispensing pharmacy.

5. The telephone number of the provider pharmacy is given to the resident or responsible party to use in the event that additional information is needed regarding medication therapy.

6. Discharge medication information is entered on the discharge instruction form, continuity of care form or facility designated form.

7. The resident or responsible party is informed if the container is not child resistant. This is documented on the discharge instruction form or in the resident' s medical record.

8. If medications were brought into the nursing care center by a resident or responsible party and not destroyed, the nurse returns these medications to the resident and documents return of the medications to the resident or responsible party along with other property or valuables upon discharge.

9. Medications may not be sent with the resident upon discharge if:

a. The resident leaves or is discharged without a prescriber's order or approval.

b. The resident is discharged to a general acute care hospital, acute psychiatric hospital or acute care rehabilitation hospital (greater level of care). In this case, the nurse is to follow procedures for proper disposal of medications or return medications to the pharmacy for credit as appropriate.

c. The medication was discontinued prior to discharge.

5.3 DISCHARGE TO HOME WITH MEDICATIONS (DISCHARGERX®)

POLICY

Discharge to home allows medications to be billed to a third party or private payors when the resident is discharged with medication dispensed and billed to the facility. This reduces waste, improves continuity of care, and reduces nursing home cost. Medications are sent with the resident upon discharge only under conditions that protect the resident and assure compliance with applicable state laws.

PROCEDURES

1. Residents must have prescriber's order to discharge with medications.
2. Two days prior to discharge, the “Release of discharge to home medications form” is faxed to the pharmacy with patient demographic data, Responsible Party information, insurance information and forecasted medications to go home with the resident, including name, strength, and quantity.
3. At discharge:
    a. Double check quantities and medications. Enter corrections on the form if needed.
    b. The pharmacy will provide drug monographs along with medications; however, this information may also be printed using instructions on the form, this information should be provided to the patient/caregiver.
    c. Inform the patient/caregiver that medications are not dispensed in child resistant containers and must be stored out of reach of children.
    d. Offer pharmacist counseling to the patient/caregiver and check the appropriate box on the form. If requested, call the pharmacy.
    e. Patient or Responsible Party must sign the form along with a nurse or witness.
    f. Discharge patient with medications and directions for use/cautionary information.
    g. Fax to the pharmacy:
        1) Completed form
        2) Copy of prescriber' s order to discharge resident with medication
    h. File in patient medical record:
        1) Completed form
        2) Copy of prescriber's order to discharge resident with medication

5.4 RETURNING MEDICATIONS TO THE PHARMACY

POLICY

1. Medications, supplies and any other medical products issued by the pharmacy will be accepted for return and credit, when required by the state, following proper storage and handling guidelines to assure maintenance of the product' s strength, quality, and purity.

2. The processing and handling of returned goods will be consistent with all applicable state and federal laws and regulations.

3. Controlled substance medications shall not be accepted for return to the pharmacy' s inventory except in situations that include if the resident has expired, been transferred out of the nursing care center or the medication order has been discontinued prior to delivery of medication. In these exceptional cases, the nurse shall write "refused" on the delivery receipt with the applicable reason; medication will then be sent back to the pharmacy with the pharmacy driver as verification.

4. Additional situations when credit will not be issued for returned medications include:

    - Medications requiring special storage conditions i.e. refrigeration.
    - Special orders i.e., split tablets (half or quarter tablets).
    - Partially used bingo cards (blister-cards) which are not in unit dose/reclaimable (foil back) punch cards designed with special seal adhesive and perforated fascia for recovery of unused pharmaceuticals without damaging the blister or printed lidding stock.
    - Opened or unsealed eye drops.
    - Opened inhalers and/or inhalers not in original sealed manufacturer packaging.
    - Opened or unsealed creams and ointments.
    - Opened or unsealed liquids.
    - Opened injectable medications not in original manufacturer packaging (or removed tamper proof seals or packaging).
    - Used medications dispensed in unbreakable units.
    - IV Medications, or IV Admixtures (UNLESS manufacturer's outer bag has not been compromised and remains in original manufacturer' s packaging).

- Medications dispensed by another pharmacy other than own PharMerica pharmacy provider.
- Medication was originally dispensed more than 45 days prior to return date.
- Medication integrity has been compromised.
- The value of returned medication is less than the approved restocking/return fee.
- Medication was paid for by a third-party payor other than the client or private payor.

Contracted Accounts and Privates

1. PharMerica may issue credit for returned medication in the following cases:
    - Unit Dose packaged medications which have description NDC, lot # and expiration printed on each individual Unit Dose.
    - Full cards only refused at time of delivery.
    - Full cards only from a multiple card dispense (2 of 3).
    - The value of returned medication is more than the restocking /return fee.
    - Contractual restocking /return fee is assessed through agreements and/or prior practice.
    - Medication integrity must confirm that subsequent re-dispensing of credited medications to other residents does not in any way jeopardize any of the following factors: infection control, product stability and state/federal regulations.

Exceptions

1. PharMerica does not accept controlled substance medications back into the pharmacy unless:
    - Pharmacy Dispensing Occurrence.
    - Medication order refused by nurse at time of delivery due to discontinued/changed order or the resident was discharged or expired prior to acceptance by the nursing personnel.

PROCEDURES

1. Medications being returned for credit are to be stored in strict compliance with manufacturer directions for storage and USP standards.

2. Prior to acceptance of any returned medications /supplies, the pharmacy must receive from the nursing care center documentation of all returned medications/supplies on the appropriate forms, including any state specific form as required by regulation. These forms can be readily created on the PharMerica ViewMaster System. Examples of information that may be required include:

   a. Date returned

   b. Nurse' s or other responsible person's initials or signature verifying the information

   c. Resident's name

   d. Name, strength and form of medication

   e. Prescription (Rx) number

   f. Quantity returned

3. The nursing care center will keep a copy of the returned medication form and send the original form to the pharmacy with the medications.

4. The consultant pharmacist and/or other designated technical staff should assist the nursing care center in assuring that all returned goods are processed in a timely manner, provided that the required documentation is completed by the nursing care center nursing staff or other responsible person.

5. All return medications/supplies must be transported back to the pharmacy in a sealed traceable container to track and prevent diversion or adulteration of the return medications/supplies.

6. **If allowed by state law, all returnable Per Diem medications must be returned to the pharmacy, within 45 days of patient discharge. Facility will receive a reminder alert 7 days post discharge as a reminder. Any returnable Per Diem medications not returned will be subject to further charges.**

7. Nursing staff should contact the dispensing pharmacy for information as to which medications are allowable for return by law in their state.

5.5 DISPOSAL OF MEDICATIONS

POLICY

1. Discontinued medications and/or medications left in the nursing care center after a resident's discharge, which do not qualify for return to the pharmacy, are identified and removed from current medication supply in a timely manner according to state and federal regulations for disposition.

2. Medications included in the Drug Enforcement Administration (DEA) classification as controlled substances (or those classified as such by state regulation) are subject to special handling, storage, disposal, and record keeping in the nursing care center in accordance with federal and state laws and regulations.

3. Methods of disposition of pharmaceutical hazardous and non-hazardous waste are consistent with applicable state and federal requirements, local ordinances, and standards of practice. The nursing care center will use an approved vendor for pharmaceutical waste disposal needs.

4. Prior to return, disposal, movement to separate storage area for medications awaiting destruction or discharge to home with resident, medications should be documented on a disposition log including the following information:

    a. Date of disposition

    b. Nurse' s or other responsible person's initials or signature verifying the information

    c. Resident's name

    d. Name, strength and form of medication

    e. Prescription (Rx) number

    f. Quantity

5. Medications should be reconciled to this log at any change in custody and at the time of final disposition. Note that disposing of medications in a DEA compliant medication receptacle is considered a final disposition and medications cannot be further logged or reconciled once placed in the receptacle.

PROCEDURES

1. The director of nursing and the consultant pharmacist will monitor for compliance with federal and state laws and regulations regarding the disposal of medications.

a. The nursing care center should maintain approved containers to separate and securely store different types of pharmaceutical waste until it is scheduled for pick up.

b. Authorized personnel who have access to medications should deposit pharmaceutical waste in the appropriately labeled container. Each container used to collect, separate and store each type of pharmaceutical waste will be labeled with the type of waste to be stored in the container.

2. Controlled Substances listed in Schedules II, III, IV and V remaining in the nursing care center after the order has been discontinued are retained in the nursing care center in a securely double locked area with restricted access until destroyed as outlined by state regulation.

   a. For the State of___, the appropriate method of controlled substance destruction is as follows:

      - _____Transfer to a container for release to a pharmaceutical waste contractor
      - _____Transfer medication to trash receptacle following destruction to unusable consistency

        *Mixing medications with an undesirable substance, such as a commercially available chemical dissolution system, used coffee grounds or kitty litter, and putting them in impermeable, non-descript containers, such as empty cans or sealable bags; will further ensure the drugs are not diverted.[1]

      - _____Transfer to the toilet or hopper
      - _____Transfer to the sink
      - _____Transfer to an approved DEA Medication receptacle where the pharmacy is licensed as an authorized collector by the DEA

   b. For the State of___, these controlled substances shall be disposed of by the nursing care center in the presence of appropriately titled professionals (check appropriate line):

      - _____Licensed nurse employed by the nursing care center and a pharmacist
      - _____Two licensed nurses employed by the nursing care center
      - _____Administrator and licensed nurse employed by the nursing care center
      - Others as listed: _____

   c. A controlled medication disposition log, or equivalent form, shall be used for

documentation and shall be retained as per federal privacy and state regulations. This log shall contain the following information:

- Resident's name
- Medication name and strength
- Prescription number
- Quantity/amount disposed
- Date of disposition
- Signatures of the required witnesses

If a controlled medication is unused, refused by the resident or not given for any reason, it cannot be returned to the container. It is destroyed as outlined above and the disposal is documented on the accountability record on the line representing that dose with the required signatures. This same procedure applies to unused portions of single dose ampules and doses of controlled substances wasted for any reason.

3. Medications not listed in Schedules II, III, IV and V (non-controlled medications) shall be destroyed by the nursing care center in the presence of a pharmacist or nurse, and one other witness as per state regulation. Documentation of non-controlled medication may be completed on a medication administration record (MAR), a medication disposition log or form (or record provided for that purpose) and shall be retained as per federal privacy and state regulations.

   a. For the State of___, the appropriate method non-controlled medication destruction is as follows:

      - _____Transfer to a container for release to a pharmaceutical waste contractor
      - _____Transfer medication to trash receptacle following destruction to unusable consistency

        *Mixing medications with an undesirable substance, such as a commercially available chemical dissolution system, used coffee grounds or kitty litter, and putting them in impermeable, non-descript containers, such as empty cans or sealable bags; will further ensure the drugs are not diverted. [1]

      - _____Transfer to the toilet or hopper
      - _____Transfer to the sink

b. For the State of___, non-controlled medications shall be disposed of by the nursing care center in the presence of appropriately titled professionals (check appropriate line):

- _____Licensed nurse employed by the nursing care center and a pharmacist
- _____Two licensed nurses employed by the nursing care center
- _____Administrator and licensed nurse employed by the nursing care center
- Others as listed: _____

c. A non-controlled medication disposition log or form shall be used for documentation and shall be retained as per federal privacy and state regulations. The log shall contain the following information:

- Resident's name
- Medication name and strength
- Prescription number, if applicable
- Quantity/amount disposed
- Date of disposition
- Signatures of the required witnesses

4. Dispose of discontinued medications within 90 days of the date the medication was discontinued, unless it is reordered within that time and following applicable per state regulation.

5. Medications brought into the nursing care center that are not used and cannot be returned to the family shall be destroyed according to the above policy.

6. Outdated medications, contaminated or deteriorated medications, and the contents of containers with no label shall be destroyed according to the above policy.

7. Before discarding a medication container, mark out all identifying resident information on the prescription label making the label unreadable. This will help protect resident privacy of personal health information.

REFERENCE

1 Federal Guidelines dated February 2007 on the Proper Disposal of Prescription Drugs, http://www.whitehousedrugpolicy.gov /drugfact/factsht/proper_disposal.html.

5.6 SYRINGE AND NEEDLE DISPOSAL

POLICY

Used syringes and needles are disposed of safely and in accordance with applicable laws and safety regulations.

PROCEDURES

1. To avoid risk of needle stick/contamination, only OSHA-approved safety needles are to be used.

2. Immediately after use, syringes and needles are placed into puncture resistant, one-way containers specifically designed for that purpose. Syringes and needles are never deliberately bent or broken.

3. Whatever the location (e.g., medication room, affixed to the medication cart), the disposal containers are fitted with a lid that prohibits reaching into the container. While awaiting disposal, used containers of discarded needles are kept where residents and unauthorized staff do not have access (such as in a locked medication room).

4. When containers are two-thirds full, they are sealed and disposed of in the same manner as hazardous waste.

5.7 EPA PHARMACEUTICAL WASTE STORAGE, TRANSPORTATION, AND DISPOSAL

POLICY

The facility will dispose of pharmaceutical hazardous and non-hazardous waste using an approved system of disposal that protects employees and the environment according to applicable federal, state, and local law or regulations.

The facility should use an approved vendor for pharmaceutical waste storage, transportation, and disposal needs.

PROCEDURES

1. The facility will follow the procedures specified by the approved vendor.

5.8 FENTANYL PATCH DISPOSAL

Regulatory Update: Compliance Cue

Guidance for Pharmacy-related F-Tags in Phase 3 of the Mega Rule

PharMerica

Fentanyl Patch Disposal

On June 29, 2022, CMS released Phase 3 updated guidance for nursing home surveyors as part of the Phase 2 and 3 Requirements of Participation. Surveyors will begin using this guidance to identify noncompliance on October 24, 2022. Within the Phase 3 updates, CMS has provided new guidance concerning disposal of fentanyl patches, used for pain management.

What's Required

The FDA and manufacturer instructions recommend disposal of used fentanyl patches by folding the patch in half with the sticky sides together and flushing the patch down the toilet or drain. Fentanyl patches are not considered hazardous waste pharmaceuticals by the EPA; therefore, they are not restricted from being flushed down the toilet or drain.

If state and local laws restrict flushing of pharmaceuticals, nursing homes may use drug disposal products or systems for fentanyl patches and other controlled medications. The facility is required to show that the drug disposal product or system minimizes accidental exposure or diversion of the controlled substance.

Using a sharps container, common areas, or resident room trash cans does NOT meet the requirement of preventing accidental exposure or diversion and would therefore NOT be a compliant disposal option for fentanyl patches.

Steps to Facility Compliance

- Ensure fentanyl patches are being disposed of using compliant methods described above.
- Always reference EPA and FDA flushing requirements before flushing medications down the toilet or drain.
- If your facility does not allow flushing of pharmaceuticals based on state and local laws, PharMerica can provide a drug disposal system to meet the requirements for safe disposal.

For more detailed info on fentanyl disposal, FDA, and EPA guidelines, refer to the guide: Fentanyl Disposal: Did You Know?

How PharMerica Can Help

- PharMerica pharmacists can assist the administrator and/or other nursing care center representatives in setting standards and developing, implementing, and monitoring policies and procedures for the safe and effective disposal of medications and related equipment in the facility.
- For each quarterly QAPI meeting, work with your PharMerica pharmacist to prepare a written report summarizing appropriate medication disposal methods and resources available to meet compliance requirements.

There's a lot more at PharMerica.com

Miscellaneous Special Situations

6.0 MISCELLANEOUS SPECIAL SITUATIONS

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6.1 OUT-ON-PASS (LEAVE OF ABSENCE) MEDICATIONS

POLICY

The charge nurse on duty assures that the resident or family member/responsible party has their necessary medications before leaving the nursing care center on pass or therapeutic leave if permitted by state regulation.

PROCEDURES

1. When receiving a prescriber's order for a resident to temporarily leave the nursing care center for an extended period of time, the nurse on duty reviews the resident's medication orders and verifies the directions for use.

2. All medications provided to the resident or family member/responsible party for administration while on pass are properly labeled with full directions for use and appropriate storage requirements. Encourage providing at least a 72 hour notice to the provider pharmacy so that the medications can be prepared.

    a. When an entire medication container is to be taken on pass, the resident or responsible party must sign a record of medication release accepting liability and responsibility to administer medication provided, according to directions on the medication container and store medications appropriately. Refer to state regulations regarding out-on-pass medications for specific interpretation.

    b. Record the following information for the release of medications to the resident or family member/responsible party on the record of medication release:

        - Resident's name
        - Medication name and strength
        - Quantity
        - Prescription number, if applicable
        - Date of release of the medication
        - Signature of the person receiving the medication
        - Signature of the member of the licensed nursing staff releasing the medication

    c. Within the medication release form, a disclaimer is included noting that the medications are not being released or dispensed in child-resistant containers.

    d. Document the quantity sent and returned. Report any discrepancies to the director of nursing.

e. If the resident leaving on a pass is covered by a third party insurance (such as a Medicare Part D plan), the pharmacy may encounter refill too soon rejections from the insurance company when attempting to bill a pass supply of medications. If this occurs, the resident's nurse will be instructed to send the current supply from the medication cart (if possible) or will be notified that the nursing care center may be charged for medications not paid for by the insurance plan.

f. Note: See "Drugs/Medications Returned to Pharmacy or Released to the Patient/Resident" Form.

3. Current medication orders and directions for use are reviewed with the resident or responsible party before the resident leaves the nursing care center. If there is a question about the medication that the nurse is unable to answer, the provider pharmacy is called for the information before releasing the medication.

4. The out-on-pass medication(s) taken by the resident are recorded (on the reverse side of the resident's current medication administration record (MAR)) or similar form. Doses are not documented on the front of the MAR unless the nurse administers the medication. However, the nurse on duty at the time the resident returns to the nursing care center may enter, in the nurse's notes, a summary of the resident's or responsible party's report of compliance with the dosage instructions. [Example: "5/17/12, 7:00 p.m., Sally Johnson, daughter of Mrs. Johnson, states that resident took digoxin, as directed, each morning. (signed) M. Jones, R.N."]

5. A circled initial is placed on the MAR for each dose of regularly scheduled medications that would normally have been administered by the nursing care center while a resident is out on pass. The reason for the circled initial (e.g., "out on pass with meds") is explained in the nursing comment section on the back of the MAR for each medication dose due.

6. Medications may be self-administered by residents participating in nursing care center-sponsored activities away from the building under the following conditions:

   a. The resident's prescriber gave a self-administration order and the resident has been assessed as being safe to do so.

   b. A nursing care center staff person keeps the medications until time for administration.

   c. A staff member observes self-administration and notes it in the resident's medical record. If the staff member is lawfully authorized to administer medications, administration is noted on the MAR. If not, the charge nurse initials and circles the dose on the front of the MAR and on the reverse side documents the staff member's comments.

6.2 MEDICATION ERROR REPORTING AND ADVERSE DRUG REACTION PREVENTION AND DETECTION

POLICY

The facility utilizes a system to assure that medication usage is evaluated on an ongoing basis. Medication errors and adverse drug reactions are assessed, documented, and reported as appropriate to the resident's attending physician and/or prescribers, the Pharmaceutical Services Committee, the pharmacy, and Food and Drug Administration MedWatch Program or USP/ ISMP Medication Error Reporting Program (when applicable). Refer to state regulations if medication error and adverse reaction reporting programs are legislated.

GUIDELINES AND DEFINITIONS

1. Medication Error/Variance shall be defined as any preventable event that may cause or lead to inappropriate medication use or resident harm while the medication is in the control of the health care professional, resident or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labeling, packaging, nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use. (National Coordinating Council for Medication Error Reporting and Prevention)

2. Adverse consequence is an unpleasant symptom or event that is due to or associated with a medication, such as impairment or decline in a resident's mental or physical condition or functional or psychosocial status. It may include various types of adverse drug reactions and interactions such as medication-medication, medication-food and medication-disease.

   Note: Adverse Drug Reaction (ADR) is a form of adverse consequence. It may be either a secondary effect of a medication that is usually undesirable and different from the therapeutic effect of the medication or any response to a medication that is noxious and unintended and occurs at doses normally used for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological functions. The term "side effect" is often used interchangeably with ADR; however side effects are but one of five ADR categories. The others are hypersensitivity, idiosyncratic response, toxic reactions and adverse medication interactions. A side effect is an expected, well-known reaction that occurs with a predictable frequency and may or may not constitute an adverse consequence.

3. Medication errors and adverse drug reactions are considered significant if they:

   a. Require discontinuing a medication or modifying the dose

b. Require hospitalization

c. Result in disability

d. Require treatment with a prescription medication

e. Result in cognitive deterioration or impairment

f. Are life threatening

g. Result in death

PROCEDURES

1. The interdisciplinary team reviews the resident's medication regimen for efficacy and actual or potential medication-related problems on an ongoing basis.

2. When a resident receives a new medication, the medication order is evaluated for the following:

   a. The dose, route of administration, duration, and monitoring are in agreement with current clinical practice, clinical guidelines, and/or manufacturer's specifications for use.

   b. An active diagnosis/indication (and documented objective findings, if necessary) support the use of the medication.

   c. The resident has no known allergies to the medication.

   d. The resident is not taking other medications, nutritional supplements, including herbal products, or foods that would be incompatible with the prescribed medication.

   e. The resident does not have a condition, history, or sensitivity that would preclude the use of the medication.

   f. The prescriber documents the clinical rationale in the resident's active record for using a medication outside these stated guidelines.

3. Facility staff monitor the resident for possible medication-related adverse consequences, including mental status and level of consciousness, when the following conditions occur:

   a. A clinically significant change in condition/status.

      - An unexplained decline in function or cognition.

- A worsening of an existing problem or condition.
- A new or worsening psychiatric manifestation or distressed behavior.
- Acute onset of signs or symptoms or worsening of a chronic problem or condition.

b. Evaluation of resident's side effects of medication, including sedation, lethargy, agitation, mental status changes, or behavior changes that:

- Affect resident abilities to perform activities of daily living or interact with others,
- Cause resident to withdraw or decline usual social patterns,
- Show resident has decreased engagement in activities, and/or
- Cause diminished ability to think or concentrate.

c. Addition or discontinuation of medications and/or non-pharmacologic interventions.

d. Change in dose.

e. Addition or discontinuation of care and services such as enteral feedings.

f. Significant changes in diet that may affect medication absorption.

g. Medication error, e.g., wrong or expired medication.

4. When any of the above occurs, the prescriber and/or staff rule out medication as a cause and document it in the resident's clinical record.

   a. A review of medications as potential causes of permanent significant change that requires a Significant Change of Status MDS Assessment should be performed within the required 14-day observation period.

5. The facility staff monitors residents for possible adverse consequences and/or the need to modify the dose of one or more medications. The prescriber documents why or how these medications' benefits outweigh their risks in the resident's clinical record.

6. In the event of a significant medication error or adverse drug reaction, immediate action is taken, as necessary, to protect the resident's safety and welfare.

   a. The prescriber is notified promptly of any significant error or adverse medication reaction.

b. Any new prescriber's orders are implemented, and the resident is monitored closely for 24 to 72 hours or as directed.

c. The incident is described on the shift change report to alert staff of the need to monitor the resident.

d. The following information is documented in the resident's medical record and/or on the incident report:

- Factual description of the error or adverse reaction
- Name of prescriber and time notified
- Prescriber's subsequent orders
- Resident's condition for 24 to 72 hours or as directed

7. A nursing care center medication discrepancy report and/or adverse drug reaction report is completed. If the discrepancy and/or adverse reaction resulted in death or significant disability, the FDA MedWatch 3500 mandatory report is completed and submitted within ten (10) days. If the discrepancy or adverse reaction did not result in death or significant disability, the Pharmaceutical Services Committee reviews the information and determines whether or not to submit an FDA MedWatch 3500 voluntary report, in the case of an adverse reaction, or a Medication Error Report, in the case of a medication discrepancy.

   a. The MedWatch FDA Form 3500 is available online at http://www.fda.gov/medwatch/getforms.htm. The form may be completed online and a printed copy of the report should be retained by the nursing care center and provided to the pharmacy. (Refer to Section 10.12 – MedWatch Form 3500)

   b. The MedWatch FDA Form 3500 may be completed and mailed to:

      Department of Health and Human Services
      Food and Drug Administration
      Division of Epidemiology and Surveillance
      5600 Fisher Lane
      Rockville, MD 20857

   c. When ADRs are reported to the MedWatch program, the director of nursing, administrator and pharmacy manager will also be notified.

8. ADRs and medication errors will be communicated to the provider pharmacy and the consultant pharmacist as they occur. When an incident appears to involve a problem with medication formulation or other aspects of medication quality, the information is given to the provider pharmacy for investigation of the incident and report to the medication quality reporting program, using the FDA MedWatch voluntary report form, if appropriate.

9. Medication Error and Adverse Drug Reaction Reports are reviewed by the Pharmaceutical Services Committee and acted upon as appropriate.

10. Adverse drug reactions and medication errors identified by the consultant pharmacist during medication regimen review are reported to director of nursing. This may be included in the consultant pharmacist's monthly and/or quarterly reports.

11. Consultant pharmacist/nurse/technician monitor for medication dating as part of the quality assurance (QA) check of medication carts and rooms, as administration of expired medications is also considered a medication error. (Note: This is a random QA check, not a three-way complete audit of medication storage areas.)

12. Medication error and adverse drug reaction statistics are reviewed by the consultant pharmacist as a part of the nursing care center's Continuous Quality Improvement (CQI) program, working with the nursing care center and provider pharmacy to investigate medication incidents and determine mechanisms for process improvement. Recommend items be addressed at the CQI meetings may include:

    a. Review reports of suspected ADRs for trends or causative processes.

    b. Recommend improvements in the process to prevent or reduce ADRs in the future.

    c. Assess effectiveness of improvements.

    d. Continually review processes (from internal and external sources) to reduce and/or detect potential ADRs.

6.3 INVESTIGATIONAL MEDICATIONS

POLICY

A medication designated an "investigational new drug" by the Food and Drug Administration (FDA) is given to residents only when the use of the medication is in compliance with FDA rules and regulations, and when the nursing care center determines the medication may be safely and correctly administered by nursing care center personnel.

PROCEDURES

1. If use of the medication involves a research study, approval is obtained from the nursing care center's Institutional Review Board (IRB) or the Pharmaceutical Services Committee. All medication-related studies use a scientifically sound methodology that is appropriate to the study design and hypothesis. Such studies are conducted with full consideration of each subject's best interests.

2. If an investigational medication is prescribed for treatment use, the prescriber obtains FDA approval for such use, and all pertinent FDA guidelines for treatment use are followed.

3. The protocol for medication ordering, administration and monitoring of the investigational medication within the nursing care center is developed by the Pharmaceutical Services Committee, Patient Care Policy, or other authorized nursing care center committee.

4. Complete information regarding the treatment purpose, special handling requirements, and potential adverse effects is provided to the nursing care center and nursing personnel by the principal investigator or other agent involved in the study protocol.

5. If the provider pharmacy is to dispense the investigational medication, the dispensing pharmacy meets the following requirements for safely dispensing the investigational medication:

    a. It is able to procure the investigational medication.

    b. It is able to maintain the necessary supply of the investigational medication.

    c. It is able to implement any special handling needs in the dispensing and storing of the investigational medication.

    d. It has a copy of the protocol for monitoring the medication's effects.

6. Prior to administration, the following information is placed in the resident's medical record:

    a. An order from a physician licensed in the state, specifying the dose, directions for use, and duration of therapy. (The physician may be the listed investigator or an attending physician acting on behalf of the investigator.)

    b. A copy of a fully executed informed consent form.

    c. Information on the purpose of the treatment and known or potential adverse effects. This is left in the medical record for the duration of therapy with the investigational medication.

7. An informed consent form prepared by the investigator may be used if it is written in non-technical language the resident can understand. For non-English-speaking residents, the consent form must be written in the person's native language or adequately interpreted to them. The informed consent document may not waive or appear to waive the resident's legal rights or relieve the investigator of liability. An informed consent procedure includes documentation of the provision of the following information to the resident:

    a. A description of discomforts and risks associated with use of the investigational medication, and alternatives to it.

    b. Information about any medications required to be used in conjunction with the investigational medication.

    c. Expected benefits from the use of the investigational medication.

    d. The potential benefits, risks and alternatives to medications used with the investigational medication.

    e. The likelihood of success.

    f. The possible results of non-treatment.

    g. An offer by the investigator to answer the resident's questions about the study or the investigational treatment.

    h. A statement affirming the resident's right to withdraw from participation without jeopardizing future services or treatment.

i. A statement assuring confidentiality of any information that might identify the resident.

j. The identity and professional status of individuals responsible for authorizing and performing treatments.

k. Any professional relationship of the investigator to another health care provider or institution that might suggest a conflict of interest.

l. The relationship of the investigator to educational institutions involved in the resident's care and services.

m. Any business relationship among individuals providing the investigational medication.

8. If an individual receiving an investigational new medication applies for admission to the nursing care center, the nursing care center's IRB or Pharmaceutical Services Committee determines prior to admission whether the above conditions can be satisfied, including but not limited to:

   a. Obtaining a copy of the informed consent signed by the resident or responsible party.

   b. Obtaining a copy of the investigational medication protocol.

   c. Ensuring that the study medication is provided to the resident without interruption.

9. If stated conditions cannot be met, the resident and/or responsible party is informed. If the resident and/or responsible party due to failure to satisfy the above conditions terminates participation in the study, this is documented in the individual's admission record.

10. The investigator and the resident's attending physician are informed if the resident or responsible party withdraws consent to continue participation in the investigational medication research.

11. Investigational medications are labeled, stored, documented and accounted for in accordance with nursing care center policies and procedures for approved medications.

12. The nursing care center establishes a mechanism for ensuring that there is always a sufficient supply of the medication available for the duration of the study.

13. The nursing care center ensures that additional costs that are not part of the resident's regular care, such as medications, laboratory tests, or procedures incurred by the resident or nursing care center as a result of study participation, are not paid by the resident.

14. Records of the receipt and disposition of the medication are retained in the nursing care center for two years or as required by state or federal regulation.

6.4 MEDICATIONS NOT COVERED BY THIRD-PARTY PAYORS

POLICY

When a non-covered (non-formulary) medication is ordered for a resident eligible for medication-related benefits under Medicare Part D, Medicaid or other third-party payor programs, the provider pharmacy attempts to have the order changed to a covered (formulary) medication or to have the medication covered under a medical necessity waiver or other procedure, as state law allows.

PROCEDURES

1. When non-covered medications are ordered, the provider pharmacy or nurse consults with the resident's prescriber to seek a change to a covered item.

2. If the prescriber elects not to change the order, the physician is asked to document medical necessity (if appropriate). The prescriber, pharmacist, nurse or responsibility party then attempts to obtain coverage following third-party payor procedures, which may include a prior authorization or step therapy process.

3. If coverage is not available, and third party rules permit, the pharmacy bills the resident or responsible party, or the nursing care center, as allowed by state law.

6.5 MEDICATIONS DISPENSED BY PHYSICIANS

POLICY

Medications dispensed by physicians are packaged in accordance with nursing care center policy and shall be labeled legibly with all information required for prescription labels by state and federal regulations. These medications will only be accepted if there is a current order and included in the resident's medication profile to maintain accuracy.

PROCEDURES

1. Medications from physician-dispensed medication containers can be administered only if packaged according to nursing care center policy and labeled with the following information per state and federal regulations:

    a. Resident's full name

    b. Date of issue

    c. Physician's name and address

    d. Medication name, strength, and quantity (unless part of manufacturer's label)

    e. Full directions for use

    f. Expiration date of medication

    g. Lot number

2. Physician-dispensed medications are stored, documented, and accounted for in accordance with nursing care center policies and procedures for medications supplied by the provider pharmacy. Refer to Section 3.7 – Medications and Medication Labeling.

6.6 MEDICATION PRODUCT PROBLEM REPORTING

POLICY

Problems with medication product formulation, packaging, and/or therapeutic effect are reported to the Food and Drug Administration (FDA), in consultation with the provider pharmacy.

PROCEDURES

1. Medications are inspected prior to administration to a resident.

2. If problems are detected with the medication (crumbled tablets, melted or broken capsules, congealed liquid, or other possible indicators of poor quality), the medication is not administered, and the provider pharmacy is contacted.

3. In consultation with the provider pharmacy, a determination is made of the likely source of the problem (such as a manufacturing problem versus incorrect handling of the medication during shipment, repackaging, or storage at the pharmacy or the nursing care center).

4. If a determination is made that a manufacturing defect is the most likely problem, a FDA MedWatch Voluntary Report Form is completed and sent to the FDA. A copy of the form is retained by the nursing care center so that the information is available in the event of a follow-up request by FDA. (Refer to Section 6.2 – Medication Error Reporting and Adverse Drug Reaction Prevention and Detection.)

5. FDA medication quality report forms filed by the nursing care center or by the provider pharmacy at the nursing care center's request are reviewed by the Pharmaceutical Services Committee and acted upon as appropriate.

6.7 MEDICATION PRODUCT RECALLS

POLICY

The dispensing pharmacy maintains a record of all medications dispensed to the nursing care center. In the event of a consumer level recall by the manufacturer or the Food and Drug Administration (FDA), the nursing care center is notified by the dispensing pharmacy of actions that need to be taken regarding the affected product.

PROCEDURES

1. The dispensing pharmacy maintains a record of all medications dispensed to the residents of the nursing care center.

2. Upon receipt of a consumer level recall notice from the manufacturer or FDA, the dispensing pharmacy contacts the nursing care center and sends notification to the director of nursing with actions that need to be taken regarding the affected medication. Instructions may include steps for the return of the affected medication product to the dispensing pharmacy, proper disposal of the medication or other procedures as appropriate for the recall.

3. The nursing care center is responsible for locating the medication product and following the instructions as directed.

4. Upon notification from the nursing care center of affected product, the dispensing pharmacy may replace the recalled medication product with a new supply, if available. In the event a replacement supply is not available, the dispensing pharmacy contacts the nursing care center with recommendations for an alternative medication.

5. If alternative medication therapy is to be implemented, the nurse obtains instructions from the prescriber, including orders to discontinue the current order and begin an alternative medication.

6. If the recall information indicates that prior use of the recalled medication product may result in adverse consequences; the resident or responsible party is provided this information by the nursing care center. The nurse documents this in the resident’s medical record, including to whom the information was given.

NOTE

Recalls are actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority.

- Class I recall (customer/patient level) is a situation in which there is a reasonable probability that the use of or exposure to this product will cause serious adverse health consequences or death.

- Class II recall (pharmacy/retail level) is a situation in which use of or exposure to such product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

- Class III recall (retail or wholesale level) is a situation in which use of or exposure to such product is not likely to cause adverse health consequences.

- Market withdrawal occurs when a product has a minor violation that would not be subject to FDA legal action. The firm removes the product from the market or corrects the violation.

- Medical device safety alert is issued in situations where a medical device may present an unreasonable risk of substantial harm. In some cases, these situations are also considered recalls.

REFERENCE

1. United States Food and Drug Administration, http://www.fda.gov/oc/po/firmrecalls/recall_defin.html

2. United States Food and Drug Administration, Recall Class definitions, www.fda.gov/Safety/Recalls/ucm165546.htm

6.8 CYTOTOXIC AGENT GUIDELINES

POLICY

To protect healthcare personnel, the residents, the family and the environment from unnecessary exposure to potentially hazardous cytotoxic substances and to provide safe disposal of these agents.

NOTE

This policy relates to cytotoxic agents not administered via injectable methods; for injectable cytotoxic agents refer to the Intravenous Therapy P&P Manual and/or specialty therapies module. Refer to manufacturer's recommendations. Please also see USP<800> guidelines on Hazardous Drug Handling in Health Care Settings for more details on specific cytotoxic agents.

DEFINITIONS

1. Hazardous agents are defined as substances that can cause injury or illness through handling and that can cause potential danger if misused. A hazardous agent can be a toxicant, corrosive, or irritant, and can be flammable or it can generate pressure through heat or decomposition. Hazardous medications are associated with, or suspected of causing adverse health effects in humans. The following characteristics are included when determining whether a medication is hazardous:

    a. Carcinogenicity

    b. Genotoxicity

    c. Organ toxicity at low doses

    d. Reproductive toxicity

    e. Teratogenicity or other developmental toxicity

    f. Structure and toxicity profiles of new medications that mimic existing medications determined hazardous by above criteria

2. Antineoplastic agents are defined as substances that inhibit or prevent the growth or development of malignant cells.

3. Cytotoxic agents are defined as substances that inhibit or prevent the function of cells. Cytotoxic medications include medications used to treat cancer and in some cases, to treat certain skin conditions (e.g., psoriasis). This term includes antineoplastic agents and immunosuppressive agents with demonstrated cytotoxic potential. If a medication is classified as cytotoxic, it is also classified as hazardous, since these medications have characteristics that meet the definitions for hazardous agents.

INFORMATION

1. Examples of medications classified as antineoplastic agents and considered to be cytotoxic include:

   - Altretamine (Hexalen®)
   - Anastrozole (Arimidex®)
   - Bicalutamide (Casodex®)
   - Busulfan (Myleran®)
   - Chlorambucil (Leukeran®)
   - Cyclophosphamide (Cytoxan®)
   - Flutamide (Eulexin®)
   - Hydroxyurea (Hydrea®)
   - Leuprolide (Lupron®)
   - Megestrol **oral tablets** (Megace®)
   - Melphalan (Alkeran®)
   - Mercaptopurine (Purinethol®)
   - Methotrexate (MTX)
   - Procarbazine (Matulane®)
   - Tamoxifen (Nolvadex®)

   NOTE: Megestrol **oral suspension** (Megace®, Megace ES®) is NOT classified as cytotoxic or hazardous according to FDA labeling. The suspension is not FDA approved to treat any types of cancer or carcinomas.

   References:
   1. Megace ES [package labeling]. Spring Valley, NY: PAR Pharmaceutical Comp, Inc; 2006 Sept.
   2. Megace suspension [package labeling]. Princeton, NJ: Bristol-Myers Squibb Co.; 2007 March.
   3. Megestrol acetate tablets USP [package labeling].Spring Valley, NY: PAR Pharmaceutical Comp, Inc; 2007 Sept.
   4. Megestrol acetate tablets USP [package labeling]. Roxane Laboratories, Inc.: Columbus, OH; 2007 February.

2. The following hazardous medications require safe handling for women of child-bearing age that may be pregnant:
   - Misoprostol (Cytotec®, Arthrotec®)

Women that are pregnant or may be pregnant should not handle these medications:

- Dutasteride (Avodart®)
- Finasteride (Proscar®)

Refer to Section 3.6 for a full list of NIOSH Hazardous Drugs.

References:

1. Proscar [package labeling]. Whitehouse Station, NJ: Merck & Co.; 2007 March.
2. Avodart [package labeling]. Research Triangle Park, NC: GlaxoSmithKline; 2008 March.
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9. Gleave M, Qian J, Andreou C, et al. The effects of the dual 5alpha-reductase inhibitor dutasteride on localized prostate cancer--results from a 4-month pre-radical prostatectomy study. Prostate. 2006 Nov 1;66(15):1674-1685.

GUIDELINES

1. Medications considered hazardous only because of teratogenic properties, should be handled following universal precautions.

2. Cytotoxic medications shall be handled in accordance with OSHA guidelines and the American Society of Health-System Pharmacists (ASHP) Standards of Practice for the safety of the nurse and others from absorption of hazardous substances.

3. Cytotoxic medications considered low risk should be handled using gloves. Masks and gowns are optional. Use enhanced precautions when medications are split or crushed.

4. All unused medication(s) should be treated as cytotoxic waste and disposed of according to nursing center procedure.

PROCEDURES

1. Receiving cytotoxic medications from the pharmacy:

    a. The pharmacy will apply a cautionary label to alert the nursing staff of the cytotoxic substance. The medications will be packaged in appropriate, safe containers. (An example of a cautionary label is "CAUTION: CYTOTOXIC SUBSTANCE".)

    b. Liquids will be placed in a ChemBLOC transport bag, or similar cytotoxic container, at the pharmacy. DO NOT DISCARD the bag. Store the medication in this bag, in the medication cart.

2. Administration and handling:

    a. Nurses handling and administering cytotoxic medication are to use a non-touch technique, wearing gloves. (Note: Latex gloves are less permeable and talc-free gloves prevent contamination of the environment.)

    b. Avoid breaking or crushing oral dosage forms of cytotoxic medications. If a tablet or capsule is found broken in the package, was dropped or refused, discard medication in cytotoxic waste container (EPA RCRA Hazardous Black Container).

        Note: Many tablets are coated to protect the medication in the inner core; therefore there is no risk of inhalation if the coating is not broken. Tablets made of compressed powder must not be crushed as this poses the risk of particles being inhaled. Capsules pose no handling risk unless they have broken or have leaked. They must not be crushed or opened to minimize the risk of inhalation.

    c. If a spoon is used for medication administration, use a disposable spoon.

    d. Special requirements regarding the administration must be followed carefully as administering the cytotoxic medication before or after food can influence the severity of gastrointestinal irritation, nausea and vomiting.

    e. If the resident vomits after administration of an oral cytotoxic medication, before absorption is complete, the emesis must be treated as cytotoxic waste. Contact the prescriber about the need for administering a replacement dose.

    f. Careful hand hygiene must be adhered to throughout the process.

3. Accidental Exposure:

    a. Remove contaminated gloves or gowns immediately and discard in a cytotoxic waste container.

    b. Wash contaminated skin with soap (not germicidal agent) and water. However, do not abrade the skin by using scrub brush.

    c. If medication splashes in the eye, flood with water or an isotonic eyewash for at least 15 minutes or per nursing care center policy.

    d. Obtain medical evaluation as soon as possible and document the incident properly per nursing care center policy.

    e. Always perform hand hygiene after removing gloves.

PRECAUTIONS

1. Localized toxicity due to accidental contact with cytotoxic medications and skin and mucous membranes may include:

    a. Dermatitis

    b. Inflammation of mucous membranes

    c. Excessive lacrimation

    d. Pigmentation

    e. Blistering

    f. Miscellaneous allergic reactions

2. Short-term systemic symptoms of cytotoxic medication inhalation or ingestion may include:

    a. Lightheadedness

    b. Dizziness

    c. Nausea

d. Alopecia

e. Coughing

f. Pruritis

g. General malaise

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6.9 MEDICAID PENDING RESIDENTS

POLICY

The provider pharmacy may provide services to Medicaid pending residents as set forth in the terms of the written agreement between the provider pharmacy and the nursing care center and subject to the policy and procedures below. For each Medicaid pending resident at the nursing care center, the nursing care center shall notify the provider pharmacy whether (i) the resident is reported by the nursing care center as Medicaid pending and the resident is concurrently eligible for benefits under a third-party payer plan, including but not limited to Medicare Part D; or (ii) the resident is concurrently ineligible for benefits under a third-party payer plan, including but not limited to Medicare Part D. Provider pharmacy may, at its discretion, not extend services to Medicaid pending residents if nursing care center is past due on any payments owed to provider pharmacy.

PROCEDURES

1. The nursing care center shall notify the provider pharmacy within five (5) days of receiving notification that a new or existing resident has applied for Medicaid. At the time of notification, the nursing care center must provide Resident Census Information and all other necessary information required by the provider pharmacy in order to bill the resident or the guarantor for products and services provided to the resident.

    a. The provider pharmacy and the nursing care center shall work cooperatively to determine if the resident has alternate coverage through a third-party payer, including but not limited to Medicare Part D.

    b. The provider pharmacy and the nursing care center shall work cooperatively to encourage the resident, or their responsible party, to enroll the resident in a third-party payer plan when such plan is available to the resident.

2. The provider pharmacy and the nursing care center shall use commercially reasonable efforts to monitor the Medicaid pending status of the resident. If either the provider pharmacy or the nursing care center determines that the resident has been approved for Medicaid, the determining party will provide prompt notice to the other party.

3. The provider pharmacy shall follow the following procedures to collect charges from the resident or the guarantor.

    a. The provider pharmacy shall bill the resident or the guarantor monthly for charges. If the resident's account is not paid in full by the statement due date, the provider pharmacy will issue a past due notice at intervals of thirty (30), sixty (60), and ninety (90) days.

b. The provider pharmacy shall provide the nursing care center a monthly report listing all Medicaid pending residents.

c. The provider pharmacy and the nursing care center shall work cooperatively to collect billable charges from the resident or the guarantor.

4. For a Medicaid pending resident having coverage through a third-party payer's plan, the provider pharmacy shall bill service charges to that payer's plan. All non-covered charges, including charges prior to when eligibility was determined, and resident cost-share amounts will be billed to the nursing care center subject to the provider pharmacy's good faith attempt to collect such charges from the resident or the guarantor in accordance with the procedures set forth in Section 3.

5. For a resident without coverage through a third-party payer's plan, the nursing care center is the payer. In such cases, if the sum of all charges does not exceed $10,000, the provider pharmacy will hold nursing care center charges for up to 120 days from the date that the resident is admitted to the nursing care center. During such period, the provider pharmacy shall bill resident charges to the resident or the guarantor in accordance with the procedures set for in Section 3.

6. If on or prior to 120 days the resident has established coverage under Medicaid or a third-party payer's plan, the provider pharmacy will bill the appropriate payer the charges for the products and services rendered from the date such payer's coverage was established. Any charges for services denied by the payer will be the responsibility of the nursing care center.

7. If after the 120 hold period the resident has not been established coverage under Medicaid or a third-party payer's plan, the nursing care center will be the responsible payer for charges for products and services thereafter provided by the provider pharmacy.

8. In all cases where (i) the nursing care center has made a payment on behalf of a Medicaid pending resident; (ii) the resident subsequently establishes coverage under Medicaid or a third-party payer plan; and (iii) the nursing care center promptly notifies the provider pharmacy of such coverage, the provider pharmacy will bill Medicaid or the third-party payer and issue a credit to the nursing care center for charges paid by the nursing care center to the extent of any proceeds collected from such third-party payers.

6.10 PRIVATE PAY RESIDENTS – SERVICES AND BILLING

POLICY

This policy establishes procedures when: (i) the resident, either directly or through a guarantor or responsible party, has payment responsibility for charges for products and services provided by the provider pharmacy; or (ii) the resident is eligible for benefits under a third-party payer plan, including but not limited to Medicare Part D, but has payment responsibility for products and services provided by the provider pharmacy that are not otherwise covered by the third-party payer; and (iii) resident payments owed to provider pharmacy are past due.

PROCEDURES

1. The provider pharmacy shall bill charges for products and services to the resident, the guarantor, or the responsible party when the resident has payment responsibility for the products and services.

2. The provider pharmacy may issue a demand for payment to the responsible party when the balance of charges for products and services is greater than or equal to $500 and more than thirty (30) days past due. The provider pharmacy shall provide the nursing care center with regular reports identifying such residents.

3. The provider pharmacy and nursing care center shall cooperate to secure payment from the resident, the guarantor, or the responsible party. Provider pharmacy shall, in good faith, attempt to collect payment from the responsible party.

4. The provider pharmacy and nursing care center shall work cooperatively to determine if the resident has alternate coverage through a third-party payer, including but not limited to Medicare Part D.

5. When the resident is eligible to enroll in the Medicare Part D program, the provider pharmacy and the nursing care center will assist the resident in making an informed selection of an appropriate Medicare Part D plan for such resident.

6. If payments for the products and services are sixty (60) days past due and provider pharmacy has not received payments sufficient to reduce the resident's balance of charges to less than or equal to $250, the provider pharmacy may terminate services to resident, subject to the procedures in Section 8.

7. If at any time the balance of charges for products and services owed by resident, guarantor, or the responsible party is greater than or equal to $1,000, the provider pharmacy may terminate services to resident, subject to the procedures in Section 8.

8. The provider pharmacy shall provide the nursing care center ten (10) days notice of its intent to terminate services to the resident.

    a. If the nursing care center elects to assume payment responsibility before the expiration of ten (10) days notice, the provider pharmacy will bill the nursing care center for products and services rendered to the resident thereafter.

    b. If the nursing care center elects not to assume payment responsibility after ten (10) days notice, the provider pharmacy may terminate services to the resident without further notice.

6.11 PATIENT PACKAGE INSERTS/MEDICATION GUIDES

POLICY

TITLE 21--FOOD AND DRUGS, CHAPTER I--FOOD AND DRUG ADMINISTRATION, SUBCHAPTER C--DRUGS: GENERAL, PART 208: MEDICATION GUIDES FOR PRESCRIPTION DRUG PRODUCTS, Subpart A--General Provisions, Section 208.1 states: "It (*the Medication Guide requirement)* applies primarily to human prescription drug products used on an outpatient basis without direct supervision by a health professional."

The information in a patient package insert (PPI) or Medication Guide explains the benefits and risks associated with use of a medication or medication class. Residents receiving medications, for which Medication Guides are available, have access to these documents upon request.

PROCEDURES

1. PPIs and Medication Guides may be obtained from the dispensing pharmacy upon request by a resident.

2. If no PPI or Medication Guide is available, the information may be obtained from the FDA web site, the Nursing Drug Handbook, or other reference.

Medication Administration

7.0 MEDICATION ADMINISTRATION

Table of Contents

7.1 GENERAL GUIDELINES

POLICY

Medications are administered as prescribed in accordance with manufacturers' specifications, good nursing principles and practices and only by persons legally authorized to do so. Personnel authorized to administer medications do so only after they have familiarized themselves with the medication.

PROCEDURES

Medication Preparation:

1. Medications are prepared only by licensed nursing, medical, pharmacy or other personnel authorized by state regulations to prepare medications.

2. An adequate supply of disposable containers (such as soufflé cups, drinking cups and calibrated medication cups) are maintained on the medication cart for the administration of medications. Disposable containers are never reused.

3. Prior to administration, review and confirm medication orders for each individual resident on the Medication Administration Record. Compare the medication and dosage schedule on the resident's MAR with the medication label. If the label and MAR are different, and the container is not flagged indicating a change in directions, or if there is any other reason to question the dosage or directions, the prescriber's orders are checked for the correct dosage schedule. May apply a "direction change" sticker to label if directions have changed from the current label.

4. Since unscored tablets may not be accurately broken, their use is discouraged if a suitable alternative is available (such as liquid or half-strength tablet). Refer to Section 9.9 – Tablet Splitting Guidance for Patient Safety for further information as to why tablet splitting should be avoided. When necessary, the provider pharmacy is requested to package partial tablets/equivalent doses.

   If breaking tablets is necessary to administer the proper dose, hand hygiene is performed per facility protocol and gloves applied prior to handling tablets and the following guidelines are followed:

   a. The administration of partial tablets is clearly identified or highlighted on the resident's MAR.

   b. A tablet-splitter may be used to avoid hand contact with the tablet. Alternatively, gloves may be used by the nurse splitting the tablet.

c. If the tablet is scored, every attempt is made to break along score lines.

d. Unused tablet portions are disposed of per nursing care center procedure for waste.

5. If it is safe to do so, medication tablets may be crushed or capsules emptied out when a resident has difficulty swallowing or is tube-fed, using the following guidelines.

   a. The need for crushing medications is indicated on the resident's orders and the MAR so that all personnel administering medications are aware of this need and the consultant pharmacist can advise on safety and alternatives, if appropriate, during Medication Regimen Reviews.

   b. Long-acting, extended release or enteric-coated dosage forms should generally not be crushed; an alternative should be sought.

   c. Each medication preparation area includes a device that is specifically used for crushing medications.

   d. Medications are crushed between two soufflé cups, plastic bag/pouch, or appropriate method, to prevent contact between the medication and the crushing device.

   e. Medications which can be appropriately crushed may be ground coarsely and mixed with the appropriate vehicle (such as applesauce) so that the resident receives the entire dose ordered. Check dating of the mixing vehicle.

   f. If the resident is tube-fed, medications are crushed finely to prevent clogging the tube. Check for specific prescriber order to crush medications if required by state regulations. Crush medications if indicated for this resident only after referring to the Medications Not To Be Crushed List. Crush in tablet crusher, or with other appropriate device and clean immediately after use. For products that appear on the Medications Not To Be Crushed List, check with pharmacist regarding a suitable alternative, and request a new order from the prescriber if appropriate.

6. Liquid dosage forms may be a practical alternative in place of solid tablets, especially if tablets have a coating and will not crush finely. The nurse checks with the provider pharmacy to determine if a liquid form is available and covered by the applicable payment program. (The prescriber is contacted for a new order before changing the dosage form.)

7. When administering potent medications in liquid form or those requiring precise measurement, such as phenytoin, devices provided by the manufacturer or obtained from a supplier, (e.g., oral syringes) are used to allow accurate measurement of doses.

8. For suspensions and thick liquids that may coat calibrated measuring cups, use water to rinse medication residue and administer to the resident to ensure entire dose is given.

9. For preparation of infusion therapy products refer to Intravenous Therapy P&P Manual.

Medication Administration:

1. Medications are administered in accordance with written orders of the prescriber. If a dose seems excessive considering the resident's age and condition, or a medication order seems to be unrelated to the resident's current diagnosis or condition, the nurse calls the provider pharmacy for clarification prior to the administration of the medication. If necessary, the nurse contacts the prescriber for clarification. This interaction with the pharmacy and the resulting order clarification are documented in the nursing notes and elsewhere in the medical record as appropriate.

2. Obtain and record any vital signs as necessary prior to medication administration.

3. The timing of medication administration must align with manufacturer specifications.

4. Medications are to be administered at the time they are prepared.

5. The person who prepares the dose for administration is the person who administers the dose.

6. Provide for privacy as appropriate.

7. Note any allergies or contraindications the resident may have prior to medication administration.

8. Check expiration date on package/container. No expired medication will be administered to a resident.
    a. Drugs dispensed in the manufacturer's original container will be labeled with the manufacturer's expiration date.
    b. If the medication has a shortened expiration date, follow manufacturer's guidelines for labeling .
    c. Certain products or package types such as multi-dose vials and ophthalmic drops have specified shortened end-of-use dating, once opened, to ensure medication purity and potency (Refer to Section 9.7 – Abridged List of Medications With Shortened Expiration Dates). When date open expiration dating is not available from the manufacturer, the following may be considered in determining facility policy:
        - Injectable Multi-dose vials: 28 days after open date or per manufacturer's guidelines
        - Ophthalmic preparations (solutions, suspensions, ointments): discard per manufacturer's guidelines or may implement a facility specific policy for shortened expiration dates (See customizable form in 12.5 in Optional P/P Templates)
    d. The beyond use dating, which only lists month/year, falls to the last day of that month.

9. Verify medication is correct three (3) times before administering the medication.
   a. When pulling medication package from med cart
   b. When dose is prepared
   c. Before dose is administered

10. Residents are identified before medication is administered using at least two resident identifiers. Methods of identification may include:
    a. Check identification band
    b. Check photograph attached to medical record
    c. Verify resident identification with other nursing care center personnel

    Note: the resident's room number or physical location is not used as an identifier.

11. Hands are washed with soap and water and gloves applied before administration of topical, ophthalmic, otic, parenteral, enteral, rectal, and vaginal medications. Hands are washed with soap and water again after administration and with any resident contact. Antimicrobial sanitizer may be used in place of soap and water as allowed per state nursing regulations and facility policy. Note: Soap and water should always be used after contact with resident with Clostridium difficile ("c. diff") as antimicrobial sanitizer does not kill the spores produced by c. diff, which may result in the spread of the infection.

12. An adequate amount of water or other acceptable liquid should be given with oral medications unless a different amount is specified due to fluid restrictions or product manufacturer requirements.

13. Explain to resident the type of medication being administered and the procedure.

14. Unless otherwise specified by the prescriber, routine medications are administered according to the established medication administration schedule for the nursing care center. Medications should not be given at mealtimes or in the dining room unless specifically ordered with meal.

15. Residents are allowed to self-administer medications when specifically authorized by the prescriber, the nursing care center's Interdisciplinary Team (IDT), and in accordance with procedures for self-administration of medications and state regulations. (Refer to Section 7.3 – Self-Administration By Resident)

16. Medications supplied for one resident are never administered to another resident.

17. During administration of medications, the medication cart is kept closed and locked when out of sight of the medication nurse. No medications are kept on top of the cart. The cart must be clearly visible to the personnel administering medications when unlocked.

18. Resident's health information needs to remain private. Medication Administration Records containing resident health information must not be visible when not in direct use (Paper MAR closed, Electronic Health Record information hidden)

19. For residents not in their rooms or otherwise unavailable to receive medication on the pass, the MAR is "flagged" (e.g., electronic alerts, notes, or flags). After completing the medication pass, the nurse returns to the missed resident to administer the medication.

20. The resident is always observed after administration to ensure that the dose was completely ingested. If only a partial dose is ingested, this is noted on the MAR, and action is taken as appropriate.

Documentation:

1. The individual who administers the medication dose, records the administration on the resident's MAR immediately following the medication being given. In no case should the individual who administered the medications report off-duty without first recording the administration of any medications.

2. If a dose of regularly scheduled medication is withheld, refused, or given at other than the scheduled time (for example, the resident is not in the nursing care center at scheduled dose time, or an initial dose of antibiotic is needed), the nurse shall document either in the Electronic Medication Administration Record or the paper MAR that the dose was withheld, refused, or given at other than scheduled time, and enter an explanatory note (reverse side of paper MAR or in the designated area of the Electronic Health Record.

3. Current medications, except topicals used for treatments, are listed on the resident's medication administration record (MAR). Topical medications used in treatments are listed on the treatment administration record (TAR), unless a combined MAR/TAR is utilized by the nursing care center.

4. The administration of the resident's medication is documented by one the following processes:
    - Documentation of medication administration in the Electronic Health Record
    - Documentation of medication administration in MAR by person administering the medication (initialing in the space provided, under the date, and on the line for the specific medication dose administration and time).

    Initials on each MAR/TAR are verified with a full signature in the space provided or on the nursing care center's master employee signature log.

5. When PRN medications are administered, the following documentation is provided:
   a. Date and time of administration, dose, route of administration (if other than oral), and, if applicable, the injection site.
   b. Complaints or symptoms for which the medication was given.
   c. Results achieved from giving the dose and the time results were noted.
   d. Signature or initials of person recording administration and signature or initials of person recording effects.

6. Once removed from the package/container, unused medication doses shall be disposed of according to the nursing care center policy. (Refer to Section 5.5 – Disposal of Medications)

7. Observe resident for medication actions/reactions and record in the nurse's notes as appropriate. Any noted adverse consequence should be reported to the prescriber and/or attending physician.

7.2 PREPARATION FOR MEDICATION ADMINISTRATION

POLICY

The nursing care center maintains equipment and supplies necessary for the storage, preparation and administration of medications to residents.

PROCEDURES

1. The following equipment and supplies are acquired and maintained by the nursing care center for the proper storage, preparation, and administration of medications:

    a. Lockable medication carts, medication cabinets, drawers, or rooms with well-lit dose preparation areas.

    b. A refrigerator with a thermometer.

    c. Counter space for medication preparation with access to a convenient water source.

    d. Oral syringes, parenteral syringes, needles, droppers, soufflé cups, water pitchers, and calibrated glass or plastic medication cups, drinking cups, spoons, straws, and antimicrobial or hand sanitizer.

    e. A device for crushing tablets.

    f. Sharps container readily accessible on or near the medication cart.

2. The nurse or authorized staff member on duty ensures equipment and supplies relating to medication storage and use are clean and orderly.

3. The nurse or authorized staff member is notified if supplies are inadequate or equipment fails to work properly. The nurse reports equipment and supply deficiencies to the director of nursing.

4. If carts are furnished by the provider pharmacy, the pharmacy promptly repairs or replaces nonfunctional carts. If carts belong to the nursing care center, the cart manufacturer or distributor is notified if a problem with a medication cart occurs for prompt repair or replacement.

7.3 SELF-ADMINISTRATION BY RESIDENT

POLICY

Residents who desire to self-administer medications are permitted to do so with a prescriber's order and if the nursing care center's interdisciplinary team has determined that the practice would be safe and the medications are appropriate and safe for self-administration. Facilities must adhere to state specific laws and regulations.

PROCEDURES

1. If the resident desires to self-administer medications, an assessment is conducted by the interdisciplinary team of the resident's cognitive, physical, and visual ability to carry out this responsibility, during the care planning process.

2. The interdisciplinary team determines the resident's ability to self-administer medications by means of a skill assessment conducted as part of the care plan process.

3. The results of the interdisciplinary team assessment are recorded on the Medication Self-Administration Assessment, which is placed in the resident's medical record.

4. If the resident demonstrates the ability to safely self-administer medications, a further assessment of the safety of bedside medication storage is conducted. (Refer to Section 4.3 – Bedside Medication Storage)

5. The resident is instructed in the proper cleaning of inhalers where applicable, proper storage and the necessity of reporting each medication dose used to the nursing staff. The completion of this instruction is documented in the resident's medical record. The nursing staff, as deemed necessary, undertakes periodic review of these instructions with the resident.

6. At least once during each shift, the nursing staff checks for usage of the medications by the resident, with the exception that the resident is not awakened to obtain this information. If the resident remains asleep at the end of the shift, the incoming shift nurse is informed that this information was not obtained so that the resident may be questioned upon arising.

7. If the interdisciplinary team determines that bedside or in-room storage of medications would be a potential safety risk to other residents, the medications of residents permitted to self-administer are stored in the central medication cart or medication room. The medication nurse will provide the medication to the resident in the unopened package, when appropriate, for the resident to self-administer. The nurse then records such self-administration on the MAR in the manner described above.

7.4 CONTROLLED SUBSTANCES

POLICY

"Controlled Medications" are substances that have an accepted medical use (medications which fall under U.S. Drug Enforcement Agency (DEA) Schedules II-V), have a potential for abuse, ranging from low to high, and may also lead to physical or psychological dependence. These medications are subject to special handling, storage, disposal, and record keeping at the nursing care center, in accordance with federal and state laws and regulations.

PROCEDURES

1. Refer to Section 7.1 Medication Administration – General Guidelines.

2. The Director of Nursing and the Consultant Pharmacist establish a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation, and determine that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.

3. Controlled medications are obtained from the locked cabinet or safe, or medication cart.

4. When a controlled medication is administered, the licensed nurse administering the medication immediately enters the following information on the accountability record when removing dose from controlled storage: (Note: Refer to state regulations for particulars regarding Scheduled Classes and proper storage.)

    a. Date and time of administration

    b. Amount administered

    c. Signature of the nurse administering the dose

    Note: Liquid controlled substance medications dispensed in original bottles from the manufacturer are generally dispensed in multi-dose containers which may be opaque to protect contents from light and may not allow exact volume tracking. Additionally, FDA-approved labeling for some medications requires them to be dispensed in the manufacturer's original containers.

    The actual volume may slightly vary from the stated amount due to container shape, material, and medication formulation.

When a controlled medication is administered, the licensed nurse administering the medication immediately enters the following information on the accountability record when removing dose from controlled storage: (Note: Refer to state regulations for particulars regarding Scheduled Classes and proper storage.)

a. Record starting volume from the label

b. Log each administered dose

c. Subtract dose from previous volume to calculate remaining amount

d. Report any discrepancies between recorded and observed volume per facility policy

5. Administer the controlled medication and document dose administration on the MAR.

6. When a dose of a controlled medication is removed from the container for administration but refused by the resident or not given for any reason, it is not placed back in the container. It must be destroyed according to policy and the disposal documented on the accountability record on the line representing that dose. The same process applies to the disposal of unused partial tablets and unused portions of single dose ampules.

7. At each shift change, a physical inventory of controlled medications, as defined by state/federal regulations, is conducted and is documented on an audit record.

8. Current controlled medication accountability records and audit records are kept by the nursing care center. When completed, audit and accountability records are kept on file according to state and federal regulations.

9. Any discrepancy in a controlled substance medication count is reported to the director of nursing immediately (the pharmacy must be notified immediately of any e-kit discrepancy). The DON investigates the discrepancy and researches all the records related to medication administration and the supply of the medication, including medication reconciliation. Medication reconciliation is made from the last known date and time of reconciliation (e.g., during the last shift count, receipt of a full medication container, etc.). A thorough search in all drug storage areas, the resident's room and other locations where medications may have been used/placed during the medication administration are made to locate any missing container or medication supply.

   If a loss of a supply of a medication is found, the DON investigates the suspected loss and researches all the records related to medication receipt, its use since receipt, all persons involved with medication administration and the supply of the medication, and identifies the last known point in time that the medication was available. The dispensing pharmacy should be notified and the pharmacy should verify that the medication was

actually dispensed. A thorough search in all drug storage areas, the resident's room and other locations where medications may have been used/placed during the medication administration are made to locate any missing container or medication supply.

1) After a thorough investigation has been completed and the supply cannot be found, a supply must be obtained for the resident.
2) Document the loss and the investigation process. Notify the prescriber and family if doses have been missed.
3) *If diversion is discovered and substantiated, timely notifications must be made to appropriate agencies, such as local law enforcement, Drug Enforcement Administration, State Board of Nursing, State Board of Pharmacy, the state Medicaid Fraud Control Unit, and possibly the State Licensure Board for Nursing Home Administrators.*

10. The director of nursing documents irreconcilable discrepancies in a report to the administrator. If a major discrepancy or a pattern of discrepancies occurs or if there is apparent criminal activity, the director of nursing notifies the administrator, the consultant pharmacist and the pharmacy manager. A determination will be made by the administrator, the pharmacy manager, and the director of nursing concerning other actions to be taken (e.g., notification of police or other enforcement agency).
11. Controlled medications should be surrendered only to a resident on pass or therapeutic leave or discharge, if appropriate, or to the DEA or other law enforcement officials functioning in a professional capacity. A documentation receipt should be obtained from the enforcement agent receiving the medications. Documentation in the medical record should include:

    a. Resident's name

    b. Medication name, strength and dosage form

    c. Date of medication release

    d. Quantity released

    e. Nurse releasing (medication) signature

    f. Party receiving (medication) signature

12. Controlled Substances remaining in the nursing care center after the order has been discontinued are retained in the nursing care center in a securely double locked area with restricted access until destroyed, as outlined by state regulation.

7.5 ORALS

POLICY

To administer oral medications in an organized, accurate and safe manner.

EQUIPMENT

- Medication cart with medications
- Refrigerated medications if applicable
- Calibrated medication cups or measuring syringe for liquid medications if applicable
- Drinking cup
- Crushing device: tablet crusher/tablet splitter
- Pitcher of water/juice
- Applesauce or other flavored semi-solid vehicle in a closed, dated container
- Spoons/straws
- Controlled substances records (if appropriate)
- Antimicrobial agent for hand hygiene

PROCEDURES

1. Refer to Section 7.1 Medication Administration – General Guidelines.

2. Refer to medication reference source for administration of any medication when added to any substance (e.g., applesauce, juice, milk).

3. Bring medication cart in the vicinity of the resident's room or location.

4. Unlock medication cart. Cart may remain unlocked only when in direct line of sight and control by the nurse or medication aide who is administering medications.

5. Review and confirm medication orders for each individual resident on the Medication Administration Record PRIOR to administering medication.

6. Perform hand hygiene.

7. Pour the correct number of tablets or capsules into the medication cup, taking care to avoid touching any of the medication unless wearing gloves.

8. If medication is liquid, pour correct amount directly into a graduated medication cup or measuring device provided with liquid. Discard excess or over pour in an appropriate manner. Do not pour medication back into the original container.

a. Shake well if needed prior to pouring.

b. Pour liquid medication on the opposite side of the container from the label, pour at eye level and check on a level surface.

c. Wipe rim and sides of bottle with tissue if needed due to spillage, and replace cap after pouring.

d. Liquid medications may be diluted in any fluid indicated by the prescriber's order. Liquid potassium supplements, bulk laxatives, and liquid stool softener may be diluted in juice at nurse's discretion.

e. For suspensions and thick liquids that may coat measuring cups, use water to rinse medication residue and administer to the resident to ensure entire dose is given.

9. Check for specific prescriber order to crush medications if required by state regulations. Crush medications if indicated for this resident only after referring to the Medications Not To Be Crushed List. Crush in tablet crusher, or with other appropriate device and clean immediately after use. For products that appear on the Medications Not To Be Crushed List, check with pharmacist regarding a suitable alternative, and request a new prescriber order if appropriate. Mix crushed medications in small amount of appropriate substance such as applesauce.

10. Administer medication and remain with resident while medication is swallowed. Do not leave a medication in a resident's room without orders to do so along with documentation of "self-administration". Use caution with residents who have difficulty with swallowing.

11. If resident is in bed, head of bed should be elevated to greater than 45 degrees prior to administration of medication and the elevation continued until the medication has likely reached the stomach.

12. Follow all medication with 4 to 8 ounces (120-240 mL) of water unless otherwise ordered, or specified by manufacturer.

13. Medications that require specific instructions for administration are administered in a way that complies with manufacturer's recommendations (e.g., Actonel®, Boniva®, Fosamax®).

14. Chart medication administration on Medication Administration Record immediately following each resident's medication administration.

7.6 HERBAL AND HOMEOPATHIC PRODUCTS

POLICY

To administer herbal and homeopathic products as ordered in a safe manner.

GUIDELINES

1. Refer to Section 7.1 Medication Administration – General Guidelines.

2. Herbal and homeopathic products are not officially or legally recognized as medications but are used with the expectation of therapeutic benefit. These products are considered "alternative therapy". Residents who desire to use these products are permitted to do so with an order from the prescriber.

3. Alternative therapy products not available from the provider pharmacy may be supplied by the resident or the resident's responsible party. In the event that the alternative therapy product cannot be administered due to a lack of availability, the nurse will document as such and notify the responsible party.

4. All alternative therapy products and their doses are confirmed with the prescriber to assure that there is no conflict with other therapies.

5. Residents who desire to self-administer alternative therapy products may do so under the Self-Administration Guidelines. Refer to Section 4.3 – Bedside Medication Storage and Section 7.3 – Self-Administration by Resident.

6. Alternative therapy products are administered and documented in the same method as medications.

7. This guideline does not in any way confer medication status to any alternative therapy product, regardless of intent or belief of the attending physician, the resident or any other person.

8. The resident or responsible party will sign an acknowledgement of this guideline, which will then be placed in the medical record.

7.7 ORAL INHALATIONS

POLICY

To allow for safe, accurate, and effective administration of medication using an oral inhaler (with or without a space/chamber).

EQUIPMENT

- Prescribed inhaler device
- Holding chamber or spacer device if ordered (Note: Holding chamber or spacer device is recommended to be used with most inhalers to facilitate proper dosing; however requires a resident-specific order.)
- Cup of water for rinsing mouth after steroid medication
- Antimicrobial agent for hand hygiene

PROCEDURES

1. Refer to Section 7.1 Medication Administration – General Guidelines.
2. Provide for privacy.
3. Determine that an adequate amount of medication is remaining in the aerosol canister. Check counter if available and beyond use expiration date.
4. Examine holding chamber or spacer device and remove any foreign objects.
5. Remove inhaler mouthpiece cap (and spacer cap). If not connected, place cap(s) upright on barrier surface.
6. Hold inhaler upright and shake well. Dry-powder inhalers are usually held in a horizontal position and are not shaken.
7. If necessary, prime inhaler.* Dry-powder inhalers require placement of the medication-containing capsule into the device.
8. If using a spacer, insert the mouthpiece on the inhaler into the flexible rubber end of the spacer.
9. Ask resident to breathe out (do not exhale into inhaler).

10. Position inhaler for administration:

    a. If not using a spacer:

    - Open mouth and position the inhaler one or two inches from mouth, OR
    - Place inhaler mouthpiece under top teeth and above tongue with mouth/lips closed around the mouthpiece.

    b. If using a spacer, place spacer in resident's mouth with mouth/lips closed around spacer mouthpiece.

11. Press down on inhaler once to release medication as resident starts to breathe in slowly through the mouth over 3 to 5 seconds. (Do not spray more than one puff at a time.) With dry-powder inhalers, the dose is activated by pushing or twisting the lever/device. Also, breathing in quickly and deeply through the mouth usually yields the best results with dry-powder inhalers.

12. Hold breath for 5-10 seconds or as long as possible to allow medication to reach deeply into lungs.

13. Slowly exhale.

14. If another puff of the same or different medication is required, follow the manufacturer's product information for administration instructions including the acceptable wait time between inhalations.

15. For steroid inhalers, provide resident with cup of water and instruct him/her to rinse mouth and spit water back into cup.

16. For dry-powder inhalers, close device according to manufacturer recommendations to ensure next dose will be ready. If capsule was manually inserted, remove the empty capsule after administration.

17. If necessary (according to package insert or other reference), wash and thoroughly dry mouthpiece. If using a spacer, wash spacer according to manufacturer's recommendations.

18. Remove and dispose of gloves, if worn. Discard any barrier used for carrying or storing the medication and supplies. Wash hands using antimicrobial soap and water or facility-approved sanitizer.

19. Store inhaler with cap on.

20. Return medication container to medication cart for storage per manufacturer's guidelines. (Refer to Section 4.1 – Storage of Medication)

* Priming of Metered Dose Inhalers (see manufacturer package insert or other reference to determine when and how each inhaler should be primed)

1. Hold the inhaler in an upright position away from the face and eyes
2. Spray the test sprays into the air to ensure medication is coming out and the device is working
3. This process should occur:
    a. Before initial use
    b. If the inhaler has not been used for several days
    c. If the inhaler has been dropped

INHALER SEQUENCING

Note: Spacing and proper sequence of the different inhalers is important for maximum drug effectiveness. If more than one inhaler is used, following the sequence below provides the most benefit to the resident. Check manufacturer's guidelines for more specific information.

1. Bronchodilators/Beta Agonists – administer first if more than one inhaler to be administered at the same med pass time
    a. These agents work by promoting bronchodilation which relaxes bronchial smooth muscle.
    b. Examples include: albuterol/Ventolin®, Proventil®; aformoterol/Brovana®, levalbuterol/Xopenex®, metaproterenol/Alupent®; pirbutero/Maxair®; bitolterol/Tornalate®.
2. Anticholinergic Agents
    a. Antagonizes the action of acetylcholine with resulting bronchodilation
    b. Minimal systemic activity
    c. Used for maintenance therapy only, not acute episodes
    d. May be more useful than traditional bronchodilators in chronic bronchitis

e. Examples include: ipratropium/Atrovent®, tiotropium/Spiriva®, umeclidinium+vilanterol /Anoro® Ellipta

3. Miscellaneous Agents

   a. Stabilizes mast cells and inhibits the release of histamine from these cells

   b. Must be used on a regular basis, not useful on a PRN basis

   c. May be used prophylactically prior to exercise

   d. Examples include: cromolyn/Intal®, nedocromil/Tilade®

4. Corticosteroids – administer last if more than one inhaler to be administered at the same med pass time

   a. Anti-inflammatory agents that may have a variety of actions useful in management of COPD

   b. Must be used on a regular basis, not PRN agents

   c. Minimal systemic activity

   d. Examples include: beclomethasone/Beclovent®/Vanceril®/Qvar®; triamcinolone/Azmacort®; flunisolide/AeroBid®; dexamethasone/Decadron®; fluticasone/Flovent®; fluticasone+salmeterol/Advair®,fluticasone+vilanterol/Breo® Ellipta

7.8 NEBULIZERS (UPDRAFT)

POLICY

To allow for safe, accurate, and effective administration of medication using a small volume nebulizer.

EQUIPMENT

- Nebulizer (updraft) device
- Medication
- Antimicrobial agent for hand hygiene

PROCEDURES

1. Refer to Section 7.1 Medication Administration – General Guidelines.
2. Assemble equipment and supplies on the resident's overbed table, with a barrier between supplies/medication and table.
3. Perform hand hygiene.
4. Position resident in semi-fowler's position.
5. Obtain baseline pulse, respiratory rate and lung sounds.
6. Draw up the medication to be nebulized if the medication is not in a unit-dose container.
7. Pour medication into a clean nebulizer cup.
8. Add the diluent, if ordered or required by the manufacturer (see package insert).
9. Assemble nebulizer equipment and attach to nebulizer compressor or gas source per manufacturer's instructions. Adjust the flow rate as ordered or per facility protocol.
10. Turn on the nebulizer and check the outflow port for visible mist.
11. Ask the resident to hold the mouthpiece gently between his/her lips (or apply face mask).
12. Instruct the resident to take a deep breath, pause briefly and then exhale normally. Repeat pattern throughout treatment.

13. Remain with the resident for the treatment unless the resident has been assessed and authorized to self-administer.

14. Monitor for medication side effects, including rapid pulse, restlessness and nervousness.

15. Stop the treatment and notify the physician if the pulse increases 20 percent above baseline or if the resident complains of nausea or vomits.

16. Tap the nebulizer cup occasionally to ensure release of droplets from the sides of the cup.

17. Encourage the resident to cough and expectorate as needed.

18. Administer therapy until medication is gone (mist has stopped) or until the designated time of treatment has been reached.

19. When treatment is complete, turn off nebulizer and disconnect T-piece, mouthpiece and medication cup.

20. Obtain post-treatment pulse, respiratory rate and lung sounds and document findings on the MAR or in the resident's medical record following facility policy.

21. Rinse and disinfect the nebulizer equipment according to manufacturer's recommendations and facility policy.

22. Wash hands thoroughly.

23. When equipment is completely dry, store in a plastic bag with the resident's name and the date on it.

24. Change equipment and tubing per nursing facility policy.

25. Disinfect outside of the compressor between residents, according to manufacturer's instructions and facility policy.

7.9 SUBLINGUALS AND BUCCALS

POLICY

To administer sublingual medications under the resident's tongue safely and accurately. To administer buccal medications in the resident's cheek safely and accurately.

EQUIPMENT

- Medication administration cup
- Medication
- Antimicrobial agent for hand hygiene

PROCEDURES

1. Refer to Section 7.1 Medication Administration – General Guidelines.

2. Perform hand hygiene.

3. Pour proper number of sublingual/buccal tablets/capsules into medication cup.

4. Explain procedure for the type of medication to be administered to the resident.

5. Have resident take a sip of water to moisten mouth, and instruct resident to swallow water.

6. Place medication in the resident's mouth or help resident to do so if capable, following the directions:

    a. Place buccal tablet in the pouch between cheek and upper or lower gum.

    b. Place sublingual tablet under the tongue. Do not touch medication. If necessary, use gloves to assist administration.

7. Instruct resident to close mouth and to not swallow or chew until the tablet has completely dissolved. Eating, drinking, and smoking should be avoided while the tablet is dissolving.

8. Instruct the resident to avoid rinsing the mouth for several minutes after the tablet has dissolved.

9. Perform hand hygiene.

7.10 ENTERAL TUBES

POLICY

The nursing care center assures the safe and effective administration of enteral formulas and medications. Selection of enteral formulas, routes and methods of administration, and the decision to administer medications via enteral tubes are based on nursing assessment of the resident's condition, in consultation with the physician, dietitian and pharmacist.

GUIDELINES

1. Refer to Section 7.1 Medication Administration – General Guidelines.
2. The physician's order must specify the route of administration of any medication via feeding tube. This should be stated in the directions at a minimum as "per tube" or "via tube", but certainly the type of tube may be specified (e.g. per PEG tube, per J-tube, per NG tube, etc.).
3. Enteral formulas, equipment, route of administration, and rate of flow are selected based on an assessment of the resident's condition and need.
4. Interactions between medications and feeding formulas, and interactions of multiple medications, are considered before administering medications through the enteral tube. If necessary, information is obtained from the provider pharmacy or consultant pharmacist.
5. In-service training on safety, administration, and monitoring of enteral solutions and medications via the enteral tube is provided by the nursing care center to nursing personnel.
6. The manufacturer's written recommendations regarding suggested time period for hanging of the product are consulted when determining the schedule for enteral feeding administration.
7. When new medication orders are received from the prescriber, the intended route of administration is also obtained. The provider pharmacy is informed that the resident is receiving medications through the enteral tube. Medications for enteral administration are obtained in easily pulverized or liquid form. The provider pharmacy is consulted to determine the best method for preparing dosage forms for enteral tube administration when liquid formulations are not available.
8. Check for specific prescriber order to crush medications if required by state regulations. Crush medications if indicated for resident only after referring to the Medications Not To Be Crushed List. Crush in tablet crusher or with other appropriate device and clean immediately after use. For products that appear on the

Medications Not To Be Crushed List, check with pharmacist regarding a suitable alternative, and request a new prescriber order if appropriate. (See Section 9.6 – Medications Not To Be Crushed)

9. Do not crush the following types of medication: enteric-coated, buccal or sublingual formulations, or sustained/extended release products.

10. Crushed medications are not mixed together. The powder from each medication is mixed with water before administration. The soufflé cup is rinsed with water to get all of the medication contained within the cup to facilitate the ordered dose. The standard of practice is that crushed medications should not be combined and given all at once via feeding tube.

11. Enteral tubes are flushed with at least **15mL** of water before administering any medications and after all medications have been administered.

12. Each medication is administered separately to avoid interaction and clumping. The enteral tubing is flushed with water between each medication to avoid physical interaction of the medications. Tablets, powders and beads (never crushed) from opened capsules, are mixed with water prior to administration via the tube. Gelatin capsules may be softened in water until dissolved and the contents extracted into the water. Any un-dissolved capsule pieces are removed and discarded prior to administration of the liquid.
    a. For residents who are fluid restricted, the prescribing practitioner should order an appropriate flush schedule including the amount of water to be used for flushing between administrations of medications.

13. Medications that are gastrointestinal (GI) irritants (e.g., potassium chloride solutions) are diluted as recommended for oral administration, since there is a high potential for gastric irritation when medications are administered directly into the stomach through enteral tubes.

14. The provider pharmacy or pharmacist is consulted when changing to a different formulation or when initiating enteral therapy for necessary dose scheduling adjustments of the medications or feeding schedule adjustments. The prescriber may need to be contacted for instructions specific to interrupting or using continuous feeding relative to medication administration.
    a. If resident is on continuous feeding via an enteral pump, turn pump off 1-2 hours prior to medication administration if medication is associated with an incompatibility; or 30 minutes prior to administration if medication should be given on an empty stomach. It may be necessary to change to intermittent feedings to avoid an interaction between enteral solution and some medications.
    b. If resident is on intermittent feeding, it may be necessary to delay feeding up to two hours to avoid a medication interaction (e.g., phenytoin) with enteral solution.

15. Consult nursing care center policy and procedure manual for enteral tube feedings for additional information.

EQUIPMENT

- Medication(s)
- Syringe (30 mL or larger) with catheter tipped syringe (no needle)
- 75–120 mL water[1] (minimum)
- Clamp
- Tablet crusher or similar device
- Drinking cup
- Gloves
- Antimicrobial agent for hand hygiene

PROCEDURES

1. Perform hand hygiene.
2. Prepare medications for administration.
   a. Inspect medication for expiration date, contamination, particulate matter, discoloration or defect.
   b. Crush each immediate-release tablets, one at a time, into a fine powder, and dissolve in water (or follow manufacturer's specification for dissolving).
   c. Open each immediate release capsules, one at a time, crush contents into a fine powder, and dissolve in water (or follow manufacturer's specification for dissolving).
   d. Dilute each liquid medication with water (additional water may be needed for viscous liquids).
   e. The pellets inside SOME microencapsulated dosage forms may be mixed with water or other liquid and poured down the feeding tube after being removed from the capsule, provided that the pellets are not crushed.
   f. Some medications require apple juice or other liquid for proper transport of the capsule contents down the tube. Check the manufacturer's instructions or contact the pharmacist if there are questions about any medications.
   g. Sustained-release capsules and enteric coated capsules should not be crushed. Consult the prescriber or pharmacist for alternative formulations and doses.
3. Provide for privacy.
4. Put on gloves.
5. Explain procedure to the resident.
6. If resident is in bed, elevate head of bed to an approximate 30 to 45-degree angle (semi- or high-Fowler's position).

7. Ensure tracheostomy cuff is inflated if applicable.
8. Verify tube placement per facility protocol.
9. Check the patient's gastric contents for residual feeding. Return any residual volume to the stomach. Follow facility protocol for prescriber notification of excessive residual volume.
10. If a pump is being used for feedings, turn it off.
11. Clamp the enteral tube to preserve a closed system.
    a. Confirm that the tracheostomy tube remains unobstructed if indicated.
12. Remove plunger from syringe and insert syringe into tubing.
13. Flush the tube with at least 15 mL of water prior to medication administration.
14. Medications are never added directly to the feeding solution. Keep in mind any possible fluid restrictions and appropriate fluid requirements the resident may have and adjust accordingly.
    a. Administer liquid medications first, then those that need to be diluted. Reserve thick medications (e.g., antacids) for last.
    b. Flush tube with the required amount of water before and after each medication unless physician orders indicate a different flush schedule due to the resident's clinical condition.
    c. Allow medication to flow down tube via gravity or per manufacturer's specifications.
15. Flush the tube with at least 15 mL of water and clamp tube to prevent medication from clogging the tube lumen.
16. Keep the tube clamped for 30 minutes before resuming suction, if indicated. Tubes attached to continuous feeding should have feeding resumed immediately unless contraindicated with specific medication manufacturer guidelines. Leave head of bed elevated for 30 minutes to prevent aspiration of stomach contents.
17. If trach in place leave trach cuff inflated for 30 minutes post medication administration.
18. Clean feeding syringe and return to bedside stand. Syringes are replaced after 24 hours or as required by state regulation.
19. Remove gloves.
20. Perform hand hygiene.

Managing Complications.

1. Check first to see that the tube is not kinked.
2. If the feeding tube becomes clogged, intervention should occur immediately. Warm water should be tried first.
3. Clogged tube – clogging can occur from internal blockage.
   a. If the clog is still present, gently "milk" the tube from top to bottom to release any clog that may be in this part of the tube.
   b. Do NOT force-flush the tube or use a rigid object in an attempt to clear the tube. If the clog is persistent, contact the MD if the above techniques fail.
4. Emesis.
   a. If emesis occurs, stop the feeding pump immediately and elevate the head of the bed to approximately 45 degrees.
   b. Check for bowel sounds.
   c. Determine if the resident is in any pain.
   d. Observe for any signs of aspiration – cough, sweating, shortness of breath, blueness of lips and skin.
   e. Notify the physician.

REFERENCES

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4. Bankhead R, Boullata J, Brantley S, Corkins M, et al. Medication administration. In: A.S.P.E.N. enteral nutrition practice recommendations. *J Parenter Enteral Nutr* 2009 Mar-Apr;33(2):160-61.

7.11 EYE DROPS

POLICY

To administer ophthalmic solution into eye in a safe and accurate manner.

EQUIPMENT

- Eye drops
- Sterile gauze pad or tissues
- Antimicrobial agent for hand hygiene
- Gloves, recommended (WHO glove guidelines define eye drops as involving mucous membranes; gloves are recommended to protect both patient and provider from transmission of infectious agents.)

PROCEDURES

1. Refer to Section 7.1 Medication Administration – General Guidelines.

2. Provide for privacy.

3. Perform hand hygiene and don gloves.

4. Shake the eye drops container, if needed.

5. Remove the cap, taking care to avoid touching the dropper tip, place cap on a clean, dry surface (such as a tissue or gauze).

6. If container has a separate dropper, draw required amount of solution into the dropper, holding the container upright. If self-contained unit, invert container.

7. Have resident tip head back slightly. Good lighting is necessary.

8. With a gloved finger, gently pull down lower eyelid to form “pouch,” while instructing resident to look up. Place other hand against resident’s forehead to steady. Hold inverted medication bottle between the thumb and index finger, and press gently to instill prescribed number of drops into “pouch” near outer corner of eye. Do NOT let tip of dropper touch the eye or any other surface. If resident blinks or drop lands on cheek, repeat administration.

9. Instruct resident to close eyes slowly to allow for even distribution over surface of the eye. The resident should also refrain from blinking or squeezing eyes shut.

10. While the eye is closed, use one finger to compress the tear duct in the inner corner (inner canthus) of the eye for 1-2 minutes. This reduces systemic absorption of the medication. Alternatively, the resident may keep his/her eyes closed for approximately three minutes.[1]

11. Wipe off tears or excess solution with clean gauze, cotton ball, or tissue.

12. If another drop of the same or different medication is prescribed for administration in the same eye at the same time, wait 3 to 5 minutes for optimal absorption then repeat procedure above.

13. If administering medications to both eyes, use a different gloved finger to apply pressure to the inner tear duct. If one eye is infected, treat the infected eye last.

14. Recap bottle.

15. Return medication container to medication cart for storage.

16. Remove and dispose of gloves. Discard any barrier used for carrying or storing the medication and supplies. Wash hands thoroughly with antimicrobial soap and water or facility-approved hand sanitizer.

7.12 EYE OINTMENTS AND GELS

POLICY

To administer ophthalmic ointment or gel into and around the eye in a safe and accurate manner.

EQUIPMENT

- Tube of ophthalmic ointment or gel
- Sterile gauze pad or tissue
- Antimicrobial agent for hand hygiene
- Gloves, recommended (WHO glove guidelines define eye drops as involving mucous membranes; gloves are recommended to protect both patient and provider from transmission of infectious agents.)

PROCEDURES

1. Refer to Section 7.1 Medication Administration – General Guidelines.

2. Provide for privacy.

3. Perform hand hygiene and don gloves.

4. Remove the cap from the medication tube, taking care to avoid touching the tip of the tube. Place the cap on a clean, dry surface (such as a tissue or gauze).

5. Have the resident tilt head back slightly. Good lighting is necessary.

6. With a gloved finger, pull the lower eyelid down and away from the eyeball to form a pocket.

7. Squeeze the tube and apply the prescribed amount of ointment or gel from the inner surface (canthus) of the lower eyelid to outer (canthus) surface. Do not touch the tip of the medication tube to the eye or the eyelid.

8. Release the eyelid and instruct the resident to gently close the eye, and to keep it closed for one (1) to two (2) minutes. While the eye is closed, it may be gently rotated to distribute the medication.

9. Instruct the resident to avoid squeezing the eye shut or rubbing the eye.

10. Replace the cap on the medication tube.

11. Wipe off any excess gel or ointment with the tissue or gauze pad on the resident's face. Use a new tissue or gauze if ointment is needed in the other eye.

12. Inform the resident that eye ointments/gels can temporarily blur the vision.

13. Return medication container to medication cart for storage.

14. Perform hand hygiene.

7.13 EAR DROPS

POLICY

To administer medication into the auditory canal in a safe and accurate manner.

EQUIPMENT

- Medication in dropper bottle/container
- Gloves, if required by state regulation
- Antimicrobial agent for hand hygiene

PROCEDURES

1. Refer to Section 7.1 Medication Administration – General Guidelines.

2. Provide for privacy.

3. Perform hand hygiene.

4. Warm the eardrops, if cold, by holding the container in hand for a few minutes. Do not warm the container in hot water, since instillation of a hot liquid into the ears can cause pain, nausea and dizziness.

5. Shake the container for suspensions.

6. Have the resident tilt head to one side, or lie down with the affected ear facing up. Good lighting is necessary.

7. Open the container and position the dropper tip near, but not inside, the ear canal opening, to avoid contamination.

8. Pull the resident's ear backward and upward to open the ear canal.

9. Place the proper number of drops into the ear canal, and replace cap on container.

10. Gently press the small, flat skin flap over the ear canal to force out air bubbles and encourage drops down the ear canal.

11. Instruct resident to stay in the same position for at least five (5) minutes.

12. Repeat the procedure for the other ear if ordered.

13. Gently wipe any excess medication off the outside of the ear.

14. Return medication container to medication cart for storage.

15. Perform hand hygiene.

7.14 NOSE DROPS

POLICY

To administer medications intended as nose drops into the nasal cavity in a safe and accurate manner.

EQUIPMENT

- Nasal solution
- Tissues
- Gloves, if required by state regulation
- Antimicrobial agent for hand hygiene

PROCEDURES

1. Refer to Section 7.1 Medication Administration – General Guidelines.
2. Provide for privacy.
3. Perform hand hygiene.
4. Have resident gently blow nose to clear the nostrils.
5. Have resident lie on a bed with the head tilted back and the neck supported. Good lighting is necessary.
6. Insert the dropper tip into the nostril about 1/3 inch, and place the prescribed dose or number of drops in the nostril. Avoid touching dropper tip to nose.
7. Instruct resident to remain in the same position for at least five (5) minutes.
8. Repeat with other nostril if ordered.
9. Rinse dropper tip with hot water and replace cap on container.
10. Return medication container to medication cart for storage.
11. Perform hand hygiene.

7.15 NASAL ADMINISTRATION

POLICY

To administer nasal medications in a safe, accurate and effective manner.

EQUIPMENT

- Nasal medication
- Tissues
- Gloves, if required by state regulation
- Antimicrobial agent for hand hygiene

PROCEDURES

1. Refer to Section 7.1 Medication Administration – General Guidelines.
2. Provide for privacy.
3. Perform hand hygiene.
4. Refer to medication package insert, medication label, or other appropriate reference to determine correct technique required for the administration of drops, sprays, pumps, gels, etc.
5. Prior to first use, prime the bottle if appropriate. Remove the protective cap and shake the bottle gently for a few seconds. Push the pump firmly and quickly 5-8 times or until a fine spray or mist appears. Priming must be repeated if the unit is not used for 5 days or more.
6. Determine that an adequate amount of medication is remaining in the medication bottle, aerosol canister or pump. Reorder as necessary.
7. Have resident gently blow nose to clear the nostrils.
8. Shake the medication container well and remove cap from nozzle.
9. Administer medication to resident or help resident to do so if capable, using the following directions:

a. Have resident keep head upright. Keeping mouth closed, insert tip of pump, spray or inhaler is into the nostril. Point the spray tip in the nose toward the back and outer side of the nose. Press a finger against the side of the nose to close one nostril and lean the head slightly forward so the spray will aim toward the back of the nose. Have resident sniff gently in through open nostril while pump or inhaler is quickly and firmly squeezed or activated.

b. Instruct resident to hold breath for a few seconds and then breathe out through mouth.

c. If alternating nostrils, note which nostril medication was administered on MAR, R for right nostril and L for left nostril.

d. Some manufacturers recommend tilting the head back for several seconds to aid the penetration of the medication.

e. If medication is in gel form without a pump or applicator, apply with a clean cotton swab, unless directed otherwise.

f. If medication is in gel form, massage the nostril externally in which the medication was administered for a few seconds.

g. Wipe any excess drainage with a clean tissue. Instruct resident to avoid blowing their nose for 15 minutes.

10. Clean container per manufacturer's instructions or wipe the spray tip with a tissue before putting on the protective cap.

11. Return medication container to medication cart for storage.

12. Perform hand hygiene.

PROCEDURES SPECIFIC TO CALCITONIN (MIACALCIN® AND FORTICAL®)

1. Provide for privacy.

2. Perform hand hygiene.

3. Prior to first use, prime the bottle. Remove the clear protective cap. The bottle should be held upright and the two side arms of the pump depressed toward the bottle until a full spray is produced. The pump is primed once the first full spray is emitted. The pump requires priming only prior to the first dose.

4. Date bottle upon opening.

5. To administer, the nozzle should be carefully placed into the nostril with the head in the upright position and the pump firmly depressed toward the bottle to spray the medication in the nose. It is not necessary to inhale while this is being done.

6. Alternate nostrils used for administration each day. Note R for right and L for left on the MAR.

7. Store the bottle in the upright position in the medication cart.

8. Perform hand hygiene.

9. The nursing staff is responsible for reviewing the dates on opened bottles and removal of expired items.

7.16 VAGINALS

POLICY

To administer vaginal medication safely and accurately.

EQUIPMENT

- Medication
- Gloves
- Water soluble gel, if appropriate
- Applicator, if appropriate
- Tissue
- Paper towel
- Antimicrobial agent for hand hygiene

PROCEDURES

1. Refer to Section 7.1 Medication Administration – General Guidelines.
2. Provide for privacy.
3. Perform hand hygiene.
4. Place tablet/suppository in applicator or draw cream/gel into applicator.
5. Have resident lie on back with knees flexed and legs spread apart, or on left side with knees bent. Good lighting is necessary.
6. Wearing gloves, examine perineum. Clean area if discharge is noted.
7. With one hand, spread apart the labia.
    a. Place applicator into vagina and advance the plunger to instill gel or cream or to release tablet or suppository.
    b. If without applicator, insert lubricated tablet or suppository approximately 3-4 inches into vaginal area.
8. Wipe lubricant from vaginal area with tissue.
9. Advise resident to remain lying down for about 30 minutes.
10. Place tissue and gloves in paper towel.

11. Discard soiled articles in covered, plastic-lined container.
12. Perform hand hygiene.

7.17 RECTAL ENEMAS

POLICY

To administer medication rectally in a safe and accurate manner.

EQUIPMENT

- Rectal enema as ordered
- Gloves
- Lubricant
- Tissue
- Paper towel
- Bedpan or commode, where applicable
- Antimicrobial agent for hand hygiene

PROCEDURES

1. Refer to Section 7.1 Medication Administration – General Guidelines.

2. Provide for privacy.

3. Assist resident in turning to left side with knees bent.

4. Prepare enema for administration.

5. Perform hand hygiene.

6. Put on gloves.

7. Separate buttocks. Good lighting is necessary.

8. Insert enema tip gently into rectum beyond sphincter, about 3 inches. Ask the resident to take a deep breath, to relax the anal sphincter.

9. Slowly empty the contents of the enema into the colon.

    a. Instruct resident to resist urge to expel colon contents while enema is being administered, and afterward for as long as possible.

    b. If resident is uncomfortable, administration flow may be too fast.

    c. Enema solution should be retained until definite lower abdominal cramping is felt.

10. Remove gloves and discard appropriately.

11. If enema was for bowel evacuation, assist resident onto a bedpan, commode, or toilet. Make the resident comfortable. Leave call signal with resident or check back at intervals.

12. Elevate head of bed to Fowler's position if the resident remains in bed. (Fowler's position is the posture taken when the head of the bed is raised 18 or 20 inches and the resident's knees are raised.)

13. Remove soiled articles. Place in covered, plastic-lined container.

14. Perform hand hygiene.

15. Document effect of enema if for bowel evacuation.

7.18 RECTAL SUPPOSITORIES

POLICY

To administer medication rectally in a safe and accurate manner.

EQUIPMENT

- Rectal suppository as ordered
- Gloves
- Lubricant
- Tissue
- Paper towel
- Bedpan or commode, where applicable
- Antimicrobial agent for hand hygiene

PROCEDURES

1. Refer to Section 7.1 Medication Administration – General Guidelines.
2. Provide for privacy.
3. Assist resident in turning to left side with knees bent.
4. Remove wrapper from suppository.
5. Put on gloves.
6. Lubricate index finger and suppository.
7. Separate buttocks. Good lighting is necessary.
8. Ask the resident to take a deep breath, to relax the anal sphincter.
9. Insert suppository gently into rectum beyond sphincter, about 3 inches.
10. Apply pressure with tissue over anus briefly until desire to expel suppository has passed.
11. Instruct resident to retain suppository for 10–15 minutes if possible.
12. Place tissue and glove in paper towel.

13. If suppository was for bowel evacuation, assist resident onto a bedpan, commode, or toilet. Make the resident comfortable. Leave call signal with resident or check back at intervals.

14. Elevate head of bed to Fowler's position if the resident remains in bed. (Fowler's position is the posture taken when the head of the bed is raised 18 or 20 inches and the resident's knees are raised.)

15. Remove soiled articles. Place in covered, plastic-lined container.

16. Perform hand hygiene.

17. Document effect of suppository if for bowel evacuation.

7.19 INTRAMUSCULARS

POLICY

To administer an aqueous suspended medication into the intramuscular tissue.

EQUIPMENT

- Medication as ordered, reconstituted if appropriate
- Safety syringe capable of holding the medication
- Sterile needle (determine appropriate needle size depending on the size of the resident and viscosity of the medication)
- Antimicrobial agent for medication product (such as alcohol swab)
- Antimicrobial agent for resident's skin (such as alcohol swab)
- Gloves
- Antimicrobial agent for hand hygiene

SITES OF ADMINISTRATION

- Ventriogluteal (front of hip area)
- Deltoid (upper arms)
- Dorsogluteal (back buttock)
- Vastus lateralis (upper lateral area of leg)
- Rectus femoris (medial upper leg)

PROCEDURES

1. Refer to Section 7.1 Medication Administration – General Guidelines.
2. Provide for privacy.
3. Perform hand hygiene.
4. Prepare medication as follows:

a. Calculate correct amount of medication. If volume is greater the 3 mL, split volume for 2 different injection sites.

b. The first person to use a multi-dose vial should date the vial when opened.

c. Shake medication well, if required.

d. Check medication for precipitation/discoloration. If present do not use.

e. If reconstitution of medication is necessary prior to administration read medication package insert, medication label, or other appropriate reference to determine correct diluent and quantity of diluent to be used.

- Break and remove seal from both vials of medication and diluent and swab stoppers with antimicrobial agent.
- Inject diluent bottle with syringe an amount of air equal to the amount of fluid to be withdrawn for reconstitution of medication. Do not allow needle to touch any surface other than stopper.
- Withdraw appropriate amount of diluent into syringe.
- Inject diluent into medication bottle slowly and observe reconstituted solution for clarity, unusual color or large particles. If there appears to be a problem, do not administer.

f. Prepare syringe and needle.

- Swab medication vial's rubber cap with antimicrobial agent.
- Pull back plunger to draw a volume of air into the syringe equal to volume of medication to be given.
- Inject air into vial.
- Withdraw correct amount of medication.
- Create air lock in syringe by pulling in a small amount of air.
- Protect needle using appropriate safety device.

5. Select appropriate site for injection.

6. Put on gloves.

7. Adjust resident's position.

8. Cleanse skin with antimicrobial agent, using circular motion from center of chosen site until an area about 3 inches in diameter has been prepared.

9. Expel air from syringe.

10. Expose site to be injected.

11. Stretch the skin so that it is taut, to ease needle insertion.

12. Using the other hand to hold the syringe, insert the needle at a 90-degree angle; use a quick, dart-like movement.

13. Pull back on plunger to see if needle is in a blood vessel. If so, do not inject and withdraw needle, secure new equipment and repeat procedure at a different time.

14. Hold the needle steady and inject the medication at slow, even rate.

15. Withdraw needle rapidly.

16. Swab the area with antimicrobial agent in a circular motion.

17. Pull down safety sleeve over needle.

18. Discard syringe and needle in designated area. Ampules and single-use vials are discarded immediately after use.

19. Remove gloves.

20. Perform hand hygiene.

21. Document the injection on the MAR along with site. Examples of site abbreviations are as follows:

SITE	CODE
Left Buttock	LB
Right Buttock	RB
Left Upper Arm	LA
Right Upper Arm	RA
Left Thigh	LT
Right Thigh	RT

7.20 INJECTABLE VIALS AND AMPULES

POLICY

Vials and ampules of injectable medications are used in accordance with the manufacturer's recommendations or the provider pharmacy's directions for storage, use, and disposal.

PROCEDURES

1. Refer to Section 7.1 Medication Administration – General Guidelines and Section 9.10– Medications with Shortened Expiration Dates.

2. Vials and ampules sent from the provider pharmacy in a box or container with the label on the outside are stored in that box or container (e.g., insulins).

3. The date opened and the initials of the first person to use the vial are recorded on multi-dose vials (on the vial label or an accessory label affixed for that purpose).

4. Ampules and single-use vials (containing no preservative) are discarded immediately after use.

5. Inspect solution in multi-dose vials prior to each use for unusual cloudiness, precipitation, or foreign bodies. The rubber stopper is inspected for deterioration.

6. If a multi-dose vial shows visible evidence of precipitation or contamination or the rubber stopper is deteriorating, it is not used, and it is returned to the provider pharmacy. A replacement vial is then ordered from the provider pharmacy.

7. The provider pharmacy determines the need for reporting a defective solution to the manufacturer and/or filing a Drug Product Problem Report with the Food and Drug Administration MedWatch program. (Refer to Section 6.2 – Medication Error Reporting and Adverse Drug Reaction Prevention and Detection)

8. Medication in multi-dose vials shall be refrigerated after they are opened unless otherwise specified by the manufacturer.

9. Discard multi-dose vials when empty, when suspected or visible contamination occurs or when the manufacturer's stated expiration date is reached, provided the manufacturer's storage conditions have been maintained.

10. If using medication from a glass ampule and a filter device to withdraw fluid, discard filter device following withdrawal of medication from ampule, and replace it with sterile safety needle or sterile cap on syringe.

11. The nursing staff is responsible for reviewing the dates on opened vials and removal of expired items.

REFERENCES

References via literature search by the Drug Information Center, McWhorter School of Pharmacy, Samford University, Birmingham, AL, July 9, 2007:

1. Centers for Disease Control and Prevention. Guidelines for the prevention of intravascular catheter-related infections. *MMWR* 2002;51(No. RR-10):1-26.
2. Chapter <797> Pharmaceutical Compounding-Sterile Preparations. *United States Pharmacopeia and National Formulary* (*USP 30-NF 25*). Rockville, MD: United States Pharmacopeia Convention; 2007:345.
3. Turco SA. *Sterile Dosage Forms. Their Preparation and Clinical Application*. 4th ed. Lea & Febiger: Philadelphia, PA; 1994:142.
4. Buchanan EC, Schneider PJ. *Compounding Sterile Preparations.* 2nd ed. Bethesda, MD: American Society of Health-System Pharmacists, Inc.; 2005:89.
5. Wilson JP, Cobb DB. Updating your multiple-dose vial policy: the background. *Hosp Pharm.* 1998;33:427-432.

7.21 INJECTABLE RECONSTITUTION FOR PARENTERAL USE

POLICY

To provide for the safe and accurate reconstitution of parenteral medications prior to administration, manufacturer information is reviewed and aseptic technique is observed.

EQUIPMENT

- Medication, as ordered
- Diluent
- Antimicrobial agent for medication product (such as alcohol swab)
- Safety syringe and sterile needle of appropriate gauge
- Gloves
- Antimicrobial agent for hand hygiene

PROCEDURES

1. Refer to Section 7.1 Medication Administration – General Guidelines.

2. Read medication package literature or other appropriate reference to determine the correct diluent and quantity of diluent to be used. Note any special steps required (such as shaking).

3. Perform hand hygiene.

4. Break and remove seal/cap from vial of medication. Swab rubber stopper on medication vial with antimicrobial agent.

5. Break and remove seal/cap from vial of diluent and wipe rubber stopper with antimicrobial agent. Use only sterile saline or sterile water for injection as diluent unless or otherwise ordered. Specific diluent may be supplied by the manufacturer with the medication. If multiple dose vial, date and initial when opened.

6. Pull back plunger to draw a volume of air into the syringe equal to the volume of diluent to be used.

7. Inject air into diluent bottle with syringe. Do not allow needle to touch any surface other than stopper.

8. Withdraw the appropriate amount of diluent into syringe.

9. Inject diluent into medication bottle slowly and observe resulting solution or suspension for clarity, unusual color, or large particles, such as precipitation. If there appears to be a problem, do not administer medication without consulting pharmacist for further information.

10. Administer medication or add to IV solution as directed and complete documentation.

11. Dispose of diluent if a single dose vial. If multiple dose vial, follow nursing care center policy for expiration dating.

12. Perform hand hygiene.

7.22 SUBCUTANEOUS

POLICY

To administer a parenteral medication via the subcutaneous route in a safe, accurate and effective manner.

EQUIPMENT

- Medication as ordered
- Safety syringe and sterile safety needle of appropriate gauge
- Antimicrobial agent for medication product (such as alcohol swab)
- Antimicrobial agent for resident's skin (such as alcohol swab)
- Antimicrobial agent for hand hygiene
- Gloves

PROCEDURES

1. Refer to Section 7.1 Medication Administration – General Guidelines.
2. For continuous subcutaneous infusion procedures, refer to the Intravenous Therapy Policy and Procedure Manual. For subcutaneous insulin therapy, Refer to Section 7.27 – Subcutaneous Administration of Continuous Insulin.
3. Provide for privacy.
4. Perform hand hygiene.
5. Prepare medication as follows:
    a. Calculate correct amount of medication. As a general guideline, if the volume is greater than 2 mL, split volume for two different sites.
    b. Check for precipitation or cloudiness. Discard if present.
    c. Shake medication well, if required.
    d. Prepare syringe and needle.

- Swab rubber cap with antimicrobial agent.
- Pull back plunger to draw a volume of air into the syringe equal to the volume of medication to be given.
- Inject air into medication vial with syringe. Do not allow needle to touch any surface other than stopper.
- Withdraw correct amount of medication.
- Create air lock in syringe by pulling a small amount of air into the syringe.
- Recap needle using appropriate safety device.

6. Adjust resident position.
7. Put on gloves.
8. Check last site of injection and select a new appropriate site for injection.
9. Cleanse skin with antimicrobial agent, using circular motion from center of chosen site until an area about 3 inches in diameter has been prepared. Allow to dry.
10. Expel air from syringe. If using pre-filled syringes, follow manufacturer's recommendations. NOTE: Directions for Lovenox state that the air is NOT to be expelled prior to injection.
11. Expose site to be injected.
12. Grasp and pinch the skin around the injection site, at least one (1) inch of flesh.
13. Hold needle with bevel side up and insert needle at a 45 degree angle to the skin surface.
14. Insert needle quickly. Release the skin.
15. Pull back on the plunger to see if needle is in a blood vessel. If so, withdraw needle, secure new equipment and medication, and repeat procedure.

    NOTE: Excluding insulin, low molecular weight heparin products and heparin products.
16. Inject medication slowly.
17. Remove needle quickly at the same angle as insertion.

18. Swab area with antimicrobial agent.

19. Apply pressure over the injection site for approximately two (2) minutes.

20. Appropriately discard waste.

21. Remove gloves.

22. Perform hand hygiene.

23. Document the injection on the MAR along with site. Examples of site abbreviations are as follows:

SITE	CODE
Left Buttock	LB
Right Buttock	RB
Left Upper Arm	LA
Right Upper Arm	RA
Left Thigh	LT
Right Thigh	RT
Left Abdomen	LS
Right Abdomen	RS

7.23 SUBCUTANEOUS INSULIN

POLICY

To administer subcutaneous insulin as ordered and in a safe, accurate and effective manner.

INSULIN VIALS

Equipment

- Safety insulin syringe
- Insulin as ordered
- Antimicrobial agent for medication product (such as alcohol swab)
- Antimicrobial agent for resident's skin (such as alcohol swab)
- Gloves
- Antimicrobial agent for hand hygiene

Procedures

1. Refer to Section 7.1 Medication Administration – General Guidelines.
2. Check prescriber's order for insulin.
3. Provide for privacy.
4. Adjust resident position.
5. Obtain insulin. Check expiration date. If refrigerated, allow warming to room temperature.
6. Date vial after first use.
7. Perform hand hygiene.
8. Rotate vial of insulin, if appropriate per type, gently between hands to mix. Do not shake the vial. Examine contents of vial. Check solution for clarity and do not use if particulate is present.
9. Prepare injection.
    a. Determine correct amount of insulin to be withdrawn.
    b. Prepare syringe.

c. Swab rubber cap of vial with antimicrobial agent.

d. Inject same volume of air as volume of insulin.

e. Hold insulin syringe with correct calibration in view (at eye level) and withdraw ordered dosage of insulin.

f. If the prescriber has ordered two types of insulin to be given, first verify that the two insulins can be mixed together. Then draw up the regular or clear insulin first, then any of the cloudy insulins after injecting the appropriate amount of air into each vial. Note: The following insulin products should never be mixed or diluted with any other insulin or solution: Apidra®, Lantus®.

g. When transporting insulin keep the needle covered and secure with the safety guard.

10. Return insulin container to medication cart for storage.

11. Put on gloves.

12. Check last site of injection and select a new appropriate site for injection.

13. Cleanse injection site with antimicrobial agent. Allow to dry.

14. Expel air from syringe.

15. Grasp and pinch the skin around the injection site if using a syringe.

16. Inject needle quickly at a 90 degree angle. Release the skin.

17. Inject insulin slowly. Leave needle in the skin for several seconds after injection with finger on the plunger or per manufacturer recommendation.

18. Remove needle and apply firm pressure over site to prevent seepage of insulin. Do not rub area.

19. Engage safety device, and discard syringe and needle in appropriate syringe disposal container. Do not recap needle.

20. Remove gloves.

21. Perform hand hygiene.

22. Document the injection on the MAR along with site. Examples of site abbreviations are as follows:

SITE	CODE
Left Buttock	LB
Right Buttock	RB
Left Upper Arm	LA
Right Upper Arm	RA
Left Thigh	LT
Right Thigh	RT
Left Abdomen	LS
Right Abdomen	RS

23. For insulins that come in a suspension ("cloudy" insulins), they must be resuspended immediately before use. Resuspension is easier when the insulin has reached room temperature. To resuspend a vial, carefully invert it at least 10 times until the suspension appears uniformly white and cloudy.

INSULIN PENS

Equipment

- Pen device and sterile safety needle of appropriate gauge
- Insulin as ordered
- Antimicrobial agent for medication product (such as alcohol swab)
- Antimicrobial agent for resident's skin (such as alcohol swab)
- Gloves
- Antimicrobial agent for hand hygiene

Procedure

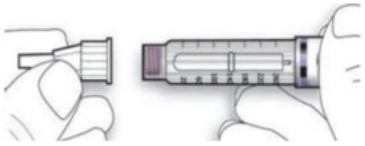
1. Refer to Section 7.1 Medication Administration – General Guidelines.
2. Check prescriber's order for insulin.
3. Provide privacy.
4. Adjust resident position.
5. Obtain insulin. Check the expiration date. If refrigerated, allow warming to room temperature. Review manufacturer specific administration and storage instructions for pen devices.
6. Date pen device after first use.
7. Prepare injection.

a. Remove cap, make sure to put aside for later to re-cap pen.

b. For insulins that come in a suspension ("cloudy" insulins), they must be resuspended immediately before use. Resuspension is easier when the insulin reaches room temperature. To re-suspend the pen, carefully invert it at least 10 times until the suspension appears uniformly white and cloudy.

c. Wipe rubber stopper with antimicrobial agent.

d. Attach a new pen needle, remove paper tab off pen needle, screw or click the needle securely in place according to the manufacturer's instructions. Remove the cap(s) from the pen to expose the needle.



8. Prime the insulin pen.

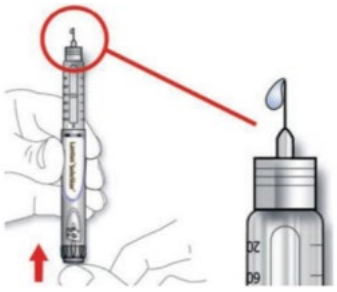
a. Priming the pen means removing the air from the needle and cartridge that may collect during normal use and ensures the pen is working correctly.

b. Each click is 1 unit.

c. Dial the pen up 2 units, unless otherwise specified by manufacturer.

d. Point pen needle towards the ceiling and gently tap the side.

e. Press the button on the bottom all the way in, you should see a drop of insulin come out. If you do not see the drop, repeat the priming process.



9. Dial the dose to the prescribed insulin dosage.

10. Choose a location on the resident for site of administration. Recommended injection sites include the abdomen, front and sides of thighs, upper and outer arms, and buttocks. Do not inject near joints, the groin, navel, middle of abdomen, or scar tissue. Rotate injection site, refer to documentation for previous site used.

11. Deliver the injection.
    a. Wipe area to be injected with an alcohol swab and allow time to air dry. Do not attempt to fan with hands, etc.
    b. Gently pinch area to be injected, ensuring insulin is administered to adipose tissue.
    c. Penetrate the skin quickly, at a 90-degree angle, using a darting motion.

    d. Deliver the dose by pressing the injection button all the way smoothly. The number in the dose window will return to "0" as you inject.
    e. Keep the injection button pressed all the way in while slowly counting to 10 before withdrawing the needle from the skin. This ensures that the full dose was administered.

    f. Withdraw needle from injection site.
    g. Remove the needle from the pen and discard it in sharp container. If you notice bleeding, wipe away using alcohol or cotton swab, and apply gentle pressure.
12. Remove gloves.
13. Perform hand hygiene.
14. Document the injection on the MAR along with the site.

SITE	CODE
Left Buttock	LB
Right Buttock	RB
Left Upper Arm	LA
Right Upper Arm	RA
Left Thigh	LT
Right Thigh	RT
Left Abdomen	LS
Right Abdomen	RS

15. Replace cap back on pen and place in the proper storage location.

7.24 IRRIGATION SOLUTIONS

POLICY

Irrigation solutions are used as prescribed following manufacturer's guidelines with proper methods of storage, and disposal. Aseptic technique is used in the handling and application of irrigation solutions.

PROCEDURES

1. Refer to Section 7.1 Medication Administration – General Guidelines.

2. Irrigation solutions are labeled with the date and time immediately upon opening.

3. Solutions prepared by the provider pharmacy are disposed of by the expiration date indicated. Solutions without an expiration date indicated are not accepted.

4. Solutions prepared in the nursing care center (e.g., Neosporin G.U.®, hydrogen peroxide solutions) are disposed of within 24 hours.

5. Solutions (e.g., water and saline for irrigation) in the original manufacturer's container are disposed of within 24 hours after opening.

6. Unless visible evidence or suspicion of contamination warrants earlier disposal or information is available for a specific medication solution being stable for less than 24 hours, the above expiration date information is to be enforced.

7. The nursing staff is responsible for reviewing dates on opened irrigation solutions and removing expired items.

8. When expired, unused solutions are poured down the drain if applicable per state regulation. If disposal via flushing or drains is not acceptable per state regulation, dispose of irrigation solution in hazardous waste container.

REFERENCES

References via literature search by the Drug Information Center, McWhorter School of Pharmacy, Samford University, Birmingham, AL, July 17, 2007:

1. Allen LV Jr, Popovich NG, Ansel HC. *Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems*. 8th ed. Philadelphia, PA: Lipincott Williams & Wilkins; 2005:501.

2. *United States Pharmacopeia and National Formulary* (USP 30-NF 25). Vol 1. Rockville, MD: United States Pharmacopeia Convention; 2007:344-345.
3. Open Container Expiration Dating in Pharmacy Areas. MUSC Medical Center Pharmacy Services Website. http://www.musc.edu/pharmacyservices/PnP/f10.pdf. Accessed July 17, 2007.
4. Extensive internet database searches (PubMed, International Pharmaceutical Abstracts [IPA]) were conducted in addition to the CDC and OSHA websites.

7.25 TRANSDERMAL DELIVERY SYSTEMS (PATCHES)

POLICY

To administer medication through the skin by continuous absorption while the patch is in place and maintaining proper placement of the patch and care of the application sites.

EQUIPMENT

- Medication patch
- Tissue or gauze for skin cleansing
- Gloves
- Antimicrobial agent for hand hygiene

PROCEDURES

1. Refer to Section 7.1 Medication Administration – General Guidelines.
2. Provide for privacy.
3. Perform hand hygiene.
4. Put on gloves.
5. Check last site of application and select a new appropriate site, rotating in accordance with manufacturer's recommendations. The application site should be a clean, dry, and hairless area on the body for patch placement.
6. Remove old patch from body and dispose of properly.
7. Cleanse area of old patch with antimicrobial agent.
8. Remove new patch from package and envelope.
9. Label patch with date and nurse's initials.
10. Apply new patch firmly against skin. Rotate sites in accordance with manufacturer's recommendations. Avoid extremities and hairy body areas.
11. Remove gloves.
12. Perform hand hygiene.

13. Document placement site on MAR. For patches applied less frequently than daily, check placement and document that patch is in place at least daily. Examples of site abbreviations are as follows:

SITE	CODE	SITE	CODE
Left upper arm	LA	Left chest	LC
Right upper arm	RA	Right chest	RC
Left upper thigh	LT	Left upper back	LB
Right upper thigh	RT	Right upper back	RB

For transdermal scopolamine:

SITE	CODE
Behind left ear	LE
Behind right ear	RE

14. Prior to transporting a deceased resident, remove all medication patches and properly dispose of patch and document.

NOTE: If resident is found without an ordered patch on the body:

- The discovering nurse shall investigate and search for the medication patch.
- Check package insert for instructions for replacing a missing or loose patch.
- The prescriber shall be notified and further instructions obtained.
- Recommend notifying the director of nursing to document incident for potential trending if patterns of missing patches occurs.

GUIDANCE SPECIFIC TO CLONIDINE (CATAPRES®)

Note: This product is available as an active pink patch with a white adhesive overlay patch. Leave corner of active pink patch sticking out and showing underneath white overlay for the easy verification of its presence. Date and initial white overlay. Remove both old patch and overlay prior to administration of next dose.

GUIDANCE SPECIFIC TO FENTANYL (DURAGESIC®)

1. All residents and their caregivers should be advised to avoid exposing the fentanyl application site to direct external heat sources, such as heating pads, electric blankets, saunas, hot tubs and heated waterbeds while wearing the system. There is a potential for temperature-dependent increases in fentanyl released from the system resulting in possible overdose.

2. A considerable amount of active fentanyl remains in the patch even after used as directed.

3. Upon patch removal, fold patch over so the adhesive side of the patch adheres to itself.

4. Dispose of in receptacle so that used patch is inaccessible.

5. It is recommended and may be required per state regulations that two licensed nurses document proper disposal.

ADDITIONAL GUIDANCE SPECIFIC TO OTHER PATCHES

1) Lidocaine patches to treat post herpetic neuropathy should not be rotated and should be applied to the painful area.
2) Buprenorphine transdermal systems should not be reapplied to the same site for more than 21 days.
3) Exelon patches should not be reapplied to the same site for more than 14 days.

Proprietary Name	**Generic/Established Name**
Catapres TTS®	Clonidine
Neupro®	Rotigotine
Lidopel®	Lidocaine HCl and epinephrine
Synera®	Lidocaine/Tetracaine
Transderm-Scop®	Scopolamine
Prostep®	Nicotine transdermal system
Habitrol®	Nicotine transdermal system
Nicotrol TD®	Nicotine transdermal system
Androderm®	Testosterone transdermal system
Duragesic®	Fentanyl
Salonpas Power Plus®	Methyl Salicylate/Menthol
Estraderm	Estradiol

7.26 TOPICAL MEDICATION ADMINISTRATION

PURPOSE

To administer topical medications in a safe, accurate, and effective manner.

EQUIPMENT REQUIRED

- Topical medication
- Examination gloves (sterile or non-sterile, depending on nature of resident's skin condition)
- Barrier (e.g., disposable tray or plastic cup)
- Medication Administration Record (MAR)
- Other necessary equipment may include: gauze, tongue depressor, cotton-tip applicator, paper applicator, tape, specified cleaning solutions, bandages, tissue or paper towel
- Appropriate discard bag for soiled materials

PROCEDURES

1. Provide privacy as necessary.
2. Position resident comfortably for safety and cleanliness during procedure.
3. Put on examination gloves.
4. Place bed cover pad under affected area if applicable.
5. Prepare items and hang cuffed plastic bag for waste available nearby.
6. Examine resident's skin for exudates, drainage or residue from previous treatment applications.
7. Remove dressing and discard into appropriate bag labeled as contaminated, if applicable.
8. If needed, choose an appropriate applicator to remove medication/treatment from the container. Once used, applicator is discarded and never reintroduced into the container.
9. Cleanse or irrigate the area per physician's order.

10. Change gloves per facility policy.

11. Apply topical treatment as per physician's order. To avoid contamination of a product, do not let the medication tube or tip touch the resident's skin.

    a. Some medications include product specific measurement applicators. Squeeze the product onto the calibrated measurement pad in a manner to produce an even ribbon.

12. Topical patch application sites should be verified. Certain patches are required to be applied to limited sites and other products must be rotated following manufacturer recommendations to prevent skin irritation. Sites of administration should be noted on the appropriate Administration record.

13. In general, topical products should be applied sparingly unless otherwise ordered.

14. If a product might drip, use a clean paper towel or barrier to protect the resident's clothing and/or bedding.

15. If resident has multiple treatment sites, the cleanest site is treated first (e.g., leg before buttocks) and each site is treated as a separate dressing.

16. Discard all used, disposable equipment into the plastic bag labeled as contaminated, if applicable.

17. Remove gloves and discard into plastic waste bag.

18. Place hands under cuff of bag and close.

19. Wash hands thoroughly with antimicrobial soap and water or facility-approved hand sanitizer.

20. Dispose of bag in red bag container in soiled utility area.

21. Note administration of the treatment by recording initials, date and time in the appropriate area on the Treatment Administration Record.

7.27 SUBCUTANEOUS ADMINISTRATION OF CONTINUOUS INSULIN

POLICY

An insulin pump or meter is intended to provide subcutaneous delivery of insulin at programmable basal and bolus rates for the daily management of diabetes mellitus in an insulin dependent diabetic patient.

PROCEDURES

1. Acquire the manufacturer's user guide for the patient's Insulin Pump.
    a. READ it carefully as it contains information about how to use, program and maintain the pump.
    b. Retain the user guide in the patient's chart or with MAR so that it is readily available for reference.
2. Keep an extra supply of the following available:
    a. Infusion sets.
    b. Insulin reservoirs or cartridges.
    c. Dressing and adhesive, if used.
    d. Extra battery specific to the pump.
    e. Extra pump battery cap (if pump requires one).
3. Assemble equipment and supplies on the resident's over-bed table, with a barrier between supplies/medication and table.
4. Sites for subcutaneous infusion may include:
    a. Thighs,
    b. Abdomen,
    c. Deltoid, or
    d. Pectoral areas.

5. Attach tubing from infusion pump to injection cap on existing subcutaneous set.

6. Start the pump.

7. Subcutaneous infusion sites should be changed when clinically indicated based on site assessment.

8. Occasionally check the infusion site for proper placement and leaks.

    a. Improperly placed infusion sites or leaks around the infusion site can result in under infusion.

9. Occasionally check the infusion set tubing for any damage, leaks or kinks while using the pump.

    a. Damaged, leaking or kinked tubing may restrict or stop insulin delivery and result in under infusion.

Medication Monitoring

8.0 MEDICATION MONITORING

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8.1 MEDICATION REGIMEN REVIEW AND REPORTING

POLICY

"Medication Regimen Review (MRR)" or Drug Regimen Review is a thorough evaluation of the medication regimen of a resident, with the goal of promoting positive outcomes and minimizing adverse consequences and potential risks associated with medication. The MRR includes review of the medical record in order to prevent, identify, report, and resolve medication-related problems, medication errors, or other irregularities. The MRR also involves collaborating with other members of the IDT, including the resident, their family, and/or resident representative.

PROCEDURES

1. The nursing care center assures that the consultant pharmacist has access to residents and the residents' medical records, the nursing care center's records of medication receipt and disposition; medication storage areas; and controlled substances records and supplies.

2. The consultant pharmacist reviews the medication regimen and medical chart of each resident at least monthly to appropriately monitor the medication regimen and ensure that the medications each resident receives are clinically indicated. Identification of irregularities may occur by the consultant pharmacist utilizing a variety of sources including medication administration records (MAR), prescriber's orders, progress notes, nurse's notes, the Resident Assessment Instrument (RAI), Minimum Data Set (MDS), laboratory and diagnostic test results, behavior monitoring information and information from the nursing care center staff and other health professionals involved in the resident's care.

3. In performing medication regimen review, the consultant pharmacist incorporates federally mandated standards of care, in addition to other applicable professional standards, such as the American Society of Consultant Pharmacists (ASCP) Practice Standards, and clinical standards such as the Agency for Health Care Policy and Research (AHCPR) Clinical Practice Guidelines and American Medical Directors Association (AMDA) Clinical Practice Guidelines.

4. More frequent medication regimen reviews may be deemed necessary. This may include when the resident experiences an acute change of condition, or the resident is expected to stay less than 30 days. In these situations, the facility will provide all necessary information to complete the MRR.

5. For interim MRRs:
   a. In accordance with state regulations, the consultant pharmacist or clinical pharmacist at the provider pharmacy works with the nursing care center nursing staff to gather pertinent information related to the resident's status and/or request for consultation.

   b. The findings are communicated to the director of nursing or designee and the medical director. These findings are documented and filed with other consultant pharmacist recommendations in the resident's chart.

6. Resident-specific MRR recommendations and findings are documented and acted upon by the nursing care center and/or physician.

7. A record of the consultant pharmacist's observations and recommendations is made available in an easily retrievable format to nurses, physicians and the care planning team within 48 hours of MRR completion.

8. The nursing care center follows up on the recommendations to verify that appropriate action has been taken. Recommendations should be acted upon within 30 calendar days or per facility specific protocols.
   a. For those issues that require physician intervention, the attending physician either accepts and acts upon the report and recommendations or rejects all or some of the report and should document his or her rationale of why the recommendation is rejected in the resident's medical record.
   b. If there is potential for serious harm and the attending physician does not concur, or refuses to document an explanation, the director of nursing and the consultant pharmacist contact the medical director. If the attending physician is also the medical director, a meeting shall be arranged to discuss issues and come to an agreement in order to ensure that no actual harm occurs.
   c. For recommendations that do not require physician intervention, the director of nursing or licensed designee will address the recommendations.
   d. Should the consultant pharmacist detect a potentially clinically significant medication issue that requires urgent action to protect the resident, he/she will promptly alert the direct care nurse for immediate action. **If** prescriber intervention is required, facility staff will ensure proper communication is provided to the attending physician, nurse practitioner or physician's assistant to ensure resolution by midnight of the next calendar day.

9. Recommendations regarding implementation of nursing care center policies, procedures, and/or methods of medication administration are made by the consultant pharmacist when appropriate.

10. The consultant pharmacist compiles, analyzes, and presents aggregate data about recommendations, responses to recommendations, and outcomes as part of the pharmacy CQI program in the nursing care center. These findings are presented to the nursing care center's Quality Assessment and Assurance Committee or Pharmaceutical Services Subcommittee.

8.2 CONSULTANT PHARMACIST QUARTERLY REPORT

POLICY

The consultant pharmacist prepares quarterly written reports on the status of the nursing care center's pharmaceutical services and nursing staff performance related to medication therapy.

PROCEDURES

1. The consultant pharmacist presents a quarterly report at the designated meeting of the Quality Assessment and Assurance Committee or Pharmaceutical Services Subcommittee.

2. Recommendations for improvement are included in the quarterly report, and are discussed during the appropriate committee meeting.

3. Quarterly reports are kept on file per facility protocol.

4. Quarterly report topics may be incorporated into the consultant pharmacist's Continuous Quality Improvement (CQI) activities.

8.3 MONITORING OF MEDICATION ADMINISTRATION

POLICY

The consultant pharmacist evaluates medication administration to verify that the resident has received medications in accordance with the prescriber's orders and nursing care center policy. Procedures, personnel, and techniques are monitored, and intervention is provided when necessary. Medication administration monitoring includes, but is not limited to, medication pass observations, which are conducted by the consultant pharmacist or other designated nursing care center or pharmacy personnel.

PROCEDURES

1. The consultant pharmacist, designated nursing staff or pharmacy designee, performs quality assurance evaluations to determine that:

    a. Medications are administered at the frequency and times indicated in the prescriber orders.

    b. "Stop order" policies, where utilized, are observed.

    c. Refusal or inability of the resident to take medications is evaluated, documented and responded to appropriately.

    d. Alteration of dosage forms, such as pill crushing, has not impaired therapeutic response.

    e. Administration of medications is documented, including the frequency and reason for administration of as needed (PRN) medications.

    f. Residents who self-administer medications are counseled regarding technique. The consultant pharmacist routinely evaluates the resident's response to therapy, storage conditions, and medication information needs.

2. The consultant pharmacist, designated nursing staff or pharmacy designee, periodically observes the medication administration techniques of staff and/or assists and advises the nursing care center in conducting medication administration ("med pass") observations as follows:

    a. The medication pass observation may include, but not be limited to:

        - Identification of the medication product given

- Observation and recording of the administration of medications, including:
    - Identification of resident
    - Preparation for administration
    - Time of administration
    - Technique of administration
    - Documentation of administration
- Reconciliation of observation with prescriber's orders, including:
    - Identification of any orders omitted
    - Verification of current orders for medication given
- Calculation of medication error rate, which is the number of errors observed divided by the opportunities for errors (doses given plus doses ordered but not given) multiplied by 100.
- Determination of significance of medication errors observed
    - Significant medication error means one that causes the resident discomfort or jeopardizes health. Criteria for judging significant medication errors as well as examples are listed below. Medication error is the preparation or administration of medications or biologicals which is not in accordance with:
        - Prescriber's orders
        - Manufacturer's specifications (not recommendations) regarding the preparation and administration of the medication or biological.
        - Accepted professional standards and principles that apply to professionals providing services. Accepted professional standards and principles include various practice regulations in each state and current commonly accepted health standards established by national organizations, boards and councils.

- The relative significance of medication errors is a matter of professional judgment. Follow three general rules in determining whether a medication error is significant or not:

  - Resident Condition: The resident's condition is an important factor to take into consideration. For example, a potent diuretic erroneously administered to a dehydrated resident may have serious consequences but if administered to a resident with a normal fluid balance may not. If the resident's condition requires rigid control, a single missed or wrong dose can be highly significant.

  - Medication Category: If the medication is from a category that usually requires the resident to be titrated to a specific blood level, a single medication error could alter that level and precipitate a reoccurrence of symptoms or toxicity. This is especially important with a medication that has a Narrow Therapeutic Index (NTI); such as a medication in which the therapeutic dose is very close to the toxic dose. Examples of medications with NTI are as follows:

    - Antiarrhythmics: digoxin (Lanoxin®)

    - Anti-asthmatics: theophylline (TheoDur®)

    - Anticoagulants: warfarin (Coumadin®)

    - Anticonvulsants: carbamazepine (Tegretol®), phenytoin (Dilantin®), valproic acid (Depakote®)

    - Antimanic Agents: lithium salts (Eskalith®, Lithobid®)

  - Frequency of Error: If an error is occurring with any frequency, there is more reason to classify the error as significant. For example, if a resident's medication was omitted several times, as verified by reconciling the number of doses delivered with the number administered, classifying that error as significant would be more in order. This conclusion may be especially valid when taken in concert with the resident's condition and the medication category.

8.4 MEDICATION MANAGEMENT

POLICY

Each resident's drug regimen is reviewed to ensure it is free from unnecessary drugs. This includes any drug

- in excessive dose (including duplicate drug therapy);
- for excessive duration;
- without adequate monitoring;
- without adequate indications for its use;
- in the presence of adverse consequences which indicate the dose should be reduced or discontinued; or
- any combination of these reasons.

Medication management is based on the care process and includes recognition or identification of the problem/need, assessment, diagnosis/cause identification, management/treatment, monitoring, and revising interventions, as warranted as well as documenting medication management steps. The attending physician plays a key leadership role in medication management by developing, monitoring, and modifying the medication regimen in conjunction with residents, their families, and/or representative(s) and other professionals and direct care staff (the IDT). In order to optimize the therapeutic benefit of medication therapy and minimize or prevent potential adverse consequences, facility staff, the attending physician/prescriber, and the consultant pharmacist perform ongoing monitoring for appropriate, effective, and safe medication use.

When selecting medications and non-pharmacological approaches, members of the IDT, including the resident, his or her family, and/or representative(s), participate in the care process to identify, assess, address, advocate for, monitor, and communicate the resident's needs and changes in condition. The facility's medication management supports and promotes:

- Involvement of the resident, his or her family, and/or the resident representative in the medication management process. Selection of medications(s) based on assessing relative benefits and risks to the individual resident;
- Evaluation of a resident's physical, behavioral, mental, and psychosocial signs and symptoms, in order to identify the underlying cause(s), including adverse consequences of medications;
- Selection and use of medications in doses and for the duration appropriate to each resident's clinical conditions, age, and underlying causes of symptoms and based on assessing relative benefit and risks to, and preferences and goals of, the individual resident;
- The use of non-pharmacological approaches, unless contraindicated, to minimize the need for medications, permit use of the lowest possible dose, or allow medications to be discontinued; and

- The monitoring of medications for efficacy and adverse consequences.
- Resident Choice – If a resident declines treatment, the facility staff and physician should inform the resident about the risks related to the lack of the medication, and discuss appropriate alternatives such as offering the medication at another time or in another dosage form, or offer an alternative medication or non-pharmacological approach.
- Advance Directives – A resident's advance directives may include withdrawing or withholding medications. Whether or not a resident has an advance directive, the facility is responsible for giving treatment, support, and other care that is consistent with the resident's condition and applicable care instructions, according to the resident's care plan.

To address the issue of antimicrobial stewardship, the center has developed an antimicrobial stewardship program that will optimize the treatment of infections while reducing the adverse events associated with antibiotic use. This program includes tools, policies, and procedures that aim to guide the center toward responsible and effective use of antibiotics.

Additional specific guidelines are applied to Psychotropic drugs which are defined as any drug that affects brain activities associated with mental processes and behavior. This includes, but are not limited to

- Antipsychotics;
- Antidepressants;
- Anti-anxiety; and
- Hypnotics

All medications included in the psychotropic medication definition may affect brain activities associated with mental processes and behavior. Use of psychotropic medications, other than antipsychotics, should not increase when efforts to decrease antipsychotic medications are being implemented. Risks associated with psychotropic medications still exist regardless of the indication for their use (e.g., nausea, insomnia, itching), therefore the requirements pertaining to psychotropic medications in §483.45(e) apply to the four categories of drugs (anti-psychotic, anti-depressant, anti-anxiety and hypnotic) listed in §483.45(c)(3) without exception.

Other medications not classified as anti-psychotic, anti-depressant, anti-anxiety, or hypnotic medications can also affect brain activity and should not be used as a substitution for another psychotropic medication listed in §483.45(c)(3), unless prescribed with a documented clinical indication consistent with accepted clinical standards of practice and in accordance with §483.45(d)(4). Categories of medications which affect brain activity include antihistamines, anti-cholinergic medications and central nervous system agents used to treat conditions such as seizures, mood disorders, pseuodobulbar affect, and muscle spasms or stiffness. The requirements pertaining to psychotropic medications apply to these types of medications when their documented use appears to be a substitution for another psychotropic medication rather than for the original or approved indication.
Based on a comprehensive assessment of a resident, the facility must ensure:

- Residents **who have not** used psychotropic drugs are not given these drugs unless the medication is necessary to treat a specific condition as diagnosed and documented in the clinical record.
- Residents who use psychotropic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.
- PRN orders for psychotropic drugs (excluding anti-psychotics) are limited to 14 days. Exception: If the attending physician or prescribing practitioner believes that it is appropriate for the PRN order to be extended beyond 14 days, he or she should document their rationale in the resident's medical record and indicate the duration for the PRN order.
- PRN orders for anti-psychotic drugs are limited to 14 days and cannot be renewed unless the attending physician or prescribing practitioner evaluates the resident for the appropriateness of that medication.

The intent of this requirement is that:

- each resident's entire drug/medication regimen is managed and monitored to promote or maintain the resident's highest practicable mental, physical, and psychosocial well-being;
- the facility implements gradual dose reductions (GDR) and non-pharmacological interventions, unless contraindicated, prior to initiating or instead of continuing psychotropic medication; and
- PRN orders for psychotropic medications are only used when the medication is necessary and PRN use is limited.

PROCEDURES

The interdisciplinary team reviews the resident's medication regimen for efficacy and actual or potential medication-related problems on an ongoing basis and with consideration of resident preferences.

1. The consultant pharmacist or member of the Interdisciplinary team compiles, analyzes, and presents findings regarding the proper monitoring of medication therapy to appropriate healthcare disciplines.

2. Residents receive medications only if ordered by the prescriber. The medical necessity is documented in the resident's medical record and in the care planning process.

3. The prescriber and the care planning team reassess the continued need for the ordered medication. Effects of the medications are documented as a part of the care planning process.

4. Non-pharmacological interventions such as behavior modification or social services and their effects are documented as a part of the care planning process, and are utilized by the prescriber in assessing the continued need for medication.

5. Initiation and dosing of medications follows recommendation from the medical literature, standards of practice, and regulations. Medication therapy is initiated at low doses and gradually increased as necessary.

6. Dose scheduling of the medications takes into account the resident's lifestyle and habits (e.g., a resident should not be awakened to receive a medication for insomnia).

7. All of the following conditions are satisfied prior to initiation and/or continuation of therapy:
   a. Possible reversible causes for the resident's condition have been ruled out.
   b. Use results in maintenance or improvement in the resident's functional status.
   c. The need for and response to therapy are monitored and documented in the resident's medical record.

8. For deviation from the recommended dosage, the clinical record contains evidence to support justification for use of a medication not meeting the dosage criteria but considered clinically appropriate by the physician. Examples include:
   a. A medical or psychiatric consultation or evaluation supporting/confirming the physician's conclusion.
   b. Physician, nurse, or other health professional documentation that the resident is being monitored for adverse consequences or complications of therapy.
   c. Documentation of resident's subjective or objective improvement or maintenance of function while on the regimen in question.
   d. Documentation that a resident's decline or deterioration is evaluated by the interdisciplinary team to determine that the regimen in question is not the cause.
   e. Documentation that the resident's age, weight, or other factors require a unique medication dose or duration.

9. The resident's medication regimen is evaluated when there is a significant negative change from baseline.

10. A resident and/or representative has the right to be informed about the resident's condition; treatment options, relative risks and benefits of treatment, required monitoring, expected outcomes of the treatment; and has the right to refuse care and treatment. If the resident refuses treatment, the nursing care center staff and physician should inform the resident about the risks related to the refusal, and discuss appropriate alternatives such as offering the medication at another time or in another dosage form, or offer an alternative medication or non-pharmacological approach, if available.

GUIDELINES FOR PSYCHOTROPIC MEDICATION MONITORING

After initiating or increasing the dose of a psychotropic medication, the behavioral symptoms must be reevaluated periodically to determine the effectiveness of the medication and the potential for reducing or discontinuing the dose.

Acute or Emergency Situations
When a psychotropic medication is being initiated or used to treat an emergency situation (i.e., acute onset or exacerbation of symptoms or immediate threat to health or safety of resident or others) related to a documented condition or diagnosis, a clinician in conjunction with the IDT must evaluate and document the situation to identify and address any contributing and underlying causes of the acute condition and verify the need for a psychotropic medication. Use of psychotropic medication to treat an emergency situation must be consistent with the requirements regarding PRN orders for psychotropic and antipsychotic medications and any continued use must be consistent with the requirements for gradual dose reduction (GDR).

Enduring Conditions
Psychotropic medications may be used to treat an enduring (i.e., non-acute; chronic or prolonged) condition. Before initiating or increasing a psychotropic medication for enduring conditions, the resident's symptoms and therapeutic goals must be clearly and specifically identified and documented. Additionally, the facility must ensure that the resident's expressions or indications of distress are:

- Not due to a medical condition or problem (e.g., pain, fluid or electrolyte imbalance, infection, obstipation, medication side effect or poly-pharmacy) that can be expected to improve or resolve as the underlying condition is treated or the offending medication(s) are discontinued;
- Not due to environmental stressors alone (e.g., alteration in the resident's customary location or daily routine, unfamiliar care provider, hunger or thirst, excessive noise for that individual, inadequate or inappropriate staff response), that can be addressed to improve the symptoms or maintain safety;
- Not due to psychological stressors alone (e.g., loneliness, taunting, abuse), anxiety or fear stemming from misunderstanding related to his or her cognitive impairment (e.g., the mistaken belief that this is not where he/she lives or inability to find his or her clothes or glasses, unaddressed sensory deficits) that can be expected to improve or resolve as the situation is addressed; and
- Persistent – The medical record must contain clear documentation that the resident's distress persists and his or her quality of life is negatively affected and, unless contraindicated, that multiple, non-pharmacological approaches have been attempted and evaluated in any attempts to discontinue the psychotropic medication.

New Admissions: The attending physician in collaboration with the consultant pharmacist must re-evaluate the use of the psychotropic medication and consider whether or not the medication can be reduced or discontinued upon admission or soon after admission. Additionally, the facility is responsible for:

- Preadmission screening for mental illness and intellectual disabilities and
- Obtaining physician's orders for the resident's immediate care.

Monitoring of Psychotropic Medications: When monitoring a resident receiving psychotropic medications, the facility must evaluate the effectiveness of the medications as well as look for potential adverse consequences. After initiating or increasing the dose of a psychotropic medication, the behavioral symptoms must be reevaluated periodically (at least during quarterly care plan review, if not more often) to determine the potential for reducing or discontinuing the dose based on therapeutic goals and any adverse effects or functional impairment.

Potential Adverse Consequences: The facility assures that residents are being adequately monitored for adverse consequences such as:

- **General**: anticholinergic effects which may include flushing, blurred vision, dry mouth, altered mental status, difficulty urinating, falls, excessive sedation, constipation
- **Cardiovascular:** signs and symptoms of cardiac arrhythmias such as irregular heart beat or pulse, palpitations, lightheadedness, shortness of breath, diaphoresis, chest or arm pain, increased blood pressure, orthostatic hypotension
- **Metabolic:** increase in total cholesterol and triglycerides, unstable or poorly controlled blood sugar, weight gain
- **Neurologic:** agitation, distress, EPS, neuroleptic malignant syndrome (NMS), parkinsonism, tardive dyskinesia, cerebrovascular event (e.g., stroke, transient ischemic attack (TIA)).

If the psychotropic medication is identified as possibly causing or contributing to adverse consequences as identified above, the facility and prescriber must determine whether the medication should be continued and document the rationale for the decision. Additionally, the medical record should show evidence that the resident, family member or representative is aware of and involved in the decision. In some cases, the benefits of treatment may outweigh the risks or burdens of treatment, so the medication may be continued.

Antipsychotic Medications

Indication for use must be thoroughly documented in the medical record. While antipsychotic medication may be prescribed for expressions or indications of distress, the IDT must first identify and address any medical, physical, psychological causes, and/or social/environmental triggers. Any prescribed antipsychotic medication must be administered at the lowest possible dosage for the shortest period of time and is subject to the GDR requirements for psychotropic medications.

Diagnoses alone do not necessarily warrant the use of an antipsychotic medication. Antipsychotic medications may be indicated if:

- behavioral symptoms present a danger to the resident or others;
- expressions or indications of distress that are significant distress to the resident;
- If not clinically contraindicated, multiple non-pharmacological approaches have been attempted, but did not relieve the symptoms which are presenting a danger or significant distress; and/or
- GDR was attempted, but clinical symptoms returned.

Gradual Dose Reduction for Psychotropic Medications
The regulation addressing the use of psychotropic medications identifies the process of tapering as a GDR and requires a GDR, unless clinically contraindicated.

Dose reductions should occur in modest increments over adequate periods of time to minimize withdrawal symptoms and to monitor symptom recurrence. Compliance with the requirement to perform a GDR may be met if, for example, within the first year in which a resident is admitted on a psychotropic medication or after the prescribing practitioner has initiated a psychotropic medication, a facility attempts a GDR in two separate quarters (with at least one month between the attempts), unless clinically contraindicated. Additional information related to gradual dose reduction may be found The American Psychiatric Association Practice Guidelines on the use of Antipsychotics to Treat Agitation or Psychosis in Patients with Dementia, 2016, https://psychiatryonline.org/doi/full/10.1176/appi.books.9780890426807.ap02 and at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3119470/, Discontinuing Medications: A Novel Approach for Revising the Prescribing Stage of the Medication-Use Process (2008).

Clinical Contraindication Requirements for Gradual Dose Reduction Psychotropic Use with a Dementia Diagnosis:

For any individual who is receiving a psychotropic medication to treat expressions or indications of distress related to dementia, the GDR may be considered clinically contraindicated for reasons that include, but that are not limited to:

- The resident's target symptoms returned or worsened after the most recent attempt at a GDR within the facility; **and**
- The physician has documented the clinical rationale for why any additional attempted dose reduction at that time would be likely to impair the resident's function or increase distressed behavior.

Clinical Contraindication Requirements for Gradual Dose Reduction Psychotropic Use in a Disorder OTHER THAN Dementia Diagnosis
For any individual who is receiving a psychotropic medication to treat a disorder other than expressions or indications of distress related to dementia (for example, schizophrenia, bipolar mania, depression with psychotic features, or another medical condition, other than dementia, which may cause psychosis), the GDR may be considered clinically contraindicated for reasons that include, but that are not limited to:

- The continued use is in accordance with relevant current standards of practice and the physician has documented the clinical rationale for why any attempted dose reduction would be likely to impair the resident's function or exacerbate an underlying medical or psychiatric disorder; **or**
- The resident's target symptoms returned or worsened after the most recent attempt at a GDR within the facility and the physician has documented the clinical rationale for why

any additional attempted dose reduction at that time would be likely to impair the resident's function or exacerbate an underlying medical or psychiatric disorder.

The requirements emphasize the importance of seeking an appropriate dose and duration for each medication and minimizing the risk of adverse consequences. The purpose of tapering a medication is to find an optimal dose or to determine whether continued use of the medication is benefiting the resident. Tapering may be indicated when the resident's clinical condition has improved or stabilized, the underlying causes of the original target symptoms have resolved, and/or non-pharmacological approaches have been effective in reducing the symptoms.

PRN Orders for Psychotropic and Antipsychotic Medications

In certain situations, psychotropic medications may be prescribed on a PRN basis, such as while the dose is adjusted, to address acute or intermittent symptoms, or in an emergency. However, residents must not have PRN orders for psychotropic medications unless the medication is necessary to treat a diagnosed specific condition. The attending physician or prescribing practitioner must document the diagnosed specific condition and indication for the PRN medication in the medical record.

The table below explains additional limitations for PRN psychotropic (other than antipsychotic medications) and PRN antipsychotic medications.

Type of PRN order	Time Limitation	Exception	Required Actions
PRN orders for Psychotropic medications, excluding antipsychotics	14 days	Order may be extended beyond 14 days if the attending physician or prescribing practitioner believes it is appropriate to extend the order.	Attending physician or prescribing practitioner should document the rationale for the extended time period in the medical record and indicate a specific duration.
PRN orders for antipsychotic medications only	14 days	none	If the attending physician or prescribing practitioner wishes to write a new order for the prn antipsychotic, the attending physician or prescribing practitioner must evaluate the resident (through direct examination) to determine if the new order for the prn antipsychotic is appropriate.

The required evaluation of a resident before writing a new PRN order for an antipsychotic entails the attending physician or **prescribing practitioner directly examining** the resident and assessing the resident's current condition and progress to determine if the PRN antipsychotic medication is still needed. As part of the evaluation, the attending physician or prescribing practitioner should, at a minimum, determine and document the following in the resident's medical record:

- Is the antipsychotic medication still needed on a PRN basis?
- What is the benefit of the medication to the resident?
- Have the resident's expressions or indications of distress improved as a result of the PRN medication?

NOTE: Report of the resident's condition from facility staff to the attending physician or prescribing practitioner does not constitute an evaluation.

Identifying Opportunities for Gradual Dose Reductions:
There are various opportunities during the care process to evaluate the effects of medications on a resident's physical, mental, and psychosocial well-being, and to consider whether the medications should be continued, reduced, discontinued, or otherwise modified. Examples of these opportunities include:

- During the monthly medication regimen review, the pharmacist evaluates resident-related information for dose, duration, continued need, and the emergence of adverse consequences for all medications;
- When evaluating the resident's progress, the attending physician or prescribing practitioner reviews the total plan of care, orders, the resident's response to medication(s), and determines whether to continue, modify, or stop a medication; and
- During the quarterly MDS review, the facility evaluates mood, function, behavior, and other domains that may be affected by medications.

The time frames and duration of attempts to taper any medication must be consistent with accepted standards of practice and depend on factors including the coexisting medication regimen, the underlying causes of symptoms, individual risk factors, and pharmacologic characteristics of the medications. Some medications (e.g., antidepressants, sedative/hypnotics, opioids) require more gradual tapering so as to minimize or prevent withdrawal symptoms or other adverse consequences. Close monitoring while medications are tapered will enable facility staff to determine whether a resident is experiencing side effects, changes in behavior, or withdrawal symptoms that originally prompted prescribing of the drug.

However, some residents with specific, enduring, progressive, or terminal conditions may need specific types of psychotropic medications or other medications which affect brain activity indefinitely. This applies to conditions such as:

- Chronic depression,
- Parkinson's disease psychosis, or
- Recurrent seizures.

Evaluating Effectiveness
If the resident's condition has not responded to treatment or has declined despite treatment, it is important to evaluate both the medication and the dose to determine whether the medication should be discontinued or the dosing should be altered, whether or not the facility has implemented GDR as required, or tapering.

Chemical Restraints
The facility must ensure that the resident is free from physical or chemical restraints imposed for the purposes of discipline or convenience and that are not required to treat the resident's medical symptoms. When the use of restraints is indicated, the facility must use the least restrictive alternative for the least amount of time and document the ongoing re-evaluation of the need for restraints.

When any medication restricts the resident's movement or cognition, or sedates or subdues the resident, and is not an accepted standard of practices for a resident's medical or psychiatric condition, the medication may be a chemical restraint.

A medication may have been required to treat a medical symptom, and as a result, the medical symptom is no longer present. In some cases, the clinical goal of the continued use of the medication is to stabilize the symptoms of the disorder so that the resident can function at the highest level possible. In other words, the clinical goal is to have no symptoms of the disorder. Although the symptom may no longer be present, the disease process is still present. For example, diseases may include:

- Chronic psychiatric illness such as schizophrenia or schizoaffective disorder, bipolar disorder, depression, or post-traumatic stress disorder;
- Neurological illness such as Huntington's disease or Tourette's syndrome; and
- Psychosis and psychotic episodes.

In such instances, if the medication is reduced or discontinued, the symptoms may return. Reducing or eliminating the use of the medication may be contraindicated and must be individualized. If the medication is still being used, the clinical record must reflect the rationale for the continued administration of the medication. If no rationale is documented, this may meet the criteria for a chemical restraint, such as for staff convenience

a. **Determination of Medical Symptoms**
The clinical record must reflect whether the staff and practitioner have identified, to the extent possible, and addressed the underlying cause(s) of distressed behavior, either before or while treating a medical symptom. Potential underlying causes for expressions and/or indications of distress may include, but are not limited to:
    - Delirium;
    - Pain;
    - The presence of an adverse consequence associated with the resident's current medication regimen; and
    - Environmental factors, such as staffing levels, over stimulating noise or activities, under stimulating activities, lighting, hunger/thirst, alteration in the resident's customary location or daily routine, physical aggression leading to altercations, temperature of the environment, and crowding.

b. **Determination of Indication for Medication Use**

- The clinical record must reflect the following: Whether there is an adequate indication for use for the medication (e.g., a psychotropic medication is not administered unless the medication is used to treat a specific condition);
- Whether an excessive dose and/or duration of the medication was administered to the resident;
- Whether there is adequate monitoring for the effectiveness of the medication in treating the specific condition and for any adverse consequences resulting from the medication;
- Whether a resident who uses a psychotropic drug(s) is receiving gradual dose reduction and behavioral interventions, unless clinically contraindicated; and
- Whether a resident who receives a psychotropic drug(s) pursuant to a PRN (pro re nata, or as needed) order is not administered the medication unless the medication is necessary to treat a diagnosed specific symptom, as documented in the clinical record.

If the practitioner orders a medication to be administered on a PRN time-limited basis for the provision of medical treatment to address an emergency medical condition (e.g., delirium), this would not be considered to be a chemical restraint. The dosage cannot exceed what is prescribed by the practitioner, and if the resident does not respond to the initial administration of the PRN medication, the practitioner must be contacted, regarding re-assessment of the resident's medical condition and evaluation of interventions. The administration of a PRN medication must be discontinued when the resident does not need the medication for treatment of the medical condition see F605 (and appendix PP) for limitations on psychotropic and anti-psychotic medication PRN orders). If staff continue to utilize a PRN medication that subdues or sedates a resident, and is not treating a medical condition, this would be considered to be a chemical restraint for staff convenience or discipline.

c. **Risks and Psychosocial Impacts Related to Use of Chemical Restraints**
A medication that is used for discipline or convenience and is not required to treat medical symptoms, may cause the resident to be:

- Subdued, sedated, or withdrawn;
- Asleep during hours that he/she would not ordinarily be asleep; or
- Limited in his/her functional capacity.

Additional effects resulting from sedating or subduing a resident may include, but are not limited to, the following:

- Loss of autonomy, dignity, self-respect and orientation;
- Confusion, cognitive decline, withdrawal, depression;
- Decreased activity levels, including social activities;
- Decline in skin integrity;
- Decline in continence level;

- Decline in physical functioning including an increased dependence in activities of daily living (e.g., ability to walk), impaired muscle strength and balance, decline in range of motion, and risk for development of contractures, increased risk of falls; and
- Weight loss if missing meals.

8.5 CONTINUOUS QUALITY IMPROVEMENT (CQI) OF THE MEDICATION USE PROCESS

POLICY

Continuous quality improvement is a mechanism for the care center to establish routine processes for assessing and improving the quality of outcomes within the care center. The care center is responsible for monitoring the quality of the entire medication use process, including the provision of pharmacy services and the outcomes of consultant pharmacist services. The consultant pharmacist is responsible for conducting ongoing assessments of the care center's effectiveness in systems audits, medication administration procedures and pharmacy services.

PROCEDURES

1. The consultant pharmacist is a member of the Pharmaceutical Services Committee/Quality Assessment and Assurance Committee, which is responsible for oversight of medication use CQI activities.

2. The consultant pharmacist assists the Pharmaceutical Services Committee/Quality Assessment and Assurance Committee in identifying process and outcome issues appropriate for CQI study.

3. The consultant pharmacist may initiate CQI studies to assess and improve quality relating to all aspects of the medication use system (prescribing, dispensing, administering, monitoring). Examples of areas of study may include:

    a. Analysis of medication regimen review process

        - Type of recommendations made
        - Response to recommendations
        - Outcome of implementation of recommendations
        - Cost savings analysis

    b. Medication administration error rate

    c. Adverse drug reactions

    d. Medication errors

e. Inservice education programs and outcomes

f. Medication storage

g. Medication administration documentation

h. Medication ordering and receipt

i. Medication delivery

j. Medication labeling

k. Overall medication utilization

l. Disease state/diagnosis management

m. Psychotherapuetic medication use

n. Adherence to pharmacy policies and procedures

o. Medication class utilization studies

p. Controlled medication use

q. Emergency medication use

Appendix of Resources

9.0 APPENDIX OF RESOURCES

Table of Contents

The purpose of this section is to provide convenient tool samples, references and resources. The contents may be used as a guide and will not be utilized by the nursing care center staff unless approved by appropriate committees.

9.1 CONTROLLED MEDICATION SCHEDULES

The Drug Enforcement Administration schedules substances and medications as controlled substances. Factors that determine control or removal of substances from Schedules include:

- Actual or relative potential for abuse
- Scientific evidence of its pharmacological effect, if known
- The state of current scientific knowledge regarding the substance
- Its history and current pattern of abuse
- The scope, duration, and significance of abuse
- What, if any, risk there is to the public health
- Its psychic or physiological dependence liability
- Whether the substance is an immediate precursor of a substance already controlled

Schedule I
Substances classified as Schedule I Controlled Substances are those with: a high potential for abuse; no currently accepted medical use in treatment in the United States; and a lack of accepted safety for use under medical supervision.

- (1-(4-Fluorobenzyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone
- 1-(1,3-Benzodioxol-5-yl)-2-(dimethylamino)pentan-1-one
- 1-(1-Phenylcyclohexyl)pyrrolidine
- 1-(2-Phenylethyl)-4-phenyl-4-acetoxypiperidine
- 1-(5-Fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-indazole3-carboxamide
- 1-[1-(2-Thienyl)cyclohexyl]piperidine
- 1-[1-(2-Thienyl)cyclohexyl]pyrrolidine
- 1-Methyl-4-phenyl-4-propionoxypiperidine
- 2-(2-((2,3-Dihydrobenzofuran-5-yl)methyl)-5-nitro-1Hbenzimidazol-1-yl)-N,N-diethylethan-1-amine
- 2-(2-(4-Ethoxybenzyl)-5-methyl-1H-benzimidazol-1-yl)-N,N-diethylethan-1-amine
- 2-(2-(4-Ethoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)-N,N-dimethylethan-1-amine
- 2-(2-(4-Ethoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)-Nethylethan-1-amine
- 2-(2-(Benzodioxol-5-ylmethyl)-5-nitro-1H-benzimidazol1-yl)-N,N-diethylethan-1-amine
- 2-(2,5-Dimethoxy-4-(n)-propylphenyl) ethanamine
- 2-(2,5-Dimethoxy-4-ethylphenyl) ethanamine

- 2-(2,5-Dimethoxy-4-methylphenyl) ethanamine
- 2-(2,5-Dimethoxy-4-nitro-phenyl) ethanamine
- 2-(2,5-Dimethoxyphenyl) ethanamine
- 2-(4-Bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine
- 2-(4-Chloro-2,5-dimethoxyphenyl) ethanamine
- 2-(4-Chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine
- 2-(4-Ethylthio-2,5-dimethoxyphenyl) ethanamine
- 2-(4-Iodo-2,5-dimethoxyphenyl) ethanamine
- 2-(4-Iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine
- 2-(4-Isopropoxybenzyl)-5-nitro-1-(2-(pyrrolidin-1-yl)ethyl)-1H-benzimidazole
- 2-(4-Isopropylthio)-2,5-dimethoxyphenyl) ethanamine
- 2-(4-Methoxybenzyl)-5-nitro-1-(2-(pyrrolidin-1-yl)ethyl)- 1H-benzimidazole (N-pyrrolidino metonitazene)
- 2-(Ethylamino)-2-(3-methoxyphenyl)cyclohexan-1-one(methoxetamine)
- 2,5-Dimethoxy-4-(n)-propylthiophenethylamine
- 2,5-Dimethoxy-4-ethylamphetamine
- 2,5-Dimethoxyamphetamine
- 2',5'-Dimethoxyfentanyl
- 2'-Fluoro ortho-fluorofentanyl
- 2-Methoxy-N-(1-phenethylpiperidin-4-yl)-Nphenylacetamide
- 3,4,5-Trimethoxyamphetamine
- 3,4-Methylenedioxyamphetamine
- 3,4-Methylenedioxymethamphetamine
- 3,4-Methylenedioxy-N-ethylamphetamine
- 3-Fluoro-N-methylcathinone
- 3-Furanyl fentanyl
- 3-Methylfentanyl
- 3-Methylmethcathinone
- 3-Methylthiofentanyl
- 4,4′-Dimethylaminorex
- 4′-Methyl-alpha-pyrrolidinohexiophenone
- 4-Bromo-2,5-dimethoxyamphetamine
- 4-Bromo-2,5-dimethoxyphenethylamine
- 4'-Chloro-alpha-pyrrolidinovalerophenone
- 4-Chloromethcathinone
- 4-Fluoroisobutyryl fentanyl
- 4-Fluoro-N-methylcathinone
- 4-Methoxyamphetamine
- 4'-Methyl acetyl fentanyl
- 4-Methyl-2,5-dimethoxyamphetamine
- 4-Methyl-alpha-ethylaminopentiophenone
- 4-Methyl-alphapyrrolidinopropiophenone
- 4-Methylaminorex (cis isomer)

- 4-Methyl-N-ethylcathinone
- 5-Methoxy-3,4-methylenedioxyamphetamine
- 5-Methoxy-N,N-diisopropyltryptamine
- 5-Methoxy-N,N-dimethyltryptamine
- 5-Nitro-2-(4-propoxybenzyl)-1-(2-(pyrrolidin-1-yl)ethyl)-1H-benzimidazole
- Acetorphine
- Acetyl Fentanyl
- Acetyl-alpha-methylfentanyl
- Acetyldihydrocodeine
- Acetylmethadol
- Acryl fentanyl
- Alfaxalone
- Alfentanil
- Allylprodine
- Alphacetylmethadol except levoalphacetylmethadol
- Alpha-ethyltryptamine
- Alphameprodine
- Alphamethadol
- alpha'-Methyl butyryl fentanyl
- Alpha-Methylfentanyl
- Alpha-Methylthiofentanyl
- alpha-Methyltryptamine
- alpha-pyrrolidinobutiophenone
- alpha-Pyrrolidinoheptaphenone
- alpha-Pyrrolidinohexanophenone
- alpha-Pyrrolidinopentiophenone
- Amineptine
- Aminorex
- Benzethidine
- Benzylmorphine
- Betacetylmethadol
- Beta-Hydroxy-3-methylfentanyl
- Beta-Hydroxyfentanyl
- beta-Hydroxythiofentanyl
- beta-Methyl fentanyl
- beta-Methylacetyl fentanyl
- Betameprodine
- Betamethadol
- beta-Methyl fentanyl
- beta-Methylacetyl fentany
- beta'-Phenyl fentanyl
- Betaprodine
- Brorphine

- Bufotenine
- Butonitazene
- Butylone
- Butyryl Fentanyl
- Cathinone
- Clonazolam
- Clonitazene
- Codeine methylbromide
- Codeine-N-oxide
- Crotonyl fentanyl
- Cyclopentyl fentanyl
- Cyclopropyl Fentanyl
- Cyprenorphine
- Desomorphine
- Dextromoramide
- Diampromide
- Diclazepam
- Diethylthiambutene
- Diethyltryptamine
- Difenoxin
- Dihydromorphine
- Dimenoxadol
- Dimepheptanol
- Dimethylthiambutene
- Dimethyltryptamine (DMT)
- Dioxaphetyl butyrate
- Dipipanone
- Drotebanol
- Ethyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate
- Ethylmethylthiambutene
- Ethylone
- Ethylphenidate
- Etizolam
- Etodesnitazene
- Etonitazene
- Etorphine (except HCl)
- Etoxeridine
- Eutylone
- Fenethylline
- Fentanyl carbamate
- Flualprazolam
- Flubromazolam
- Flunitazene

- Furanyl fentanyl
- Furethidine
- Gama Hydroxybutyric Acid (GHB)
- Heroin (Diacetylmorphine)
- Hydromorphinol
- Hydroxypethidine
- Ibogaine
- Isobutyryl fentanyl
- Isotonitazene
- Isovaleryl fentanyl
- Ketobemidone
- Levomoramide
- Levophenacylmorphan
- Lysergic acid diethylamide (LSD)
- Marijuana (Cannabis)
- Marihuana Extract
- Mecloqualone
- Mephedrone
- Mescaline
- Mesocarb
- meta-Fluorofentanyl
- meta-Fluorofuranyl fentanyl
- Methaqualone (Quaalude)
- Methcathinone (Cat)
- Methiopropamine
- Methyldesorphine
- Methyldihydromorphine
- Methylone
- Metodesnitazene
- Metonitazene
- Morpheridine
- Morphine methylbromide
- Morphine methylsulfonate
- Morphine-N-oxide
- Myrophine
- N-(1-Phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran2-carboxamide
- N-(2-Fluorophenyl)-N-(1-phenethylpiperidin-4-yl)propionamide
- N-(Adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide
- N,N-Dimethylamphetamine
- Naphyrone
- N-Benzylpiperazine
- N-Desethyl isotonitazene
- N-Ethyl-1-phenylcyclohexylamine

- N-Ethyl-2-(5-nitro-2-(4-propoxybenzyl)-1Hbenzimidazol-1-yl)ethan-1-amine
- N-Ethyl-3-piperidyl benzilate
- N-Ethylamphetamine
- N-Ethylhexedrone
- N-Ethylpentylone
- N-Hydroxy-3,4-methylenedioxyamphetamine
- Nicocodeine
- Nicomorphine
- N-Methyl-3-piperidyl benzilate
- Noracymethadol
- Norlevorphanol
- Normethadone
- Normorphine
- Norpipanone
- N-Piperidinyl etonitazene
- N-Pyrrolidino etonitazene
- Ocfentanil
- ortho-Chlorofentanyl
- ortho-Fluoroacryl fentanyl
- ortho-Fluorobutyryl fentanyl
- ortho-Fluorofuranyl fentanyl
- ortho-Fluoroisobutyryl fentanyl
- ortho-Methyl acetylfentanyl
- ortho-Methylcyclopropylfentany
- para-Chlorofentanyl
- para-Chloroisobutyryl fentanyl
- para-Fluoro furanyl fentanyl
- para-Fluoro valeryl fentanyl
- para-Fluorobutyryl fentanyl
- Para-Fluorofentanyl
- Parahexyl
- para-Methoxybutyryl fentanyl
- para-Methoxyfuranyl fentanyl
- para-Methoxymethamphetamine
- para-Methylcyclopropylfentanyl
- para-Methylfentanyl
- Pentedrone
- Pentylone
- Peyote
- Phenadoxone
- Phenampromide
- Phenomorphan
- Phenoperidine

- Phenyl fentanyl
- Pholcodine
- Piritramide
- Proheptazine
- Properidine
- Propiram
- Protonitazene
- Psilocybin (Magic Mushroom)
- Psilocyn (Magic Mushroom)
- Racemoramide
- Tetrahydrocannabinols
- Tetrahydrothiofuranyl fentanyl
- Thebacon
- Thiofentanyl
- Thiofuranyl fentanyl
- Tilidine
- Trimeperidine
- Valeryl fentanyl
- Zipeprol

Schedule II
Substances classified as Schedule II Controlled Substances are those with: a high potential for abuse; a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions; and abuse potential which may lead to severe psychological or physical dependence.

- 1-Phenylcyclohexylamine
- 1-Piperidinocyclohexanecarbonitrile (PCC, Precursor of PCP)
- Alfentanil (Alfenta)
- Alphaprodine (Nisentil)
- Amobarbital (Amytal®)
- Amphetamine (Adderall®, Dexedrine®, Obetrol®)
- Anileridine (Leritine®)
- Benzoylecgonine (Cocaine metabolite)
- Bezitramide (Burgodin®)
- Carfentanil (Wilnil®)
- Cocaine
- Cocoa Leaves
- Codeine
- Dexmethylphenidate (Focalin®)
- Dextroamphetamine (Dexedrine®)
- Dextropropoxyphene, bulk

- Dihydrocodeine (Didrate®, Parzone®)
- Dihydroetorphine (DHE)
- Diphenoxylate
- Diprenorphine
- Dronabinol in an oral solution (Syndros®)
- Ecognine (Cocaine precursor, in Coca leaves)
- Ethylmorphine (Dionin®)
- Etorphine HCl
- Fentanyl (Actiq®, Duragesic®, Fentora®, Innovar®, Oralet®, Sublimaze®)
- Glutethimide (Doriden®, Dorimide®)
- Hydrocodone (Dihydrocodeinone®)
- Hydrocodone combinations (Donnatussin®-DC, Entex®-HC, Hycodan®, Hycotuss®, Hydrocet®, Lortab®, Norco®, Tussafed®-HCG, Tussionex®, Vicodin®, Vicoprofen®,Zydone®, Zyrphen®-HC)
- Hydromorphone (Dilaudid®)
- Isomethadone (Isoamidone®)
- Levo-alphacetylmethadol (LAAM, long acting methadone)
- Levomethadyl acetate
- Levomethorphan
- Levorphanol (Levo-Dromoran®)
- Lisdexamfetamine (Vyvanse®)
- Meperidine (Demerol®, Mepergan®)
- Meperidine intermediate-A (Meperidine precursor)
- Meperidine intermediate-B (Meperidine precursor)
- Meperidine intermediate-C (Meperidine precursor)
- Metazocine
- Methadone (Amidone®, Dolophine®, Methadose®)
- Methadone intermediate (Methadone precursor)
- Methamphetamine (Desoxyn®, ICE, Crank, Speed)
- Methylphenidate (Concerta®, Methylin®, Ritalin®)
- Metopon
- Moramide-intermediate
- Morphine (Avinza®, B&O Suppositories®, Duramorph®, Kadian®, MSContin®, MSIR®, Oramorph®, RMS®, Roxanol®)
- Morphine, Anhydrous (Opium Tincture®)
- Nabilone (Cesamet®)
- Norfentanyl
- Noroxymorphone
- Oliceridine
- Opium extracts
- Opium fluid extract
- Opium poppy (Papaver somniferum)
- Opium tincture (Laudanum)

- Opium, granulated (Granulated opium)
- Opium, powdered (Powdered opium)
- Opium, raw (opium, gum opium)
- Oripavine
- Oxycodone and combinations (Endocet®, OxyContin®, Percocet®, Percodan®, Roxicet®, Roxicodone®, Tylox®)
- Oxymorphone (Numorphan®, Opana®)
- Pentobarbital (Neumbutal®)
- Phenazocine (Narphen®, Prinadol®)
- Phencyclidine (PCP®, Sernylan®)
- Phenmetrazine (Preludin®)
- Phenylacetone (P2P, phenyl-2-propanone, benzyl, methyl ketone)
- Piminodine
- Poppy Straw (Opium poppy capsules, poppy heads)
- Poppy Straw Concentrate (Concentrate of Poppy Straw, CPS)
- Racemorphan (Dromoran®)
- Remifentanil (Ultiva®)
- Secobarbital (Seconal®)
- Sufentanil (Sufenta®)
- Thebaine (Precursor of many narcotics)
- Thiafentanil (Thianil®)

Schedule III

Substances classified as Schedule III Controlled Substances are those with: a potential for abuse less than the medications in Schedules I and II; a currently accepted medical use in treatment in the United States; and abuse potential which may lead to moderate or low physical dependence or high psychological dependence.

- [3,2-c]-Furazan-5α-androstan-17β-ol
- [3,2-c]Pyrazole-androst-4-en-17β-ol
- 13β-Ethyl-17β-hydroxygon-4-en-3-one
- 17α-Methyl-3α,17β-dihydroxy-5α-androstane
- 17α-Methyl-3β,17β-dihydroxy-5α-androstane
- 17α-Methyl-3β,17β-dihydroxyandrost-4-ene
- 17α-Methyl-4-hydroxynandrolone
- 17α-Methyl-5α-androstan-17β-ol
- 17α-Methyl-androst-2-ene-3,17β-diol
- 17α-Methyl-androsta-1,4-diene-3,17β-diol
- 17α-Methyl-androstan-3-hydroxyimine-17β-ol
- 17α-Methyl-Δ1-dihydrotestosterone
- 17β-Hydroxy-androstano[2,3-d]isoxazole
- 17β-Hydroxy-androstano[3,2-c]isoxazole
- 18a-Homo-3-hydroxy-estra-2,5(10)-dien-17-one

- 19-Nor-4,9(10)-androstadienedione
- 19-Nor-4-androstenediol
- 19-Nor-4-androstenedione
- 19-Nor-5-androstenediol
- 19-Nor-5-androstenedione
- 1-Androstenediol
- 1-Androstenedione
- 2α,17α-Dimethyl-17β-hydroxy-5β-androstan-3-one
- 2α,3α-Epithio-17α-methyl-5α-androstan-17β-ol
- 3α,17β-Dihydroxy-5α-androstane
- 3β-Hydroxy-estra-4,9,11-trien-17-one
- 4-Androstenediol
- 4-Androstenedione
- 4-Chloro-17α-methyl-17β-hydroxy-androst-4-en-3-one
- 4-Chloro-17α-methyl-17β-hydroxy-androst-4-ene-3,11-dione
- 4-Chloro-17α-methyl-androst-4-ene-3β,17β-diol
- 4-Chloro-17α-methyl-androsta-1,4-diene-3,17β-diol
- 4-Dihydrotestosterone (Anabolex®, Andractim®, Pesomax®, Stanolone®)
- 4-Hydroxy-19-nortestosterone
- 4-Hydroxy-androst-4-ene-3,17-dione
- 4-Hydroxytestosterone
- 5-Androstenediol
- 5-Androstenedione
- 5α-Androstan-3,17-dione
- 5α-Androstan-3,6,17-trione
- 6-Bromo-androsta-1,4-diene-3,17-dione
- 6-Bromo-androstan-3,17-dione
- 6α-Methyl-androst-4-ene-3,17-dione
- Amobarbital & noncontrolled active ingredient (Amobarbital/ephedrine® capsules)
- Amobarbital suppository dosage form
- Anabolic steroids (“Body Building” Drugs)
- Aprobarbital (Alurate®)
- Barbituric acid derivative (Barbiturates not specifically listed)
- Benzphetamine (Didrex®, Inapetyl®)
- Bolasterone
- Boldenone (Equipoise®, Parenabol®, Vebonol®, dehydrotestosterone)
- Boldione
- Buprenorphine (Buprenex®, Subutex®, Suboxone®, Temgesic®)
- Butabarbital (Butisol®, Butibel®)
- Butalbital combinations (Fiorinal®, Butalbital with aspirin)
- Butobarbital (butethal)
- Calusterone (Methosarb®)
- Chlorhexadol (Mechloral®, Mecoral®, Medodorm®, Chloralodol®)

- Chlorotestosterone (same as clostebol)
- Chlorphentermine (Pre-Sate®, Lucofen®, Apsedon®, Desopimon®)
- Clortermine (Voranil®)
- Clostebol (Alfa-Trofodermin®, Clostene®, 4-chlorotestosterone)
- Codeine Combinations:
    - with Acetaminophen (Tylenol® with Codeine)
    - with Aspirin and combinations (Ascomp® with Codeine, Empirin® with Codeine)
    - with Butalbital (Fiorinal®)
    - with Carisprodol (Soma® Compound with Codeine)
    - with Promethazine (Phenergan with Codeine®)
    - with Psuedoephedrine (Cycofed®, Nucofed®)
- Dehydrochlormethyltestosterone (Oral-Turinabol®)
- Desoxymethyltestosterone (Madol®)
- Dihydrocodeine combinations (Baltussin®, ColdCough-PD®, Compal®, Cophene-S®, Novahistine®DH, Pancof®PD, Synalgos-DC®,)
- Dihydrotestosterone (same as stanolone)
- Dronabinol (Marinol®)
- Drostanolone (Drolban®, Masterid®, Permastril®)
- Embutramide (Tributane®)
- Estra-4,9,11-triene-3,17-dione
- Ethylestrenol (Maxibolin®, Orabolin®, Durabolin-O®, Duraboral®)
- Ethylmorphine combination product
- Fluoxymetsterone (Anadroid-F®, Halotestin®, Ora-Testryl®)
- Formebolone (Esiclene®, Hubernol®)
- Furazabol (Frazalon®; Miotolon®)
- Gamma Hydroxybutyric Acid preparations (Xyrem®)
- Ketamine (Ketaset®, Ketalar®, Special K, K)
- Lysergic acid (LSD precursor)
- Lysergic acid amide (LSD precursor)
- Mestanolone (Assimil®; Ermalone®; Methybol®; Tantarone®)
- Mesterolone (Androviron®, Proviron®, Testiwop®)
- Methandienone
- Methandranone
- Methandriol (Sinesex®, Stenediol,® Troformone®)
- Methandrosternolone (Dianabol®, Metabolina®, Nerobol®, Perbolin®)
- Methasterone
- Methenolone (Primobolan®, Primobolan Depot®, Primobolan S®)
- Methyldienolone
- Methyltestosterone (Android®, Oreton®, Testred®, Virilon®)
- Methyltrienolone (Metribolone®)
- Methyprylon (Noludar®)
- Mibolerone (Cheque® Matenon®)

- Morphine combination product/50 mg/(100 ml or 100gm)
- Morphine, Anhydrous (Paregoric®)
- Nalorphine (Nalline®)
- Nandrolone Decanoate (Pri-Andriol®)
- Norbolethone (Genabol®)
- Norclostebol (Anabol-4-19, Lentabol®)
- Norethandrolone (Nilevar®, Pronabol®, Solevar®)
- Normethandrolone (Lutenin®, Matronal®, Orgasteron®)
- Opium combination product 25 mg/du (Paregoric®, other combination products)
- Oxandrolone (Anavar®, Lonavar®, Provitar®, Vasorome®)
- Oxymesterone (Anamidol®, Balnimax®, Oranabol®, Oranabol 10®)
- Oxymetholone (Anadrol-50®, Adroyd®, Anapolon®, Anasteron®, Pardroyd®)
- Pentobarbital & noncontrolled active ingredients (FP-3)
- Pentobarbital suppository dosage form (WANS)
- Perampanel (Fycompa®)
- Phendimetrazine (Bontril®, Melfiat®, Prelu-2®, Rapdone®)
- Prostanozol
- Secobarbital & noncontrolled active ingredients
- Secobarbital suppository dosage form
- Stanozolol (Winstrol®, Winstrol-V®)
- Stenbolone
- Stimulant compounds previously excepted (mediatric)
- Sulfondiethylmethane
- Sulfonmethane
- Talbutal (Lotusate®)
- Testolactone (Teslac®)
- Testosterone (Androderm®, Androgel®, Striant®, Testim®)
- Testosterone Cypionate (Depo-Testadiol®, Depo-Testosterone®, Duo-Span®)
- Testosterone Enanthate (Delatestryl®)
- Tetrahydrogestrinone (THG)
- Thiamylal (Surital®)
- Thiopental (Pentothal®)
- Tiletamine & Zolazepam combination Product (Telazol®)
- Trenbolone (Finaplix-S®, Finajet®, Parabolan®)
- Vinbarbital (Delvinal®, vinbarbitone)
- Δ1-Dihydrotestosterone (1-Testosterone)

Schedule IV

Substances classified as Schedule IV Controlled Substances are those with: a low potential for abuse less than the medications in Schedules III; a currently accepted medical use in treatment in the United States; and abuse potential which may lead to limited physical dependence or psychological dependence relative to the medications in Schedule III.

- Alprazolam (Niravam®, Xanax®)
- Barbital (Veronal®, Plexonal®, Barbitone®)
- Brexanolone (Allopregnanolone®)
- Bromazepam (Lexotan®, Lexatin®, Lexotanil®)
- Butorphanol (Stadol®, Stadol NS®, Torbugesic,® Torbutrol®)
- Camazepam (Albego®, Limpidon®, Paxor®)
- Carisoprodol (Soma®)
- Cathine (Constituent of "Khat" plant)
- Chloral betaine (Beta Chlor®)
- Chloral Hydrate (Aquachloral®, Somnote®, Noctec®)
- Chlordiazepoxide and combinations (H-Tran®, Librium®, Limbitrol®)
- Clobazam (Urbadan®, Urbanyl®)
- Clonazepam (Klonopin®)
- Clorazepate (GenXene®, Tranxene®)
- Clotiazepam (Trecalmo®, Rize®, Clozan®, Veratran®)
- Cloxazolam (Akton®, Enadel®, Sepazon®, Tolestan®)
- Delorazepam
- Dexfenfluramine (Redux®)
- Dextropropoxyphene dosage forms (Darvon; propoxyphene; Darvocet; Propacet)
- Diazepam (Diastat®, Dizac®, Valium®)
- Dichloralphenazone (Midrin®, dichloralantipyrine)
- Diethylpropion (Radtue®)
- Difenoxin 1 mg/25 ug AtSO4/du (Motofen®)
- Eluxadoline (Viberzi®)
- Estazolam (ProSom®)
- Eszopiclone (Lunesta®)
- Ethchlorvynol (Placidyl®)
- Ethinamate (Valmid, Valamin®)
- Ethyl loflazepate
- Fencamfamin (Reactivan®)
- Fenfluramine (Pondimin®, Ponderal®)
- Fenproporex (Gacilin®, Solvolip®)
- Fludiazepam
- Flunitrazepam (Rohypnol®, Narcozep®, Darkene®, Roipnol®)
- Flurazepam (Dalmane®)
- Fospropofol (Lusedra®)
- Halazepam (Paxipam®)
- Haloxazolam
- Ketazolam (Anxon®, Loftran®, Solatran®, Contamex®)
- Lemborexant
- Loprazolam
- Lorazepam (Ativan®)
- Lorcaserin (Belviq®)

- Lormetazepam (Noctamid®)
- Mazindol (Sanorex®, Mazanor®)
- Mebutamate (Capla®)
- Medazepam (Nobrium®)
- Mefenorex (Anorexic®, Amexate®, Doracil®, Pondinil®)
- Mephobarbital (Methylphenobarbital, Mebaral®)
- Meprobamate and combinations (Equagesic®, Miltown®, Equanil®, Micrainin®, Meprospan®)
- Methohexital (Brevital®)
- Midazolam (Versed®)
- Modafinil (Provigil®)
- Nimetazepam (Erimin®)
- Nitrazepam (Mogadon®)
- Nordiazepam (Nordazepam®, Demadar®, Madar®)
- Oxazepam (Serax®)
- Oxazolam (Serenal®, Convertal®)
- Paraldehyde (Paral®)
- Pemoline (Cylert®)
- Pentazocine and combinations (Talacen®, Talwin®, Talwin®NX)
- Petrichloral (Pentaerythritol chloral®, Periclor®)
- Phenobarbital (Luminal®, Bellergal-S®)
- Phentermine (Adipex-P®, Atti-Plex®, Fastin®, Ionamin®, Obe-Nix®, Zantryl®)
- Pinazepam (Domar®)
- Pipradrol (Detaril®, Stimolag Fortis®)
- Prazepam (Centrax®)
- Quazepam (Doral®)
- Remimazolam
- Sibutramine (Meridia®)
- Solriamfetol
- SPA (Lefetamine®)
- Suvorexant
- Temazepam (Restoril®)
- Tetrazepam
- Tramadol (Ultracet)
- Triazolam (Halcion®)
- Zaleplon (Sonata®)
- Zolpidem (Ambien®)
- Zopiclone (Lunesta®)
- Zuranolone (Zurzuvae®)

Schedule V

Substances classified as Schedule V Controlled Substances are those with: a low potential for abuse relative to medications in Schedules IV; a currently accepted medical use in treatment in

the United States; and abuse potential which may lead to limited physical dependence or psychological dependence relative to the medications in Schedule IV.

- Brivaracetam (Briviact®)
- Cenobamate (Xcopri®)
- Codeine with Chlorpheniramine and Pseudoephedrine (Phenylhistine®DH, Ryna-C®)
- Codeine with Guaifenesin (Brontex®, Cheratussin®AC, Dex-Tuss®, Diabetic Tussin®C, Guiafenesin-AC, Iophen-C®NR, Mytussin®AC, Romilar®AC, Tussi-Organidin®NR, Tussiden-C®)
- Codeine with Promethazine (Prometh® with Codeine)
- Difenoxin preparations - 0.5 mg/25 ug AtSO4/du
- Dihydrocodeine preparations 100mg/(100 ml or 100gm)
- Diphenoxylate and combinations (Lomotil®, Lonox®)
- Ethylmorphine preparations 100 mg/(100 ml or 100 gm)
- Ezogabine (Potiga®)
- Ganaxolone
- Lacosamide (Vimpat®)
- Lasmiditan (Reyvow®)
- Opium preparations - 100 mg/(100 ml or 100 gm) (Parepectolin®, Kapectolin PG®, Kaolin Pectin P.G. ®)
- Pregabalin (Lyrica®)
- Pyrovalerone (Centroton®, Thymergix®)

REFERENCE

“Controlled Substances – Alphabetical Order.” Drug Enforcement Agency, January 12, 2026. Accessed January 16, 2026.
https://www.deadiversion.usdoj.gof/schedules/orangebook/c_cs_alpha.pdf

SIDE ONE

GRADUAL DOSE REDUCTION IN THE NURSING FACILITY

Federal regulations at F605 require that residents who are using psychotropic medications receive gradual ... ions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.

Gradual dose reduction (GDR) refers to the stepwise tapering of a dose to determine if symptoms, con... managed by a lower dose or if the dose or medication can be discontinued.

Psychotropic Medications

Psychotropic drugs affect brain activities associated with mental processes and behavior. These me... limited to, medications in the following categories:

- **Antipsychotics**
- **Antidepressants**
- **Anxiolytics**
- **Hypnotic**

Other Medications Affecting Brain Activity

Medications not classified as antipsychotic, antidepressant, anxiolytic, or hypnoti... ct brain ... should not be used as a substitution for a psychotropic medication, unless prescribed with a docu... l in ... nsistent w... accepted clinical standards of practice. Categories of medications which affect brain ...

- **Anticholinergics**
- **Antihistamines**
- **Central ... ...**

These medications may be used to treat conditions such as mood diso... sr... ar affect... s, and stiffness.

Requirements pertaining to psychotropic medications apply to th... when ... docum... e appears to be a substitution for another psychotropic medication rather th... igina... ed indication.

Gradual Dose Reductio... ...dications

CMS guidance emphasizes the importance of seeking a... pro... ation for each ... dic... n and minimizing risk of adverse consequences.

- The purpose of a GDR or tapering of medicati... n o... to determi... ether continued use of the medication is benefiting the resident.
- Tapering may be indicated when the reside... h... ed or ... the underlying causes of the original target symptoms have resolved, and ... ica... proach... en effective in reducing the symptoms.
- Documentation in the resident's ... ing attempt... d/or clinical contraindications must be clear, due to the serious and p... ... psych... pic medications.

Frequency of GDR/Tapering

- Dose reductions should occur ... dequa... of time to minimize withdrawal symptoms and to monitor symptoms ... currence...
- Time frames and d... attem... st be cons... n accepted standards of practice and depend on factors includin... dicat... nderlyi... uses of symptoms, individual risk factors, pharmacologic characteristic...
- Some medi... ... ng to ... or prevent withdrawal symptoms or other adverse conseque...

Within the first y... a... nitted ... otropic medication or after the prescribing practitioner has initiated ... psycho... should ... pted in two separate quarters (with at least one month between attem... unless ... dicated.

...hen Grad... ...e Reduction May Be Contraindicated

...ts receivin... ...ic medi... treat indications of distress related to dementia (e.g., schizophrenia, bipolar ...ep... ...wit... ...c featur... ...er medical condition, other than dementia, which may cause psychosis), the **GDR ...e r... ...in... ...contrai... ...d for reasons that include, but are not limited to:**

...n accordan... ...ith relevant current standards of practice and the physician has documented the clinical ...ny atte... ...dose reduction would be likely to impair the resident's function or exacerbate an underlying ...iatric di...

...ses... ...et sym... ...returned or worsened after the most recent attempted GDR within the facility and the physician h... ...nted t... ...rationale for why additional attempted dose reductions, at that time, would likely impair the ...funct... ...exacerbate an underlying medical or psychiatric disorder, or increase stressed behavior.

...nt with sp... ...enduring, progressive, or terminal conditions such as chronic depression, Parkinson's disease ...chosis, or recurrent seizures may need a specific type of psychotropic medication or other medication which affect brain activity, indefinitely.

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SIDE TWO

GRADUAL DOSE REDUCTION IN THE NURSING FACILITY

PRN Orders for Psychotropic and Antipsychotic Medications

Psychotropic medications may be prescribed on a PRN basis, such as while a dose is adjusted, to address acute or intermitte or in an emergency. For a resident to have a PRN order for a psychotropic medication, an attending physician or prescribing pr document the diagnosed specific condition and indication for the PRN medication in the resident's medical record.

Type of PRN Order	Time Limitation	Exception	Required Action
Order for psychotropic medication, excluding antipsychotics	14 days	Order may be extended beyond 14 days if the attending physician/prescribing practitioner believes it is appropriate to extend the order.	Attending physician/prescribin document the rationale for th medical record and indicate a
Order for antipsychotic medications only	14 days	None.	If attending physician/prescribing pr order for PRN antipsychotic, the attend practitioner must first evaluate the reside order is appropriat d document findings

Psychtropic Medications and Medications Affectin vity

Brand names provided if available, *generic equivalents are*

Antipsychotics	**First generation agents** • *chlorpromazine* • *haloperidol* • *perphenazine* • *nh* • *loxapine* • *thioridazine* • *thiothixene* • *pe* **Second generation (atypical) agents** • Abilify®/*aripiprazole* • Latuda®/*lurasidone* • Ri del®/q e • Clozaril®/*clozapine* • Vraylar®/*cariprazine* • *eri* lazid® erin • Geodon®/*ziprasidone* • Rexulti®/*brexpiprazole* • *olanz* • Lybalvi/*olanzapine and samidorphan*
Antidepressants	**Selective Serotonin Reuptake Inhibitors (SSR** • Celexa®/*citalopram* • Lexapro®/*esc* *uoxetine* Ce ®/*citalopr* **Serotonin-Norepinephrine Reuptake Inhi** • Cymbalta®/*duloxetine* • Effexor® *venlafaxine* **Tricyclic Antidepressants (TCAs)** • Elavil®/*amitriptyline* • No amin **Atypical Antidepressants** • Wellbutrin®/*bupropion*
Anxiolytics	**Benzodiazepines** • Ativan®/*lorazepam* • Onfi/*clob* • Valium®/*diazepam* • Xanax®/*alprazolam* **Non-benzodiazepine hypn** • Buspar® **Antidepressa** • See abov
Hypnotics	**Benzod** • Ati *nazepa* estoril®/*temazepam* • Valium®/*diazepam* • Hal *stazola* • Serax®/*oxazepam* • Xanax®/*alprazolam* **Non b es** • Ambie ta®/es • Rozerem®/*ramelteon* • Sonata®/*zaleplon* **edating** (e.g., trazodon **ating** (e.g., diph e, hydroxyzine) **exin rec ists** • Da borexant • Quviviq/*daridorexant*
	• *ropine* • Gocovri®/*amantadine* • Levsin®/*hyoscyamine* **s** ®/*pro* • Vistaril®/*hydroxyzine* • Benadryl®/*diphenhydramine* **rvous (CNS) Agents** al®/*la* • Namenda®/*memantine* • Nuedexta®/*dextromethorphan/quinidine* • Lyrica®/*pregabalin* umax® • Neurontin®/*gabapentin* • Tegretol®/*carbamazepine* • Valium®/*diazepam*

ascp www.ascp.com

The information contained herein is designed to serve as a guide. The material is not intended to be exhaustive and is subject to change. The information is correct to the best of the knowledge of the developers. It is the responsibility of health care professionals to use their professional judgment for safe and effective drug therapy, compliance with governmental regulations and agency guidelines.

Reference: Centers for Medicare & Medicaid Services, State Operations Manual, Appendix PP.

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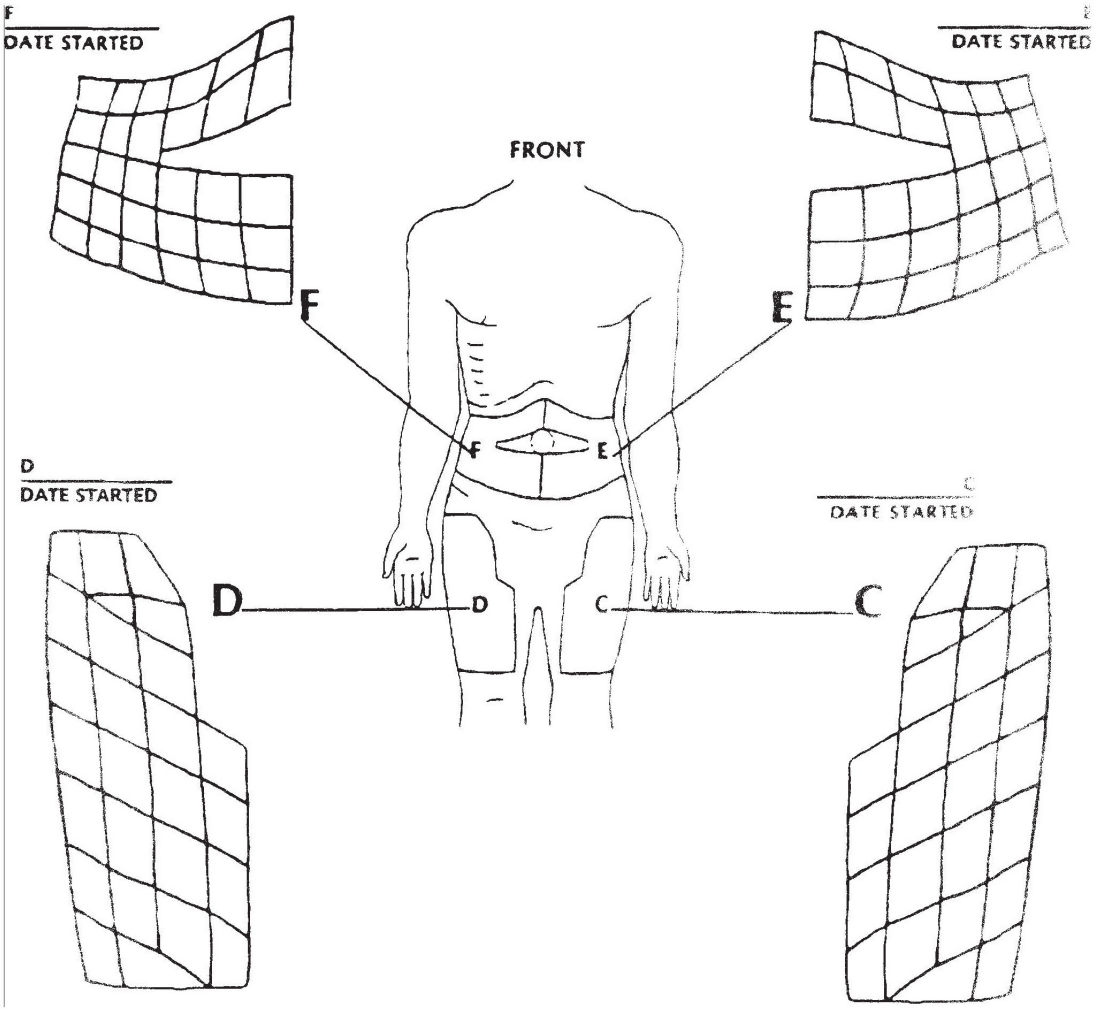
Form # A96102

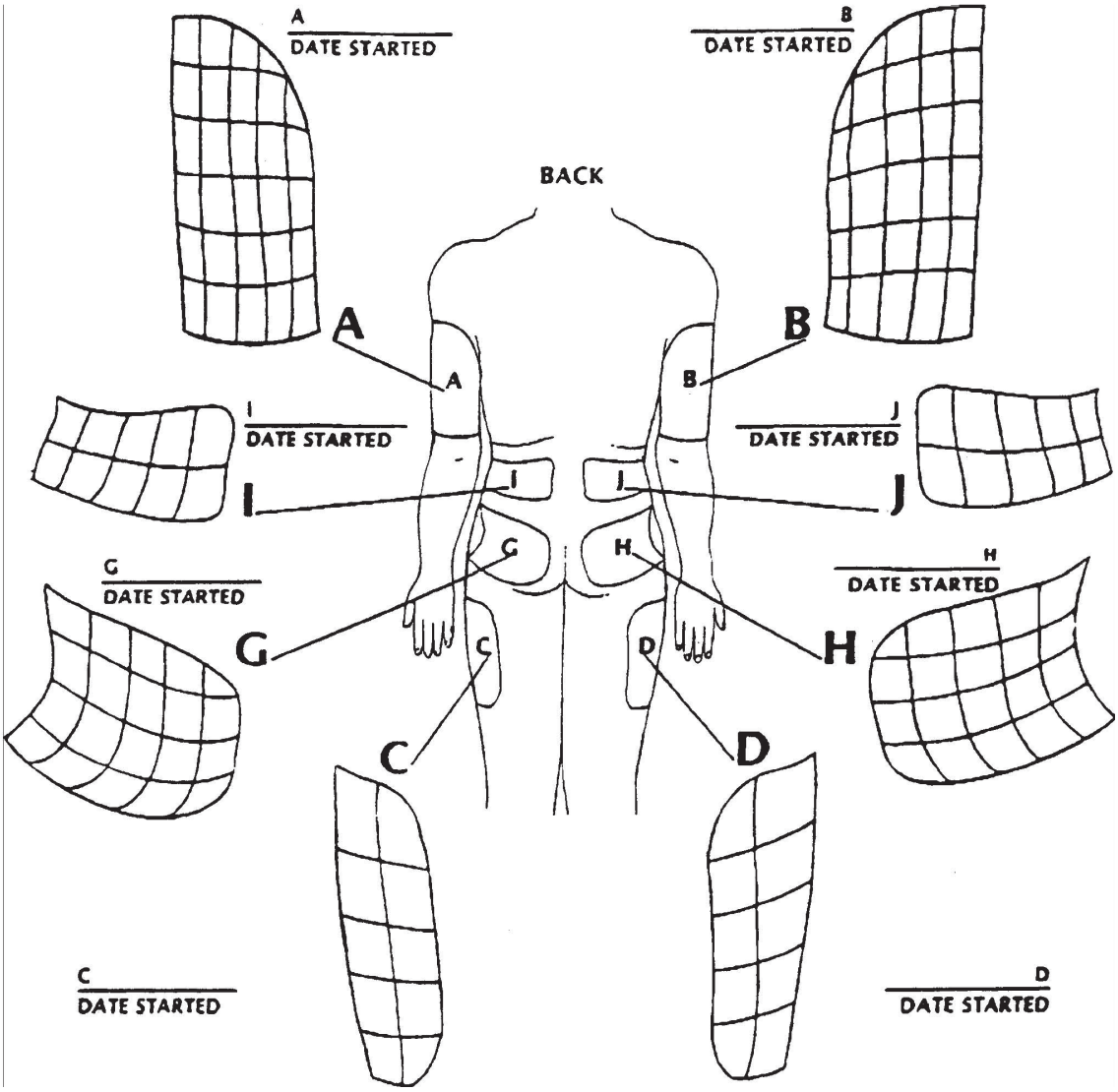
Reorder From: MED·PASS Designing Solutions for Senior Care 800-438-8884

9.3 INSULIN INJECTION SITE ROTATION GRID

This body map is designed to assist in documenting insulin injection administrations.

- Date the form as it is initiated.
- Place an "X" in the map space to indicate the site utilized for the injection.
- Suggested pattern is to rotate injections in one area for one week or until each site has been used once. Then move to another body area. This system will assist in rotating insulin injection sites over the 12 body areas and avoid using any one area or site too frequently.




A
DATE STARTED
B
DATE STARTED
BACK
A
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I
DATE STARTED
J
DATE STARTED
I
J
G
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H
DATE STARTED
G
H
C
D
C
DATE STARTED
D
DATE STARTED

9.4 MEDICAL ABBREVIATIONS

Note: Abbreviations marked with an **asterisk (*)** are those deemed error-prone, often misinterpreted and should not be used in medical communication. The care center/facility policy on use of abbreviations should be adhered to and this list is not intended to supersede that policy, but rather to serve as a reference.

Abbreviations Associated Primarily with the History and Admission of the Resident:

ADL	activities of daily living	NEG	negative
ADM	admission, admit	NKA	no known allergies
A/P	assessment and plan	NPO	nothing per os; nothing by mouth
ASX	asymptomatic	O	objective
A&W	alive and well	P	plan
BRP	bathroom privileges	PMH	past medical history
BSC	bedside commode	PPN	physician progress notes
CC	chief complaint	PPOC	physician plan of care
CO	cardiac output	PTA	prior to admission
C/O	complains of	ROS	review of systems/symptoms
D/C* or DC*	discontinue, discharge	RXN	reaction
DOB	date of birth	S	subjective
DT	due to	SF	sugar free
DX	diagnosis	SH	social history
ER	emergency room	S&S	signs and symptoms
FH	family history	TPR	temperature, pulse, respirations
F/U	follow up	UK	unknown
H/O	history of	VS	vital signs
H&P	history and physical	W/C	wheelchair
HPI	history of present illness	WDWN	well-developed, well-nourished
Hx	history	WF	white female
MDS	minimum data set	WM	white male
N	normal	WNL	within normal limits
NA	not applicable	WTD	wet to dry
NAD	no acute distress	W/U	work up
NC	non-contributory	YO	years old

Abbreviations Associated Primarily with Laboratory Tests:

ABG	arterial blood gases	LDL	low density lipoprotein
ADH	antidiuretic hormone	LFT	liver function test
AFB	acid fast bacilli	Lytes	electrolytes
Alb	albumin	MCH	mean corpuscular hemoglobin
ALT (SGPT)	alanine amino transferase	MCHC	mean corpuscular hemoglobin concentration
ANA	antinuclear antibody		
ASO	antistreptolysin O titer	MCV	mean corpuscular volume
AST (SGOT)	aspartate transferase	Na	sodium
BCP	blood chemistry panel/profile	PFT	pulmonary function test
Bili	bilirubin	Plt	platelet
BUN	blood urea nitrogen	PMN	polymorphonuclear monocyte
CBC	complete blood count	PT	prothrombin time
CBG	capillary blood glucose	PTT	partial thromboplastin time
CEA	carcinoembryonic antigen	RBC	red blood cell
Chol	cholesterol	Retic	reticulocyte
CK	creatinine kinase	RF	rheumatoid factor
Cl	chloride	RFT	renal function test
CO2	carbon dioxide	Segs	neutrophils
CPK	creatine phosphokinase	SGOT	serum glutamic-oxaloacetic transaminase
CrCl	creatinine clearance		
CSF	cerebrospinal fluid	SGPT	serum glutamic-pyruvic transaminase
Diff	differential		
ESR	erythrocyte sedimentation rate	SMAC	Sequential Multiple Analyzer Computer
FBS	fasting blood sugar		
Fe	iron	Sp. Gr.	specific gravity
GFR	glomerular filtration rate	SR	sedimentation rate
GTT	glucose tolerance test	T_3	triiodothyronine
HAA	hepatitis associated antigen	T_4	thyroxine
Hct	hematocrit	TBG	thyroxine binding globulin
HDL	high density lipoprotein	TIBC	total iron binding capacity
Hgb	hemoglobin	TNTC	too numerous to count
$HgbA_{1c}$	glycosylated hemoglobin	TP	total protein
INR	international normalized ratio	UA	urinalysis
K	potassium	WBC	white blood cell
LDH	lactate dehydrogenase		

Abbreviations Associated Primarily with X-Ray Studies:

BE	barium enema	IVP	intravenous pyelogram
CAT	computerized axial tomography	MRI	magnetic resonance imaging
CXR	chest x-ray	UGI	upper gastrointestinal study

Abbreviations Associated Primarily with Medical Conditions:

AF or A Fib	atrial fibrillation
AI	aortic insufficiency
AIDS	acquired immune deficiency syndrome
AKA	above knee amputation
ALS	amlyotrophic lateral sclerosis
AMI	acute myocardial infarction
ARF	acute renal failure
ASCVD	arteriosclerotic/ atherosclerotic coronary vascular disease
ASHD	arteriosclerotic/ atherosclerotic heart disease
BBB	bundle branch block
BKA	below knee amputation
BPH	benign prostatic hypertrophy
Ca	carcinoma/cancer
CABG	coronary artery bypass graft
CAD	coronary artery disease
CAH	chronic active hepatitis
CF	cystic fibrosis
CHF	chronic heart failure
CLL	chronic lymphocyte leukemia
CML	chronic myelogenous leukemia
CMV	cytomegalovirus
COLD	chronic obstructive lung disease
COPD	chronic obstructive pulmonary disease
CP	chest pain
CRA	chronic renal adenopathy
CRF	chronic renal failure
CRI	chronic renal insufficiency
CV	cardiovascular
CVA	cerebrovascular accident
DJD	degenerative joint disease/osteoarthritis
DKA	diabetic ketoacidosis
DM	diabetes mellitus
DOE	dyspnea on exertion
DVT	deep vein thrombosis
ECG/EKG	electrocardiogram
EEG	electroencephalogram
ESRD	end stage renal disease
FUO	fever of unknown origin
FX	fracture
GERD	gastroesophageal reflux disease
HA	headache
HD	hemodialysis
HH	hiatal hernia
HOH	hard of hearing
HTN	hypertension
IBD	inflammatory bowel disease
IBS	irritable bowel syndrome
I&D	incision and drainage
IDDM	insulin dependent diabetes mellitus
IHSS	idiopathic hypertropic subaortic stenosis
JVD	jugular venous distention
LAH	left atrial hypertrophy
LES	lower esophageal sphincter
LVH	left ventricular hypertrophy
MI	myocardial infarction
MRSA	methicillin resistant *Staph. Aureus*
NIDDM	non-insulin dependent diabetes mellitus
NRS	normal sinus rhythm
OBS	organic brain syndrome
PA	pernicious anemia
PAC	premature atrial contraction
PAT	paroxysmal atrial tachycardia
PND	paroxysmal nocturnal dyspnea
PSVT	paroxysmal supraventricular tachycardia
PUD	peptic ulcer disease
PVC	premature ventricular contraction
PVD	peripheral vascular disease
RA	rheumatoid arthritis

REM	rapid eye movement	SOB	shortness of breath
RF	renal failure	SVT	supraventricular tachycardia
RIND	reversible ischemic neurologic disability	TB	tuberculosis
		TIA	transient ischemic attach
ROM	range of motion	TURP	transurethral resection of the prostate
RSR	regular sinus rhythm		
RSV	respiratory syncytial virus	URI	upper respiratory infection
RVH	right ventricular hypertrophy	UTI	urinary tract infection
SBO	small bowel obstruction	VF	ventricular fibrillation
SDAT	senile dementia of the Alzheimer type	VRE	vancomycin resistant *Enterobacter*
SIADH	syndrome of inappropriate ADH secretion	VRSA	vancomycin resistant *Staph. Aureus*
SLE	systemic lupus erythematosis		

Abbreviations Associated Primarily with Prescriptions and Directions:

aa	of each	IM	intramuscular
ac	before meals	**IU***	international units
AD*	right ear	IV	intravenous
Ad lib	as desired	IVPG	intravenous piggyback
AM	morning	Kg	kilogram
amp	ampule	Liq	liquid
Amt	amount	mcg	microgram
Aq	aqueous (water)	MDI	metered dose inhaler
AS*	left ear	mg	milligram
AU*	both ears	**mL***	milliliter
BID	twice daily; two times daily	mmHg	millimeters of mercury
BT*	bedtime	mmol	milliosmol
Cap	capsule	mosml	milliosmol
cc*	cubic centimeter; milliliter	NG	nasogastric
DPI	dry powder inhaler	NPO	nothing by mouth
elix	elixir	**OD***	right eye; once daily
G*	gram	**OS***	left eye
Gal	gallon	OT	occupational therapy
Gm	gram	**OU***	both eyes
Gr	grain	Oz	ounce
HHN	hand- held nebulizer	O2	oxygen
Hr	hour	pc	after meals
HS	bedtime	PCA	patient controlled analgesia
ID	intradermal	PO	per os; by mouth; orally

PR	per rectum
PRN	pro re naja; whenever necessary; as needed
PT	physical therapy
QD*	everyday; once daily
QHS*	every bedtime; nightly at bedtime
QID*	four times daily; four times a day
QN*	every night; nightly
QNS	quantity not sufficient
QOD*	every other day
qs	quantity sufficient; as much as desired
QS	every shift
R	rectal
s	without
SC*	subcutaneous
Sig	directions for use
sl	sublingual
SO	standing order
SQ*	subcutaneous
ss*	sliding scale; one-half (apothecary system); steady state; single-stranded
stat	immediately
subcut	subcutaneous
SubQ*	subcutaneous
Supp	suppository
Syr	syrup
Tab	tablet
Tbsp	tablespoon
TID*	three times daily; three times a day
tinct	tincture
TIW*	three times weekly
TO	telephone order
tsp	teaspoon
U*	unit
ud*	as directed
µg*	microgram
ung	ointment
VO	verbal order

Abbreviations Associated Primarily with Anatomy and Physiology:

Abd	abdominal
Ax	axillary
BM	bowel movement
BP	blood pressure
BSA	body surface area
BX	biopsy
CNS	central nervous system
DBP	diastolic blood pressure
GI	gastrointestinal
GU	genitourinary
LLE	left lower extremity
LLQ	lower left quadrant
LS	lumbosacral
LUE	left upper extremity
LUQ	left upper quadrant
NG	nasogastric
RLE	right lower extremity
RLQ	right lower quadrant
RUE	right upper extremity
RUQ	right upper quadrant
SS	substernal
TPR	temperature, pulse, respiration
VS	vital signs

Abbreviations Associated Primarily with Medication Names:

ACE	angiotensin converting enzyme
ACTH	adrenocorticotropic hormone
APAP*	acetaminophen
ASA	aspirin
AZT*	Zidovudine (Retrovir®)
CPZ*	Compazine® (prochlorperazine)
D5NS	5% dextrose in normal saline
D5W	5% dextrose in water
D10NS	10% dextrose in normal saline
D10W	10% dextrose in water
DPT*	Demerol® (meperidine) – Phenergan® (promethazine) – Thorazine® (chlorpromazine)
DSS	dioctyl sodium sulfosuccinate
EC	enteric-coated
ETOH	ethanol/alcohol
FA	folic acid
$FeSO_4$	ferrous sulfate (iron)
FFP	fresh frozen plasma
5-FU	5-fluorouracil
H_2blocker	histamine-2 receptor antagonist
HC	hydrocortisone
HCl*	hydrochloric acid
HCT*	hydrocortisone
HCTZ*	hydrochlorothiazide
KCl	potassium chloride
$MgSO_4$*	magnesium sulfate
MOM	milk of magnesia
MS*	morphine sulfate
MSO_4*	morphine sulfate
MTX*	methotrexate
MVI	multiple vitamin infusion
NoAC*	novel/new anticoagulant
NPH	Neutral Protamine Hagedorn (insulin)
NS	normal saline
NSAID	non-steroidal anti-inflammatory drugs
OTC	over-the-counter
PCN	penicillin
PPD	purified protein derivative
PTU	propylthiouracil
PZI	protamine zinc insulin
RAI	radioactive iodine
SMX-TMP	sulfamethoxazole and trimethoprim
SSKI	saturated solution of potassium iodide
SSRI*	selective serotonin reuptake inhibitor; sliding scale regular insulin
T3	Tylenol with codeine No. 3
TAC*	triamcinolone
TPN	Total Parenteral Nutrition
IV vanc	intravenous vancomycin
$ZnSO_4$*	zinc sulfate

9.5 SAMPLE MEDICATION ADMINISTRATION SCHEDULE

Medication frequency and times of administration are to be interpreted as follows unless specified otherwise by the prescriber.

1. For residents of the following beds (units): _____

daily	9 am
bid (twice a day)	9 am - 5 pm
tid (three times a day)	9 am - 1 pm - 5 pm
qid (four times a day)	9 am - 1 pm - 5 pm - 9 pm
ac (before meals)	6:30 am - 11:30 am - 4:30 pm (approximately)
pc (after meals)	9 am - 1 pm - 5 pm (approximately)
bedtime	10 pm for sedative/hypnotics** 9 pm for all other meds
q6h (every 6 hours)	6 am - 12 noon - 6 pm - 12 midnight
q12h (every 12 hours)	9 am - 9 pm

For residents of the following beds (units): _____

daily	8 am
bid (twice a day)	8 am - 4 pm
tid (three times a day)	8 am - 12 noon - 4 pm
qid (four times a day)	8 am - 12 noon - 4 pm - 8 pm
ac (before meals)	6:30 am - 11:30 am - 4:30 pm (approximately)
pc (after meals)	9 am - 1 pm - 5 pm (approximately)
bedtime	10 pm for sedative/hypnotics** 8 pm for all other meds
q6h (every 6 hours)	6 am - 12 noon - 6 pm - 12 midnight
q12h (every 12 hours)	8 am - 8 pm

**The resident is not to be awakened to administer a sedative/hypnotic, even if it is ordered to be given routinely. The resident is to be given the opportunity to fall asleep without chemical induction. For this reason, sedative/hypnotics are scheduled at a time after the resident would normally be asleep. If the resident is asleep at the scheduled medication administration time, the nurse's initials should be placed in the block, circled, and an explanation made on the back of the MAR. The dose may be administered as late as 2 am if the resident is not resting well.

2. Antibiotic orders are to be written on the MAR and administered as follows for residents of the following beds (units): _____

daily	9 am
bid (twice a day)	9 am - 9 pm
tid (three times a day)	9 am - 1 pm - 5 pm
qid (four times a day)	9 am - 1 pm - 5 pm - 9 pm

For residents of the following beds (units): _____

daily	8 am
bid (twice a day)	8 am - 8 pm
tid (three times a day)	8 am - 12 noon - 4 pm
qid (four times a day)	8 am - 12 noon - 4 pm - 8 pm

3. Medications with specific dosing administration specifications commonly used in skilled nursing care centers:

   a. Bisphosphonates (Actonel®, Fosamax®) should be administered in the morning with a full glass of plain water (180 – 240 mL) at least 30 minutes prior to the first food, beverage, or medication. At least 30 minutes should elapse before taking any other medications. Sit upright and do not lie down for at least 30 minutes post dose. Do not take at bedtime or before arising.

   b. Bisphosphonates (Boniva®) should be administered in the morning with a full glass of plain water (180 – 240 mL) at least 60 minutes prior to the first food, beverage, or medication. At least 60 minutes should elapse before taking any other medications. Sit upright and do not lie down for at least 60 minutes post dose. Do not take at bedtime or before arising.

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Oral Medications That Should Not Be Crushed or Altered

The following table contains available drugs that have characteristics that may make it inappropriate to crush or alter the dosage form to help facilitate drug delivery. There are a variety of reasons for crushing tablets or capsule contents prior to administering to the patient. Patients may have enteral feeding which do not permit the administration of tablets or capsules, an oral solution for a particular medication may not be available from the manufacturer or readily prepared by pharmacy, patients may have difficulty swallowing capsules or tablets, or mixing of powdered medication with food or drink may make the drug more palatable. **Generally, medications which should not be crushed fall into one of the following categories:**

Extended Release Products: The formulation of some tablets is specialized as to allow the medication within it to be slowly released into the body. This may be accomplished by centering the drug within the core of the tablet, with a subsequent shedding of multiple layers around the core. Wax melts in the GI tract, releasing drug contained within the wax matrix (e.g., OxyCONTIN). Capsules may contain beads which have multiple layers which are slowly dissolved with time.

Medications Which Are Irritating to the Stomach: Tablets which are irritating to the stomach may be enteric-coated which delays release of the drug until the time when it reaches the small intestine. Enteric-coated aspirin is an example of this.

Foul-Tasting Medication: Some drugs are quite unpleasant to taste so the manufacturer coats the tablet in a sugar coating to increase its palatability. By crushing the tablet, this sugar coating is lost and the patient tastes the unpleasant tasting medication.

Common Abbreviations for Extended Release Products

CD	Controlled dose
CR	Controlled release
CRT	Controlled release tablet
LA	Long-acting
SR	Sustained release
TR	Timed release
TD	Time delay
SA	Sustained action
XL	Extended release
XR	Extended release

Sublingual Medication: Medication intended for use under the tongue should not be crushed. While it appears to be obvious, it is not always easy to determine if a medication is to be used sublingually. Sublingual medications should indicate on the package that they are intended for sublingual use.

Effervescent Tablets: These are tablets which, when dropped into a liquid, quickly dissolve to yield a solution. Many effervescent tablets, when crushed, lose their ability to quickly dissolve.

Potentially Hazardous Substances: Certain drugs, including antineoplastic agents, hormonal agents, some antivirals, some bioengineered agents, and other miscellaneous drugs, are considered potentially hazardous when used in humans based on their characteristics. Examples of these characteristics include carcinogenicity, teratogenicity, reproductive toxicity, organ toxicity at low doses, genotoxicity, or new drugs with structural and toxicity profiles similar to existing hazardous drugs. Exposure to these substances can result in adverse effects and should be avoided. Crushing or breaking a tablet or opening a capsule of a potentially hazardous substance may increase the risk of exposure to the substance through skin contact, inhalation, or accidental ingestion. The extent of exposure, potency, and toxicity of the hazardous substance determines the health risk. Institutions have policies and procedures to follow when handling any potentially hazardous substance. **Note: All potentially hazardous substances may not be represented in this table. Refer to institution-specific guidelines for precautions to observe when handling hazardous substances.**

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Oral Medications That Should Not Be Crushed or Altered

Recommendations

1. It is not advisable to crush certain medications.
2. Consult individual monographs prior to crushing capsule or tablet.
3. If crushing a tablet or capsule is contraindicated, consult with your pharmacist to determine whether an oral solution exists or can be compounded.

Drug Product	Dosage Form	Reasons/Comments
Abilify MyCite Kits (ARIPiprazole)	Tablet	Drug-device combination
Absorica, Absorica LD (ISOtretinoin)	Capsule	Mucous membrane irritant; teratogenic potential
Acetaminophen ER	Tablet	Extended release
Aciphex (RABEprazole)	Tablet	Extended release
Aciphex Sprinkle (RABEprazole)	Capsule	Slow release. Capsule may be opened and contents sprinkled on soft food (e.g., applesauce, fruit- or vegetable-based baby food, yogurt) or emptied into a small amount of liquid (e.g., infant formula, apple juice, pediatric electrolyte solution). Granules should not be chewed or crushed.
Acticlate (Doxycycline Hyclate)	Capsule, tablet	Film-coated. Tablet is scored and may be split; 150 mg tablets can be broken into two-thirds or one-third to provide a 100 mg and 50 mg strength, respectively.
Actiq (FentaNYL)	Lozenge	Slow release. This lollipop delivery system requires the patient to dissolve it slowly.
Actoplus Met XR (Pioglitazone and Metformin)	Tablet	Variable release
Actonel (Risedronate)	Tablet	Irritant. Chewed, crushed, or sucked tablets may cause oropharyngeal irritation.
Adalat CC (NIFEdipine)	Tablet	Extended release
Adderall XR (Dextroamphetamine and Amphetamine)	Capsule	Extended release[a]
Adenovirus (Types 4, 7) Vaccine	Tablet	Teratogenic potential; enteric-coated; do not disrupt tablet to avoid releasing live adenovirus in upper respiratory tract
Adhansia XR (Methylphenidate)	Capsule	Extended release. Capsule may be opened, sprinkled onto a tablespoon of applesauce or yogurt, and consumed without chewing within 10 minutes
Advagraf (Tacrolimus)	Capsule	Extended release
Advicor (Niacin and Lovastatin)	Tablet	Variable release
Adzenys XR-ODT (Amphetamine)	Orally disintegrating tablet	Extended release; sublingual form[g]
Aemcolo (Rifamycin)	Tablet	Delayed release; manufacturer recommendation
Afeditab CR (NIFEdipine)	Tablet	Extended release
Afinitor (Everolimus)	Tablet	Manufacturer recommendation; mucous membrane irritant; hazardous substance[k]; pharmacokinetic amorphous solid dispersion technology may be affected.
Aggrenox (Aspirin and Dipyridamole)	Capsule	Extended release. Capsule may be opened; contents include an aspirin tablet that may be chewed and dipyridamole pellets that may be sprinkled on applesauce.

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Drug Product	Dosage Form	Reasons/Comments
Akeega (Niraparib and Abiraterone Acetate)	Tablet	Manufacturer recommendation; caregivers who are or could be pregnant should wear gloves if handling tablets
Alavert Allergy and Sinus (Loratadine and Pseudoephedrine)	Tablet	Extended release
Alecensa (Alectinib)	Capsule	Manufacturer recommendation
Alkindi Sprinkle (Hydrocortisone)	Capsule	Oral granules contained within the capsule; do not crush or chew granules
Allegra-D (Fexofenadine and Pseudoephedrine)	Tablet	Extended release
ALPRAZolam XR	Tablet	Extended release
Altace (Ramipril)	Capsule	Manufacturer recommendation; capsule may be opened and contents mixed with 120 mL of water, apple juice, or applesauce
Altoprev (Lovastatin)	Tablet	Extended release
Alunbrig (Brigatinib)	Tablet	Manufacturer recommendation
Alvaiz (Eltrombopag)	Tablet	Manufacturer recommendation
Alyftrek (Vanzacaftor, Tezacaftor, and Deutivacaftor)	Tablet	Manufacturer recommendation
Ambien CR (Zolpidem)	Tablet	Extended release
Amitiza (Lubiprostone)	Capsule	Manufacturer recommendation
Amnesteem (ISOtretinoin)	Capsule	Mucous membrane irritant; teratogenic potential
Ampyra (Dalfampridine)	Tablet	Extended release
Amrix (Cyclobenzaprine)	Capsule	Extended release
Aplenzin (BuPROPion)	Tablet	Extended release
Apriso (Mesalamine)	Capsule	Extended release
Aptensio XR (Methylphenidate)	Capsule	Slow release. Capsule may be opened, sprinkled onto a tablespoon of applesauce or yogurt, and consumed without chewing within 10 minutes.
Aptivus (Tipranavir)	Capsule	Taste. Oil emulsion within spheres
Arakoda (Tafenoquine)	Tablet	Manufacturer recommendation
Aricept 23 mg (Donepezil)	Tablet	Film-coated; chewing or crushing may increase rate of absorption
Arava (Leflunomide)	Tablet	Teratogenic potential; hazardous substance[k]
Arthrotec (Diclofenac and Misoprostol)	Tablet	Delayed release; enteric-coated
Arymo ER (Morphine)	Tablet	Slow release; tablet disruption may cause a potentially fatal overdose.
Asacol HD (Mesalamine)	Tablet	Slow release
Aspirin enteric-coated	Capsule, tablet	Delayed release; enteric-coated
Astagraf XL (Tacrolimus)	Capsule	Extended release; pharmacokinetic amorphous solid dispersion technology may be affected
Atelvia (Risedronate)	Tablet	Extended release; tablet coating is an important part of the delayed release
Augmentin XR (Amoxicillin and Clavulanate)	Tablet	Extended release[b,h]

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Drug Product	Dosage Form	Reasons/Comments
Augtyro (Repotrectinib)	Capsule	Manufacturer recommendation
Auryxia (Ferric Citrate)	Tablet	May cause discoloration of mouth and teeth
Austedo (Deutetrabenazine)	Tablet	Manufacturer recommendation
Austedo XL (Deutetrabenazine)	Tablet	Extended release
Auvelity (Dextromethorphan and Bupropion)	Tablet	Extended release
Ayvakyt (Avapritinib)	Tablet	Canadian manufacturer recommendation (not in US labeling)
Avelox (Moxifloxacin)	Tablet	Canadian manufacturer recommendation (not in US labeling)
Avodart (Dutasteride)	Capsule	Mucus membrane irritation; capsule should not be handled by pregnant women due to teratogenic potential[j]; hazardous substance[k]
Avmapki (Avutometinib)	Capsule	Manufacturer recommendation
Azulfidine EN-tabs (SulfaSALAzine)	Tablet	Delayed release
Bafiertam (Monomethyl fumarate)	Capsule	Delayed release
Balcoltra (Ethinyl Estradiol and Levo-norgestrel)	Tablet	Hazardous agent
Balversa (Erdafitinib)	Tablet	Manufacturer recommendation
Bayer Aspirin (Aspirin)	Tablet	Delayed release
Bayer Aspirin, EC Low Dose 81 mg (Aspirin)	Tablet	Delayed release
Bayer Aspirin, Regimen Adult Low Strength 81 mg (Aspirin)	Tablet	Enteric coated
Bayer Aspirin, Regimen Regular Strength 325 mg (Aspirin)	Caplet	Enteric-coated
Belbuca (Buprenorphine)	Buccal film	Sublingual form[g]; chewing or swallowing may result in lower bioavailability
Belsomra (Suvorexant)	Tablet	Pharmacokinetic amorphous solid dispersion technology may be affected
Benzonatate	Capsule	Swallow whole; pharmacologic action may cause choking if chewed or opened and swallowed
Biaxin XL (Clarithromycin)	Tablet	Extended release
Biltricide (Praziquantel)	Tablet	Taste[h]
Binosto (Alendronate)	Tablet	Effervescent tablet[f]
Biphentin (Methylphenidate)	Capsule	Controlled release
Bisac-Evac (Bisacodyl)	Tablet	Enteric-coated[c]
Bisacodyl	Tablet	Enteric-coated[c]
Boniva (Ibandronate)	Tablet	Irritant. Chewed, crushed, or sucked tablets may cause oropharyngeal irritation
Bonjesta (Doxylamine and Pyridoxine)	Tablet	Controlled release
Bosulif (Bosutinib)	Tablet	Manufacturer recommendation; hazardous substance[k]
Brincidofovir	Tablet	Manufacturer recommendation; hazardous substance[k]

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Drug Product	Dosage Form	Reasons/Comments
Brenzavvy (Bexagliflozin)	Tablet	Manufacturer recommendation
Briviact (Brivaracetam)	Tablet	Film-coated[b]; manufacturer recommendation
Brukinsa (Zanubrutinib)	Capsule, tablet	Manufacturer recommendation; tablet is scored and may be split in half
Bunavail (Buprenorphine and Naloxone)	Buccal film	Chewing or swallowing may result in lower peak concentrations and bioavailability
Buprenorphine and Naloxone Sublingual	Tablet	Sublingual form[g]
Buproban (BuPROPion)	Tablet	Extended release
BuPROPion SR	Tablet	Extended release
BuPROPion XL	Tablet	Extended release
Bylvay (Odevixibat)	Capsule	Manufacturer recommendation[a]
Cabometyx (Cabozantinib)	Tablet	Manufacturer recommendation; film-coated; hazardous substance[k]
Calan SR (Verapamil)	Tablet	Extended release[h]
Calquence (Acalabrutinib)	Capsule	Manufacturer recommendation
Campral (Acamprosate)	Tablet	Delayed release; enteric-coated
Caprelsa (Vandetanib)	Tablet	Manufacturer recommendation[n]; irritant; hazardous substance[k]
Carbaglu (Carglumic Acid)	Tablet	Tablets should be dispersed completely in water
Carbatrol (CarBAMazepine)	Capsule	Extended release[a]
Cardizem CD (DilTIAZem)	Capsule	Extended release
Cardizem LA (DilTIAZem)	Tablet	Extended release
Cardura XL (Doxazosin)	Tablet	Extended release
Cartia XT (DilTIAZem)	Capsule	Extended release
Casodex (Bicalutamide)	Tablet	Hazardous substance[k]
Cefaclor ER	Tablet	Extended release
Ceftin (Cefuroxime)	Tablet	Taste[b]. Use suspension for children
Cefuroxime	Tablet	Taste[b]. Use suspension for children
CellCept (Mycophenolate)	Capsule, tablet	Teratogenic potential; hazardous substance[i,k]
Cerdelga (Eliglustat)	Capsule	Preferably taken with water
Cesamet (Nabilone)	Capsule	Pharmacokinetic amorphous solid dispersion technology may be affected
Chlor-Trimeton Allergy (Chlorpheniramine)	Tablet	Extended release[b]
Chlorpheniramine ER	Tablet	Extended release[b]
Cholbam (Cholic Acid)	Capsule	Capsules may be opened and the contents mixed with food/drink.
Cibinqo (Abrocitinib)	Tablet	Manufacturer recommendation
Ciprofloxacin XL	Tablet	Extended release[b]
Claravis (ISOtretinoin)	Capsule	Mucous membrane irritant; teratogenic potential
Claritin-D 12-Hour (Loratadine and Pseudoephedrine)	Tablet	Extended release

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Drug Product	Dosage Form	Reasons/Comments
Claritin-D 24-Hour (Loratadine and Pseudoephedrine)	Tablet	Extended release
Codeine Contin (Codeine)	Tablet	Controlled release
Colace (Docusate)	Capsule	Taste$_e$
Colazal (Balsalazide)	Capsule	Manufacturer recommendation; contents may be sprinkled on applesauce and mixture may be chewed
Colestid (Colestipol)	Tablet	Slow release
Cometriq (Cabozantinib)	Capsule	Manufacturer recommendation; hazardous substance$_k$
Concerta (Methylphenidate)	Tablet	Extended release
Contrave (Naltrexone and Bupropion)	Tablet	Extended release
ConZip (TraMADol)	Capsule	Variable release; tablet disruption may cause overdose
Copiktra (Duvelisib)	Capsule	Manufacturer recommendation
Coreg CR (Carvedilol)	Capsule	Extended release$_a$; may add contents to chilled applesauce and consume immediately.
CoreMino (Minocycline)	Tablet	Extended release
Cotazym (Pancrelipase)	Capsule	Enteric-coated$_a$
Cotellic (Cobimetinib)	Tablet	In the clinical trial, tablets were administered whole; do not chew, cut, or crush
Cotempla XR-ODT (Methylphenidate)	Orally disintegrating tablet	Extended release; orally disintegrating tablet designed to disintegrate on the tongue
Creon (Pancrelipase)	Capsule	Extended release$_a$; enteric-coated contents
Cresemba (Isavuconazium)	Capsule	Manufacturer recommendation
Crixivan (Indinavir)	Capsule	Taste. Capsule may be opened and mixed with fruit puree (e.g., banana).
Cuvrior (Trientine Tetrahydrochloride)	Tablet	Manufacturer recommendation; scored tablet may be spilt in half if needed.
CycloPHOSphamide	Capsule, tablet	Hazardous substance$_k$; manufacturer recommendation
Cymbalta (DULoxetine)	Capsule	Delayed release$_a$; may add contents to apple juice or applesauce but not chocolate
Danziten (Nilotinib)	Tablet	Manufacturer recommendation
Dartisla-ODT (Glycopyrrolate)	Orally disintegrating tablet	Orally disintegrating tablet designed to disintegrate on the tongue
Daurismo (Glasdegib)	Tablet	Manufacturer recommendation
Delzicol (Mesalamine)	Capsule	Slow release$_a$
Depakene (Valproic Acid)	Capsule	Slow release; mucous membrane irritant$_b$; hazardous substance$_k$
Depakote (Divalproex)	Tablet	Delayed release; hazardous substance$_k$
Depakote ER (Divalproex)	Tablet	Extended release; hazardous substance$_k$
Depakote Sprinkles (Divalproex)	Capsule	Delayed release$_a$; hazardous substance$_k$
Detrol LA (Tolterodine)	Capsule	Extended release
Dexedrine (Dextroamphetamine)	Capsule	Extended release
Dexilant (Dexlansoprazole)	Capsule	Delayed release$_a$

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Drug Product	Dosage Form	Reasons/Comments
Diacomit (Stiripentol)	Capsule	Manufacturer recommendation[l]
Diamicron MR (Gliclazide)	Tablet	Modified release; may split 60 mg modified release tablets in half; 30 mg modified release tablets must be swallowed whole
Diamox Sequels (AcetaZOLAMIDE)	Capsule	Extended release
Dibenzyline (Phenoxybenzamine)	Capsule	Hazardous substance[k]
Diclegis (Doxylamine and Pyridoxine)	Tablet	Delayed release; manufacturer recommendation
Diflunisal	Tablet	Manufacturer recommendaton
DiltiaZEM	Capsule	Extended release
Dilt-XR (DiltiaZEM)	Capsule	Extended release
Ditropan XL (OxyBUTYnin)	Tablet	Extended release
Divalproex ER	Tablet	Extended release
Doryx (Doxycycline)	Tablet	Delayed release; tablet may be crushed without damaging or crushing delayed-release pellets
Doryx MPC (Doxycycline)	Tablet	Delayed release
Drisdol (Ergocalciferol)	Capsule	Liquid filled[d]
Drizalma Sprinkle (DULoxetine)	Capsule	Delayed release[a]
Droxia (Hydroxyurea)	Capsule	Manufacturer recommendation[o]; hazardous substance[k]
Duavee (Estrogens [Conjugated/ Equine] and Bazedoxifene)	Tablet	Manufacturer recommendation; hazardous substance[k]
Duexis (Ibuprofen and Famotidine)	Tablet	Manufacturer recommendation
Dulcolax (Bisacodyl)	Capsule	Liquid-filled
Dulcolax (Bisacodyl)	Tablet	Enteric-coated[c]
Durlaza (Aspirin)	Capsule	Extended release
EC-Naprosyn (Naproxen)	Tablet	Delayed release; enteric-coated
Ecotrin Arthritis Strength (Aspirin)	Tablet	Enteric-coated
Ecotrin (Aspirin)	Tablet	Enteric-coated
Ecotrin Low Strength (Aspirin)	Tablet	Enteric-coated
Edluar (Zolpidem)	Tablet	Sublingual form[g]
E.E.S. (Erythromycin)	Tablet	Enteric-coated[b]
Effer-K (Potassium Bicarbonate and Potassium Citrate)	Tablet	Effervescent tablet[f]
Effervescent Potassium	Tablet	Effervescent tablet[f]
Effexor XR (Venlafaxine)	Capsule	Extended release[a]
Elepsia XR (LevETIRAcetam)	Tablet	Extended release
Emend (Aprepitant)	Capsule	Manufacturer recommendation; pharmacokinetic NanoCrystal technology may be affected
Emrosi (Minocycline)	Capsule	Extended release
Enablex (Darifenacin)	Tablet	Slow release
Ensacove (Ensartinib)	Capsule	Manufacturer recommendation
Entocort EC (Budesonide)	Capsule	Extended release; enteric-coated[a]

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Drug Product	Dosage Form	Reasons/Comments
Envarsus PA	Tablet	Extended release
Envarsus XR (Tacrolimus)	Tablet	Extended release
Epclusa (Sofosbuvir and Velpatasvir)	Tablet	Pharmacokinetic amorphous solid dispersion technology may be affected
Equetro (CarBAMazepine)	Capsule	Extended release[a]
Ergomar (Ergotamine)	Tablet	Sublingual form[g]
Erivedge (Vismodegib)	Capsule	Manufacturer recommendation; hazardous substance[k]
Erleada (Apalutamide)	Tablet	Manufacturer recommendation
Eryc (Erythromycin)	Capsule	Enteric-coated[a]
Ery-Tab (Erythromycin)	Tablet	Delayed release; enteric-coated
Erythromycin Base	Tablet	Enteric-coated
Erythromycin Delayed Release	Capsule	Enteric-coated pellets[a]
Erythromycin Ethylsuccinate	Tablet	Taste[b]
Erythromycin Stearate	Tablet	Enteric-coated
Etoposide	Capsule	Hazardous substance[k]
Etrasimod	Tablet	Manufacturer recommendation
Evekeo ODT (Amphetamine)	Oral disintegrating tablet	Sublingual form[g]
Evista (Raloxifene)	Tablet	Taste; teratogenic potential[l]; hazardous substance[k]
Evrysdi (Risdiplam)	Tablet	Film-coated; tablet may be dispersed in nonchlorinated water
Exelon (Rivastigmine)	Capsule	Canadian manufacturer recommendation
Exjade (Deferasirox)	Tablet	Do not chew or swallow whole; do not give as tablets meant to be given as a liquid
Exkivity (Mobocertinib)	Capsule	Manufacturer recommendation
Exservan (Riluzole)	Film	Sublingual form[g]
Ezallor Sprinkle (Rosuvastatin)	Capsule	Manufacturer recommendation[a]
Fabhalta (Iptacopan)	Capsule	Manufacturer recommendation
Fareston (Toremifene)	Tablet	Hazardous substance[k]
Farydak (Panobinostat)	Capsule	Manufacturer recommendation; hazardous substance[k]
Feldene (Piroxicam)	Capsule	Mucous membrane irritant
Felodipine	Tablet	Extended release
FentaNYL	Lozenge	Slow release; lollipop delivery system requires the patient to slowly dissolve in mouth
Fentora (FentaNYL)	Tablet	Buccal tablet; swallowing whole or crushing may reduce effectiveness
Ferrous Sulfate	Tablet	Delayed release[b]
Fetzima (Levomilnacipran)	Capsule	Extended release
Fexinidazole	Tablet	Manufacturer recommendation
Fibricor (Fenofibric Acid)	Tablet	Manufacturer recommendation
Fleet Laxative (Bisacodyl)	Tablet	Enteric-coated[c]
Flomax (Tamsulosin)	Capsule	Slow release; manufacturer recommendation. Capsules may be opened and contents mixed with food.

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Drug Product	Dosage Form	Reasons/Comments
Fludara (Fludarabine)	Tablet	Manufacturer (Canadian) recommendation; hazardous substance[k]
FLUoxetine Weekly	Capsule	Delayed release
FluvoxaMINE ER	Capsule	Slow release
Focalin XR (Dexmethylphenidate)	Capsule	Extended release[a]
Forfivo XL (BuPROPion)	Tablet	Extended release
Fortamet (MetFORMIN)	Tablet	Extended release
Fosamax (Alendronate)	Tablet	Mucous membrane irritant
Fosamax Plus D (Alendronate and Cholecalciferol)	Tablet	Mucous membrane irritant
Fotivda (Tivozanib)	Capsule	Manufacturer recommendation
Fruzaqla (Fruquintinib)	Capsule	Manufacturer recommendation
Galafold (MigALAstat)	Capsule	Manufacturer recommendation
Galzin (Zinc Acetate)	Capsule	Manufacturer recommendation[i]; possible gastric irritation
Gengraf (CycloSPORINE)	Capsule	Teratogenic potential; hazardous substance[k]
Geodon (Ziprasidone)	Capsule	Hazardous substance[k]
Gepirone (Exxua)	Tablet	Extended release
Gilotrif (Afatinib)	Tablet	Canadian manufacturer recommendation (not in US labeling); hazardous substance[k]
Gleevec (Imatinib)	Tablet	Manufacturer recommendation[n]; mucous membrane irritant; hazardous substance[k]
Gleostine (Lomustine)	Capsule	Manufacturer recommendation; hazardous substance[k]
GlipiZIDE XL	Tablet	Extended release
Glucophage XR (MetFORMIN)	Tablet	Extended release
Glucotrol XL (GlipiZIDE)	Tablet	Extended release
Glumetza (MetFORMIN)	Tablet	Extended release
Gocovri (Amantadine)	Capsule	Extended release[a]
Gomekli (Mirdametinib)	Capsule	Manufacturer recommendation
Gomekli (Mirdametinib)	Tablet	Manufacturer recommendation; tablet may be swallowed whole or (for patients unable to swallow whole) an oral suspension may be prepared from tablet(s)
Gralise (Gabapentin)	Tablet	Extended release[b]
GuaiFENesin and Pseudoephedrine	Tablet	Slow release
Halfprin (Aspirin)	Tablet	Enteric-coated
Harvoni (Ledipasvir and Sofosbuvir)	Tablet	Pharmacokinetic amorphous solid dispersion technology may be affected
Hernexeos (Zongertinib)	Tablet	Manufacturer recommendation
Hetlioz (Tasimelteon)	Capsule	Manufacturer recommendation
Holkira Pak (Ombitasvir, Paritaprevir, Ritonavir, and Dasabuvir)	Tablet	Canadian manufacturer recommendation
Horizant (Gabapentin)	Tablet	Extended release[b]
Hycamtin (Topotecan)	Capsule	Manufacturer recommendation; hazardous substance[k]

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Drug Product	Dosage Form	Reasons/Comments
Hydrea (Hydroxyurea)	Capsule	Manufacturer recommendation$_o$; hazardous substance$_k$
HYDROcodone	Capsule	Extended release; capsule disruption may cause a potentially fatal overdose
Hydromorph Contin (HYDROmorphone)	Capsule	Extended release
Hydromorphone ER	Tablet	Extended release
Hysingla ER (HYDROcodone)	Tablet	Extended release; tablet disruption may cause a potentially fatal overdose
Ibrance (Palbociclib)	Capsule, tablet	Manufacturer recommendation
Ibsrela (Tenapanor)	Tablet	Canadian manufacturer recommendation (not in US labeling)
Ibtrozi (Taletrectinib)	Capsule	Manufacturer recommendation
Iclusig (PONATinib)	Tablet	Manufacturer recommendation; hazardous substance$_k$
Idhifa (Enasidenib)	Tablet	Manufacturer recommendation
Imbruvica (Ibrutinib)	Capsule, tablet	Manufacturer recommendation$_o$
Imdur (Isosorbide Mononitrate)	Tablet	Extended release$_h$
Imitrex (SUMAtriptan)	Tablet	Manufacturer recommendation
Impavido (Miltefosine)	Capsule	Hazardous substance$_k$
Inderal LA (Propranolol)	Capsule	Extended release
Indomethacin ER	Capsule	Extended release$_{b,c}$
Ingrezza Sprinkle (Valbenazine)	Capsule	Manufacturer recommendation; capsule may be opened and the contents sprinkled on soft food (e.g., applesauce, pudding, yogurt); granules should not be chewed or crushed. Do not administer via gastrostomy, nasogastric, or other enteral tubes.
Inlyta (Axitinib)	Tablet	Manufacturer recommendation$_o$; hazardous substance$_k$
Inluriyo (Imlunestrant)	Tablet	Manufacturer recommendation
InnoPran XL (Propranolol)	Capsule	Extended release
Inpefa (Sotagliflozin)	Tablet	Manufacturer recommendation
Inqovi (Decitabine and Cedazuridine)	Tablet	Manufacturer recommendation; hazardous substance$_k$
Intelence (Etravirine)	Tablet	Pharmacokinetic amorphous solid dispersion technology may be affected. Tablet should be swallowed whole and not crushed; tablet may be dispersed in water.
Intuniv (GuanFACINE)	Tablet	Extended release
Invega (Paliperidone)	Tablet	Extended release
Invokamet XR (Canagliflozin and Metformin)	Tablet	Extended release
Invokana (Canagliflozin)	Tablet	Canadian manufacturer recommendation
Iressa (Gefitinib)	Tablet	Note: Tablet may be dissolved in 120 to 240 mL of water
Isoptin SR (Verapamil)	Tablet	Extended release$_h$; pharmacokinetic amorphous solid dispersion technology may be affected
Isosorbide Mononitrate ER	Tablet	Extended release
ISOtretinoin	Capsule	Mucous membrane irritant; teratogenic potential
Isradipine	Capsule	Slow release
Itovebi (Inavolisib)	Tablet	Manufacturer recommendation

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Drug Product	Dosage Form	Reasons/Comments
Jakavi (Ruxolitinib)	Tablet	Canadian manufacturer recommendation (not in US labeling[n])
Jalyn (Dutasteride and Tamsulosin)	Capsule	Mucous membrane irritant; capsule should not be handled by pregnant women due to teratogenic potential[j]; hazardous substance[i,k]
Janumet XR (Sitagliptin and Metformin)	Tablet	Extended release
Jaypirca (Pirtobrutinib)	Tablet	Manufacturer recommendation
Jentadueto XR (Linagliptin and Metformin)	Tablet	Extended release
Jesduvroq (Daprodustat)	Tablet	Manufacturer recommendation
Jornay PM (Methylphenidate)	Capsule	Extended release[a]
Juxtapid (Lomitapide)	Capsule	Manufacturer recommendation
Kadian (Morphine)	Capsule	Extended release[a]. Do not give via NG tubes; may add contents to applesauce without crushing. Capsule disruption may cause a potentially fatal overdose.
Kaletra (Lopinavir and Ritonavir)	Tablet	Film-coated; pharmacokinetic amorphous solid dispersion technology may be affected; pregnant women or women who may become pregnant should not handle crushed or broken tablets; active ingredients surrounded by wax matrix to prevent health care exposure.
Kalydeco (Ivacaftor)	Tablet	Pharmacokinetic amorphous solid dispersion technology may be affected
Kapspargo Sprinkle (Metoprolol)	Capsule	Extended release[a]
Kapvay (ClonIDine)	Tablet	Extended release
Kazano (Alogliptin and Metformin)	Tablet	Not scored; manufacturer recommendation[l]
K-Dur (Potassium Chloride)	Tablet	Slow release[b]
Keppra (LevETIRAcetam)	Tablet	Taste[b,e]
Keppra XR (LevETIRAcetam)	Tablet	Extended release[b]
Ketoprofen ER	Capsule	Extended release
Khedezla (Desvenlafaxine)	Tablet	Extended release
Kisqali (Ribociclib)	Tablet	Manufacturer recommendation
Kisqali Femara Co-Pack (Ribociclib and Letrozole)	Tablet	Manufacturer recommendation (ribociclib); hazardous substance (letrozole)[k]
Klor-Con (Potassium Chloride)	Tablet	Extended release[b]
Klor-Con M (Potassium Chloride)	Tablet	Slow release[b]; some strengths are scored; to make liquid, place tablet in 120 mL of water; disperse 2 minutes; stir
Klor-Con Sprinkle	Capsule	Extended release
Kombiglyze XR (Saxagliptin and Metformin)	Tablet	Extended release; tablet matrix may remain in stool
Korlym (Mifepristone)	Tablet	Reproductive toxicity; hazardous substance[k]
Koselugo (Selumetinib)	Capsule	Manufacturer recommendation
Krazati (Adagrasib)	Tablet	Manufacturer recommendation
Krintafel (Tafenoquine)	Tablet	Manufacturer recommendation
K-Tab (Potassium Chloride)	Tablet	Extended release[b]

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Drug Product	Dosage Form	Reasons/Comments
LaMICtal XR (LamoTRIgine)	Tablet	Extended release
Latuda (Lurasidone)	Tablet	Manufacturer recommendation$_{t}$
Lazcluze (Lazertinib)	Tablet	Manufacturer recommendation
Lenvima (Lenvatinib)	Capsule	Manufacturer recommendation; may dissolve in a small glass of liquid
Lescol XL (Fluvastatin)	Tablet	Extended release
Letairis (Ambrisentan)	Tablet	Film-coated; hazardous substance$_{k}$
Leukeran (Chlorambucil)	Tablet	Hazardous substance$_{k,o}$
Levbid (Hyoscyamine)	Tablet	Extended release$_{h}$
Lialda (Mesalamine)	Tablet	Delayed release, enteric-coated
Linzess (Linaclotide)	Capsule	Manufacturer recommendation$_{a}$
Lipidil EZ (Fenofibrate)	Tablet	Film-coated; manufacturer recommendation
Lipidil Supra (Fenofibrate)	Tablet	Film-coated; manufacturer recommendation
Lithium Carbonate ER	Tablet	Extended release
Lithobid (Lithium)	Tablet	Extended release
Lonsurf (Trifluridine and Tipiracil)	Tablet	Manufacturer recommendation; hazardous substance$_{k}$
Lorbrena (lorlatinib)	Tablet	Manufacturer recommendation
Lovaza (Omega-3 Fatty Acids)	Capsule	Contents of capsule may erode walls of styrofoam or plastic materials
Lumakras (Sotorasib)	Tablet	Manufacturer recommendation$_{n}$
Lupkynis (Voclosporin)	Capsule	Manufacturer recommendation
Lybalvi (Olanzapine and Samidorphan)	Tablet	Do not divide tablets
Lynparza (Olaparib)	Tablet	Manufacturer recommendation; pharmacokinetic amorphous solid dispersion technology may be affected
Lyrica CR (Pregabalin)	Tablet	Extended release
Lysodren (Mitotane)	Tablet	Manufacturer recommendation
Lytgobi (Futibatinib)	Tablet	Manufacturer recommendation
Macrobid (Nitrofurantoin)	Capsule	Manufacturer recommendation
Mag-Tab SR (Magnesium L-Lactate)	Tablet	Extended release
Matulane (Procarbazine)	Capsule	Hazardous substance$_{k,n}$
Mavenclad (Cladribine)	Tablet	Manufacturer recommendation; hazardous substance$_{k}$
Mavyret (Glecaprevir and Pibrentasvir)	Tablet	Pharmacokinetic amorphous solid dispersion technology may be affected
Mayzent (Siponimod)	Tablet	Film-coated; manufacturer recommendation
Mekinist (Trametinib)	Tablet	Manufacturer recommendation
Mestinon ER (PyRIDostigmine)	Tablet	Extended release$_{b}$
Metadate CD (Methylphenidate)	Capsule	Extended release$_{a}$
Methylphenidate (AB rated generics to Methylin ER)	Tablet	Slow release
Metoprolol Succinate ER	Tablet	Extended release
Mezavant	Tablet	Delayed release

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Drug Product	Dosage Form	Reasons/Comments
Mezera (Mesalamine)	Tablet	Delayed release
Micro-K (Potassium Chloride)	Capsule	Extended release[a,b]
Minolira (Minocycline)	Tablet	Extended release[h]
Mirapex ER (Pramipexole)	Tablet	Extended release
Morphine Sulfate Extended Release	Capsules (once-daily formulation [pellets])	Extended release[a]. Do not give via gastric/NG tubes; may add contents to applesauce without crushing. Capsule disruption may cause a potentially fatal overdose.
Morphine Sulfate Extended Release	Capsules (once- or twice-daily formulation [polymer coated pellets])	Extended release[a]. Do not give via NG tubes; may add contents to applesauce without crushing. Capsule disruption may cause a potentially fatal overdose.
Morphine Sulfate Extended Release	Tablet	Extended release[b]; tablet disruption may cause a potentially fatal overdose
Motpoly XR (Lacosamide)	Capsule	Extended release[b]
Motrin (Ibuprofen)	Tablet	Taste[b,e]
MS Contin (Morphine)	Tablet	Extended release[b]; tablet disruption may cause a potentially fatal overdose
Mucinex (GuaiFENesin)	Tablet	Slow release
Mucinex DM (GuaiFENesin)	Tablet	Slow release[b]
Multaq (Dronedarone)	Tablet	Hazardous substance[k]
Mycapssa (Octreotide)	Capsule	Delayed release
Mydayis (Dextroamphetamine and Amphetamine)	Capsule	Extended release[a]
Myfortic (Mycophenolate)	Tablet	Delayed release; enteric-coated; teratogenic potential; hazardous substance[k]
Myorisan (ISOtretinoin)	Capsule	Mucous membrane irritant; teratogenic potential
Myrbetriq (Mirabegron)	Tablet	Extended release
Mytesi (Crofelemer)	Tablet	Delayed release
Namenda XR (Memantine)	Capsule	Extended release[a,b]
Namzaric (Memantine and Donepezil)	Capsule	Slow release[a]
Naprelan (Naproxen)	Tablet	Extended release
Neoral (CycloSPORINE)	Capsule	Teratogenic potential; hazardous substance[k]
Nerlynx (Neratinib)	Tablet	Manufacturer recommendation
Nesina (Alogliptin)	Tablet	Film-coated; manufacturer recommendation
Neurontin (Gabapentin)	Capsule	ISMP recommendation[b]
Neurontin (Gabapentin)	Tablet	ISMP recommendation[h]
NexIUM (Esomeprazole)	Capsule	Delayed release[a]
Niacin	Capsule, tablet	Extended release
Niaspan (Niacin)	Tablet	Extended release
Nifedical XL (NIFEdipine)	Tablet	Extended release
NIFEdipine ER	Tablet	Extended release
Nimotop (Nimodipine)	Tablet	Canadian manufacturer recommendation

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Drug Product	Dosage Form	Reasons/Comments
Ninlaro (Ixazomib)	Capsule	Hazardous substance$_k$; manufacturer recommendation
Nitrostat (Nitroglycerin)	Tablet	Sublingual route$_g$
Nocdurna (Desmopressin)	Tablet	Sublingual route$_g$
Norpace CR (Disopyramide)	Capsule	Extended release; form within a special capsule
Northera (Droxidopa)	Capsule	Manufacturer recommendation
Norvir (Ritonavir)	Tablet	Manufacturer recommendation; crushing tablets has resulted in decreased bioavailability of drug$_b$; pharmacokinetic amorphous solid dispersion technology may be affected
Noxafil (Posaconazole)	Tablet	Delayed release$_b$; pharmacokinetic amorphous solid dispersion technology may be affected
Nubeqa (Darolutamide)	Tablet	Manufacturer recommendation
Nucynta ER (Tapentadol)	Tablet	Extended release; tablet disruption may cause a potentially fatal overdose
Nurtec ODT (Rimegepant)	Orally disintegrating tablet	Orally disintegrating$_g$
Octasa (Mesalamine)	Tablet	Delayed release
Ofev (Nintedanib)	Capsule	Taste
Ogsiveo (Nirogacestat)	Tablet	Manufacturer recommendation
Ojemda (Tovorafenib)	Tablet	Manufacturer recommendation
Ojjaara (Momelotinib)	Tablet	Manufacturer recommendation
Omtryg (Omega-3 Fatty Acids)	Capsule	Manufacturer recommendation; contents of capsule may be erosive
Onglyza (SAXagliptin)	Tablet	Manufacturer recommendation
Onureg (AzaCITIDine)	Tablet	Manufacturer recommendation; hazardous substance$_k$
Opsumit (Macitentan)	Tablet	Teratogenic potential; hazardous substance$_k$
Opsynvi (Macitentan and Tadalafil)	Tablet	Film coated; teratogenic potential; hazardous substance$_k$
Oracea (Doxycycline)	Capsule	Delayed release
Orapred ODT (PrednisoLONE)	Orally disintegrating tablet	Orally disintegrating. Do not break, cut, split, or use partial tablet; may swallow whole or allow tablet to dissolve on tongue.
Oravig (Miconazole)	Buccal tablet	Buccal form
Orenitram (Treprostinil)	Tablet	Slow release
Orgovyx (Relugolix)	Tablet	Manufacturer recommendation
Orkambi (Lumacaftor and Ivacaftor)	Tablet	Pharmacokinetic amorphous solid dispersion technology may be affected
Orphenadrine Citrate ER	Tablet	Extended release
Ortikos (Budesonide)	Capsule	Extended release
Oseni (Alogliptin and Pioglitazone)	Tablet	Manufacturer recommendation$_t$
Oserdu (Elacestrant)	Tablet	Manufacturer recommendation
Osmolex ER (Amantadine)	Tablet	Extended release$_b$
Otezla (Apremilast)	Tablet	Manufacturer recommendation; film-coated
Oxaydo (OxyCODONE)	Tablet	Not amenable to crushing; may obstruct feeding tubes$_b$
Oxtellar XR (OXcarbazepine)	Tablet	Extended release

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Drug Product	Dosage Form	Reasons/Comments
OxyCONTIN (OxyCODONE)	Tablet	Extended release; surrounded by wax matrix; tablet disruption may cause a potentially fatal overdose
Oxy-IR (OxyCODONE)	Tablet	Canadian manufacturer recommendation
OxyMORphone ER	Tablet	Extended release
OxyNeo (OxyCODONE)	Tablet	Extended release
Pancreaze (Pancrelipase)	Capsule	Slow-release[a]; enteric-coated contents
Pancrelipase	Capsule	Slow-release[a]; enteric-coated contents
Paxil CR (PARoxetine)	Tablet	Extended release
Paxil (PARoxetine)	Tablet	Film-coated[b]
Pemazyre (Pemigatinib)	Tablet	Manufacturer recommendation
Pentasa (Mesalamine)	Capsule	Extended release[a]
Pertzye (Pancrelipase)	Capsule	Slow-release[a]; enteric-coated contents
Pexeva (PARoxetine)	Tablet	Film-coated[b]
Phenytek (Phenytoin)	Capsule	Extended release; manufacturer recommendation[l]
Piqray (Alpelisib)	Tablet	Film-coated; manufacturer recommendation
Plaquenil (Hydroxychloroquine)	Tablet	Manufacturer recommendation (for film-coated tablets)
Plendil (Felodipine)	Tablet	Extended release
Pomalyst (Pomalidomide)	Capsule	Manufacturer recommendation; teratogenic potential; hazardous substance[k]
Ponvory (Ponesimod)	Tablet	Film-coated; manufacturer recommendation
Pradaxa (Dabigatran)	Capsule	Bioavailability increases by 75% when the pellets are taken without the capsule shell
Prevacid (Lansoprazole)	Capsule	Delayed release[a]
Prevacid (Lansoprazole)	Suspension	Slow release. Contains enteric-coated granules. Not for use in NG tubes; mix with water only
Prevacid SoluTab (Lansoprazole)	Tablet	Orally disintegrating. Do not swallow; dissolve in water only and dispense via dosing syringe or NG tube
Prevpac (Lansoprazole, Amoxicillin, and Clarithromycin)	Capsule, tablet	Manufacturer recommendation
Prevymis (Letermovir)	Oral pellets, tablets	Manufacturer recommendation
PriLOSEC (Omeprazole)	Capsule	Delayed release[a,b]
PriLOSEC OTC (Omeprazole)	Tablet	Delayed release
Pristiq (Desvenlafaxine)	Tablet	Extended release
Procardia (NIFEdipine)	Capsule	Pharmacokinetics may be altered if not taken whole
Procardia XL (NIFEdipine)	Tablet	Extended release
Procysbi (Cysteamine)	Capsule	Delayed release[a]
Prograf (Tacrolimus)	Capsule	Pharmacokinetic amorphous solid dispersion technology may be affected
Prolopa (Benserazide and Levodopa)	Capsule	Manufacturer recommendation
Promacta (eltrombopag)	Tablet	Manufacturer recommendation

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Drug Product	Dosage Form	Reasons/Comments
Propecia (Finasteride)	Tablet	Women who are, or may become, pregnant should not handle crushed or broken tablets due to teratogenic potential[j]; hazardous substance[k]
Proscar (Finasteride)	Tablet	Women who are, or may become, pregnant should not handle crushed or broken tablets due to teratogenic potential[j]; hazardous substance[k]
Protonix (Pantoprazole)	Tablet	Slow release[b]
Purinethol (Mercaptopurine)	Tablet	Teratogenic potential[j]; hazardous substance[k]
Pylera (Bismuth Subcitrate, Metronidazole, and Tetracycline)	Capsule	Mucous membrane irritant
Pyrukynd (Mitapivat)	Tablet	Manufacturer recommendation
Pytest (Carbon 14 Urea)	Capsule	Manufacturer recommendation; hazardous substance[k]
Qelbree (Viloxazine)	Capsule	Extended release[a]
Qinlock (Ripretinib)	Tablet	Manufacturer recommendation
Qtern (Dapagliflozin and Saxagliptin)	Tablet	Manufacturer recommendation
Qternmet XR (Dapagliflozin, Saxagliptin, and Metformin)	Tablet	Manufacturer recommendation
Qudexy XR (Topiramate)	Capsule	Extended release[a]
QuiNIDine ER	Tablet	Extended release[n]; enteric-coated
Ranexa (Ranolazine)	Tablet	Slow release
Rapamune (Sirolimus)	Tablet	Manufacturer recommendation; hazardous substance[k]; pharmacokinetic NanoCrystal technology may be affected[b]
Rayaldee (Calcifediol)	Capsule	Extended release
Rayos (PrednisONE)	Tablet	Delayed release[b]; release is dependent upon intact coating
Razadyne ER (Galantamine)	Capsule	Extended release
Rebetol (Ribavirin)	Capsule	Manufacturer recommendation; hazardous substance[k]
Remeron SolTab (Mirtazapine)	Tablet	Orally disintegrating form[g]
Renagel (Sevelamer)	Tablet	Manufacturer recommendation[b]; expands in liquid if broken/ crushed.
Renvela (Sevelamer)	Tablet	Manufacturer recommendation[b]; expands in liquid if broken or crushed
Retevmo (Selpercatinib)	Capsule	Manufacturer recommendation
Revlimid (Lenalidomide)	Capsule	Manufacturer recommendation; teratogenic potential; hazardous substance[k]
Revuforj (Revumenib)	Tablet	Manufacturer recommendation; tablets may be crushed and dispersed in water
Reyataz (Atazanavir)	Capsule	Oral powder is available; see prescribing information for administration instructions
Reyvow (Lasmiditan)	Tablet	Film-coated; manufacturer recommendation
Rezlidhia (Olutasidenib)	Capsule	Manufacturer recommendation
Rezurock (Belumosudil)	Tablet	Film-coated; manufacturer recommendation
Ribasphere (Ribavirin)	Capsule	Manufacturer recommendation

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Drug Product	Dosage Form	Reasons/Comments
Rinvoq (Upadacitinib)	Tablet	Extended release
RisperiDONE M-Tab	Orally disinigrating tablet	Orally disintegrating. Do not chew or break tablet; after dissolving under tongue, tablet may be swallowed
Ritalin LA (Methylphenidate)	Capsule	Extended release[a]
Ritalin-SR (Methylphenidate)	Tablet	Extended release
Romvimza (Vimseltinib)	Capsule	Manufacturer recommendation
ROPINIRole ER	Tablet	Extended release
Roszet (Ezetimibe and Rosuvastatin)	Tablet	Manufacturer recommendation
Roweepra (LevETIRAcetam)	Tablet	Taste[b]
Roweepra ER (LevETIRAcetam)	Tablet	Extended release[b]
Rozlytrek (Entrectinib)	Capsule	Manufacturer recommendation
Rukobia (Fostemsavir)	Tablet	Extended release
Rybelsus (Semaglutide)	Tablet	Manufacturer recommendation
Rydapt (Midostaurin)	Capsule	Manufacturer recommendation
Rytary (Carbidopa and Levodopa)	Capsule	Extended release[a]
Rythmol SR (Propafenone)	Capsule	Extended release
Salofalk (Mesalamine)	Tablet	Delayed release
SandIMMUNE (CycloSPORINE)	Capsule	Teratogenic potential; hazardous substance[k]
Saphris (Asenapine)	Tablet	Sublingual form[g]
Scemblix (Asciminib)	Tablet	Manufacturer recommendation
Sensipar (Cinacalcet)	Tablet	Tablets are not scored and cutting may cause inaccurate dosage
Seroquel XR (QUEtiapine)	Tablet	Extended release
Siklos (Hydroxyurea)	Tablet	Manufacturer recommendation[n]; hazardous substance[k]
Simcor (Niacin and Simvastatin)	Tablet	Tablet contains extended release niacin
Sinemet CR (Carbidopa and Levodopa)	Tablet	Extended release[h]
Sirturo (Bedaquiline)	Tablet	Manufacturer recommendation[l]
Sitavig (Acyclovir)	Tablet	Buccal tablet; swallowing whole or crushing eliminates or reduces effectiveness
Skyclarys (Omaveloxolone)	Capsule	Manufacturer recommendation; contents may be sprinkled onto two tablespoonsful of applesauce and consumed immediately.
Slo-Niacin (Niacin)	Tablet	Slow release[h]
Slow Fe (Ferrous Sulfate)	Tablet	Extended release; manufacturer recommendation[b]
Slow Iron (Ferrous Sulfate)	Tablet	Extended release; manufacturer recommendation[b]
Slow-Mag (Magnesium Chloride)	Tablet	Delayed release
Slynd (Drospirenone)	Tablet	Manufacturer recommendation; hazardous substance
Solodyn (Minocycline)	Tablet	Extended release
Soriatane (Acitretin)	Capsule	Teratogenic potential; hazardous substance[k]
Sotyktu (Deucravacitinib)	Tablet	Manufacturer recommendation
Sovuna (Hydroxychloroquine)	Tablet	Film coated; 300 mg tablet is scored and may be divided but not crushed

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Drug Product	Dosage Form	Reasons/Comments
Sporanox (Itraconazole)	Capsule	Pharmacokinetic amorphous solid dispersion technology may be affected
Sprycel (Dasatinib)	Tablet	Film-coated. Manufacturer recommendation[n]; active ingredients are surrounded by a wax matrix to prevent health care exposure. Caregivers who are or could become pregnant should not handle crushed or broken tablets; hazardous substance[k]
Stalevo (Levodopa, Carbidopa, and Entacapone)	Tablet	Manufacturer recommendation; combining multiple tablets or portions of tablets may lead to an overdose of entacapone
Staxyn (Verdenafil)	Orally disintegrating tablet	Sublingual form[g]
Stivarga (Regorafenib)	Tablet	Manufacturer recommendation; hazardous substance[k]; pharmacokinetic amorphous solid dispersion technology may be affected
Strattera (AtoMOXetine)	Capsule	Capsule contents can cause ocular irritation
Suboxone (Buprenorphine and Naloxone)	Buccal film	Sublingual form[g]
Sudafed 12-Hour (Pseudoephedrine)	Capsule	Extended release[b]
Sudafed 24-Hour (Pseudoephedrine)	Capsule	Extended release[b]
Sular (Nisoldipine)	Tablet	Extended release
Supeudol (OxyCODONE)	Tablet	Canadian manufacturer recommendation
Sustiva (Efavirenz)	Tablet	Manufacturer recommendation; tablets should not be broken (capsules should be used if dosage adjustment needed)
Symax Duotab (Hyoscyamine)	Tablet	Controlled release
Symax SR (Hyoscyamine)	Tablet	Extended release
Symbravo (Meloxicam and Rizatriptan)	Tablet	Manufacturer recommendation
Symdeko (Tezacaftor and Ivacaftor)	Tablet	Manufacturer recommendation[i]; pharmacokinetic amorphous solid dispersion technology may be affected
Synjardy XR (Empagliflozin and Metformin)	Tablet	Extended release
Syprine (Trientine)	Capsule	Manufacturer recommendation; potential risk of contact dermatitis
Tabloid (Thioguanine)	Tablet	Hazardous substance[k,o]
Tabrecta (Capmatinib)	Tablet	Manufacturer recommendation
Tafinlar (Dabrafenib)	Capsule	Manufacturer recommendation; hazardous substance[k]
Tafinlar (Dabrafenib)	Table for oral suspension	Do not chew, crush, or swallow whole; tablets for oral suspension are meant to be administered as a liquid
Tagrisso (Osimertinib)	Tablet	Note: May be dissolved in 60 mL of water
Talicia (Omeprazole, Amoxicillin, and Rifabutin)	Capsule	Manufacturer recommendation; delayed release
Talzenna (Talazoparib)	Capsule	Manufacturer recommendation
Tamoxifen	Tablet	Hazardous substance[k,o]
Targin (Oxycodone and Naloxone)	Tablet	Extended release; tablet disruption may cause a potentially fatal overdose
Tarpeyo (Budesonide)	Capsule	Delayed release

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Oral Medications That Should Not Be Crushed or Altered

Drug Product	Dosage Form	Reasons/Comments
Tasigna (Nilotinib)	Capsule	Manufacturer recommendation$_n$; hazardous substance$_k$; altering capsule may lead to high blood levels, increasing the risk of toxicity
Tavenos (Avacopan)	Capsule	Manufacturer recommendation
Taztia XT (DiltiaZEM)	Capsule	Extended release$_a$
Tazverik (Tazemetostat)	Tablet	Manufacturer recommendation
Tecfidera (Dimethyl Fumarate)	Capsule	Manufacturer recommendation; delayed release; irritant
Tegretol-XR (CarBAMazepine)	Tablet	Extended release$_b$
Temodar (Temozolomide)	Capsule	Manufacturer recommendation$_o$; hazardous substance$_k$. Note: If capsules are accidentally opened or damaged, rigorous precautions should be taken to avoid inhalation or contact of contents with the skin or mucous membranes.
Tepmetko (Tepotinib)	Tablet	Manufacturer recommendation; tablets may be dispersed in noncarbonated water without crushing
Tessalon Perles (Benzonatate)	Capsule	Swallow whole; pharmacologic action may cause choking if chewed or opened and swallowed.
Teva-Oxycodan (Oxycodone and Aspirin)	Tablet	Manufacturer recommendation
Thalomid (Thalidomide)	Capsule	Manufacturer recommendation$_o$; teratogenic potential; hazardous substance$_k$
Theo-24 (Theophylline)	Capsule	Extended release$_a$; contains beads that dissolve through GI tract
Theochron (Theophylline)	Tablet	Extended release
Theophylline ER	Tablet	Extended release
Tiazac (DilTIAZem)	Capsule	Extended release$_a$
Tibsovo (Ivosidenib)	Tablet	Manufacturer recommendation; pharmacokinetic amorphous solid dispersion technology may be affected
Tirosint (Levothyroxine)	Capsule	Manufacturer recommendation; liquid-filled
Tolsura (Itraconazole)	Capsule	Manufacturer recommendation$_b$
Topamax Sprinkle (Topiramate)	Capsule	Taste$_a$
Topamax (Topiramate)	Capsule	Taste$_a$
Topamax (Topiramate)	Tablet	Taste
Toprol XL (Metoprolol Succinate)	Tablet	Extended release$_h$
Toviaz (Fesoterodine)	Tablet	Extended release
Tracleer (Bosentan)	Tablet	Teratogenic potential; hazardous substance$_{jk}$; women who are or may be pregnant should not handle crushed or broken tablets
TraMADol ER	Tablet	Extended release
Tranexamic Acid	Tablet	Manufacturer recommendation
Trental (Pentoxifylline)	Tablet	Extended release
Tretinoin	Capsule	Manufacturer recommendation$_o$
Treximet (Sumatriptan and Naproxen)	Tablet	Unique formulation enhances rapid drug absorption
TriCor (fenofibrate and derivatives)	Tablet	Pharmacokinetic NanoCrystal technology may be affected
Triglide (fenofibrate and derivatives)	Tablet	Pharmacokinetic NanoCrystal technology may be affected

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Drug Product	Dosage Form	Reasons/Comments
Trijardy XR (Empagliflozin, Linagliptin, and Metformin)	Tablet	Extended release
Trikafta (Elexacaftor, Tezacaftor, and Ivacaftor)	Tablet	Manufacturer recommendation[f]; pharmacokinetic amorphous solid dispersion technology may be affected
TriLipix (Fenofibrate)	Capsule	Extended release
Trokendi XR (Topiramate)	Capsule	Extended release
Trospium and Xanomeline (Cobenfy)	Capsule	Manufacturer recommendation; do not open
Trulance (Plecanatide)	Tablet	Manufacturer recommendation; see package insert for instructions on crushing administration
Truqap (Capivasertib)	Tablet	Manufacturer recommendation
Tukysa (Tucatinib)	Tablet	Manufacturer recommendation
Turalio (Pexidartinib)	Capsule	Manufacturer recommendation
Tylenol 8 Hour (Acetaminophen)	Caplet	Extended release
Uceris (Budesonide)	Tablet	Extended release; coating on tablet designed to break down at pH of ≥7
Ultram ER (TraMADol)	Tablet	Extended release. Tablet disruption my cause a potentially fatal overdose.
Uniphyl (Theophylline)	Tablet	Slow release
Uptravi (Selexipag)	Tablet	Manufacturer recommendation; film-coated
Urocit-K (Potassium Citrate)	Tablet	Wax-coated; prevents upper GI release
Uroxatral (Alfuzosin)	Tablet	Extended release
Urso Forte (Ursodiol)	Tablet	Tablet is scored and may be split
Vadadustat (Vafseo)	Tablet	Manufacturer recommendation; film-coated
Valcyte (ValGANciclovir)	Tablet	Irritant potential[b]; teratogenic potential; hazardous substance[k]
Vanflyta (Quizartinib)	Tablet	Manufacturer recommendation
Vanrafia (Atrasentan)	Tablet	Manufacturer recommendation
Vascepa (Omega-3 Fatty Acids)	Capsule	Manufacturer recommendation
Venclexta (Venetoclax)	Tablet	Manufacturer recommendation; film-coated; pharmacokinetic amorphous solid dispersion technology may be affected
Venlafaxine ER	Tablet	Extended release
Veozah (Fezolinetant)	Tablet	Film coated
Verapamil SR	Tablet	Extended release[h]
Verelan (Verapamil)	Capsule	Sustained release[a]
Verelan PM (Verapamil)	Capsule	Extended release[a]
Verzenio (Abemaciclib)	Tablet	Manufacturer recommendation
VESIcare (Solifenacin)	Tablet	Manufacturer recommendation; taste
Videx EC (Didanosine)	Capsule	Delayed release; enteric-coated
Viekira XR (Ombitasvir, Paritaprevir, Ritonavir, and Dasabuvir)	Tablet	Extended release; pharmacokinetic amorphous solid dispersion technology may be affected
Vijoice (Alpelisib)	Tablet	Manufacturer recommendation[n]
Vimovo (Naproxen and Esomeprazole)	Tablet	Delayed release

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Drug Product	Dosage Form	Reasons/Comments
Vimpat (Lacosamide)	Tablet	Film-coated[b,p]; manufacturer recommendation
Viokace (Pancrelipase)	Tablet	Mucous membrane irritant[p]
Viramune XR (Nevirapine)	Tablet	Extended release[b]
Vitrakvi (Larotrectinib)	Capsule	Manufacturer recommendation[b]
Vivjoa (Oteseconazole)	Capsule	Manufacturer recommendation
Vivotif (Typhoid Vaccine)	Capsule	Manufacturer recommendation; enteric-coated
Voltaren-XR (Diclofenac)	Tablet	Extended release
Vonjo (Pacritinib)	Capsule	Manufacturer recommendation
Voranigo (Vorasidenib)	Tablet	Manufacturer recommendation
Votrient (PAZOPanib)	Tablet	Manufacturer recommendation; crushing significantly increases AUC and Tmax; hazardous substance[k]
Vumerity (Diroximel Fumarate)	Capsule	Manufacturer recommendation; delayed release
Vykat XR (Diazoxide Choline)	Tablet	Extended release
Vyndamax (Tafamidis)	Capsule	Manufacturer recommendation
Vyndaqel (Tafamidis)	Capsule	Manufacturer recommendation
Wakix (Pitolisant)	Tablet	Canadian manufacturer recommendation (not in US labeling)
Wayrilz (Rilzabrutinib)	Tablet	Manufacturer recommendation
Welireg (Belzutifan)	Tablet	Manufacturer recommendation
Wellbutrin (BuPROPion)	Tablet	Manufacturer recommendation
Wellbutrin SR (BuPROPion)	Tablet	Extended release
Wellbutrin XL (BuPROPion)	Tablet	Extended release
Widaplik (Amlodipine, Indapamide, and Telmisartan)	Tablet	Manufacturer recommendation
Xalkori (Crizotinib)	Capsule	Manufacturer recommendation[n]; hazardous substance[k]
Xalkori (Crizotinib)	Capsule, coated pellets	Oral pellets contained within the capsule; do not crush or chew pellets; manufacturer recommendation; hazardous substance[k]
Xanax XR (ALPRAZolam)	Tablet	Extended release[b]
Xartemis XR (Oxycodone and Acetaminophen)	Tablet	Extended release; tablet disruption may cause a potentially fatal overdose
Xeljanz XR (Tofacitinib)	Tablet	Extended release; manufacturer recommendation
Xeloda (Capecitabine)	Tablet	Manufacturer recommendation[o]; hazardous substance[k]
Xenleta (Lefamulin)	Tablet	Film-coated; manufacturer recommendation
Xigduo XR (Dapagliflozin and Metformin)	Tablet	Extended release
Ximino (Minocycline)	Capsule	Extended release
Xolremdi (Mavorixafor)	Capsule	Manufacturer recommendation
Xospata (Gilteritinib)	Tablet	Manufacturer recommendation
Xpovio (Selinexor)	Tablet	Manufacturer recommendation
Xtampza ER (OxyCODONE)	Capsule	Extended release[a,b]
Xtandi (Enzalutamide)	Capsule	Manufacturer recommendation; hazardous substance[k]

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DID YOU KNOW?

Oral Medications That Should Not Be Crushed or Altered

Drug Product	Dosage Form	Reasons/Comments
Xtandi (Enzalutamide)	Tablet	Manufacturer recommendation; film-coated; hazardous substance$_k$
Yonsa (Abiraterone)	Tablet	Manufacturer recommendation; hazardous substance$_k$; caregivers who are or could be pregnant should wear gloves if handling tablets
Yosprala (Aspirin and Omeprazole)	Tablet	Delayed release
Zegerid OTC (Omeprazole and Sodium Bicarbonate)	Capsule	Delayed release$_b$
Zegfrovy (Sunvozertinib)	Tablet	Manufacturer recommendation
Zejula (Niraparib)	Capsule	Manufacturer recommendation
Zelboraf (Vemurafenib)	Tablet	Manufacturer recommendation (based on tablet properties); hazardous substance$_k$; pharmacokinetic amorphous solid dispersion technology may be affected
Zenatane (ISOtretinoin)	Capsule	Mucous membrane irritant; teratogenic potential
Zenpep (Pancrelipase)	Capsule	Delayed release$_a$; enteric-coated contents
Zepatier (Elbasvir and Grazoprevir)	Tablet	Pharmacokinetic amorphous solid dispersion technology may be affected
Zeposia (Ozanimod)	Capsule	Manufacturer recommendation
Zituvimet XR (Sitagliptin and Metformin)	Tablet	Extended release
Zokinvy (Lonafarnib)	Capsule	Manufacturer recommendation$_a$
Zolinza (Vorinostat)	Capsule	Manufacturer recommendation$_o$; irritant; avoid contact with skin or mucous membranes; use gloves to handle; hazardous substance$_k$
Zolpidem	Capsule	Manufacturer recommendation
Zolpidem sublingual	Tablet	Sublingual form$_g$
Zomig-ZMT (ZOLMitriptan)	Tablet	Orally disintegrating form$_g$
Zonatuss (Benzonatate)	Capsule	Swallow whole; pharmacologic action may cause choking if chewed or opened and swallowed
Zortress (Everolimus)	Tablet	Manufacturer recommendation; mucous membrane irritant; hazardous substance$_k$; pharmacokinetic amorphous solid dispersion technology may be affected
Zubsolv (Buprenorphine and Naloxone)	Sublingual tablet	Sublingual form$_g$
Zunveyl (Benzgalantamine)	Tablet	Delayed release; manufacturer recommendation
Zuplenz (Ondansetron)	Film	Sublingual form$_g$
Zyban (BuPROPion)	Tablet	Slow release
Zydelig (Idelalisib)	Tablet	Manufacturer recommendation
Zyflo CR (Zileuton)	Tablet	Extended release
ZyrTEC-D Allergy & Congestion (Cetirizine and Pseudoephedrine)	Tablet	Extended release
Zytiga (Abiraterone)	Tablet	Manufacturer recommendation; hazardous substance$_k$; caregivers who are or could be pregnant should wear gloves if handling uncoated or broken, damaged, or crushed tablets

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Oral Medications That Should Not Be Crushed or Altered

a. Capsule may be opened and the contents taken without crushing or chewing; soft food, such as applesauce or pudding, may facilitate administration (refer to manufacturer's labeling for specific recommendations); contents may generally be administered via nasogastric tube using an appropriate fluid, provided entire contents are washed down the tube.
b. Liquid dosage forms of the product are available; however, dose, frequency of administration, and manufacturers may differ from that of the solid dosage form.
c. Antacids and/or milk may prematurely dissolve the coating of the tablet.
d. Capsule may be opened and the liquid contents removed for administration.
e. The taste of this product in a liquid form would likely be unacceptable to the patient; administration via nasogastric tube should be acceptable.
f. Effervescent tablets must be dissolved in the amount of diluent recommended by the manufacturer.
g. Tablets/film are made to disintegrate under (or on) the tongue.
h. Tablet is scored and may be broken in half without affecting release characteristics.
i. Skin contact may enhance tumor production; avoid direct contact.
j. Prescribing information recommends that women who are, or may become, pregnant should not handle medication, especially if crushed or broken; avoid direct contact.
k. Potentially hazardous or hazardous substance; refer to institution-specific guidelines for precautions to observe when handling this substance.
l. Altering (e.g.,, chewing, crushing, splitting, opening) the dosage form has not been studied, according to the manufacturer.
m. The manufacturer's labeling states tablets should not be broken; however, available data do not indicate any safety or efficacy concerns with this practice.
n. For patients unable to swallow whole, capsules may be opened or tablet may be dispersed in liquid; follow manufacturer instructions for preparation and administration. Use appropriate handling precautions if indicated.
o. There are published reports of compounded extemporaneous preparation (refer to drug monograph). Use appropriate handling precautions if indicated.
p. In some cases, dosage form may be opened and/or crushed for enteral feeding tube administration; refer to drug monograph for detailed recommendations.

References

Lexidrug Online, Oral Medications That Should Not Be Crushed or Altered. Waltham, MA: UpToDate, Inc.; September 15, 2025. https://online.lexi.com/lco/action/doc/retrieve/docid/patch_f/4227#monograph-tab-content. Accessed September 19, 2025.

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Abridged List of Medications with Shortened Expiration Dates

Once certain products are opened and in use, they must be used within a specific timeframe to avoid reduced stability, sterility and potentially reduced efficacy. Product-specific storage and expiration details can be found in the drug product's Package Insert (PI) under the "How Supplied/Storage & Handling" section. ***A drug product's Beyond Use Date (BUD) is the manufacturer supplied expiration date OR the shortened date after opening (see BUD Notes below), whichever comes first.***

These in-use medications should be labeled such that the "DATE OPENED" is noted, clearly visible and securely attached to a part of the package to not be discarded. This date is to be referenced when auditing to clear medications prior to expiration.

This list is abridged to cover some common medications whose package inserts detail shortened expirations once in-use. Users should also be familiar with USP BUD standards that may dictate in-use BUDs for other medications (e.g., eye drops, ear drops, injectable MDVs, etc.).

Asthma | Allergy | COPD		
Generic Name	**Brand Name**	**Beyond Use Date (BUD) Notes**
Acetylcysteine	Mucomyst	Store unopened vials at room temperature; once opened, store under refrigeration and use within 96 hours. A color change may occur in opened vials (light purple) and does not affect the safety or efficacy.
Aclidinium	Tudorza	45 days after opening pouch, when device locks out, or when dose indicator displays 0.
Aclidinium/Formoterol	Duaklir Pressair	2 months after opening bag, when device locks out, or when dose indicator displays 0.
Arformoterol	Brovana solution	Prior to dispensing, store in protective foil pouch under refrigeration at 2°C to 8°C (36°F to 46°F). Protect from light and excessive heat. After dispensing, unopened foil pouches may be stored at 20°C to 25°C (68°F to 77°F) for up to 6 weeks. Only remove vial from foil pouch immediately before use.
Albuterol	ProAir RespiClick	13 months after opening foil pouch or when counter reads 0.
	Ventolin HFA	12 months after removal from foil pouch or when counter reads 0.
Albuterol/Budesonide	Airsupra	12 months after opening foil pouch or when dose indicator displays 0.
Albuterol/Ipratropium	Combivent Respimat	3 months after first actuation or when device locks out.
	Duoneb	Store in foil and away from heat and light. Unit-dose vials should remain stored in protective foil pouch at all times. Once removed from the foil pouch, the individual vials should be used within one week. Discard if the solution is not colorless.

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Abridged List of Medications with Shortened Expiration Dates

Asthma | Allergy | COPD, Continued		
Generic Name	**Brand Name**	**Beyond Use Date (BUD) Notes**
Budesonide	Pulmicort Respules	When an envelope has been opened, the shelf life of the unused ampules is 2 weeks when protected. Return unused ampules to the aluminum foil envelope after opening, to protect them from light. Any opened ampule must be used promptly.
Budesonide/ Formoterol	Symbicort	3 months after removal from foil pouch or when counter reads 0.
	Breyna	3 months after removal from foil pouch.
Fluticasone	Flovent Diskus	**50mcg strength**: 6 weeks after removal from protective foil pouch or when counter reads 0. **100mcg** and **250mcg strength**: 2 months after removal from foil pouch or when counter reads 0.
	ArmonAir Digihaler	30 days after removal from protective foil pouch or when counter reads 0.
	Arnuity Ellipta	6 weeks after removal from foil pouch or when counter reads 0.
Fluticasone/ Salmeterol	Advair Diskus	30 days after removal from protective foil pouch or when counter reads 0.
	AirDuo Digihaler	30 days after removal from foil pouch or when the counter reads 0.
	AirDuo Respimat	30 days after removal from foil pouch or when the counter reads 0.
	Wixela Inhub	30 days after removal from foil pouch or when the counter reads 0.
Fluticasone/Vilanterol	Breo Ellipta	6 weeks after removal from foil tray pouch or when counter reads 0.
Fluticasone/Vilanterol/ Umeclidinium	Trelegy Ellipta	6 weeks after removal from foil tray or when counter reads 0.
Formoterol	Foradil Aerolizer	Capsules should always be stored in the blister and only removed immediately before use, discard by the manufacturer's expiration date on product.
	Perforomist Inhalation Solution	Prior to dispensing, store in refrigerator at 2°C to 8°C (36°F to 46°F). After dispensing, store in refrigerator at 2°C to 8°C (36°F to 46°F) or room temperature at 20°C to 25°C (68°F to 77°F) for up to 3 months. Protect from light and heat. Unit-dose vials should always be stored in the foil pouch and only removed immediately before use.
Glycopyrrolate	Lonhala Magnair	Store vials in the protective foil pouch. After opening the foil pouch, unused unit-dose vials should be returned to, and stored in, the foil pouch. Once a foil pouch is opened, discard the vials if not unused within 7 days. An opened unit-dose vial should be used right away. Discard any unit-dose vial if the solution is not colorless.
Glycopyrrolate/ Formoterol	Bevespi Aerosphere	3 months after removal from foil pouch or when dose indicator reads 0.
Glycopyrrolate/ Formoterol/Budesonide	Breztri Aerosphere	3 months (**120-inhalation cannister**) or 3 weeks (**28-inhalation cannister**) after removal from foil pouch or when counter reads 0.
Indacaterol	Arcapta Neohaler	Remove capsule from blister immediately prior to use. Discard if not used immediately.
Levalbuterol	Xopenex Solution	2 weeks from when foil pouch is opened. Vials removed from the pouch, if not used immediately, should be protected from light and used within 1 week.
Mometasone	Asmanex Twisthaler	45 days after removal from foil pouch or when the counter reads 0.
Olodaterol	Striverdi Respimat	3 months after cartridge is inserted into inhaler or when device locking mechanism is engaged.

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Abridged List of Medications with Shortened Expiration Dates

Asthma | Allergy | COPD, Continued		
Generic Name	**Brand Name**	**Beyond Use Date (BUD) Notes**
Salmeterol	Serevent Diskus	6 weeks after removal from foil pouch or when counter reads 0.
Tiotropium	Spiriva Respimat	3 months after first use or when device locking mechanism is engaged.
	Spiriva Handihaler	Only remove from foil immediately before use, once removed, the capsule should be used immediately; if capsule is not used immediately it should be discarded.
Tiotropium/Olodaterol	Stiolto Respimat	3 months after cartridge is inserted into inhaler or when locking mechanism is engaged.
Umeclidinium	Incruse Ellipta	6 weeks after opening the foil tray or when the counter reads 0.
Umeclidinium/ Vilanterol	Anoro Ellipta	6 weeks after opening the foil tray or when the counter reads 0.

Insulins			
	Generic Name	**Brand Name**	**Beyond Use Date (BUD) Notes After Accessing Insulin for First Use**
Rapid Acting (RA)	I. glulisine	Apidra	vial - 28 days/pen - 28 days
	I. lispro-aabc	Lyumjev	vial - 28 days/pen - 28 days
	I. aspart	Novolog	vial - 28 days/pen - 28 days
	I. lispro	Fiasp	vial - 28 days/pen - 28 days
Short Acting (SA)	I. Regular	Novolin-R	vial - 42 days/pen - 28 days
		Humulin-R	vial - 31 days
Intermed. Acting	I. NPH	Novolin-N	vial - 42 days/pen - 28 days
		Humulin-N	vial - 31 days/pen - 14 days
Long Acting	I. glargine	Lantus	vial - 28 days/pen - 28 days
		Toujeo	pen - 56 days
		Semglee	vial - 28 days/pen - 28 days
		Basaglar	pen - 28 days
	I. degludec	Tresiba	vial - 56 days/pen - 56 days
70/30 RA MIX	I. aspart protamine susp/I. aspart	Novolog 70/30	vial - 28 days/pen - 14 days
70/30 SA MIX	I. NPH/ I. Regular	Novolin 70/30	vial - 42 days/pen - 28 days
		Humulin 70/30	vial - 31 days/pen - 10 days
75/25 RA MIX	I. lispro protamine/ I. lispro	Humalog 75/25	vial - 28 days/pen - 10 days
50/50 RA MIX	I. lispro protamine/ I. lispro	Humalog 50/50	pen - 10 days
U-500 Strength	I. Regular	Humulin-R U-500	vial - 40 days/pen - 28 days

Please see the PharMerica 2025 Insulin Comparison Chart for further detailed information, such as pre-use and in-use.

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Abridged List of Medications with Shortened Expiration Dates

Miscellaneous			
	Generic Name	Brand Name	Beyond Use Date (BUD) Notes After Accessing Insulin for First Use
Eye	Latanoprost	Xalatan	6 weeks (42 days) after opening or moving to room temp.
	Latanoprostene Bunod	Vyzulta	8 weeks (56 days) after opening or moving to room temp.
Nasal	Calcitonin Nasal Spray	Miacalcin Nasal Spray	30 doses OR 35 days at room temp (opened or unopened).
Solutions	Epoetin Alfa	Epogen (Multidose) Procrit (Multidose)	Store unused portions of Epogen/Procrit in multiple- dose vials at 36°F to 46°F (2°C to 8°C). Discard 21 days after initial entry.
	Furosemide Soln.	Lasix	Discard open bottle after 90 days.
	Lorazepam Soln.	Ativan Intensol	90 days after opening [REFRIGERATED].
Subcutaneous	Liraglutide	Victoza/Saxenda	30 days at controlled room temperature (15°C to 30°C) or in a refrigerator (2°C to 8°C). Keep the pen cap on when not in use and protect from excessive heat and sunlight.
	Semaglutide	Ozempic	56 days after opening at controlled room temperature (15°C to 30°C) or in a refrigerator (2°C to 8°C). Do not freeze, keep the pen cap on when not in use, and protect from excessive heat and sunlight.
		Wegovy	If needed, prior to cap removal, the single-use Wegovy pen can be kept from 8°C to 30°C up to 28 days.
Tests	Tuberculin Tests	Tubersol	30 days after opening [REFRIGERATED].
Bulk	Bulk PO Meds	I.e., Tylenol, Miralax, etc.	Store and discard per manufacturer instructions, unless more stringent Beyond Use Date is applied per adopted policy or local regulation.
Injectable MDV's	Generally, all Injectable Multi-Dose Vials (unless individual products' PIs state otherwise)		28 days after opening [REFRIGERATED].
DM Supplies	Glucose Control Solutions and Test Strips	I.e., Accu-Chek, FreeStyle, etc.	Most: 90 days after opening. CHECK BRAND and that particular manufacturer's recommendation.

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9.8 TABLE OF WEIGHTS, MEASURES AND CONVERSIONS

MEASURES	EQUIVALENT	NOTE
1 kilogram (kg)	1000 grams (gm)	
1 gram (gm)	1000 milligrams (mg)	
1 milligram (mg)	1000 micrograms (mcg) 0.001 gram (gm)	
1 microgram (mcg)	1000 nanograms	
1 liter (l)	1000 milliliters (mL)	
1 milliliter (mL)	1 mL 1 cc	
1 pint (pt)	16 ounces (oz)	
1 quart (qt)	2 pints	
1 gallon (gal)	4 quarts	
5 grains (gr)	325 mg	sometimes rounded off to 300 mg
1 grain (gr)	65 mg	sometimes rounded off to 60 mg
1/2 grain (gr)	32 mg	sometimes rounded off to 30 mg
1/4 grain (gr)	16 mg	sometimes rounded off to 15 mg
1/100 grain (gr)	0.6 mg	
1/150 grain (gr)	0.4 mg	
1/200 grain (gr)	0.3 mg	
1 teaspoonful (tsp)	5 mL	
1 tablespoonful (tbsp)	15 mL	
1 fluid ounce (oz)	30 mL	

Tablet Splitting Guidance for Patient Safety

As part of our mission to consistently provide high quality pharmacy services, PharMerica offers the following guidance to ensure that each patient receives the precise dose of medication, as prescribed. The following guiding principles are in alignment with the American Pharmacists Association (APhA) recommendations for safe tablet splitting processes.

In the best interest of patient safety, tablet splitting should be avoided unless no other dosage form is available to achieve the desired dose as prescribed by the physician. Our review of numerous pharmacy journals and professional references concludes that tablet splitting is inconsistent with best practices as it may not yield the intended dose of medication.

Specific dosages are provided by pharmaceutical manufacturers, and have been thoroughly tested and approved by the United States Food and Drug Administration. These specific doses have undergone extensive clinical and environmental testing in order to meet strict safety and clinical outcome guidelines, prior to any marketing or availability to the consumer.

By splitting a medication tablet, the intact tablet is altered by exposing internal ingredients. This may cause the patient undesirable outcomes, such as foul odor or bitter taste. Also, split tablets often crumble, leaving small portions of powdered ingredients to remain with the container. This could lead to making the medication difficult to administer or cause the patient to reject a needed medication. Crumbled or powdered ingredients left behind in the container indicate an inaccurate dose was administered.

Tablets with odd shapes, enteric coatings, extended release dosages (e.g. SA, ER, or XL designations), un-scored tablets or narrow therapeutic index products should not be split. Liquid dosage forms are a practical alternative in place of solid tablets if unusual doses are required.

PharMerica will assist your facility by periodically identifying current orders written for partial tablets that are not appropriate for splitting. The pharmacy or consultant pharmacist can also assist you to determine if alternative dosage forms are available and covered by the applicable payment program. If a new order is needed, your servicing PharMerica pharmacy will contact your nursing facility and/or the prescribing physician with the recommended alternative. We also recommend that facility nurses bring new orders written for partial tablets to the attention of their PharMerica pharmacy and explore available alternative options.

Improved outcomes and patient safety remain our highest priorities. Thank you for your support.

PharMerica Corporation

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Examples Of Medications That Should Not Be Split

Narrow Therapeutic Index Drugs
Coumadin (warfarin), Lanoxin (digoxin), and Synthroid (levothyroxine) Although tablets may be scored, splitting the tablet would not achieve a precise dose. Accurate dosing is essential to achieving a desired therapeutic effect.

Extended release dosage forms
Procardia (Nifedipine ER), Ambien CR (zolpidem CR)
Wax matrix tablet formulations cannot be split. Timed-release formulations will be inaccurate if tablet is split.

Odd Shapes
Coreg (carvedilol)
Oval shape with mid-bulge feature. Precise tablet splitting cannot be achieved.

Not Scored
Zyprexa, Aricept, Abilify
These tablets are not scored. Splitting interferes with the stability of the product and accurate dosing is unlikely. Other dosage forms are available.

COMMONLY USED DRUGS – SPLITTING NOT RECOMMENDED

DRUG	USE
Amiodarone	Cardiac
Clonazepam	Seizures
Furosemide	Hypertension
HCTZ	Hypertension
Lorazepam	Anxiety

DRUG	USE
Metformin	Glucose control
Metoprolol	Hypertension
Trazadone	Depression
Triamterene/HCTZ	Hypertension
Warfarin	Anticoagulant

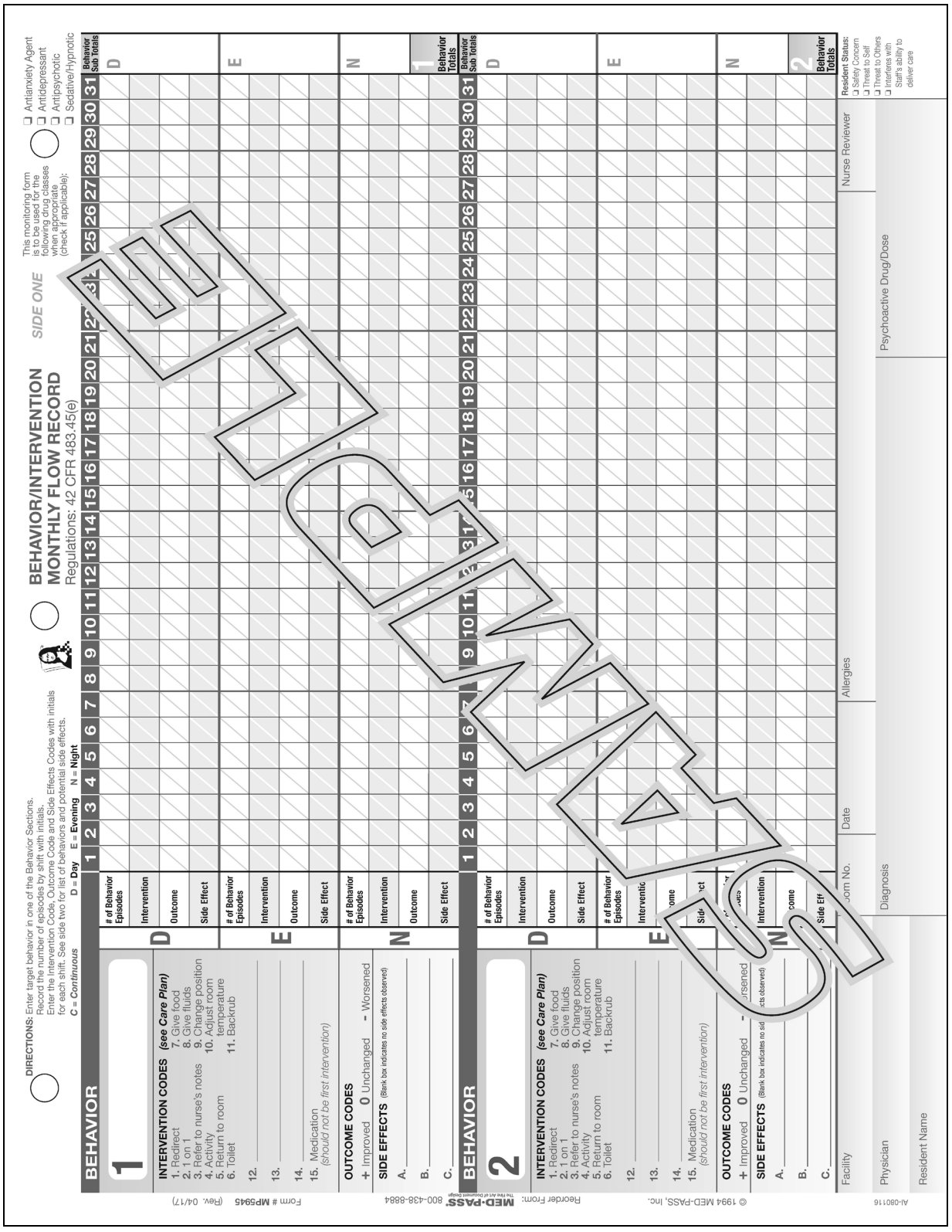
Examples shown above are not inclusive of all medications where tablet splitting is not recommended. Contact your local PharMerica pharmacy for further guidance.

Sample decision guide from the American Pharmacists Association (APhA)

Questions to ask to determine if a tablet can be split:

1. Is the tablet taken for one's heart such as digoxin *(Lanoxin)* or for a thyroid condition such as levothyroxine *(Synthroid, etc)*?
   ○ Yes, don't split the tablet ○ No, go to the next question
2. Is the tablet scored *(indented line in the center of the tablet)*?
   ○ Yes, go to the next question ○ No, don't split the tablet
3. Is the tablet a controlled or modified-release product *(i.e., does it have ER, SA, CR, or LA in the name)*?
   ○ Yes, don't split the tablet ○ No, go to the next question
4. Does the tablet contain more than one active ingredient?
   ○ Yes, don't split the tablet ○ No, go to the next question
5. Does the tablet easily break into pieces with minimal handling?
   ○ Yes, don't split the tablet ○ No, go to the next question
6. Is the tablet coated and/or does it specify under-the-tongue administration *(sublingual)* or inserting inside the mouth by the cheek *(buccal)*?
   ○ Yes, don't split the tablet ○ No, splitting is possible
7. Does it have a foul taste, can it cause birth defects in a pregnant woman if handled, or can it cause mouth irritation?
   ○ Yes, don't split the tablet ○ No, splitting is possible

References:
1. APhA Tableting Specification Steering Committee. Tableting Specifications Manual. 7th ed. APhA Publishing, 2005.
2. Noviasky J, Lo V, Luft DD. Which medications can be split without compromising efficacy and safety? J Fam Prac. 2006;55(8):707-708.
3. [No authors listed]. Pill splitting. Harv Mens Health Watch. 2008;13(4):7.


BEHAVIOR/INTERVENTION MONTHLY FLOW RECORD
Regulations: 42 CFR 483.45(e)
SIDE ONE
DIRECTIONS: Enter target behavior in one of the Behavior Sections. Record the number of episodes by shift with initials. Enter the Intervention Code, Outcome Code and Side Effects Codes with initials for each shift. See side two for list of behaviors and potential side effects.
C = Continuous D = Day E = Evening N = Night
This monitoring form is to be used for the following drug classes when appropriate (check if applicable):
Antianxiety Agent
Antidepressant
Antipsychotic
Sedative/Hypnotic
BEHAVIOR 1
INTERVENTION CODES (see Care Plan)
1. Redirect
2. 1 on 1
3. Refer to nurse's notes
4. Activity
5. Return to room
6. Toilet
7. Give food
8. Give fluids
9. Change position
10. Adjust room temperature
11. Backrub
12.
13.
14.
15. Medication (should not be first intervention)
OUTCOME CODES
+ Improved 0 Unchanged - Worsened
SIDE EFFECTS (Blank box indicates no side effects observed)
A.
B.
C.
# of Behavior Episodes
Intervention
Outcome
Side Effect
D
E
N
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Behavior Sub Totals
1 Behavior Totals
BEHAVIOR 2
2 Behavior Totals
Resident Status:
Safety Concern
Threat to Self
Threat to Others
Interferes with Staff's ability to deliver care
Facility
Physician
Resident Name
Diagnosis
Date
Allergies
Nurse Reviewer
Psychoactive Drug/Dose
Form # MP5945 (Rev. 04/17)
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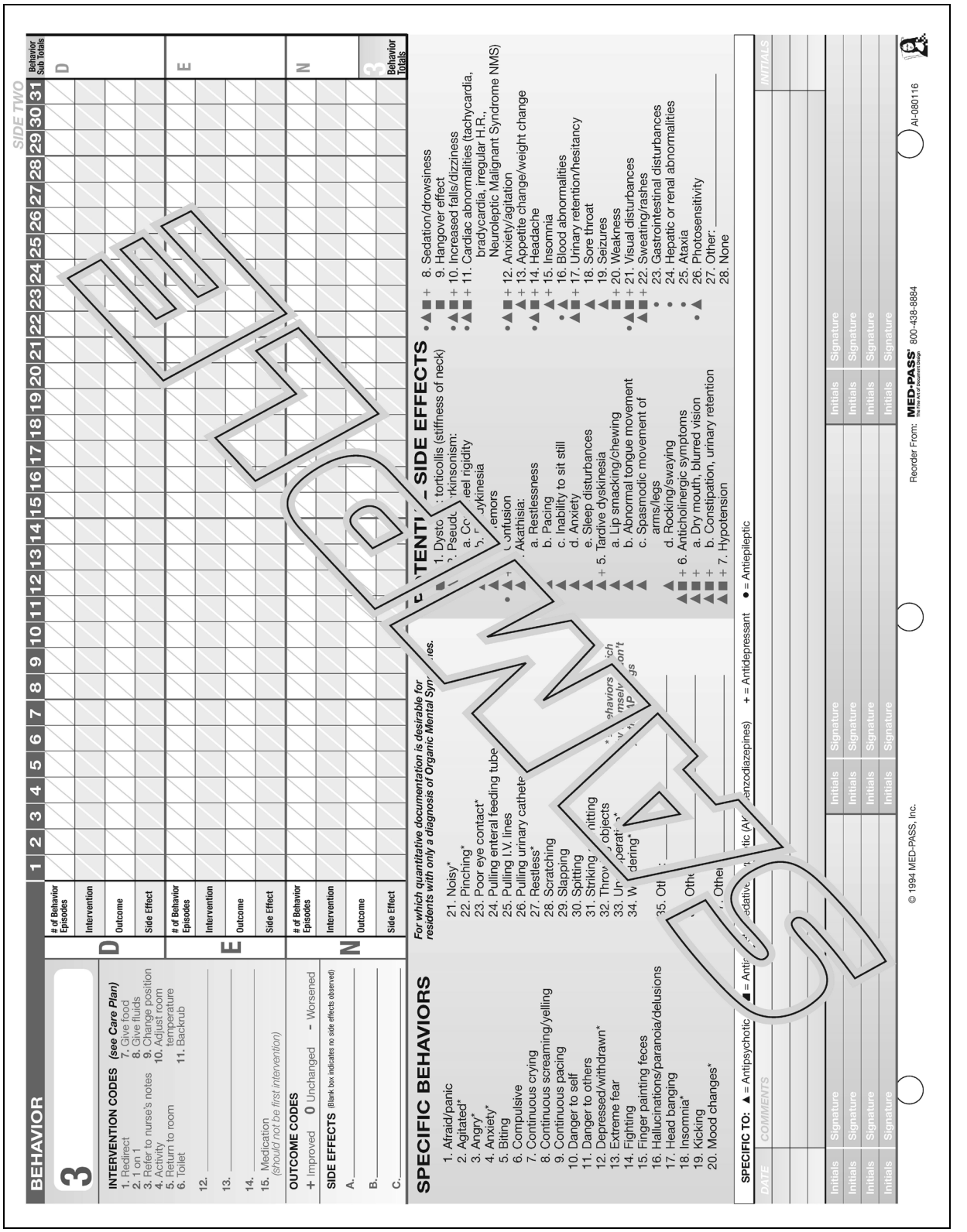
SAMPLE


SIDE TWO
BEHAVIOR
3
INTERVENTION CODES (see Care Plan)
1. Redirect
2. 1 on 1
3. Refer to nurse's notes
4. Activity
5. Return to room
6. Toilet
7. Give food
8. Give fluids
9. Change position
10. Adjust room temperature
11. Backrub
12.
13.
14.
15. Medication (should not be first intervention)
OUTCODE CODES
+ Improved 0 Unchanged - Worsened
SIDE EFFECTS (Blank box indicates no side effects observed)
A.
B.
C.
D
E
N
# of Behavior Episodes
Intervention
Outcome
Side Effect
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Behavior Sub Totals
Behavior Totals
SPECIFIC BEHAVIORS
For which quantitative documentation is desirable for residents with only a diagnosis of Organic Mental Syn
1. Afraid/panic
2. Agitated*
3. Angry*
4. Anxiety*
5. Biting
6. Compulsive
7. Continuous crying
8. Continuous screaming/yelling
9. Continuous pacing
10. Danger to self
11. Danger to others
12. Depressed/withdrawn*
13. Extreme fear
14. Fighting
15. Finger painting feces
16. Hallucinations/paranoia/delusions
17. Head banging
18. Insomnia*
19. Kicking
20. Mood changes*
21. Noisy*
22. Pinching*
23. Poor eye contact*
24. Pulling enteral feeding tube
25. Pulling I.V. lines
26. Pulling urinary catheter
27. Restless*
28. Scratching
29. Slapping
30. Spitting
31. Striking
SIDE EFFECTS
1. Dysto
: torticollis (stiffness of neck)
2. Pseudo
rkinsonism:
a. Co
eel rigidity
b. D
Dykinesia
c. T
emors
d. Confusion
e. Akathisia:
a. Restlessness
b. Pacing
c. Inability to sit still
d. Anxiety
e. Sleep disturbances
5. Tardive dyskinesia
a. Lip smacking/chewing
b. Abnormal tongue movement
c. Spasmodic movement of arms/legs
d. Rocking/swaying
6. Anticholinergic symptoms
a. Dry mouth, blurred vision
b. Constipation, urinary retention
7. Hypotension
8. Sedation/drowsiness
9. Hangover effect
10. Increased falls/dizziness
11. Cardiac abnormalities (tachycardia, bradycardia, irregular H.R., Neuroleptic Malignant Syndrome NMS)
12. Anxiety/agitation
13. Appetite change/weight change
14. Headache
15. Insomnia
16. Blood abnormalities
17. Urinary retention/hesitancy
18. Sore throat
19. Seizures
20. Weakness
21. Visual disturbances
22. Sweating/rashes
23. Gastrointestinal disturbances
24. Hepatic or renal abnormalities
25. Ataxia
26. Photosensitivity
27. Other:
28. None
SPECIFIC TO: ▲ = Antipsychotic ■ = Antianxiety/sedative/hypnotic (Benzodiazepines) + = Antidepressant ● = Antiepileptic
DATE
COMMENTS
INITIALS
Initials Signature
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Antibiotic Stewardship Duties

Consultant Pharmacist

In addition to customary duties, the Consultant Pharmacist will participate in the following Antibiotic Stewardship Program duties:

1. On a monthly visit, will review medication and medical records for patients prescribed antibiotics and make appropriate recommendations. Focus of review includes:
   a. Antibiotic course for appropriateness of administration and/or indication
   b. Documentation of adverse events, if applicable
   c. Microbiologic culture data, if available, to assess proper antibiotic selection
2. Supports the facilities efforts through education as part of normal in-service process

Additionally, the Consultant Pharmacist can participate in the following duties at the request of facility leadership for an added fee:

1. Participate in the Antibiotic Stewardship subcommittee that sets standards for antibiotic prescribing practices for all healthcare providers prescribing antibiotics using practice guidelines, local resistance patterns, and institution formularies
2. Timely, prospective consults for newly ordered antibiotics/new admissions to be handled via a process similar to iMRR
3. Customize treatment guidelines using location antibiogram (bacteria sensitivity report)
4. Monthly retrospective auditing of antibiotic prescribing practices to provide feedback to prescibers/facilities
5. Additional antibiotic stewardship consulting activities

_____ _____
Consultant Pharmacist Signature Date

_____ _____
Medical Director Signature Date

_____ _____
Director of Nursing Signature Date

9.12 STANDING ORDER FOR EMERGENCY USE OF NALOXONE

PURPOSE

This standing order has been created to reduce the risk of fatal opioid overdose. Naloxone is a pure opioid antagonist indicated for the reversal of opioid overdose induced by natural or synthetic opioids in the setting of respiratory depression or unresponsiveness. Rapid administration of naloxone can prevent death and reduce disability or injury from opioid overdose. Naloxone is contraindicated in patients with hypersensitivity to naloxone or any excipients within its formulation.

POLICY

This standing order authorizes staff members of _____ who are trained in naloxone use to administer naloxone to an individual in the event of respiratory depression, unresponsiveness, or respiratory or cardiac arrest when an overdose from opioid is suspected. A list of trained staff members shall be maintained at the facility, if applicable.

PROCEDURES

1. Assessment
    - When an individual is suspected of an opioid overdose the staff member will promptly conduct an initial assessment to evaluate the need for naloxone. This assessment shall include looking for the following signs:
        - Decreased level of consciousness
            - Difficult to arouse
            - Unresponsive to noxious stimuli
            - Inability to communicate or follow commands
        - Decreased respiratory status
            - Decrease (<8 breaths per minute) or absence of respiratory rate
            - Shallow breath or shortness of air
            - Choking, gurgling or snoring noises
            - Complaints of chest tightness
        - Other signs of opioid overdose
            - Pinpoint pupils
            - Blue colored lips or fingertips
            - Cold, clammy, or pale skin
2. Activation of Emergency Services
    - If the staff member determines naloxone administration should be given, he/she will seek help and activate emergency medical services by calling 911. If the individual needs to be left alone while help is sought, the individual should be

placed in the recovery position (body lying on one side supported by a bent knee, with head tilted back) to prevent aspiration.

3. Administration of Naloxone (Dosage forms may differ between facilities)

- **Intramuscular – Naloxone Solution Vial (0.4mg/mL) + Needle & Syringe**
  - Remove caps from naloxone vial and needle
  - Withdraw 1mL (0.4mg) from vial
  - Inject into upper arm or thigh muscle
  - If no response is seen after 2 to 5 minutes, repeat dose
- **Intramuscular – Prefilled Syringe (2mg/2mL)**
  - Remove protective caps from delivery syringe and naloxone vial
  - Screw naloxone vial gently into delivery syringe
  - Attach safety needle to pre-filled naloxone syringe
  - Inject 2mg intramuscularly or subcutaneously
  - If no response is seen after 2 to 5 minutes, repeat dose
- **Intranasal - Mucosal Atomization Device (MAD) + Prefilled Syringe (2mg/2mL)**
  - Remove protective caps from delivery syringe and naloxone vial
  - Screw naloxone vial gently into delivery syringe
  - Attach mucosal atomizer device onto pre-filled naloxone syringe
  - Spray half of the naloxone vial (1 mg) in one nostril and the other half (1 mg) in the other nostril
  - If no response is seen after 2 to 5 minutes, repeat dose
- **Intranasal- NARCAN Nasal Spray (4mg/0.1mL)**
  - Remove spray unit from packaging
  - Tilt head back and insert nozzle into one nostril
  - Press plunger firmly to administer dose (4mg)
  - If no response is seen after 2 to 5 minutes, administer another dose in other nostril using a new spray unit
- **Intramuscular – Evzio Auto-injector (0.4mg/0.4mL)**
  - Remove device from outer case
  - Pull off red safety guard
  - Place black end against outer thigh, through clothing if necessary
  - Press firmly and hold in place for 5 seconds to administer dose (0.4mg)
  - If no response is seen after 2 to 5 minutes, repeat dose with new auto-injector

Documentation
Documentation, including a description or summary of the event must be completed and maintained at the facility. It shall include:

- Patient presentation
- Date and time of event
- Dose, route, and number of administrations
- Patient's response
- Type of Naloxone product (spray, pre-filled syringe +MAD device)

_____ _____

Signature of approving Medical Director Effective Date

_____

Name of approving Medical Director

Emergency Use of Naloxone Documentation

Patient Name: _____ DOB: _____ Date: _____

Facility/Location: _____ Time: _____

Patient Presentation: _____

_____

_____

_____

Rescuer Name: _____ EMS Contacted: Yes No

Naloxone Product Name: _____

NDC: _____ Lot: _____ Exp: _____

Dose Administered: _____ Route: _____ Number of Administrations: _____

Patient's Response: _____

_____

_____

_____

Notes: _____

_____

_____

_____

_____

_____

Hazardous Drug Assessment of Risk

Drug Name	
Dosage Form	
HAZARD: ☐ **Antineoplastic (Group 1)** ☐ **Non-Antineoplastic (Group 2)** ☐ **Reproductive Risk (Group 3)**	
Packaging System:	☐ Unit Dose ☐ Bottle ☐ Inhaler ☐ IV Bag ☐ Ampule ☐ Vial ☐ Syringe ☐ Tube ☐ Other ____
Manipulation:	☐ Packing ☐ Splitting ☐ Crushing ☐ Opening/Pouring ☐ IV Admixture ☐ Compounding ☐ Other_____
Area of Exposure:	☐ Skin ☐ Inhalation ☐ Mucous Membrane ☐ Systemic ☐ Other _____
Risk of Exposure:	☐ Significant ☐ Elevated ☐ Moderate ☐ Negligible
Rationale for alternative containment strategies	
Alternative containment strategies and/or work practices employed to minimize exposure:	**PPE to be used:** ☐ Medical Gloves ☐ Chemo Gloves ☐ Mask ☐ Gown ☐ Shield ☐ Respirator ☐ Goggles

Annual Review Date:	Reviewed By:
Annual Review Date	Reviewed By:
Annual Review Date:	Reviewed By:
Annual Review Date:	Reviewed By:

Hazardous Drug (HD) Risk Assessment Considerations for Completing

1. **Review NIOSH list**: https://www.cdc.gov/niosh/docs/2016-161/
    a. A facility must follow the containment measures outlined by NIOSH Table 5 and USP<800> to prevent occupational exposure of hazardous drugs.
    b. However, a facility can do an Assessment of Risk (AoR) to define alternative containment measures for all hazardous drugs **except** antineoplastics (NIOSH Table 1) requiring manipulation (crushing, compounding, etc) or active pharmaceutical ingredient (API) powder formulations.

2. **Hazardous Drug Name and Dosage Form**: Fill-in the HD being evaluated at the top of the form.
    a. Some Common Dosage Forms to consider:
        i. Stock Dosage Form
            1) Capsule or Coated Tablet
            2) Tablet – Uncoated, Oral Dissolving Tablet (ODT)
            3) Liquids – Oral, Nebules,
            4) Inhalants
            5) Injection – Vials, Ampules, Syringe
            6) Powder, Granules, Pure Chemical
            7) Suppository
            8) Topical, applied (Cream, Gel, Ointment, Spray, etc.)
            9) Topical, contained (Patch)
        ii. Dispensed Dosage Form
            1) Oral Solid
            2) Oral Liquid
            3) Oral Powder (Sprinkles, PEG, Dissolve)
            4) Oral Syringe/Dropper (PO or Neb)
            5) Inhaler
            6) Parenteral Vial, Ampule, Syringe
            7) IV Solution
            8) Rectal/Vaginal Suppository/Insert
            9) Topical Applied
            10) Topical Contained

3. **Hazard**: Check the NIOSH Group that the HD falls into, based on the current NIOSH list.
    a. Group 1: Antineoplastic; **MANIPULATION MUST COMPLY WITH ALL PUBLISHED STANDARDS**; Drugs only requiring counting or repackaging (unless required by the manufacturer) are eligible for AoR.
    b. Group 2: Non-anti-neoplastic; Review and complete Assessment of Risk
    c. Group 3: Reproductive Risk Only; Review and complete Assessment of Risk

4. **Packaging System**: Check the type of packaging system that will be used with the HD.
    1) Ampule
    2) Bulk bottle
    3) Inhaler
    4) IV bag (including piggybacks)
    5) Syringe
    6) Tube
    7) Unit dose
    8) Vial
    9) Other (write-in other packaging type)

5. **Manipulation**: Check the type of manipulation that will take place with the HD. If the manipulation is not listed, check Other and write in in the type of manipulation.

Potential Contact	Compounding/Packaging Activity	Administration Activity
Product Contact (gloves)	• Unit dose or Multidose Packaging	• Oral without Manipulation • Suppository/Insert, Vaginal or Rectal
Dust Potential (gloves, mask)	• Crushing, Grinding, Dispersing	• Dispersed Oral (Crushed)
Spill Potential (gloves, gown)	• Fluid Mixing, Dissolving, Dilution	• Pressured Oral (Syringe, Neb) • Site Injection (IM, IV to port, SQ)
Aerosol Potential (gloves, gown, face shield)	• Aspiration, Injection	• Line injection (PB, Primary line) • Topical/patch application

6. **Area of Exposure**: Check the area of the body that is at risk of exposure with manipulation of the HD. If the exposure area is not listed, check other and write in the exposure area.

7. **Risk of Exposure**: Check expected risk that exposure could occur with the type and frequency of manipulation of the HD.
    a. Negligible – for example: manipulation is less than monthly (rare) or less than 2 doses
    b. Moderate – for example: manipulation is monthly and less than 30 doses
    c. Elevated – for example: manipulation is weekly to monthly or more than 30 doses
    d. Significant – for example: manipulation is daily to weekly or more than 100 doses

8. **Rationale for NOT Requiring All USP <800> Containment Strategies**: Fill-in the reason that a modified PPE or other containment strategy is appropriate for the HD in your setting.

9. **Alternative Containment Strategies and/or Work Practices Employed to Minimize Exposure**: Check the specific PPE that will be required for manipulation of the HD. Fill-in any other practices employed (such as crushing devices or other work procedures) that will be used to minimize exposure.

Resources for more information on USP <800> Compliance and performing an Assessment of Risk:

- United States Pharmacopeia: https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare
- Wolters Kluwer: https://info.pharmacyonesource.com/hazardous-drug-compounding-tips-and-best-practices
- CPNP: https://cpnp.org/medication/usp800

Hazardous Drug Risk Acknowledgement

Employee Name: _____

I understand that working with and/or near hazardous drugs in a health care setting may cause or contribute to health concerns and/or illnesses such as: skin rashes, infertility, miscarriage, birth defects, and possibly leukemia or other cancers.

I understand that the facility maintains detailed policies and procedures on the proper storage, handling, transport and disposal of hazardous drugs.

The facility has put in place a variety of administrative, engineering and work practice controls to reduce the risk of occupational exposure to hazardous drugs. I understand facility's policies and procedures will be reviewed and amended if needed on an annual basis and the policies and procedures seek to reflect information, standards and regulations from relevant local, state and federal regulatory bodies as well as practice standards from professional associations.

I have been provided with didactic training that reflects the policies and procedures on hazardous drugs and have been afforded the opportunity to ask questions. After completion of the training that is relevant to my job duties, I may have been required to take and successfully pass written testing and may have also had my hazardous drug handling techniques observed and documented on the Hazardous Drug Competency.

Retraining and competency evaluation will occur annually if pertinent to my job duties. I received and successfully completed this training prior to performing any activity associated with hazardous drugs. I understand facility's policies and procedures and agree to abide by them at all times. I also agree that I will immediately seek out the facility director or my direct supervisor should a question occur during work activities.

I acknowledge that failure to follow the established policies and procedures may put me at risk of exposure to hazardous substances which can lead to acute effects such as skin rashes; chronic effects, including adverse reproductive events such as infertility, miscarriage, or birth defects; and possibly the development of cancer.

Employee Signature: _____ ***Date:*** _____

Pharmacy Forms Samples

10.0 PHARMACY FORMS SAMPLES

Table of Contents

10.1 ADVERSE DRUG REACTION (ADR) FORM

Suspected Adverse Drug Reaction definition:
An adverse drug reaction is any response to a drug, which is noxious and unintended and occurs at doses used in man for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological functions. (World Health Organization)

Often ADRs are thought of as a secondary effect of a drug that is usually undesirable and different from the therapeutic and helpful effects of the drug or suspected allergic reaction in a resident with no documented history of allergy to that medication.

Categories of ADRs include side effects, hypersensitivity, idiosyncratic responses, toxic reactions and adverse drug interactions.

Reporting procedure:

- Complete this form when an adverse drug reaction is suspected
- Forward a completed form to the prescribing and primary care physicians
- Fax a completed form to the pharmacy and care center
- Update resident's record as appropriate

Type of Reaction: (circle appropriate letter A-G)

Mild	**A -** Reaction occurred but required no change in treatment with suspected drug
	B - Suspected drug was held, discontinued or changed but no antidote or additional treatment was needed
Moderate	**C** - Suspected drug was held, discontinued or changed AND minimal pharmacologic intervention (such as antipruritics) was needed
	D - Suspected drug was held, discontinued, or changed AND/OR an antidote or significant pharmacologic intervention (steroids, epinephrine) was required to reverse the reaction
Severe	**E** - Reaction required hospitalization and significant pharmacologic intervention with no permanent organ toxicity or impairment
	F - Reaction was potentially life threatening and caused permanent harm or disability
Death	**G** - Reaction caused death

Resident Name:_____ **Date of Event:** _____

Nursing Care Center Name & Room Number: _____

Suspected Medication (Drug): _____

(page 2 of form)

Resident Name: _____

Clinical signs and symptoms of reaction: (check appropriately)

❑ headache	❑ rash	❑ hypotension	❑ nausea
❑ agitation	❑ hives	❑ hypertension	❑ vomiting
❑ confusion	❑ flushing	❑ tachycardia	❑ diarrhea
❑ uneasiness	❑ pruritis	❑ bradycardia	❑ cramps
❑ EPS	❑ SOB	❑ angina	❑ dizziness
❑ hallucinations	❑ bronchospasm	❑ syncope	❑ seizures
❑ respiratory depression		❑ other: _____	

Physician notified: _____

Orders Received: _____

Outcome: (mark appropriately)

- ❑ Drug discontinued
- ❑ Drug dose modified
- ❑ Treatment needed to reverse reaction
- ❑ Long term care stay prolonged
- ❑ Cognitive impairment or deterioration
- ❑ Hospitalization required
- ❑ Disability resulted
- ❑ Life threatening
- ❑ Death
- ❑ Allergy added to profile
- ❑ Other: _____

Resident's Current Status: _____

Person completing form: _____

Date: _____

ANTIPSYCHOTIC MEDICATION REVIEW

One medication per form

Diagnosis: | **REVIEW DATES ▶**

Medication: | **TOTAL DAILY DOSE ▶**

A. An appropriate diagnosis or target behavioral symptom(s) [see 42 CFR 483.45(d-e)] is documented to support the use of the Antipsychotic Medication listed above and appears in the resident's Physician Order Sheet and care plan. ☐ No ☐ Yes

The Antipsychotic Medication listed above is not used if the only indication is one or more of the following: 1) wandering; 2) poor self-care; 3) restlessness; 4) impaired memory; 5) mild anxiety; 6) insomnia; 7) unsociability; 8) inattention or indifference to surroundings; 9) fidgeting; 10) nervousness; 11) uncooperativeness; or 12) verbal expressions or behavior that do not represent a danger to the resident or others [see 42 CFR 483.45(d-e)] ☐ No ☐ Yes

B. If the diagnosis is "Dementing Illnesses with Associated Behavioral Symptoms" complete the target behavior symptom(s) to the right and indicate the number of episodes per month. **# Episodes Per Month**

- Behavior 1:
- Behavior 2:
- Behavior 3:

C. Do these "Target Behavioral Symptoms" cause the resident to present a danger to themselves or to others (including staff) or interfere with staff's ability to give care? ☐ No ☐ Yes

OR

D. Do psychotic symptoms (Hallucinations, Paranoia, Delusions) not exhibited as "Target Behavioral Symptoms" listed above cause impairment in functional capacity? ☐ No ☐ Yes

If so briefly explain here and in care plan _____

E. Note the presence of the following adverse effects (if any) experienced by documenting the number of days out of the month in which they occurred. **# of Days per Month Occurred**

See [42 CFR 483.45(d-e)] for additional information.

Movement Adverse Effects

- Increase in Disorientation or Confusion
- Lethargy
- Other: (Explain)
- Muscle Spasm of Neck, Back, Face (Dystonic Reaction)
- Motor Restlessness (Akathisia)
- Parkinson's-Like Tremors (Hands, Arms, Head)
- Movements of Mouth, Tongue, Jaw (Tardive Dyskinesia)
- Other: (Explain)
- Other: (Explain)

Movement Adverse Effects are specifically evaluated using the Abnormal Involuntary Movement Scale (AIMS) on the back of this form.

F. If the antipsychotic medication is used to manage behaviors, stabilize mood or treat a psychiatric disorder, has a tapering/GDR been attempted? ☐ No ☐ Yes

Note: The regulation addressing use of antipsychotic medications identifies the process of tapering as a "Gradual Dose Reduction (GDR)" and requires a GDR unless clinically contraindicated. Within the first year in which a resident is admitted on an antipsychotic medication or after the facility has initiated an antipsychotic medication, the facility must attempt a GDR in separate quarters (with at least one month between the attempts), unless clinically contraindicated. After the first year, a GDR must be attempted annually, unless clinically contraindicated.

Date: ____ Date: ____ Date: ____ Date: ____

If Yes, indicate dates to right.

Date: ____ Date: ____ Date: ____ Date: ____

If a clinical contraindication to GDR/tapering (see 42 CFR 483.45(e) for more detail) has been properly and fully documented on the Physician Order sheet and care plan, specify the reason below.

_____

_____

G. Resident behavior shows/appears:

- ☐ No change
- ☐ Improvement
- ☐ Controlled

1 Signature/Title	Date	3 Signature/Title	Date
2 Signature/Title	Date	4 Signature/Title	Date

Resident Name | Clinical Record # | Room # | Physician

Form # MP5562 (Rev. 12/16) Reorder From: MED-PASS® The First Art of Document Design 800-438-8884 AI-110816

MOVEMENT CODES:

0 = None **1** = Minimal/Normal	**2** = Mild **3** = Moderate	**4** = Severe

ABNORMAL INVOLUNTARY MOVEMENT SCALE (AIMS)
EXAMINATION PROCEDURE

INSTRUCTIONS: This exam is used for assessing side effects of antipsychotic drugs only; it should not be used for antianxiety, antidepressant or sedative drugs. Complete examination procedure before making rating. While conducting the examination, have resident sit in a firm chair without arms. For all MOVEMENT ratings (sections A, B and C) rate highest severity observed. Write in one code for each evaluation.

	Codes	ASSESSMENT DATES 1	2	3	4
SECTION A. Facial And Oral Movements					
1. **Muscles of Facial Expression** (movements of forehead, eyebrows, periorbital area, cheeks; incl. frowning, blinking, smiling, grimacing)	0 1 2 3 4				
2. **Lips and Perioral Area** (e.g. puckering, pouting, smacking)					
3. **Jaw** (e,g. biting, clenching, chewing, mouth opening, lateral movement)					
4. **Tongue** - Rate only increase in movement both in and out of mouth, NOT inability to sustain movement					
SECTION B. Extremity Movements					
5. **Upper (arms, wrists, hands, fingers)** include choreic movements, (i.e. rapid, objectively purposeless, irregular, spontaneous), athetoid movements, (i.e., slow, irregular, complex, serpentine). Do NOT include tremor, (i.e., repetitive, regular, rhythmic)	0 1 2 3 4				
6. **Lower (legs, knees, ankles, toes)** e.g., lateral knee movement, foot tapping, heel dropping, foot squirming, inversion and eversion of foot.					
SECTION C. Trunk Movements					
7. **Neck, shoulders, hips** - e.g., rocking, twisting, squirming, pelvic gyrations	0 1 2 3				
SECTION D. Global Judgments					
8. **Severity of abnormal movements**	0 1 2 3 4				
9. **Incapacitation due to abnormal movements**					
10. **Resident's awareness of abnormal movements** Rate only resident's reported perception.	0 = No awareness 1 = Aware, no distress 2 = Aware, mild distress 3 = Aware, moderate distress 4 = Aware, severe distress				
SECTION E. Dental Status					
11. **Current problems with teeth and/or dentures**	**N** = No **Y** = Yes				
12. **Does resident usually wear dentures**	**N** = No **Y** = Yes				

INSTRUCTIONS FOR CONDUCTING THE RESIDENT EXAMINATION:
Complete examination procedures before making actual movement ratings. The chair to be used in this examination should be firm and without arms.

SECTION A. Facial And Oral Movements
- Ask resident to open mouth. (Observe tongue at rest within mouth.) Do this twice.
- Ask resident to protrude tongue. (Observe abnormalities of tongue movement.)

SECTION B. Extremity Movements
- Flex and extend resident's left and right arm (one at a time.) (Note any rigidity and rate on NOTES below.)
- Ask resident to extend both arms outstretched in front with palms down. (Observe trunk, legs, and mouth.)
- Have resident walk a few paces, turn, and walk back to chair. (Observe hands and gait.) Do this twice.
- Ask resident to tap thumb, with each finger, as rapidly as possible for 10-15 seconds; separately with right hand, then with left hand. (Observe facial and leg movements.)

SECTION C. Trunk Movements
- Ask resident to stand up. (Observe in profile. Observe all body areas again, hips included.)
- Have resident sit in chair with hands on knees, legs slightly apart, and feet flat on floor. (Look at entire body for movements while in this position.)
- Ask resident to sit with hands hanging unsupported. If male, between legs, if female and wearing a dress, hanging over knees. (Observe hands and other body areas.)
- Ask resident whether he/she notices any movements in mouth, face, hands, or feet. If yes, ask to describe and to what extent they *currently* bother resident or interfere with his/her activities.

SECTION E. Dental Status
- Ask resident whether there is anything in his/her mouth (i.e. gum, candy, etc.) and if there is, to remove it.
- Ask resident about the *current* condition of his/her teeth. Ask resident if he/she wears dentures. Do teeth or dentures bother resident now?

INTERPRETATION OF THE AIMS SCORE
- No single score exceeding 1 (in items 1 to 10), resident **may be at low risk for movement disorders.**
- A score of 2 in only one of the 7 body areas (items 1 to 7), resident **may be borderline and should be observed more closely.**
- A score of 2 in 2 or more of the 7 body areas (items 1 to 7), resident **should be referred for a complete neurological exam.**
- A score of 3 or 4 in only one of the 7 body areas (items 1 to 7), resident **should be referred for a complete neurological exam.**

1	Signature/Title	Date	3	Signature/Title	Date
2	Signature/Title	Date	4	Signature/Title	Date

Resident Name	Clinical Record #	Room #	Physician

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DYSKINESIA IDENTIFICATION SYSTEM - CONDENSED USER SCALE (DISCUS)

Previous DISCUS Score/Date (if any)

EXAM TYPE CODES: 1. Baseline 2. Annual 3. Semi-Annual 4. D/C - 1 Month 5. D/C - 2 Month 6. D/C - 3 Month 7. Admission 8. Other

COOPERATION CODES: 1. None 2. Partial 3. Full

DISCUS SCORING
0 - NOT PRESENT (movements not observed or some movements observed but not considered abnormal)
1 - MINIMAL (abnormal movements are difficult to detect or movements are easy to detect but occur only once or twice in a short non-repetitive manner)
2 - MILD (abnormal movements occur infrequently and are easy to detect)
3 - MODERATE (abnormal movements occur frequently and are easy to detect)
4 - SEVERE (abnormal movements occur almost continuously and are easy to detect)
NA - NOT ASSESSED (an assessment for an item is not able to be made)

Current Psychotropics/ Anticholinergic and Total MG/Day

mg
mg
mg
mg

ASSESSMENT (Score each DISCUS item using scoring above)

		EXAM DATES	1	2	3	4
		EXAM TYPE CODES:				
		COOPERATION CODES:				
FACE	1.	Tics				
	2.	Grimaces				
EYES	3.	Blinking				
ORAL	4.	Chewing/Lip Smacking				
	5.	Puckering/Sucking/ Thrusting Lower Lip				
LINGUAL	6.	Tongue Thrusting/ Tongue in Cheek				
	7.	Tonic Tongue				
	8.	Tongue Tremor				
	9.	Athetoid/Myokymic/ Lateral Tongue				
HEAD/ NECK/ TRUNK	10.	Retrocollis/Torticollis				
	11.	Shoulder/Hip Torsion				
UPPER LIMB	12.	Athetoid/Myokymic Finger-Wrist-Arm				
	13.	Pill Rolling				
LOWER LIMB	14.	Ankle Flexion/ Foot Tapping				
	15.	Toe Movement				
		TOTAL SCORE (Items 1 - 15 only)	1	2	3	4

Comments:

EVALUATION (See reverse side for more information)

	EXAM DATES	1	2	3	4
1.	Greater than 90 days neuroleptic exposure?	Y N	Y N	Y N	Y N
2.	Scoring/intensity level met?	Y N	Y N	Y N	Y N
3.	Other diagnostic conditions? (If yes, specify below)	Y N	Y N	Y N	Y N
	1				
	2				
	3				
	4				
4.	Last Exam Date				
	Last Total Score				
	Last Conclusion				

Preparer Signature and Title for Items 1 - 4 (if different from physician):

1 2
3 4

5. Conclusion (check one per Exam Date)

A. No TD (if scoring prerequisite met, list other diagnostic conditions or explain in comments				
B. Probable TD				
C. Masked TD				
D. Withdrawal TD				
E. Persistent TD				
F. Remitted TD				
G. Other (specify in Comments)				

6. Comments:

	Rater Signature and Title	Next Exam Date	Physician's Signature	Date
1				
2				
3				
4				

Resident Name | I.D. # | Room # | Physician

Sprague, R.L. & Kalachnik, J.E. (1991). Reliability, validity, and a total score cutoff for the Dyskinesia Identification System: Condensed User Scale (DISCUS) with mentally ill and mentally retarded populations. *Psychopharmacology Bulletin, 27* (1). 51-58.

Simplified Diagnoses for Tardive Dyskinesia (SD-TD)

PREREQUISITES

The 3 prerequisites are as follows. Exceptions may occur.

1. A history of at least three months' total cumulative neuroleptic exposure. Include amoxapine and metoclopramide in all categories below as well.
2. **SCORING / INTENSITY LEVEL.** The presence of a **TOTAL SCORE OF FIVE (5) OR ABOVE.** Also be alert for any change from baseline or scores below five which have at least a "moderate" (3) or "severe" (4) movement on any item or at least two "mild" (2) movements on two items located in different body areas.
3. Other conditions are not responsible for the abnormal involuntary movements.

DIAGNOSES

The diagnosis is based upon the current exam and its relation to the last exam. The diagnosis can shift depending upon: (a) whether movements are present or not, (b) whether movements are present for 3 months or more (6 months if on a semi-annual assessment schedule), and (c) whether neuroleptic dosage changes occur and effect movements.

- **NO TD.** - Movements **are not** present on this exam **or** movements are present, but some other condition is responsible for them. The last diagnosis must be NO TD, PROBABLE TD, or WITHDRAWAL TD.
- **PROBABLE TD.** - Movements **are** present on this exam. This is the first time they are present **or** they have never been present for 3 months or more. The last diagnosis must be NO TD or PROBABLE TD.
- **PERSISTENT TD.** - Movements **are** present on this exam **and** they have been present for 3 months or more with this exam or at some point in the past. The last diagnosis can be any except NO TD.
- **MASKED TD.** - Movements **are not** present on this exam **but** this is due to a neuroleptic dosage increase or reinstitution after a prior exam when movements were present. Also use this conclusion if movements are not present due to the addition of a non-neuroleptic medication to treat TD. The last diagnosis must be PROBABLE TD, PERSISTENT TD, WITHDRAWAL TD, or MASKED TD.
- **REMITTED TD** - Movements **are not** present on this exam **but** PERSISTENT TD has been diagnosed **and** no neuroleptic dosage increase or reinstitution has occurred. The last diagnosis must be PERSISTENT TD or REMITTED TD. If movements re-emerge, the diagnosis shifts back to PERSISTENT TD.
- **WITHDRAWAL TD.** - Movements **are not seen while** receiving neuroleptics or at the last dosage level **but are seen within** 8 weeks following a neuroleptic reduction or discontinuation. The last diagnosis must be NO TD or WITHDRAWAL TD. If movements continue for 3 months or more after the neuroleptic dosage reduction or discontinuation, the diagnosis shifts to PERSISTENT TD. If movements do not continue for 3 months or more after the reduction or discontinuation, the diagnosis shifts to NO TD.

INSTRUCTIONS

1. The rater completes the Assessment according to the standardized exam procedure. If the rater also completes Evaluation items 1-4, he/she must also sign the preparer box. The form is given to the physician. Alternatively, the physician may perform the assessment.
2. The physician completes the Evaluation section. The physician is responsible for the entire Evaluation section and its accuracy.
3. **It is recommended that the physician examine any individual who meets the 3 prerequisites or who has movements not explained by other factors. Neurological assessments or differential diagnostic tests which may be necessary should be obtained.**
4. File form according to policy or procedure.

OTHER CONDITIONS (partial list)

1. Age
2. Blind
3. Cerebral Palsy
4. Contact Lenses
5. Dentures / No Teeth
6. Down's Syndrome
7. Drug Intoxication (specify)
8. Encephalitis
9. Extrapyramidal Side-Effects (specify)
10. Fahr's Syndrome
11. Heavy Metal Intoxication (specify)
12. Huntington's Chorea
13. Hyperthyroidism
14. Hypoglycemia
15. Hypoparathyroidism
16. Idiopathic Torsion Dystonia
17. Meige Syndrome
18. Parkinson's Disease
19. Stereotypies
20. Syndenham's Chorea
21. Tourette's Syndrome
22. Wilson's Disease
23. Other (specify)

Informed Consent

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Facility Information	
Facility Name:	Facility Address:

Resident Information			
Resident Name:	DOB: DD/MM/YYYY	Room #:	Bed:

Drug Information			
Name:	Dose:	Administration Route:	Frequency:
Anticipated Duration of Therapy:		Start Date: DD/MM/YYYY	Prescriber:
Purpose:			
Will this medication be titrated? ☐ Yes ☐ No		If yes, provide titration schedule:	
Expected Benefits:			
Potential Side Effects:		Boxed Warnings:	
Potential Risks of Withholding Medication:		Alternative Therapies:	

History of Present Illness (Purpose of Medication)	
Diagnosis (ICD-10 if available):	Diagnosis Date:
Target symptoms or behavioral/safety concerns:	
Prior Medications Trialed for This Purpose:	Will any of these medications be continued? ☐ Yes ☐ No If yes, indicate which medications:
Nonpharmacologic Interventions Trialed or to Continue:	

Staff Attestation
By providing my initials below, I verify that the resident and/or legal representative has been informed of the reason for treatment, intended benefits and potential risks, and has had the opportunity to voice concerns and ask questions regarding the selected therapy. All questions regarding treatment have been answered based on available drug information resources and appropriate educational materials have been provided to the resident and/or legal representative. _____ Staff Initials

Consent (to be completed by resident/legal representative)			
☐ I CONSENT to the use of the medication as described above. ☐ I DECLINE and DO NOT CONSENT to the use of the medication as described above.			
Resident or Legal Representative Name:	Signature: (type name)	Relationship to Resident:	Date: DD/MM/YYYY
Staff Name	Signature: (type name)	Title:	Date: DD/MM/YYYY

This sample form provides a general template for documenting informed consent to receiving a medication. It is the responsibility of facility leadership to ensure compliance with all applicable requirements regarding informed consent for the practice site, including documentation specifications. Facility leadership also retain responsibility for appropriately training staff to understand informed consent regulations, including the resident's right to withdraw consent at any time.

Informed Consent

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Staff Attestation
By providing my initials below, I verify that the resident and/or legal representative has been informed of the reason for treatment, intended benefits and potential risks, and has had the opportunity to voice concerns and ask questions regarding the selected therapy. All questions regarding treatment have been answered based on available drug information resources and appropriate educational materials have been provided to the resident and/or legal representative. __________ Staff Initials

Consent (to be completed by resident/legal representative)			
☐ I CONSENT to the use of the medication as described above. ☐ I DECLINE and DO NOT CONSENT to the use of the medication as described above.			
Resident or Legal Representative Name:	Signature:	Relationship to Resident:	Date:
Staff Name	Signature:	Title:	Date:

Staff Attestation
By providing my initials below, I verify that the resident and/or legal representative has been informed of the reason for treatment, intended benefits and potential risks, and has had the opportunity to voice concerns and ask questions regarding the selected therapy. All questions regarding treatment have been answered based on available drug information resources and appropriate educational materials have been provided to the resident and/or legal representative. __________ Staff Initials

Consent (to be completed by resident/legal representative)			
☐ I CONSENT to the use of the medication as described above. ☐ I DECLINE and DO NOT CONSENT to the use of the medication as described above.			
Resident or Legal Representative Name:	Signature:	Relationship to Resident:	Date:
Staff Name	Signature:	Title:	Date:

Staff Attestation
By providing my initials below, I verify that the resident and/or legal representative has been informed of the reason for treatment, intended benefits and potential risks, and has had the opportunity to voice concerns and ask questions regarding the selected therapy. All questions regarding treatment have been answered based on available drug information resources and appropriate educational materials have been provided to the resident and/or legal representative. __________ Staff Initials

Consent (to be completed by resident/legal representative)			
☐ I CONSENT to the use of the medication as described above. ☐ I DECLINE and DO NOT CONSENT to the use of the medication as described above.			
Resident or Legal Representative Name:	Signature:	Relationship to Resident:	Date:
Staff Name	Signature:	Title:	Date:

This sample form provides a general template for documenting informed consent to receiving a medication. It is the responsibility of facility leadership to ensure compliance with all applicable requirements regarding informed consent for the practice site, including documentation specifications. Facility leadership also retain responsibility for appropriately training staff to understand informed consent regulations, including the resident's right to withdraw consent at any time.

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Informed Consent Annex A: Supplemental Information for Psychotropic Medications

Overview

This resource is designed to assist healthcare professionals with completing **Informed Consent** documentation related to **psychotropic medications**.

Per CMS State Operations Manual requirements at §483.10(c), residents (or their legal representative if the resident lacks health care decision-making capacity) have the right to be informed of and participate in their treatment:

> "Prior to initiating or increasing a psychotropic medication, the resident, family, and/or resident representative must be informed of the benefits, risks, and alternatives for the medication, including any black box warnings for antipsychotic medications."

To demonstrate compliance, the resident's medical record must include documentation that the resident or legal representative was informed in advance of the risks and benefits of the proposed care, the treatment alternatives or other options, and was able to choose the option they preferred. Documentation should also detail use of any interpretative aids (e.g., translation services and audiovisual aids) that were made available and utilized by the resident or representative to assist in making their decision.

In the event that a resident or representative withdraws informed consent, the prescribing physician shall be notified and a new consent form recognizing the declination to receive treatment should be completed and documented in the resident's medical record. For medications requiring gradual taper for discontinuation, prescribers shall inform the resident or representative of the proposed taper schedule and any concerns that may impact rate of discontinuation.

Note: a written consent form may serve as evidence of a resident's consent to psychotropic medication, but other types of documentation are also acceptable.

Healthcare professionals involved in the resident's treatment plan may choose from options below that accurately reflect the resident's condition and target medication use, recognizing that this list is not exhaustive and is intended as a reference guide only.

**For emergency situations requiring immediate administration of a medication without time to obtain informed consent, facilities shall refer to their respective state regulations and guidance outlined within the facility's policy and procedure manual. When the risk of immediate harm has surpassed, facility staff should discuss with the resident or representative the reasoning for their treatment decision and any potential adverse consequences associated with the medication(s) administered.*

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1. **Purpose (Indication):** Identifies the resident's diagnosis for which a psychotropic medication is proposed to be initiated or increased according to accepted professional standards. Diagnoses alone do not necessarily warrant the use of a psychotropic medication; therefore, medication purpose should be clearly supported in the resident's medical record through provider progress notes, nursing notes, etc.

Neurological Conditions	Psychiatric/Mood Disorders
• Alzheimer's Dementia • Cerebral Palsy • Cerebral Vascular Accident (CVA), Transient Ischemic Attack (TIA), or Stroke • Huntington's Disease • Non-Alzheimer's Dementia • Parkinson's Disease Psychosis • Seizure Disorder • Tourette's Syndrome • Traumatic Brain Injury	• Bipolar Disorder • Borderline Personality Disorder • Depression • Generalized Anxiety Disorder • Major Depressive Disorder (MDD) • Obsessive Compulsive Disorder (OCD) • Post Traumatic Stress Disorder (PTSD) • Psychotic Disorder • Schizophrenia, Schizophreniform, or Schizoaffective Disorder • Severe Agitation / Delirium • Sleep/Wake Disorder (e.g., Insomnia)

2. **Target Symptoms or Behaviors:** Details the resident's current condition and behaviors that are being targeted with initiation of or increase in the selected medication.

Emotional		Physical		Other	
• Anhedonia • Emotional Outbursts • Fear/Panic • Guilt • Hopelessness	• Irritability • Loss of Interest • Mood Swings • Nervousness • Sadness • Worthlessness	• Aggression • Akathisia • Biting • Crying • Destroying Property • Fatigue • Fidgeting/ Restlessness • Hitting	• Kicking • Pacing • Pushing/ Shoving • Scratching • Spitting • Throwing Objects	• Appetite Changes • Cursing • Difficulty Concentrating • Disorganized Speech • Hallucinations • Delusions	• Inappropriate Advances • Memory Issues • Sleep Disturbances • Social Withdrawal • Threatening • Yelling

It may be appropriate to include supporting details when describing target behaviors/symptoms:
- Acute worsening, rapid onset or exacerbation of symptoms
- Chronic, persistent symptoms that impact quality of life or cause significant stress
- Minimal to no improvement in symptoms with non-pharmacologic interventions
- Behaviors pose immediate threat or danger to themselves and others

3. **Expected Benefits:** Explains how the prescribed medication is intended to have a positive impact on the resident's condition. Expected benefits should align with target symptoms and behaviors.

Expected Benefits	
• Improve Appetite • Improve Concentration • Improve Functionality • Improve Quality of Life • Improve Quality of Sleep • Improve Safety to Themselves and Others • Short-Term Improvement in Agitation and Behavioral Disturbances	• Stabilize Mood • Reduce and Prevent Symptoms of Psychosis • Reduce Anxiety • Reduce Incidence of Hallucinations and/or Delusions • Reduce Reliance on PRN Medications • Reduce Target Symptoms and Behaviors: _____

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4. **Potential Side Effects:** Discussions with the resident or legal representative should identify potential common and most relevant rare side effects that may happen with initiation of/increase in the psychotropic medication. Example side effects below are common enough to warrant close monitoring by facility staff and can range in severity. Note that not all side effects can be predicted, and residents should report any deleterious effects experienced after initiation of/increase in the medication.

A. Antidepressants

Common Side Effects	Other Side Effects
• Agitation • Dizziness • Drowsiness • Dry Mouth • Gastrointestinal Distress • Headaches • Hypertension *(SNRIs, MAOIs)* • Insomnia • Nausea • Orthostatic Hypotension • Sedation • Sexual Dysfunction • Weight Gain *(mirtazapine, imipramine)*	• Activation of Mania or Hypomania • Anaphylactic Reactions • Decreased Seizure Threshold *(bupropion)* • ECG Changes (e.g., QTc Prolongation) • Hyponatremia • Increased Risk of Bleeding • Seizures • Serotonin Syndrome • Withdrawal Syndrome

B. Antipsychotics

Common Side Effects	Other Side Effects
• Confusion or Disorientation • Constipation or Diarrhea • Dizziness • Dry Mouth • Extrapyramidal Symptoms (EPS)* • Headache • Hyperglycemia • Hypertriglyceridemia • Increased Appetite • Nausea • Orthostatic Hypotension • Somnolence or Sedation • Weight Gain	• Anaphylactic Reactions • Cerebrovascular Accidents (CVA) or Transient Ischemic Attacks (TIA) • ECG Changes • Hematologic Abnormalities *(clozapine)* • Hepatotoxicity • Hyperprolactinemia • Neuroleptic Malignant Syndrome (NMS) • Risk of Falls and/or Fractures • Seizures *(clozapine)* • Serotonin Syndrome • Tardive Dyskinesia (TD) • Temperature Dysregulation

**EPS includes various movement syndromes such as akathisia (inner restlessness), medication-induced Parkinsonism, and dystonia (muscle spasms).*

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C. Anxiolytics (Anti-Anxiety)	
Common Side Effects	**Other Side Effects**
• Ataxia • Confusion or Disorientation • Dizziness • Dry Mouth • Headache • Irritability or Restlessness • Memory Issues • Nausea • Somnolence or Sedation • Urinary Retention	• Anaphylactic Reactions • CNS Depression • Dependence • Depression or Suicidal Thinking *(BZDs)* • Paradoxical Reactions • Risk of Falls and/or Fractures • Respiratory Depression • Serotonin Syndrome • Visual Disturbances • Withdrawal Syndrome

D. Hypnotics	
Common Side Effects	**Other Side Effects**
• Abnormal Dreams • Balance and Coordination Issues • Confusion or Disorientation • Dizziness • Drowsiness • Dysgeusia (Metallic Taste) • Fatigue • Headache • Nausea • Somnolence or Sedation • Transient Incontinence	• Anaphylactic Reactions • CNS Depression • Complex Sleep Behaviors • Delirium • Dependence • Hallucinations or Delusions • Depression or Suicidal Thinking *(BZDs)* • Rebound Insomnia • Respiratory Depression • Risk of Falls and/or Fractures • Thinking or Behavioral Changes *(Z-Drugs)* • Withdrawal Syndrome

5. **Boxed Warnings:** Formerly known as "Black Box Warnings," these prominently featured clauses are the highest safety-related warnings the FDA issues, intended to bring attention to significant adverse effects or special problems a medication might produce, with the potential to cause significant harm or disability.

Antidepressants

• **Suicidal Thoughts and Behaviors:** Antidepressants increase the risk of suicidal thinking and behaviors in pediatric and young adult patients.
 	
Additional Drug-Specific Warnings:
• Hepatotoxicity (Nefazodone)
  • Treatment with nefazodone hydrochloride tablets should not be initiated in individuals with active liver disease or with elevated baseline serum transaminases.
  • Patients should be advised to be alert for signs and symptoms of liver dysfunction and nefazodone should be discontinued if clinical signs or symptoms suggest liver failure.

Antipsychotics

• **Increased Mortality in Elderly Patients with Dementia-Related Psychosis:** Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death.
  • Analyses of 17 placebo-controlled trials in patients taking atypical antipsychotics revealed that risk of death in drug-treated patients was 1.6 to 1.7 times higher than those in placebo-treated patients.
  • Cause of death varies, but appears to be predominantly either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature.

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Antipsychotics, Cont.

Additional Drug-Specific Warnings:

- Suicidal Thoughts and Behaviors (Aripiprazole, Brexpiprazole, Cariprazine, Lumateperone, Lurasidone, Olanzapine/Fluoxetine, Quetiapine)
  - *See warnings listed under the Antidepressants section above.*
- Severe Neutropenia (Clozapine)
  - Clozapine can cause severe neutropenia, which can lead to serious and fatal infections.
  - Patients must have a baseline blood absolute neutrophil count (ANC) measured before treatment initiation and periodically during treatment.
- Orthostatic Hypotension, Bradycardia and Syncope (Clozapine)
  - Episodes of orthostatic hypotension, bradycardia, syncope, and cardiac arrest have occurred with rapid dose escalations of clozapine but can occur with initial treatment.
  - Use with caution in individuals with cardiovascular disease or conditions predisposing their risk of hypotension. Titrate doses slowly and use divided dosages to minimize risk.
- Seizures (Clozapine)
  - Seizures have occurred with clozapine treatment and appear to be dose-related.
  - Use with cation in individuals with history of seizures or other predisposing risk factors for seizures. Titrate doses slowly and use divided dosages to minimize risk.
- Myocarditis, Pericarditis and Cardiomyopathy (Clozapine)
  - Fatal myocarditis and cardiomyopathy have occurred with treatment.
  - Discontinue clozapine and obtain a cardiac evaluation upon symptoms of chest pain, tachycardia, palpitations, dyspnea, fever, flu-like symptoms, and hypotension.
- QTc Prolongation (Droperidol, Thioridazine)
  - Cases of QT prolongation and/or torsade de pointes have been reported in patients receiving droperidol at or below recommended doses.
    - All patients should undergo a 12-lead ECG prior to initiation.
    - Droperidol is contraindicated in patients with known or suspected QT prolongation, including patients with congenital long QT syndrome.
  - Thioridazine has been shown to prolong the QTc interval in a dose-related manner.
    - Reserve use for treatment of schizophrenia in patients who do not adequately respond or are unable to tolerate other antipsychotics.
- Bronchospasm (Loxapine)
  - Loxapine inhalation (Adasuve Inhalation) can cause bronchospasm that has the potential to lead to respiratory distress and respiratory arrest, particularly in patients with lung diseases.
  - Only administer in a certified healthcare setting with access to emergency rescue personnel and short-acting bronchodilators.
- Post-Injection Delirium and Sedation (Olanzapine)
  - Adverse reactions with signs and symptoms consistent with olanzapine overdose, in particular, sedation (including coma) and/or delirium, have been reported following injections of long-acting injectable olanzapine (Zyprexa Relprevv).
  - Long-acting injectable olanzapine must be administered in a registered health care facility with ready access to emergency response services and patients must be observed for at least 3 hours post-injection.
  - The long-acting injectable is only available through a restricted distribution program called ZYPREXA RELPREVV Patient Care Program and requires prescriber, healthcare facility, patient, and pharmacy enrollment.

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Anxiolytics

- Risks From Concomitant Use with Opioids (Benzodiazepines)
  - Concomitant use of BZDs and opioids may result in profound sedation, respiratory depression, coma, and death.
  - Reserve concomitant prescribing to patients for whom alternative treatment options are inadequate. Limit dosages and durations to the minimum required.
- Abuse, Misuse, and Addiction (Benzodiazepines)
  - Use of BZDs exposes users to risks of abuse, misuse, and addiction, which can lead to overdose or death.
  - Abuse and misuse of BZDs commonly involve concomitant use of other medications, alcohol, and/or illicit substances, which is associated with an increased frequency of serious adverse outcomes.
- Dependence and Withdrawal Reactions (Benzodiazepines)
  - Continued use of BZDs may lead to clinically significant dependence. Risk of dependence and withdrawal increase with longer treatment duration and higher daily dose.
  - Abrupt discontinuation or rapid dose reductions after continued use may precipitate acute withdrawal reactions, which can be life threatening. Use a gradual taper to discontinue or reduce dosages.

Additional Drug-Specific Warnings:

- Suicidal Thoughts and Behaviors (Bupropion)
  - *See warnings under the Antidepressants section above.*
- Individualization of Dosage (Midazolam)
  - Do not exceed intravenous doses of 2.5mg in healthy adults. Lower doses may be necessary in older adults and those receiving concomitant CNS depressants.
  - Titrate subsequent doses slowly and administer over at least 2 minutes. Allow an additional 2 minutes post administration to evaluate for sedative effects.

Hypnotics

- Complex Sleep Behaviors (Z-Drugs)
  - Complex sleep behaviors including sleepwalking, sleep-driving, and engaging in other activities while not fully awake may occur following the use.
- Risks From Concomitant Use with Opioids (BZDs)
  - *See warnings listed under the Anxiolytics section above.*
- Abuse, Misuse, and Addition (BZDs)
  - *See warnings listed under the Anxiolytics section above.*
- Dependence and Withdrawal Reactions (BZDs)
  - *See warnings listed under the Anxiolytics section above.*

Additional Drug-Specific Warnings:

- Suicidal Thoughts and Behaviors (Doxepin, Trazodone)
  - *See warnings listed under the Antidepressants section above.*

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6. **Risks of Withholding Treatment:** Details what adverse outcomes the resident may experience through abstaining from treatment or refraining from dose increases. To assist residents or representatives in making treatment decisions, facility staff should discuss how potential risks listed here compare to expected benefits.

Risks of Withholding Treatment

- Decline in Functional Ability
- Decreased Concentration
- Development or Worsening of Psychosis
- Frequent Mood Swings
- Increased Administration of PRN Medications
- Increased Incidence of Behavioral Disturbances
- Increased Incidence of Hallucinations or Delusions
- Increased Incidence of Manic Episodes
- Increased Incidence of Target Symptoms or Behaviors:_____
- Risk of Harm to Themself or Others
- Social Isolation or Withdrawal from Activities
- Symptoms Consistent with Drug Withdrawal
- Worsening of Agitation or Aggression
- Worsening of Anxiety
- Worsening of Depression or Suicidal Thinking
- Worsening of Insomnia

7. **Treatment Alternatives:** Pharmacologic or nonpharmacologic interventions may be listed as alternative treatment options but should be consistent with accepted standards of practice and clinical guidelines. Any alternative medications listed without an official FDA-approved indication aligned with the resident's diagnosis should be backed by sufficient clinical evidence supporting its use and potential adverse consequences with the alternative medication should be clearly communicated.

Example Treatment Alternatives

- Cognitive Behavioral Therapy
- OTC or Dietary Supplements
  - Ashwagandha
  - Magnesium Glycinate
  - Melatonin
  - St. John's Wort
- Nonpharmacologic Interventions
  - Art or Music Therapy
  - Essential Oils
  - Regular Physical Activity
  - Relaxation Techniques (e.g., Deep Breathing Exercises)
  - Sleep Hygiene
- Other Non-Psychotropic Medications
  - Propranolol or Hydroxyzine for Anxiety
  - Doxylamine for Insomnia
- Other Psychotropic Medication: _____
- PRN Medications: _____

EMERGENCY/CONTROLLED SUBSTANCE INVENTORY AND KIT VERIFICATION

Month________ Year________ Wing________

ACCOUNTABLE DRUGS ARE TO BE COUNTED AT EACH CHANGE OR SHIFT. THE LAST PERSON WHOSE NAME APPEARS ON THIS SHEET IS RESPONSIBLE FOR THE DRUGS.

DATE	SHIFT	NURSE'S SIGNATURE		EDK		IV		NARCOTIC		REFRIGERATOR		
		OFF DUTY	ON DUTY	YELLOW LOCK #	RED LOCK #	YELLOW LOCK#	RED LOCK #	YELLOW LOCK #	RED LOCK #	YELLOW LOCK #	RED LOCK #	R.P.H. NOTIFIED
	DAYS											
	AFTER-NOON											
	MID-NIGHTS											
	DAYS											
	AFTER-NOON											
	MID-NIGHTS											
	DAYS											
	AFTER-NOON											
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	DAYS											
	AFTER-NOON											
	MID-NIGHTS											
	DAYS											
	AFTER-NOON											
	MID-NIGHTS											

P7060ECS

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MED PASS OBSERVATION

INSTRUCTIONS:
To be completed by Nurse Consulting Services at intervals according to Facility Policy & Procedures or as needed for Quality Assessment purposes only.

Facility Name	Station	Time Started ☐ AM ☐ PM	Time Finished ☐ AM ☐ PM
Facility Staff Name(s)		Date	

	TECHNIQUES OBSERVED	Met	Not Met	N/A
1.	Med cart: no missing supplies; clean, always visible or locked.	☐	☐	☐
2.	Fluids and adjunctive foods are covered and dated.	☐	☐	☐
3.	Resident identified per policy.	☐	☐	☐
4.	Resident privacy maintained and positioned properly.	☐	☐	☐
5.	For meds with parameters, vital signs are taken prior to admin.	☐	☐	☐
6.	Correct medication verified by visual check of med, label, & MAR.	☐	☐	☐
7.	Items dated when opened (if applicable).	☐	☐	☐
8.	Liquid medication measured accurately, shaken, and/or diluted when appropriate.	☐	☐	☐
9.	Proper crushing technique; non-crushable meds have MD order. "Do not crush" information is available.	☐	☐	☐
10.	Administer adequate (i.e., 8 oz) fluids with medications when manufacturer so specifies (e.g., with administration of bulk laxatives, NSAIDs or solid/liquid potassium supplements).	☐	☐	☐
11.	Administer medications with food or antacids when so specified by manufacturer.	☐	☐	☐
12.	Residents observed to ensure medications are swallowed, excluding sublingual tablets.	☐	☐	☐
13.	Medication record is charted consistently/properly.	☐	☐	☐
14.	Medications are not left on top of cart or at resident's bedside.	☐	☐	☐
15.	Refused/withheld medications are properly noted.	☐	☐	☐
16.	PRN medications administered/documented appropriately.	☐	☐	☐
17.	Proper hand washing technique at appropriate times.	☐	☐	☐
18.	Properly administer ophthalmic products avoiding contact of the product with the eye. Wait 3-5 minutes between drops, 5-10 minutes between different medications, as indicated per manufacturer's recommendations.	☐	☐	☐
19.	Transdermal patches dated and initialed properly, rotated, and removed. Patch placement is documented.	☐	☐	☐
20.	Properly administer medication via **metered dose inhalers** (MDIs). Proper administration includes: (a) shaking MDI well; (b) positioning MDI 2 finger widths in front of resident's mouth (or using spacer); (c) having resident exhale first then take a slow, deep breath as MDI is activated; (d) holding breath for a count of 10 after inhalation before slowly exhaling, and; (e) waiting a minute between puffs if multiple puffs are ordered. (f) waiting five minutes between different medications assuring correct sequence (Bronchodilator - Anticholinergics - Miscellaneous - Corticosteroids). **Other inhalation devices** (HandiHalers, DISKUS, Aerolizer and other similar devices) administered per manufacturer's recommendations.	☐	☐	☐
21.	**Nebulizers:** Nurse observes resident during entire treatment (5-15 minutes) unless self administration assessment is completed.	☐	☐	☐
22.	Properly mix insulin suspensions (e.g., "rolling" and appropriate sequence of mixing is followed) without creating air bubbles.	☐	☐	☐
23.	Enteral tubes are flushed before and after all medications are administered with at least 15 mL of water. Enteral tubing is flushed with 5 to 15 mL of water between each medication administration.	☐	☐	☐
24.	Controlled drugs documented properly at time of administration.	☐	☐	☐
25.	Full signatures/initials are on administration sheets.	☐	☐	☐
26.	Administration book closed or covered to protect resident health information.	☐	☐	☐
27.	Other: Bare hands are not used to touch or handle meds	☐	☐	☐

Reviewer Notes

REVIEWER SUMMARY OF TECHNIQUE

CALCULATED ERROR RATE

ERROR TYPES/NO.: Incorrect Drug _____ Dose _____ Route _____ Dosage Form _____ Omission _____ Time _____

TOTAL NO. OF ERRORS (Significant + Non-Significant) x 100 = NaN % ERROR RATE

TOTAL NO. OF DOSES GIVEN (Doses Given + Doses Ordered But Not Given)

Observer's Signature/Title

Form # PMC-MPOR-P (Rev. 05/17)

Reorder From: MED-PASS 800-433-8884

XFM 041868R

F02

PharMerica
Value. Trust. Performance.

MEDICATION REORDER SHEET

NURSING FACILITY:	STATION:	DATE:	PAGE ____ OF ____

FIRST AND LAST NAME OF PERSON FAXING:	SIGNATURE OF PERSON FAXING:

INSTRUCTIONS: To re-order, peel bottom right portion of prescription label. If you are out of meds, in order to ensure med availability please check the box CHECK IF OUT OF MEDS and INITIAL which authorizes the pharmacy to dispense and bill the facility for a 7-day generic or 4-day brand prescription in the event a payor source is not available. Otherwise, the prescription will be refilled on the reorder date shown on the label. Please call your pharmacy if you need a medication immediately.

NEW ORDERS should be on a separate sheet

TO ENSURE TIMELY REFILLS, SUBMIT ORDER AFTER THE DATE LISTED ON LABEL.

REORDER LABEL **EXAMPLE:** [redacted] 1234567.01 CYCLE RESIDENT, FIRST AMOXICILLIAN 20 MG XXXXXX GENERIC: AMOXI 06/14/09 FACS HSTAT/ROM/B Order After 09/17/09	REORDER LABEL	REORDER LABEL
CHECK IF OUT OF MEDS ☐ INITIAL ☐	CHECK IF OUT OF MEDS ☐ INITIAL ☐	CHECK IF OUT OF MEDS ☐ INITIAL ☐
REORDER LABEL	REORDER LABEL	REORDER LABEL
CHECK IF OUT OF MEDS ☐ INITIAL ☐	CHECK IF OUT OF MEDS ☐ INITIAL ☐	CHECK IF OUT OF MEDS ☐ INITIAL ☐
REORDER LABEL	REORDER LABEL	REORDER LABEL
CHECK IF OUT OF MEDS ☐ INITIAL ☐	CHECK IF OUT OF MEDS ☐ INITIAL ☐	CHECK IF OUT OF MEDS ☐ INITIAL ☐
REORDER LABEL	REORDER LABEL	REORDER LABEL
CHECK IF OUT OF MEDS ☐ INITIAL ☐	CHECK IF OUT OF MEDS ☐ INITIAL ☐	CHECK IF OUT OF MEDS ☐ INITIAL ☐
REORDER LABEL	REORDER LABEL	REORDER LABEL
CHECK IF OUT OF MEDS ☐ INITIAL ☐	CHECK IF OUT OF MEDS ☐ INITIAL ☐	CHECK IF OUT OF MEDS ☐ INITIAL ☐

TO ENSURE TIMELY REFILLS, SUBMIT ORDER AFTER THE DATE LISTED ON LABEL.

F02

TO ENSURE TIMELY REFILLS, SUBMIT ORDER AFTER THE DATE LISTED ON LABEL.

PHMRS

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MED STATION REVIEW

Facility _____ Date _____

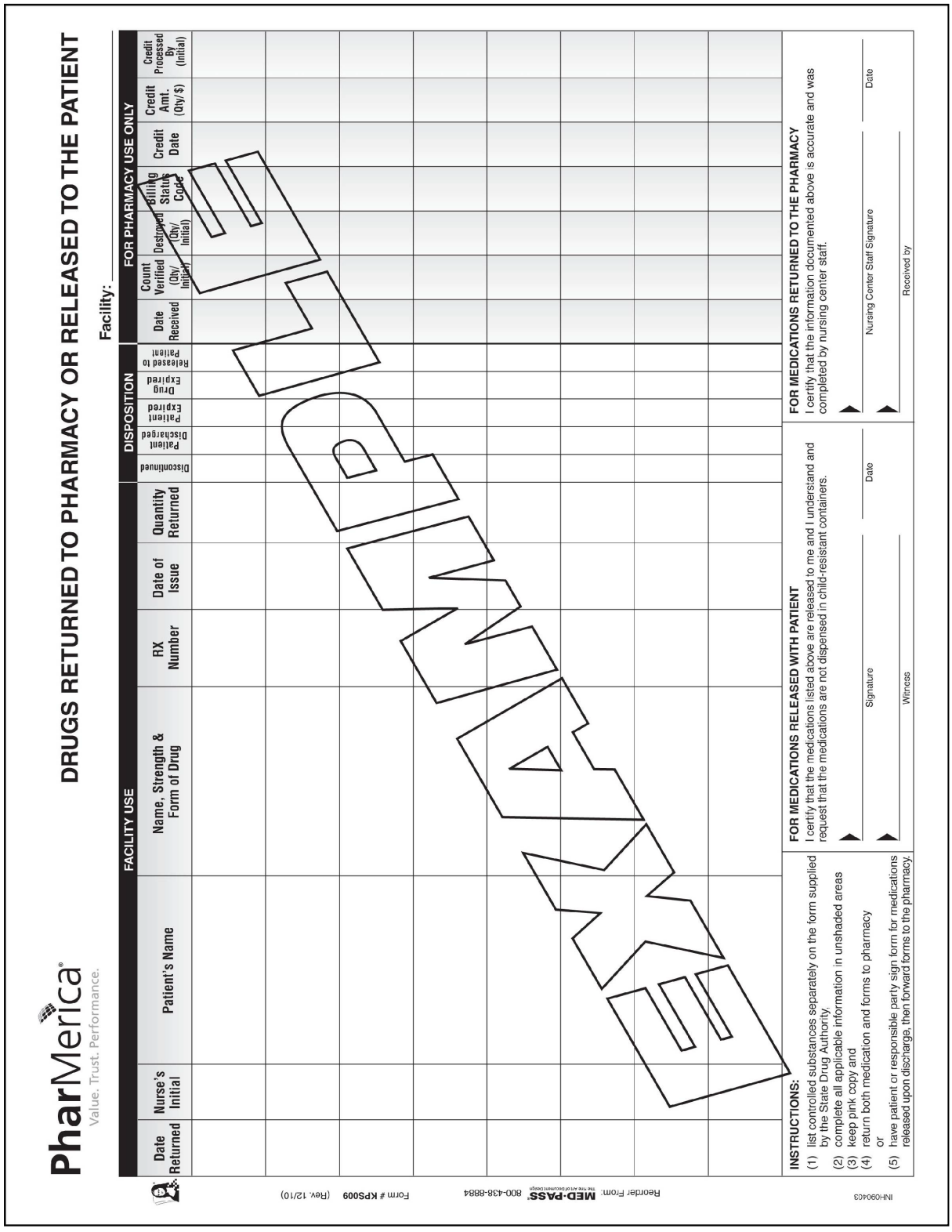
Station _____ Reviewer _____

Code	Criteria	Met	Not Met	N/A
	Controlled Drugs			
1	Count reconciled per required policy/regulation			
2	Controlled meds have count sheet per policy			
3	Correct disposition of discontinued/outdated meds			
4	Meds stored/locked as per regulation/policy			
	Order, Receipt and Disposition			
5	Order book/record conforms to regulations			
6	Ordering/Receiving medications procedure followed			
7	No outdated or deteriorated meds			
8	Discontinued meds removed in a timely manner			
	Security and Storage			
9	Lighting, ventilation, cleanliness			
10	External products stored separately from internals			
11	All medication storage areas/keys secure			
12	Meds for hospitalized residents stored separately			
13	Proper storage disposal of syringes			
14	No items stored directly on floor			
15	Bedside medications appropriately stored			
16	Med/Tx carts in good working order			
17	Light available and functional as required			
18	Refrigerator clean/defrosted/Temp 36 to 46 degrees F			
19	Refrigerator with stocked with meds/adjunctive food only			
20	Adjunctive foods covered and dated			
	Emergency Medication Services			
21	Emergency pharmacy phone numbers readily available			
22	Content of EDK posted			
23	Kits conform with regulation and securely stored/sealed			
24	Usage forms completed			
25	Controlled EDK in compliance			
	Packaging and Labeling			
26	Labels are legible and contain all required information			
27	Rx Labels altered only by pharmacist			
28	Change of directions stickers used appropriately			
29	Date opened documented where required			
30	Bulk medications properly labeled			
31	Medication containers intact			
32	Alcoholic beverages appropriately labeled			
	Other			
33	Crusher available and clean/functional			
34	Hand washing/cleaning conforms to policy			
35	Blood glucose monitor calibrated			
36	Stop orders posted			
37	Proper drug references available			
38	Pharmacy Policy and Procedure Manual available/updated			

In-Service Notes

Reminder:

Totals	
Opportunities Noted	
Percent Compliance	


PharMerica
Value. Trust. Performance.
DRUGS RETURNED TO PHARMACY OR RELEASED TO THE PATIENT
Facility:
FACILITY USE
DISPOSITION
FOR PHARMACY USE ONLY
Date Returned
Nurse's Initial
Patient's Name
Name, Strength & Form of Drug
RX Number
Date of Issue
Quantity Returned
Discontinued
Patient Discharged
Patient Expired
Drug Expired
Released to Patient
Date Received
Count Verified (Qty/ Initial)
Destroyed (Qty/ Initial)
Billing Status Code
Credit Date
Credit Amt. (Qty/ $)
Credit Processed By (Initial)
INSTRUCTIONS:
(1) list controlled substances separately on the form supplied by the State Drug Authority.
(2) complete all applicable information in unshaded areas
(3) keep pink copy and
(4) return both medication and forms to pharmacy
or
(5) have patient or responsible party sign form for medications released upon discharge, then forward forms to the pharmacy.
FOR MEDICATIONS RELEASED WITH PATIENT
I certify that the medications listed above are released to me and I understand and request that the medications are not dispensed in child-resistant containers.
Signature
Date
Witness
FOR MEDICATIONS RETURNED TO THE PHARMACY
I certify that the information documented above is accurate and was completed by nursing center staff.
Nursing Center Staff Signature
Date
Received by
EXAMPLE
Reorder From: MED-PASS® 800-438-8884
Form # KPS009 (Rev. 12/10)
INH-090403

Reset Form

FDA

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

MEDWATCH

FORM 3500

For use by Health Professionals for VOLUNTARY reporting of adverse events, product problems and product use/medication errors

Form Approved: OMB No. 0910-0291
Expires: 09-30-2027
See PRA statement on page 8.

FDA USE ONLY
Triage unit sequence #
FDA Rec. Date

Note: *For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jan-1900.*

A. PATIENT INFORMATION

1. **Patient Identifier** *(In confidence)*

2. **Age**
☐ Year(s) ☐ Week(s) ☐ Month(s) ☐ Day(s)
or **Date of Birth** *(e.g., 01-Jan-1900)*

3. **Sex**
☐ Male
☐ Female

4. **Weight**
☐ lb
☐ kg

5. **Race and/or Ethnicity** *(Select all that apply)*
☐ American Indian or Alaska Native
☐ Asian
☐ Black or African American
☐ Hispanic or Latino
☐ Middle Eastern or North African
☐ Native Hawaiian or Pacific Islander
☐ White

B. ADVERSE EVENT, PRODUCT PROBLEM

1. **Type of Report** *(Check all that apply)*
☐ Adverse Event
☐ Product Use/Medication Error
☐ Product Problem *(e.g., defects/malfunctions)*
☐ Problem with Different Manufacturer of Same Medicine

2. **Outcome Attributed to Adverse Event** *(Check all that apply)*
☐ Death – Date of death *(e.g., 01-Jan-1900)*:
☐ Hospitalization (*Initial or prolonged*)
☐ Life-threatening
☐ Disability or Permanent Damage
☐ Required Intervention to Prevent Permanent Impairment/Damage
☐ Congenital Anomaly/Birth Defects
☐ Other Serious or Important Medical Events

3. **Date of Event** *(e.g., 01-Jan-1900)*

4. **Date of this Report** *(e.g., 01-Jan-1900)*

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
* Please see instructions

Form FDA-3500 MedWatch (09/2025) Page 1 of 8 *(continued on next page)*
MedWatch Health Professionals Voluntary Reporting

5. **Describe Event, Problem or Product Use/Medication Error** Characters Remaining (max. 4,000):

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

* Please see instructions

6. Relevant Test/Laboratory Data	Low Test Range	High Test Range	Date *(e.g., 01-Jan-1900)*

Additional comments Characters Remaining (max. 2,000):

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, pregnancy, tobacco product use, liver/kidney problems, etc.)* Characters Remaining (max. 2,000):

C. PRODUCT AVAILABILITY

1. **Product Available for Evaluation?** *(Do not send product to FDA)*
   - ☐ Yes
   - ☐ No
   - ☐ Returned to Manufacturer on *(e.g., 01-Jan-1900)* _____

2. **Do you have a picture of the product? While not required, pictures of all sides of the product will help FDA review your report.** *(Check yes if you are including pictures.)*
   - ☐ Yes

D. SUSPECT PRODUCTS

SUSPECT PRODUCT #1

1. **Name, Strength, Manufacturer/Compounder** *(From product label).*

Product Name | Strength | Unit

NDC # or Unique ID | Manufacturer/Compounder Name | Lot #

Place and Date of Purchase

Name

Address

City | State/Province/Region | ZIP/Postal Code

Country

Website (If purchased online) | Purchase Date

2. **Dose or Amount** | **Frequency** | **Route**

Unit | **Other Frequency** | **Other Route**

3. **Treatment/Therapy/Usage Dates** *(Give best estimate of length of treatment/usage (start/stop) or date of dose reduction.)*

Therapy/Usage started on *(e.g., 01-Jan-1900)*

Therapy/Usage stopped on *(e.g., 01-Jan-1900)*

Dose reduced on *(e.g., 01-Jan-1900)*

OR Duration | Unit

Is therapy/usage still on-going? ☐ Yes ☐ No

4. **Diagnosis for use** *(Indication)*

5. **Product Type** *(Check all that apply)*

Drug or Biologic

- ☐ Brand
- ☐ Generic or Biosimilar
- ☐ Over-the-Counter (OTC)
- ☐ Compounded product *(By a Pharmacy or an Outsourcing Facility)*

Cosmetics *(Select One)*

- ☐ Cosmetics for professional use only
- ☐ Cosmetics sold on a retail basis

Other Product Types

- ☐ Cannabinoid hemp products *(Such as products containing CBD)*
- ☐ Other

6. **Expiration Date** *(e.g., 01-Jan-1900)*

7. **Event Abated after use Stopped or Dose Reduced?** ☐ Yes ☐ No ☐ Doesn't apply

8. **Event Reappeared after Reintroduction?** ☐ Yes ☐ No ☐ Doesn't apply

Form FDA-3500 MedWatch (09/2025) **Page 4 of 8** *(continued on next page)*

MedWatch Health Professionals Voluntary Reporting

SUSPECT PRODUCT #2

1. **Name, Strength, Manufacturer/Compounder** *(From product label).*

Product Name | Strength | Unit

NDC # or Unique ID | Manufacturer/Compounder Name | Lot #

Place and Date of Purchase

Name

Address

City | State/Province/Region | ZIP/Postal Code

Country

Website (If purchased online) | Purchase Date

2. **Dose or Amount** | **Frequency** | **Route**

Unit | **Other Frequency** | **Other Route**

3. **Treatment/Therapy/Usage Dates** *(Give best estimate of length of treatment/usage (start/stop) or date of dose reduction.)*

Therapy/Usage started on *(e.g., 01-Jan-1900)*

Therapy/Usage stopped on *(e.g., 01-Jan-1900)*

Dose reduced on *(e.g., 01-Jan-1900)*

OR Duration | Unit

Is therapy/usage still on-going? ☐ Yes ☐ No

4. **Diagnosis for use** *(Indication)*

5. **Product Type** *(Check all that apply)*

Drug or Biologic

- ☐ Brand
- ☐ Generic or Biosimilar
- ☐ Over-the-Counter (OTC)
- ☐ Compounded product *(By a Pharmacy or an Outsourcing Facility)*

Cosmetics *(Select One)*

- ☐ Cosmetics for professional use only
- ☐ Cosmetics sold on a retail basis

Other Product Types

- ☐ Cannabinoid hemp products *(Such as products containing CBD)*
- ☐ Other

6. **Expiration Date** *(e.g., 01-Jan-1900)*

7. **Event Abated after use Stopped or Dose Reduced?**

☐ Yes ☐ No ☐ Doesn't apply

8. **Event Reappeared after Reintroduction?**

☐ Yes ☐ No ☐ Doesn't apply

E. SUSPECT MEDICAL DEVICE

1. Brand Name	2a. Procode	2b. Common Device Name

3. Manufacurer Name, City and State

4. Model #	Lot #	Catalog #

Expiration Date *(e.g., 01-Jan-1900)*	Serial #

Unique Device Identifier *(UDI)* # — Characters Remaining (max. 1,000):

5. Operator of device	6a. If Implanted, Give Date *(e.g., 01-Jan-1900)*	6b. If Explanted, Give Date *(e.g., 01-Jan-1900)*
☐ Health Professional ☐ Patient/Consumer ☐ Other		

7a. Is this a single-use device that was reprocessed and reused on a patient?	7b. If Yes to Item 7a, Enter Name, Address of Reprocessor	8. Was this device ever serviced by a third-party servicer?
☐ Yes ☐ No		☐ Yes ☐ No ☐ Unknown

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

1. Product names and therapy dates *(Exclude treatment of event)*

	Product Name	Therapy Start Date *(e.g., 01-Jan-1900)*	Therapy End Date *(e.g., 01-Jan-1900)*
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

G. REPORTER *(See confidentiality section on next page)*

1. **Name and Address**

Last Name	First Name

Address

City	State/Province/Region	ZIP/Postal Code

Country

Phone #	Email

2. **Health Professional?**	3. **Occupation**	4. **Also Reported to:**
☐ Yes ☐ No		☐ Manufacturer/Compounder ☐ User Facility ☐ Distributor/Importer ☐ Packer

5. **If you do NOT want your identity disclosed to the manufacturer, please mark this box:** ☐

ADVICE ABOUT VOLUNTARY REPORTING

Detailed instructions available at:
https://www.fda.gov/safety/medwatch-forms-fda-safety-reporting/instructions-completing-form-fda-3500

Report adverse events, product problems or product use errors with:

- Medications (drugs or biologics)
- Cannabinoid hemp products (such as products containing CBD)
- Medical devices (including diabetes glucose-test kit, hearing aids, breast pumps, and many more)
- Combination products (medication & medical devices)
- Blood transfusions, gene therapies, and human cells and tissue transplants (for example, tendons, bone, and corneas)
- Cosmetics (such as moisturizers, shampoos and conditioners, face and body washes, deodorants, nail care products, hair dyes and relaxers, and tattoos)

Report product problems – quality, performance or safety concerns such as:

- Suspected counterfeit product
- Suspected contamination
- Questionable stability
- Defective components
- Poor packaging or labeling
- Therapeutic failures (product didn't work)

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- Death
- Life-threatening
- Hospitalization (initial or prolonged)
- Disability or permanent damage
- Congenital anomaly/birth defect
- Required intervention to prevent permanent impairment or damage
- Other serious (important medical events)

Report even if:

- You're not certain the product caused the event
- You don't have all the details

How to report:

- Use section D for all products except medical devices
- Attach additional pages if needed
- Use a separate form for each patient
- Report either to FDA or the manufacturer (or both)
- Just fill in the sections that apply to your report

How to submit report:

- To report by phone, call toll-free: 1-800-FDA (332)-1088
- To report by mail: Attn: MedWatch Program, White Oak Campus, Building 22, G0207, 10903 New Hampshire Av., Silver Sprint, MD 20993
- To fax report: 1-800-FDA (332)-0178
- To report online: www.fda.gov/medwatch/report.htm

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

Where to submit adverse events related to the following products:

- If your report involves an animal drug, device, pet food and livestock feed problems, go to http://www.fda.gov/vetproductreporting
- If your report involves a health problem or a product problem with a tobacco product, including e-cigarettes (nicotine-coning vapes) or nicotine pouches, go to https://www.safetyreporting.hhs.gov or call 1-877-287-1373 to report.
- If your report involves a health problem or product problem with foods or special nutritional products such as infant formulas, dietary supplements, or medical foods, go to https://www.safetyreporting.hhs.gov or call 1-888-723-3366 to report.
- If your report involves an adverse event with a vaccine, go to https://www.vaers.hhs.gov to report or call 1-800-822-7967.

Confidentiality:

The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity, including the identity of a self-reporter, may be shared with the manufacturer unless requested otherwise.

The information in this box applies only to requirements of the Paperwork Reduction Act of 1995

The burden time for this collection of information has been estimated to average 40 minutes per response, including the time to review instructions, search existing data sources, gather and maintain the data needed, and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

Please DO NOT RETURN this form to the PRA Staff e-mail above.

OMB statement:

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

Temperature Log for Refrigerator – Fahrenheit

DAYS 1–15

CDC recommends the use of a **digital data logger (DDL)** for vaccine temperature monitoring. Using a DDL, or other appropriate **temperature monitoring device (TMD)**, check and record the storage unit temperature each workday using one of the options below. Save each month's log for 3 years, unless state/local jurisdictions require a longer period.

For detailed guidance on TMDs and all aspects of vaccine storage and handling, see CDC's *Vaccine Storage and Handling Toolkit* at www.cdc.gov/vaccines/hcp/storage-handling

Month/Year _____ VFC PIN or other ID # _____

Facility Name _____

Option 1: Minimum/Maximum (Min/Max) Temperatures* (preferred)

1. Most DDLs display minimum and maximum temperatures. Check and record the min/max temperatures at the start of each workday.
2. Document both of these temperatures in the min/max temperature rows under the appropriate date.

Option 2: Current Temperature

1. If the TMD does not display min/max temperatures, check and record the current temperature twice, at the start and end of the workday.
2. Document these temperatures by writing an "X" in the row that corresponds to the refrigerator temperature under the appropriate day of the month.
3. If using a DDL without min/max, review continuous temperature data daily.

If the temperature is out of range, TAKE ACTION!

1. Do not discard the vaccine unless directed to by your state/local health dept and/or the manufacturer(s).
2. Label the vaccine "Do Not Use" and store it under proper conditions as quickly as possible.
3. Complete the *Vaccine Storage Troubleshooting Record*†.
4. Notify your vaccine coordinator, or call the immunization program at your state or local health dept for guidance.

Day of Month		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Staff Initials																
Option 1	Time															
	Min Temp															
	Max Temp															
Option 2	Time	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM
	46°F															
	45°F															
	44°F															
	43°F															
	42°F															
	41°F															
	40°F to 36°F															
DANGER! Temperatures above 46°F or below 36°F are out of range. If found, write these temperatures and room temperature below. Contact your state/local health dept immediately!																
Action	Write any out-of-range temps (above 46°F or below 36°F) here.															
	Room Temp															

* "Min/max" means the lowest (minimum) and highest (maximum) temperatures recorded during a specific time period.

† *Vaccine Storage Troubleshooting Record* found at www.immunize.org/catg.d/p3041.pdf.

Adapted with appreciation from California Department of Public Health

Immunize.org

FOR PROFESSIONALS www.immunize.org / FOR THE PUBLIC www.vaccineinformation.org

www.immunize.org/catg.d/p3037F.pdf
Item #P3037F (2/4/2025)

Scan for PDF

Temperature Log for Refrigerator – Fahrenheit

DAYS 16–31

CDC recommends the use of a **digital data logger** (DDL) for vaccine temperature monitoring. Using a DDL, or other appropriate **temperature monitoring device** (TMD), check and record the storage unit temperature each workday using one of the options below. Save each month's log for 3 years, unless state/local jurisdictions require a longer period.

For detailed guidance on TMDs and all aspects of vaccine storage and handling, see CDC's *Vaccine Storage and Handling Toolkit* at www.cdc.gov/vaccines/hcp/storage-handling

Month/Year _____ VFC PIN or other ID # _____

Facility Name _____

Option 1: Minimum/Maximum (Min/Max) Temperatures* (preferred)

1. Most DDLs display minimum and maximum temperatures. Check and record the min/max temperatures at the start of each workday.
2. Document both of these temperatures in the min/max temperature rows under the appropriate date.

Option 2: Current Temperature

1. If the TMD does not display min/max temperatures, check and record the current temperature twice, at the start and end of the workday.
2. Document these temperatures by writing an "X" in the row that corresponds to the refrigerator temperature under the appropriate day of the month.
3. If using a DDL without min/max, review continuous temperature data daily.

If the temperature is out of range, TAKE ACTION!

1. Do not discard the vaccine unless directed to by your state/local health dept and/or the manufacturer(s).
2. Label the vaccine "Do Not Use" and store it under proper conditions as quickly as possible.
3. Complete the *Vaccine Storage Troubleshooting Record*†.
4. Notify your vaccine coordinator, or call the immunization program at your state or local health dept for guidance.

Day of Month		16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Staff Initials																	
Option 1	Time																
	Min Temp																
	Max Temp																
Option 2	Time	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM
	46°F																
	45°F																
	44°F																
	43°F																
	42°F																
	41°F																
	40°F to 36°F																
DANGER! Temperatures above 46°F or below 36°F are out of range. If found, write these temperatures and room temperature below. Contact your state/local health dept immediately!																	
Action	Write any out-of-range temps (above 46°F or below 36°F) here.																
	Room Temp																

* "Min/max" means the lowest (minimum) and highest (maximum) temperatures recorded during a specific time period.

† *Vaccine Storage Troubleshooting Record* found at www.immunize.org/catg.d/p3041.pdf.

Adapted with appreciation from California Department of Public Health

Temperature Log for Refrigerator – Celsius

DAYS 1–15

CDC recommends the use of a **digital data logger** (DDL) for vaccine temperature monitoring. Using a DDL, or other appropriate **temperature monitoring device** (TMD), check and record the storage unit temperature each workday using one of the options below. Save each month's log for 3 years, unless state/local jurisdictions require a longer period.

For detailed guidance on TMDs and all aspects of vaccine storage and handling, see CDC's *Vaccine Storage and Handling Toolkit* at www.cdc.gov/vaccines/hcp/storage-handling

Month/Year_____ **VFC PIN or other ID #** _____

Facility Name _____

Option 1: Minimum/Maximum (Min/Max) Temperatures* (preferred)

1. Most DDLs display minimum and maximum temperatures. Check and record the min/max temperatures at the start of each workday.
2. Document both of these temperatures in the min/max temperature rows under the appropriate date.

Option 2: Current Temperature

1. If the TMD does not display min/max temperatures, check and record the current temperature twice, at the start and end of the workday.
2. Document these temperatures by writing an "X" in the row that corresponds to the refrigerator temperature under the appropriate day of the month.
3. If using a DDL without min/max, review continuous temperature data daily.

If the temperature is out of range, TAKE ACTION!

1. Do not discard the vaccine unless directed to by your state/local health dept and/or the manufacturer(s).
2. Label the vaccine "Do Not Use" and store it under proper conditions as quickly as possible.
3. Complete the *Vaccine Storage Troubleshooting Record*†.
4. Notify your vaccine coordinator, or call the immunization program at your state or local health dept for guidance.

Day of Month		1		2		3		4		5		6		7		8		9		10		11		12		13		14		15	
Staff Initials																															
Option 1	Time																														
	Min Temp																														
	Max Temp																														
		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
Option 2	Time																														
	8°C																														
	7°C																														
	6°C																														
	5°C																														
	4°C																														
	3°C																														
	2°C																														

DANGER! Temperatures above 8°C or below 2°C are out of range. If found, write these temperatures and room temperature below. Contact your state/local health dept immediately!

Action																															
	Write any out-of-range temps (above 8°C or below 2°C) here.																														
	Room Temp																														

* "Min/max" means the lowest (minimum) and highest (maximum) temperatures recorded during a specific time period.

† *Vaccine Storage Troubleshooting Record* found at www.immunize.org/catg.d/p3041.pdf.

Adapted with appreciation from California Department of Public Health

Temperature Log for Refrigerator – Celsius

DAYS 16–31

CDC recommends the use of a **digital data logger** (DDL) for vaccine temperature monitoring. Using a DDL, or other appropriate **temperature monitoring device** (TMD), check and record the storage unit temperature each workday using one of the options below. Save each month's log for 3 years, unless state/local jurisdictions require a longer period.

For detailed guidance on TMDs and all aspects of vaccine storage and handling, see CDC's *Vaccine Storage and Handling Toolkit* at www.cdc.gov/vaccines/hcp/storage-handling

Month/Year_____ **VFC PIN or other ID #** _____

Facility Name _____

Option 1: Minimum/Maximum (Min/Max) Temperatures* (preferred)

1. Most DDLs display minimum and maximum temperatures. Check and record the min/max temperatures at the start of each workday.
2. Document both of these temperatures in the min/max temperature rows under the appropriate date.

Option 2: Current Temperature

1. If the TMD does not display min/max temperatures, check and record the current temperature twice, at the start and end of the workday.
2. Document these temperatures by writing an "X" in the row that corresponds to the refrigerator temperature under the appropriate day of the month.
3. If using a DDL without min/max, review continuous temperature data daily.

If the temperature is out of range, TAKE ACTION!

1. Do not discard the vaccine unless directed to by your state/local health dept and/or the manufacturer(s).
2. Label the vaccine "Do Not Use" and store it under proper conditions as quickly as possible.
3. Complete the *Vaccine Storage Troubleshooting Record*†.
4. Notify your vaccine coordinator, or call the immunization program at your state or local health dept for guidance.

Day of Month		16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Staff Initials																	
Option 1	Time																
	Min Temp																
	Max Temp																
Option 2	Time	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM
	8°C																
	7°C																
	6°C																
	5°C																
	4°C																
	3°C																
	2°C																
DANGER! Temperatures above 8°C or below 2°C are out of range. If found, write these temperatures and room temperature below. Contact your state/local health dept immediately!																	
Action	Write any out-of-range temps (above 8°C or below 2°C) here.																
	Room Temp																

* "Min/max" means the lowest (minimum) and highest (maximum) temperatures recorded during a specific time period.

† *Vaccine Storage Troubleshooting Record* found at www.immunize.org/catg.d/p3041.pdf.

Adapted with appreciation from California Department of Public Health

Vaccine Storage Troubleshooting Record

(check one) ○ Refrigerator ○ Freezer ○ Ultra-Cold Freezer

Use this form to document any unacceptable vaccine storage event, such as exposure of vaccines to temperatures that are outside the manufacturers' recommended storage ranges.

Date & Time of Event
If multiple, related events occurred, see Description of Event below.

Date:

Time:

Storage Unit Temperature
at the time the problem was discovered

Temp when discovered:

Minimum temp: Maximum temp:

Room Temperature
at the time the problem was discovered

Temp when discovered:

Comment (optional):

Person Completing Report

Name:

Title: Date:

Description of Event (If multiple, related events occurred, list each date, time, and length of time out of storage.)

- General description (i.e., what happened?)
- Estimated length of time between event and last documented reading of storage temperature in acceptable range (2°C to 8°C [36°F to 46°F] for refrigerator; -50°C to -15°C [-58°F to 5°F] for freezer; -90°C to -60°C [-130°F to -76°F] for ultra-cold freezer).
- Inventory of affected vaccines, including (1) lot numbers and (2) whether purchased with public (e.g., VFC) or private funds. Document this information on the *Vaccine Storage Emergency Response Worksheet* (see www.immunize.org/catg.d/p3051.pdf) or a separate sheet, and maintain the inventory with this troubleshooting record.
- At the time of the event, what else was in the storage unit (were there water bottles in the refrigerator and/or frozen coolant packs in the freezer)?
- Prior to this event, have there been any storage problems with this unit and/or with the affected vaccines?
- Include any other information you feel might be relevant to understanding the event.

Action Taken (Document thoroughly. This information is critical to determining whether the vaccine might still be viable.)

- When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state/local health department and/or the manufacturer[s].)
- Who was contacted regarding the incident (e.g., supervisor, state/local health department, manufacturer—list all)?
- What did you do / are you currently doing to prevent a similar problem from occurring in the future?

Results

- What happened to the vaccine?
- Was the vaccine able to be used? If not, was it returned to the distributor? (Note: For public-purchased vaccine, follow your state/local health department instructions for vaccine disposition.)

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www.immunize.org/catg.d/p3041.pdf

Item #P3041 (5/12/2025)

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10.14 SELF-ADMINISTRATION OF MEDICATIONS CONSENT AND ASSESSMENT

Resident Name: _____

Physician: _____

Part I: Informed Consent

- I have been advised of my right to self-administer medications, unless my physician and/or Interdisciplinary Team determine that this practice would be unsafe for me.
- I have been advised of the benefits and risks of self-medicating. I understand that by self-medicating, I might not be able to take advantage of all the safety monitoring performed when the Med Nurse passes meds.
- I understand that I will have to meet certain assessment criteria, established by the Interdisciplinary Team, before I can self-administer my medications.

☐ I wish to have my med nurse administer my medications

_____

Signature of Resident Date

☐ I wish to self-administer my medications

_____

Signature of Responsible Party Representing the Resident Date

_____

Signature of Person Presenting Form to Resident Date

DO NOT REMOVE FROM CHART

Part II: Assessment of Resident's Cognitive, Physical, and Visual Ability to Self-Administer Medications (to be completed only if resident wishes to self-medicate)

- Ask the resident to answer the following questions for each medication and score at right:

Medication Name (fill in) ➔										
	Pass	**Fail**	**Pass**	**Fail**	**Pass**	**Fail**	**Pass**	**Fail**	**Pass**	**Fail**
What is the name of the medication?										
What does it look like?										
Why do you take it?										
When do you take it?										
How much do you take each time?										
What are the major side effects to watch for?										
How would you pour this medication from the prescription container? (Special attention to liquids, multi-tablet doses, etc.)										
How would you administer this medication to yourself? (Special attention to ophthalmics, otics, ointments, etc.)										

Comments:

DO NOT REMOVE FROM CHART

Part III: **Determination of Resident's Ability to Self-Medicate**
(to be completed only if resident wishes to self-medicate)

The Interdisciplinary Team has determined that:

- ❑ The resident can safely self-medicate and should be allowed to exercise this right.
- ❑ The resident cannot safely self-medicate, based on the following reasons:

_____

_____

_____

Therefore the right is withdrawn, since it would pose a danger to the resident or to others.

Signed: (Representative of Interdisciplinary Committee)

_____

(Signature) (Date)

The above information has been explained to me and I understand it

_____

(Signature of Resident) (Date)

_____

(Signature of Responsible Party) (Date)

DO NOT REMOVE FROM CHART

10.15 SELF-MEDICATION ASSESSMENT FORM (SMAF)

(Note: Use ONLY if resident wishes to self-administer medications)

Date:
Resident:
Medical Record#:

IDT members involved:

_____

_____

_____

Medications *(list only meds resident wants to self-administer):*

_____

_____

_____

ASSESSMENT:

1. Cognitive ability:
   - ❑ Adequate
   - ❑ Limited
   - ❑ Not adequate (*If limited or not adequate, indicate reasons):*
     _____
     _____
2. List any physical limitations to safe administration:
   _____
   _____
3. Special problems with complexity, difficulty, or other reasons:
   _____
   _____
4. Special medication needs (e.g., nitroglycerin/NTG):
   _____
   _____

IDT DETERMINATION:

Indicate the specific level approved or describe any restrictions on one or more medications. If recommending not to permit self-administration, explain why:

_____
_____
_____

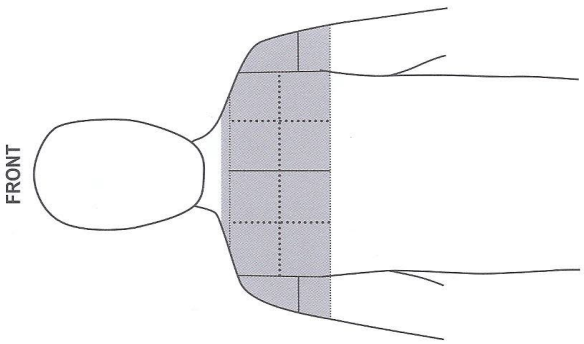
Resident Signature: _____ Date: _____

Nurse Signature: _____ Date: _____

10.16 TOPICAL PATCH ROTATION SITE CHART

Resident Name: _____ Room #: _____

Physician: _____ MR #: _____



EXP-200037

Place Site # on Diagram to the Right

Site	Date	Site	Date
1		17	
2		18	
3		19	
4		20	
5		21	
6		22	
7		23	
8		24	
9		25	
10		26	
11		27	
12		28	
13		29	
14		30	
15		31	
16		32	

PharMerica

Controlled Substance Change of Shift Count Sheet

Date & Time	Nursing Leaving	Nurse Starting	# Inventory Sheets & Cards	Change this shift	Reason for change (i.e. order received, returned)
05/13/2024 7pm	Shelly Smith	Jenny Jones	15	-1	AC admit

Pharmacy Products and Services

11.0 PHARMACY PRODUCTS AND SERVICES

Table of Contents

11.1 MEDICAL RECORDS SERVICES

1. Medical Records. On a monthly basis, Customer will receive Pharmacy's medical record service. The medical records package will include the following records (the "Medical Records") for each Resident serviced by Pharmacy for the applicable month:
   a. Physician Order Sheets (POS)
   b. Medication Administration Records (MAR's)
   c. Treatment Administration Records (TAR's)
2. Pharmacy shall:
   a. Periodically update Customer with Medical Record format options supported by the Medical Records service.
   b. Confer with Customer on an as-needed basis to establish Customer's desired Medical Records delivery date for a given month.
   c. Perform Medical Records data entry up until the cut-off deadline prior to the delivery date.
   d. Deliver Medical Records to Customer's facility.
3. Client shall, or require the Customer to:
   a. Abide by the Medical Record format options supported by the Medical Records service.
   b. Reasonably adjust the monthly delivery date to account for weekends and holidays.
   c. Provide Pharmacy with a by-name room roster at least two business days prior to the cut-off deadline.
   d. By the 5th day of each month send complete and accurate data and edits necessary for Pharmacy to update Medical Records.
   e. Use the method of delivery for sending all data and edits to Pharmacy as required by Pharmacy.

11.2 VIEWMASTERX™ SERVICES

1. Description. The PharMerica ViewMasteRx™ System, which includes the website portal, information and software (collectively referred to in this Schedule as the "System"), is a core component of Pharmacy's cost-containment and services solution. The System is proprietary and for use in the creation, management, and storage of Pharmacy, Client and Resident data. The System is designed to provide Client with retrievable management information and other value-added functionality, which may be enhanced or modified by Pharmacy from time to time.

2. Pharmacy Obligations. Pharmacy shall:
   a. Configure the accounts for Client's assigned system administrators and/or users.
   b. Establish Client account within the System.
   c. Provide administrative access to Client's assigned system administrators within fifteen (15) days after Pharmacy has been provided the necessary information from Client to configure the System for Client's account.
   d. Provide website tools for the administration of user accounts.
   e. Provide technical support to the system administrators.
   f. Advise Client as to the necessary Internet connectivity and technical infrastructure required for Client to implement and use the System.

3. Client Obligations. Client shall, or cause Customer to, as the case may be:
   a. Designate a System administrator and provide Pharmacy other information necessary to establish Client's account.
   b. Assure System security and notify Pharmacy of any change in the authorized system administrators.
   c. Provide a secure Internet connection and computer hardware using a high speed Internet connection between Client and the Internet.
   d. Provide and maintain user accounts so authorized by Client's system administrators.
   e. All Product returns to the Pharmacy shall be submitted and processed using the System.

4. Modification/Termination. Pharmacy may unilaterally, at any time and in its sole discretion, amend, modify, revise, update or otherwise change or terminate all or part of the System and/or this Schedule. The Schedule shall also terminate upon termination or expiration of the Agreement.

5. Client acknowledges and understands that Client's use of Pharmacy's System is contingent and dependent upon the prior provision by Client of information required by Pharmacy for System set up and implementation. Accordingly, Client agrees to provide such information so required by Pharmacy by designating the following individual as

Client's corporate or facility representative who will be responsible for System and will cooperate with Pharmacy to accomplish System set up and implementation.

RxForecaster®

1. Description. Pharmacy's service for costing-out anticipated drug Charges prior to ordering Medications for a Resident. This service can be accessed by Client and Customer either through Pharmacy's secure web-portal or telephonically.

11.3 NURSE CONSULTING SERVICES

1. Nurse Consulting Services. PharMerica employs a Nurse Consulting Services organization intended to satisfy specific service needs of the Customer. Nurse Consulting Services are only performed upon Client request. Client may place orders for Nurse Consulting Services through the NCS Service Link https://pharmerica.com/uncategorized/pmc-ncs-menu-of-services/ , which will schedule the service for the Customer. The Nurse Consulting Services organization employs qualified pharmacy nurses and pharmacy technicians who upon request can be scheduled to perform the following:

Available Service	Time Required for Service (Approximate)	Required Notice for Scheduling
Perform medication cart audits, which includes: i) a check of all Medications for proper labeling, date opened and expiration dates; ii) removal of all discontinued Medications; iii) inspection of the sharps container and assessment of the condition and serviceability; iv) inspection of the narcotic box; and v) cleaning of the medication cart and assurance that locking mechanisms are in working order.	2-4 hours per cart	14 day notice
Perform POS Review with documentation review to validate physician orders for better Resident care.	10-15 min per resident	14 day notice
Perform MAR Review with documentation review to validate document for nurse to pass medicine.	10-15 min per resident	14 day notice
Perform audits to assure accuracy among and between Resident's charts (POSs/TARs), the MARs and the Medications in the medication cart.	5 hours per audit	14 day notice
Perform Medication room audits and inspect for proper storage, temperature controls, and Medication expiration dates.	30-60 minutes per med Room	14 day notice
Perform a Treatment Cart Review in order to satisfy state and federal medication storage requirements.	30-60 minutes per cart	14 day notice
Observe Medication passes of those facility staff that the Client so designates and report the error rate.	45-60 min per nurse	14 day notice
Perform a Narcotics Review with documentation review for the protection of facility staff and residents.	60 min per 20 residents	14 day notice
Perform a preparatory pre-survey audit or a mock audit, which includes a med-pass observation of designated facility staff, a medication cart audit and a medication room/storage area audit.	16 hours	14 day notice
Perform a Root Cause Analysis to determine process gaps and provide written solutions for both Pharmacy and Client Issues.	2-4 hours	14 day notice
Provide educational training sessions for the Client's staff. The sessions may be selected from PharMerica's existing suite of education programs.	1-2 hour blocks	14 day notice

11.4 RxNOW ELECTRONIC EMERGENCY DRUG KIT

1. Program Description. RxNow is an electronic emergency drug kit and software program (referred to as "EEK") that provides on-site access to emergency and first-dose medications.

2. Pharmacy's Responsibilities. Pharmacy will:
   a. Provide EEK, router, and establish a secure virtual private network (VPN) connection.
   b. Provide access to EEK by creating users' accounts and consultative support on connectivity and technical infrastructure required for implementation of EEK.
   c. Provide delivery, training and technical support for EEK.
   d. Provide and restock inventory of medications for the EEK by type, number and quantity in Pharmacy's sole discretion and as allowed by Applicable Law.

3. Client's Responsibilities. Client will, or cause Customer to, as the case may be:
   a. Provide a standard 120 volt power outlet and power supply for the EEK at its own cost. It is recommended, but not required, to be on a generator backed up circuit.
   b. Provide access to the internet through a VPN connection and obtain a fixed IP address from its internet service provider.
   c. Provide a safe and secure location in the Customer's facility for the EEK that deters unauthorized access and safeguards PHI being viewed on the screen by unauthorized persons. Client shall be responsible for all costs associated with the replacement of stolen, lost or intentionally damaged inventory. Client shall allow and participate in a complete inventory of the EEK and its peripherals as requested by Pharmacy.
   d. Process and obtain all first-dose, STAT, and emergency eligible prescription fills through the EEK. For those medications available through the EEK at the time of an order, any request for a STAT or other special delivery not a part of the regularly scheduled delivery for Client shall, at Pharmacy's sole discretion, incur a charge for delivery at the contracted rate.
   e. Assist Pharmacy in restocking medications of the EEK in a manner consistent with Applicable Law.
   f. Participate in periodic user group meetings and product innovation advisory panels that will be held at mutually agreed upon times, not to exceed four (4) times per year.
   g. Assist Pharmacy in capturing metrics regarding the impact of the EEK on facility operations, reduction in costs, and quality improvement.
   h. Utilize the EEK only in connection with Pharmacy's Services and Products during the term of the Pharmacy Services Agreement.

4. The EEK shall remain Pharmacy's exclusive property. Client shall not do anything to infringe upon Pharmacy's ownership rights in the EEK, including but not limited to,

Pharmacy's intellectual property rights. Client shall not reverse engineer, disassemble or decompile any software or other tangible objects which are provided by Pharmacy hereunder.

5. With respect to the EEK, Client: (i) shall only use medications provided by the Pharmacy in the EEK or as expressly authorized by Pharmacy; (ii) is responsible for any loss of or damage to the EEK that occurs when the EEK is in its possession, including, but not limited to, any theft, vandalism, or other misuse; (iii) shall return the EEK to Pharmacy upon termination of this Agreement, for any reason, in substantially the same condition as it was on the date first provided to Client, with reasonable wear and tear taken into account; (iv) may not assert any ownership interest in the EEK; (v) shall cooperate with Pharmacy in the filing of, and hereby authorizes Pharmacy to so file, any Uniform Commercial Code financing statements or other filings requested by Pharmacy, to evidence that the EEK is owned by Pharmacy; and (vi) shall not allow any type of lien or claim to attach to EEK and will defend and indemnify Pharmacy from the same.

6. From time to time, Pharmacy may add functionality to the EEK that expands the breadth of the application beyond what is initially included. Pharmacy is not required to provide this expanded functionality to Client as part of the basic EEK functionality as these added functions may require additional hardware or software enhancements not presently available for the EEK provided.

7. The contents of the EEK shall remain the property of Pharmacy until properly dispensed to a patient. Once an item is removed from the EEK, the Client will be billed for the ingredient cost of the medication set forth in the pricing schedule of this Agreement. Any items returned to the EEK in a condition suitable for reuse, as determined solely by Pharmacy and as allowed by Applicable Law, shall be credited to Client.

   Client acknowledges and agrees that Pharmacy will incur upfront costs to procure an RxNow automated medicine EEK. Therefore, if Client terminates the Agreement prior to three (3) years from date of implementation, Client shall pay Pharmacy as liquidated damages, and not as a penalty, a lump sum payment, to account for the remaining balance of the RxNow equipment fee, to be calculated by multiplying the monthly cost per EEK by the number of months remaining until the third (3) anniversary date of implementation.

8. LIMITATION OF WARRANTIES. PHARMACY EXCLUDES AND DISCLAIMS ALL EXPRESS, IMPLIED, OR STATUTORY WARRANTIES AND CONDITIONS NOT STATED HEREIN, INCLUDING ANY WARRANTIES OF MERCHANTABILITY. ALL WORK PRODUCT PREPARED BY PHARMACY OR WHICH IS PROVIDED TO CLIENT FOR INSTALLATION AND USE AT CLIENT'S FACILITIES IS PROVIDED ON AN "AS IS" AND "WHERE IS" BASIS, WITHOUT WARRANTY OF ANY KIND. NOTWITHSTANDING ANYTHING TO THE CONTRARY CONTAINED IN THIS SCHEDULE: (I) PHARMACY'S AGGREGATE LIABILITY IN CONNECTION WITH THIS SCHEDULE AND THE PROVISION OF SERVICES AND PRODUCTS UNDER THIS SCHEDULE, REGARDLESS OF THE FORM OF ACTION GIVING RISE TO SUCH LIABILITY (WHETHER IN CONTRACT, TORT, OR OTHERWISE), SHALL

NOT EXCEED $10,000; AND (II) IN NO EVENT MAY PHARMACY BE LIABLE, WHETHER IN CONTRACT, IN TORT, OR UNDER ANY OTHER LEGAL THEORY, FOR ANY INDIRECT, EXEMPLARY, SPECIAL, PUNITIVE, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, INCLUDING ANY LOST DATA, LOST PROFITS, OR INJURY TO GOODWILL OR REPUTATION, ARISING FROM OR RELATING TO THIS SCHEDULE, EVEN IF PHARMACY IS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES IN ADVANCE. THE LIMITATIONS OF LIABILITY CONTAINED IN THIS SECTION AND ELSEWHERE IN THIS SCHEDULE ARE A FUNDAMENTAL PART OF THE BASIS OF THE PARTIES' BARGAIN HEREUNDER, AND THE PARTIES WOULD NOT HAVE ENTERED INTO THE AGREEMENT ABSENT SUCH LIMITATIONS.

11.5 ELECTRONIC MESSAGING INTERFACE ("EMI") SERVICES

1. EMI Program Description. EMI helps facilitate the exchange of certain electronic data (an "Interface") between Pharmacy's proprietary ordering/dispensing system ("System") and Client's Electronic Health/Medical Records software ("EHR/EMR") (collectively referred to as "Software Systems"), including but not limited to, the exchange of census and prescription information between the two Software Systems. Pursuant to this Schedule, Client and Pharmacy agree to use commercially reasonable efforts to jointly implement EMI, if feasible, between the parties' respective Software Systems.

2. Development and Testing of EMI. Pharmacy supports EMI integration with a variety of EHR/EMR software and third-party vendors. Notwithstanding the above, Pharmacy makes no representation or warranty that full EMI integration is possible with Client's EHR/EMR software and/or third-party vendor. The implementation of EMI between the parties is limited to the interfaces allowed by Client's EHR/EMR software and/or third-party vendor. Client understands and agrees that while Pharmacy's System supports the following Interfaces, Client's EHR/EMR software and/or third-party vendor may not support certain Interfaces and/or offer all or any of the listed Interfaces below:
   a. Prescription Orders Interface – enables prescription orders to be electronically transmitted to Pharmacy.
      1) New orders entered into Client's EHR/EMR software will be electronically transmitted to Pharmacy.
      2) Refill orders entered into Client's EHR/EMR software will be electronically transmitted to Pharmacy.
      3) Discontinued or terminated orders entered into Client's EHR/EMR software will be electronically transmitted to Pharmacy.
   b. Census Interface – enables census transactions entered into Client's EHR/EMR software for Admissions, Discharges and Transfers to be electronically transmitted to Pharmacy.
   c. Dispensing Information Interface – Client's EHR/EMR software accepts the return transmission of dispensing information for orders received by the Pharmacy. The dispensing information may or may not include the following: the name of the drug dispensed, the Rx Number, Days Supply, Quantity, etc.
   d. As part of the development and testing process, the parties agree to allow, in conjunction with any third-party EHR/EMR vendor, the setting up of test environments within their respective Software Systems with a secure "live" internet connection. The test environments will be used exclusively for the testing of the Interface functions during the development process and after release for support and maintenance of the Interface. The Interface will not be launched into a production environment until both parties and the third-party EHR/EMR vendor certify in writing that the Interface is performing as designed and has passed all required testing. Notwithstanding the above, Pharmacy may terminate this Schedule at its sole

discretion upon written notice to Client should it appear that EMI is not commercially feasible between the parties' Software Systems and/or is cost prohibitive to implement.

3. Pharmacy's Responsibilities. Pharmacy will:
   a. Use commercially reasonable efforts to develop functional Interfaces between Pharmacy's system and Client's EHR/EMR software.
   b. Pharmacy shall be responsible for the internal cost associated with modifying Pharmacy's system to enable EMI, but shall not be responsible for any costs or expenses associating with modifying Client's EHR/EMR software or any third-party EHR/EMR vendor expenses unless a separate written agreement between the third-party vendor and Pharmacy is executed.
   c. Support EMI and Interfaces with adequate internal hardware, telecommunication infrastructure and technical support for Pharmacy's System.
   d. At its sole discretion, Pharmacy may determine that the development of such Interfaces is not feasible or is cost prohibitive. In such circumstances, Pharmacy may terminate this Schedule and the parties will work together in good faith to find reasonable alternative solutions.
   e. Receive all admission, census and prescription information electronically from the Client.

4. Client's Responsibilities. Client will:
   a. Send admission, census and prescription information electronically via the interface.
   b. Receive all prescription dispensing information from the Pharmacy electronically.
   c. Keep the census information updated in the Software Systems.
   d. Provide information required by Pharmacy for development, testing, and implementation of EMI and Interfaces.
   e. Designate an individual as Client's corporate or Customer representative who will be responsible for development, testing, and implementation of EMI and Interfaces.
   f. Cooperate with Pharmacy to accomplish development, testing, and implementation of EMI and Interfaces.
   g. Provide minimum requirements for a secure Internet connection using high speed Internet connection between the Customer and Pharmacy's System.
   h. Be responsible for any third-party EHR/EMR vendor costs, including but not limited to, licensing fees, product support and training, service fees, implementation costs for EMI, and/or any other costs which Client is required to pay pursuant to its contract with its EHR/EMR third-party vendor.
   i. Provide Pharmacy with access to Client's resident data including, but not limited to, Clinical, MDS (Minimum Data Set), patient census information, eMAR information, and eTAR information.

j. Use EMI and Interfaces only in connection to its use of Pharmacy's services at the Customer during the term of the Agreement.

k. Participate in periodic user group meetings and product innovation advisory panels that will be held at mutually agreed upon times, not to exceed four (4) times per year.

l. Participate in periodic marketing initiatives, such as Client testimonials and other related marketing campaigns.

m. Assist Pharmacy in capturing metrics regarding the impact of EMI on facility operations, reduction in costs, and quality improvement.

5. Maintenance. From time to time, Client's EHR/EMR third-party vendor may update its EHR/EMR software to add functionality that changes or expands the breadth of EMI or Interfaces beyond the initial functionality. Client understand and agrees that Pharmacy is not required to provide additional EMI or Interfaces as a result of any expanded functionality as the added functions may require additional software enhancements not presently available or supported. Notwithstanding the above, at Client's request, Pharmacy may elect, at its sole option, to make commercially reasonable efforts to further develop and expand existing Interfaces to include the updated functionality of Client's EHR/EMR software.

6. Modification and Termination. Pharmacy may unilaterally, at any time and in its sole discretion, amend, modify, revise, update or otherwise change or terminate all or part of the EMI, Interfaces, the System and/or this Schedule. This Schedule and the services provided hereunder shall also terminate upon termination or expiration of the Agreement.

7. Rights Upon Termination. Upon termination of this Schedule, all rights granted to Client hereunder will immediately cease, and Client shall permanently desist from the further use of EMI and Interfaces with the System. Client shall return to Pharmacy any and all materials provided by Pharmacy, including Confidential Information in Client's possession. Termination of this Schedule by Pharmacy has no effect on the Agreement.

8. Limitations On Use. The parties acknowledge and agree that Pharmacy's System consists of proprietary data and information, protected under United States copyright law and other laws of general applicability. The parties further agree that Pharmacy's rights, title, and interest in and to the System are and shall remain with the Pharmacy and this Agreement does not convey to any other party any interest in or rights to Pharmacy's System. The Agreement does not grant, and Client does not have, any right or authority, express or implied, to sublicense, assign, or transfer any part of the System, to any other person or entity for any reason. Any purported sublicense, assignment, or transfer is void. Client shall refrain from copying, disassembling, reverse engineering, decompiling, translating or modifying the System, or granting or purporting to grant any other person or entity the right to do so. Client shall not do anything to infringe upon Pharmacy's ownership rights in the services provided hereunder.

9. Confidentiality. Client agrees that the System contains Confidential Information, as that term is defined below, of Pharmacy and its third party licensors. Client shall not transfer, distribute or disclose the System or Confidential Information, or any part thereof, to any other person, firm or corporation, except as specifically authorized in writing by Pharmacy. Client shall, on behalf of itself and its personnel, retain all Pharmacy Confidential Information and trade secrets in strictest confidence and shall not publish or disclose such Confidential Information or trade secrets at any time during the Term of the Agreement or after its termination. All copies, summaries or notes relating to such information and data are the property of Pharmacy and are subject to all the terms and conditions of the Agreement. Confidential Information means any technical and non-technical information and data related to a disclosing party's past, current, future or proposed operations, products, services, financial position, and business, as well as those of its business partners, suppliers, licensors and customers. Notwithstanding the foregoing, information or data is not Confidential Information if the disclosed information or data: (i) was in the public domain at the time it was communicated to the receiving party; (ii) entered the public domain subsequent to the time it was communicated to the receiving party through no fault of the receiving party or any third party which was bound by an obligation of confidentiality; or (iii) was already known to the receiving part at the time of disclosure, as evidenced by its written records.

10. Indemnity. Client shall hold harmless and indemnify Pharmacy and its directors, officers, agents and employees from and against any and all loss, liability, damage, or expense, including reasonable attorneys' fees and costs as and when incurred, with respect to any third-party vendor claim arising out of Pharmacy's development, testing and implementation of EMI and Interfaces between the parties' respective Software System or the services provided hereunder.

11. LIMITATION OF WARRANTIES. PHARMACY EXCLUDES AND DISCLAIMS ALL EXPRESS, IMPLIED OR STATUTORY WARRANTIES AND CONDITIONS NOT STATED HEREIN, INCLUDING ANY WARRANTIES OF MERCHANTABILITY. ALL WORK PRODUCT PREPARED BY PHARMACY OR WHICH IS PROVIDED TO CLIENT FOR INSTALLATION AND USE AT CLIENT'S FACILITIES IS PROVIDED ON AN "AS IS" AND "WHERE IS" BASIS, WITHOUT WARRANTY OF ANY KIND. NOTWITHSTANDING ANYTHING TO THE CONTRARY CONTAINED IN THIS SCHEDULE: (I) PHARMACY'S AGGREGATE LIABILITY IN CONNECTION WITH THIS SCHEDULE AND THE PROVISION OF SERVICES AND PRODUCTS UNDER THIS SCHEDULE, REGARDLESS OF THE FORM OF ACTION GIVING RISE TO SUCH LIABILITY (WHETHER IN CONTRACT, TORT, OR OTHERWISE), SHALL NOT EXCEED $10,000; AND (II) IN NO EVENT WILL PHARMACY BE LIABLE, WHETHER IN CONTRACT, IN TORT, OR UNDER ANY OTHER LEGAL THEORY, FOR ANY INDIRECT, EXEMPLARY, SPECIAL, PUNITIVE, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, INCLUDING ANY LOST DATA, LOST PROFITS, OR INJURY TO

GOODWILL OR REPUTATION, ARISING FROM OR RELATING TO THIS SCHEDULE, EVEN IF PHARMACY IS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES IN ADVANCE. THE LIMITATIONS OF LIABILITY CONTAINED IN THIS SECTION AND ELSEWHERE IN THIS SCHEDULE ARE A FUNDAMENTAL PART OF THE BASIS OF THE PARTIES' BARGAIN HEREUNDER, AND THE PARTIES WOULD NOT HAVE ENTERED INTO THE PHARMACY SERVICES AGREEMENT OR THIS SCHEDULE ABSENT SUCH LIMITATIONS.

11.6 RxALLOW SERVICE

1. Description. The RxAllow program is the process Pharmacy utilizes to maximize Third Party Payer approval of previously denied claims for Residents' Medications. The Client's Charges will be credited for the amount subsequently approved by the Payer.
2. Process. When Pharmacy seeks payment from a Resident's Third Party Payer plan and that Payer denies the Resident coverage for the Medication then Pharmacy will:
   a. Request from the Third Party Payer a transitional or emergency supply.
      1) If granted, dispense the Medication to Customer. In such case payment will be made to Pharmacy by the Third Party Payer for the transitional or emergency supply.
      2) If not granted, dispense the Medication to Customer and Charge the Medication to the Client.
   b. Pharmacy will provide appropriate forms to the Customer or the prescriber to obtain a change in prescription if the Third Party Payer will pay for an alternate Medication (e.g., a therapeutic interchange), or present to the Client the conditions that shall be met before the Third Party Payer will approve coverage for the originally prescribed Medication (e.g., a Prior Authorization).
      1) Pharmacy will attempt to contact the prescriber or Customer at least two times to encourage completion and return of the forms provided.
   c. If the prescriber or the Customer returns the form to Pharmacy and changes the originally ordered Medication to an alternate Medication covered by the Third Party Payer, Pharmacy will dispense the alternate Medication and charge the Resident's Third Party Payer.
   d. If the prescriber or the Customer does not return the form, or returns the form but does not change the Medication to an alternate Medication covered by the Third Party Payer, or the Third Party Payer does not authorize payment for the prescribed Medication (e.g., Prior Authorization denied), then Pharmacy will continue to dispense the originally ordered Medication and Charge the Client.
3. Client Obligations. Client will, or cause Customer to, as the case may be:
   a. Provide a response within seventy-two (72) hours to requests from Pharmacy for a covered alternative Medication (therapeutic interchange).
   b. Complete and return all forms relating to Prior Authorizations within five (5) business days of the request from Pharmacy.
   c. Comply with global authorization requests for all prescribers.
   d. Participate in monthly Client engagement calls and use best efforts to address any action items.
   e. Participate in weekly RxAllow calls and use best efforts to address any action items.
   f. Participate in quarterly business reviews (QBRs) and use best efforts to address any action items.

11.7 TRANSITIONAL CARE SERVICES

DischargeRx

1. Program Description. DischargeRx is a transitional care medication program that allows the Client to discharge their Residents home from the Customer with their remaining medications and an additional 14 or 30-day refill of their active Medications. There is no cost to Client for the use of the DischargeRx program.

2. Pharmacy's Responsibilities. Pharmacy will:
   a. Provide training and technical support for DischargeRx.
   b. Provide medications and all associated forms for the completion of all medication orders through the DischargeRx program.
   c. Handle billing of resident's Part D plan for cost of medications.

3. Client's Responsibilities. Client will, or cause Customer to as the case may be:
   a. Provide 48 hour notice of any upcoming resident.
   b. Offer this program to 75% or more of their discharging Residents.
   c. Provide a primary contact within the business office, or a discharge coordinator to be the manager of this program at the Customer.
   d. Assist Pharmacy in capturing metrics regarding the impact of DischargeRx on facility operations and give feedback on quality improvement opportunities.
   e. Utilize DischargeRx only in connection with Pharmacy's Services and Products during the term of the Pharmacy Services Agreement.

4. Client shall release medications only to the Resident named on the prescription label, or their Responsible Party.

5. If Resident's medication coverage plan cannot be determined, Pharmacy will offer alternative payment methods to the Resident.

6. Pharmacy may make changes to the process for the DischargeRx program that expands the breadth of the program beyond what is initially included if necessary. The program offered may vary by facility and Customer needs.

7. The medications dispensed through the DischargeRx program shall remain property of Pharmacy until signed for and a confirmed method of payment is determined for the ingredient cost of the medication set forth by the formulary for the specific insurance plan. Any items refused by the Resident will still be charged to the Resident's insurance plan unless the Customer is able to return the medications to the Pharmacy. Any co-pays or additional costs are the responsibility of the Resident or their Responsible Party.

TransitionRx

1. Program Description. TransitionRx is a pre-admission referral program that partners with hospitals to allow PharMerica to provide Admission Assessments, complete with

medications and lower cost alternatives to review with the admitting physician, before or during the Resident's admission.

2. PHARMACY's Responsibilities. Pharmacy will:
   a. Provide training and technical support for TransitionRx.
   b. Provide medications and all associated forms for the completion of all medication orders through the TransitionRx program.
   c. Provide alternative recommendations for a lower cost initial dispense.

3. Client's Responsibilities. Client will, or cause Customer to as the case may be:
   a. Provide 72 hour notice of any upcoming Resident admissions.
   b. Provide a primary contact within the business office, or a discharge coordinator to be the manager of this program at the Customer.
   c. Assist Pharmacy interfaces with the Customer's referral sources (i.e., hospitals).
   d. Assist Pharmacy in capturing metrics regarding the impact of TransitionRx on facility operations and give feedback on quality improvement opportunities.
   e. Utilize TransitionRx only in connection with Pharmacy's Services and Products during the term of the Pharmacy Services Agreement.

4. Client shall release medications only to the Resident named on the prescription label, or their Responsible Party.

Optional P&P Templates

12.0 OPTIONAL P&P TEMPLATES

Table of Contents

Disposal of Hazardous Waste Pharmaceuticals	PharMerica Value. Trust. Performance.
Applicable to: Facility Operations	**Approved By:**
Effective Date: 10/2019	**Revision Date:**

EPA Hazardous Waste Pharmaceuticals- Storage & Disposal

1. Background

A new final rule, titled "*Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine*" was published in the *Federal Register* on *February 22, 2019*. This *Environmental Protection Agency* (EPA) rule governs the removal and destruction of hazardous waste, and the following three parts are included: the *sewering ban*, Subpart P, and the nicotine exception.

a. The Sewer ban

The Sewer Ban prevents any hazardous waste pharmaceuticals from being flushed down the toilet or disposed of down the drain. The ban only applies to hazardous waste pharmaceuticals, however the EPA recommends not sewering any pharmaceutical in order to protect the environment and drinking water.

b. Subpart P

Subpart P expands the designation of hazardous waste generators to certain healthcare facilities, which potentially subjects them to stricter regulations for hazardous waste pharmaceuticals disposal. Healthcare facilities may be categorized as, Very Small Quantity Generators (VSQG), Small Quantity Generators (SQG), or Large Quantity Generators. Hazardous pharmaceutical waste is defined as any item that exhibits one of the following four characteristics: ignitability, corrosivity, reactivity, or toxicity. These items are either acutely hazardous (P-listed) or toxic/hazardous (U-listed) and can include prescription drugs, dietary supplements, over-the-counter drugs, homeopathic products, and Drug Enforcement Administration (DEA) controlled substances. Empty containers (blister pack, cup, syringe, IV bag, ampule, etc.) are no longer considered hazardous and can be disposed of as non-hazardous waste as long as the hazardous pharmaceutical has been completely removed. A pharmaceutical is not considered hazardous waste if it is legitimately able to be used/reused (lawfully donated for its intended purpose) or reclaimed.

c. The Nicotine exception

The Nicotine exception exempts over-the-counter nicotine replacement products (i.e. patches, lozenges, and gums) from being considered acute hazardous waste. Prescription and liquid nicotine products are still considered hazardous waste. Because this part of the rule is more lenient than the law currently in place, states can choose whether or not to adopt it.

Healthcare facilities, defined in this rule as *nursing*, *skilled nursing*, and *inpatient hospice settings*, must now comply with this regulation. *Assisted living facilities*, *independent living communities*, *group homes*, and *continuing care retirement communities* are considered *residential households and are exempt from compliance*. The various parts of the rule have different compliance deadlines by state, with states being allowed to adopt the parts ahead of the deadline(s). Individual facilities must be aware of what is happening in their specific area; local regulators should be consulted.

	Less Stringent	More Stringent	
	Nicotine Exemption	Sewer Ban	Subpart P
Non Authorized States	August 21, 2019	August 21, 2019	August 21, 2019
Authorized States	Not Required	August 21, 2019	July 1, 2021
Authorized States Requiring Statutory Amendment	Not Required	August 21, 2019	July 1, 2022

2. **Policy**

   Facility personnel are responsible for disposing pharmaceutical hazardous and non-hazardous waste using an approved system of disposal that protects employees and the environment according to applicable federal, state and local laws or regulations.

3. **Responsibilities**

   a. The facility administrator or his/her designee is responsible for using an approved vendor for pharmaceutical waste disposal needs, if required.

   b. The facility administrator or his/her designee is responsible for complying with EPA rules and regulations regarding the disposal of hazardous waste pharmaceuticals.

Procedures – Waste disposal

1. **Non-hazardous pharmaceutical waste**

   a. Can be disposed of and managed with normal waste

   b. Empty containers that once held hazardous pharmaceuticals can be disposed of with normal waste

      i. Containers should no longer be rinsed to facilitate emptying
      ii. The following dispensing containers are considered empty, even if residue remains:
         (1) Unit dose/packet/cups that have had contents fully removed by commonly employed methods such as medication administration
         (2) IV bags that have had the contents fully administered
         (3) Syringes that have had the plunger fully depressed
         (4) Aerosols/tubes/gels/creams that cannot be emptied further or with less than one inch of residue

   c. Pharmaceutical waste disposal - Including but not limited to: prescription drugs, dietary supplements, over-the counters, or homeopathic products with a reasonable expectation of being legitimately used/reused, lawfully redistributed for its intended purpose, or reclaimed are not considered hazardous waste

2. **Hazardous pharmaceutical waste**

   a. Considered a solid waste that exhibits characteristics of ignitability, corrosivity, reactivity, or toxicity or is – listed

   b. Can be further defined as acute hazardous waste (P-listed), non-acute hazardous waste (U-listed) and controlled substance hazardous waste. A complete list of acute and non-acute hazardous waste, as defined by the EPA, can be found here: https://www.epa.gov/hw/defining-hazardous-waste-listed-characteristic-and-mixed-radiological-wastes

Example P-Listed Drugs	Example U-Listed Drugs	Example HD Controlled Drugs
Epinephrine	Insulin	Fentanyl Spray
Nitroglycerin	Reserpine	Phenobarbital
Warfarin	Selenium	Testosterone Gel
Phenol	Vaccines	Diazepam Gel

   c. Cannot be disposed of by sewering

   d. Three types of hazardous waste may need to be managed at the facility level:

      i. Non-creditable hazardous waste
         (1) Items are repackaged, dispensed, broken/leaking, expired > 1 year
            (i) An item is dispensed if it is provided by an off-site pharmacy
         (2) Accounted for as hazardous waste generated by the facility
         (3) Cannot be returned to the servicing pharmacy or a reverse distributor
         (4) Must be disposed of by an approved hazardous waste facility

ii. Potentially creditable hazardous waste
  (1) Items are undispensed, in original manufacturer packaging, unexpired, or less than 1 year past expiration
  (2) Accounted for as hazardous waste generated by the facility
  (3) Can be sent to a reverse distributor for potential credit
    (i) Will be evaluated for credit and sent on to an approved hazardous waste disposal facility if warranted

iii. Controlled substance hazardous waste
  (1) Accounted for as hazardous waste generated by the facility
  (2) Must be destroyed by a method that is approved by the DEA that meets their non- retrievable standard or combusted

e. The facility shall make a one-time notification of generator status if they are operating under Subpart P. The facility must submit this notification to the Regional EPA Administrator using FORM 8700-12. The facility should also notify the pharmacy of their generator status.

3. The facility will categorize themselves as:

a) Very Small Quantity Generators (VSQG)

i. Generates ≤ 100 kg (220.4 lbs) of hazardous waste (U-listed) and ≤ 1 kg (2.2 lbs) of acute hazardous waste (P-listed) per month

ii. Facilities with ≤ 20 beds are assumed to be VSQG

iii. Facilities with > 20 beds must demonstrate they qualify
  (1) Monthly calculations and documentation required
    (i) Copies of documentation must be kept for 3 years and made readily available during an inspection

iv. Must decide if they will operate under Part 266 Subpart P, as it is optional for this generator status group

b) Small Quantity Generators (SQG)

i. Generates between 100 kg (220.4 lbs) and 1000 kg (2204 lbs) of hazardous waste (U-listed) and ≤ 1 kg (2.2 lbs) of acute hazardous waste (P-listed) per month

ii. Must follow and operate under Part 266 Subpart P

c) Large Quantity Generators (LQG)

i. Generates ≥ 1000 kg (2204 lbs) of hazardous waste (U-listed) and ≥ 1 kg (2.2 lbs) of acute hazardous waste (P-listed) per month

ii. Must follow and operate under Part 266 Subpart P

d. Once subject to Part 266 Subpart P, there are no generator categories and all facilities are regulated the same for their hazardous waste pharmaceuticals.

i. The facility does NOT have to track how much hazardous waste pharmaceuticals are generated per month.

ii. Both hazardous and non-hazardous pharmaceutical waste pharmaceuticals can be accumulated together in the same container.

iii. The facility does NOT have to segregate acute (P-listed) and non-acute (U-listed) hazardous waste pharmaceuticals.

iv. The facility will maintain 2 containers:
  (1) Non-creditable pharmaceutical waste
  (2) Potentially creditable pharmaceutical waste

v. Hazardous waste pharmaceuticals may only be released to an EPA-approved treatment-storage-disposal (TSD) facility. They cannot be returned to the pharmacy or released to a reverse distributor.

e. If NOT operating under Part 266 Subpart P, the VSQG facility:

i. Must track how much hazardous waste pharmaceuticals are generated each month.

ii. Segregate hazardous from non-hazardous pharmaceutical waste.

iii. Designate hazardous pharmaceutical waste as non-acute (U-listed) and acute (P-listed) hazardous waste drugs.

iv. Maintain the following containers:
(1) Non-hazardous pharmaceutical waste
(2) Hazardous pharmaceutical waste
(i) Non-acute (U-listed) hazardous pharmaceutical waste
(ii) Acute (P-listed) hazardous pharmaceutical waste

v. May continue to return hazardous pharmaceuticals to:
(1) Their servicing pharmacy in accordance with established policies and procedures as long as the pharmacy is operating under Subpart P.
(2) A reverse distributor can be utilized by a VSQG facility for items that are considered potentially creditable hazardous waste pharmaceuticals
(3) May render inert and dispose of via landfill if allowed by state and local laws and regulations

f. The facility will maintain approved containers to separate and securely store different types of pharmaceutical hazardous waste until it is scheduled for pick-up or destroyed based on DEA standards

i. Containers must be:
(1) Structurally sound, in good condition, and compatible (non-reactive) with contents
(2) Kept closed and secured in a manner that prevents unauthorized access to its contents

ii. A containment system should be in place to prevent a release into the environment should the primary container fail or leak.

g. Authorized personnel who have access to medications are required to deposit pharmaceutical waste in the appropriately labeled container.

h. Individual containers used to collect, separate, and store each type of hazardous pharmaceutical waste will be labeled according to management standards.

i. Non-creditable hazardous waste pharmaceuticals must be labeled with the words "Hazardous Waste Pharmaceuticals"
(1) Accumulation time limit is 1 year on-site.

ii. Potentially creditable hazardous waste pharmaceuticals require no labeling.
(1) There is no accumulation time limit on-site.

i. The Administrator or designee must inspect all waste containers weekly and maintain a record of inspections

j. Paperwork and documentation maintenance of pharmaceutical hazardous waste should be retained on-site for a minimum of 3 years, filed and separated by year.

k. Facilities are responsible for training all employees who handle hazardous waste pharmaceuticals on the appropriate management and disposal as well as emergency procedures, upon hire and regularly according to applicable laws and regulations.

i. Employee records of training must be retained by the facility as long as the facility exists.

l. If a release of hazardous pharmaceutical waste that could threaten humans outside of the facility occurs, the Administrator will notify the U.S. National Response Center at (800) 424-8802.

TPN (*Total Parenteral Nutrition*) **Policy & Procedures**	PharMerica Value. Trust. Performance.
Applicable to: Nursing Facilities, Pharmacy Operations	**Approved By:**
Effective Date: 10/2019	**Revision Date:**

TPN Policy

1. Policy

The policy and procedures within this document help create a uniform process for pharmacy personnel and facility employees to follow regarding ordering, handling, and formulation of TPNs.

The following list details procedures that must be followed:

- All compounded TPN orders will be sent out on a regularly scheduled delivery once available.
- Lab collections take place Mondays and Thursdays pursuant to a signed prescriber order.
  - Lab collection can take place more or less often, if clinically appropriate.
- The following are used (when appropriate): Dextrose 10%, Clinimix®, Kabiven®, or custom compounds (3-in-1 or 2-in-1 with lipids separate).

TPN Procedures

1. TPN Regular Handling (Monday through Friday)

- For **New Orders/New Starts**
  - The nursing facility is responsible for faxing new TPN orders to the pharmacy. Additionally, the following information is needed for a complete order:
    - Basic Metabolic Panel or Comprehensive Metabolic Panel within the last 3 days
    - Height, weight, and indication for TPN
    - Line access that supports TPN use
    - Current TPN formula, if applicable
    - Discharge Summary, if available
  - The pharmacist is responsible for writing the recommended TPN formula and faxing the recommendation back to the facility.
  - The nursing facility is responsible for contacting the prescribing physician with the pharmacist's recommendations.
  - The physician is responsible for approving or changing the pharmacist's recommendations, and then signing and faxing recommendation sheet back to the pharmacy.
  - **After** the pharmacist has received the physician-signed recommendation sheet, the compounding technician is responsible for preparing the TPN as written.

***Note**: If the pharmacy receives the new order or physician-signed recommendation sheet without sufficient time to prepare prior to next scheduled delivery, the After-hours procedure will be followed.*

  - The pharmacist is responsible for charting the resident's course of dosing and/or monitoring services in accordance with pharmacy policy.

- For **Continuation Orders**
  - The nursing facility is responsible for faxing lab results to the pharmacy.
  - The pharmacist is responsible for writing the recommended TPN formula and faxing the recommendation back to the facility.
  - The nursing facility is responsible for contacting the prescribing physician with the pharmacist's recommendations.
  - The physician is responsible for approving or changing the pharmacist's recommendations, and then signing and faxing recommendation sheet back to the pharmacy.
  - **After** the pharmacist has received the physician-signed recommendation sheet, the compounding technician is responsible for preparing the TPN as written.
  - The pharmacist is responsible for charting the resident's course of dosing and/or monitoring services in accordance with pharmacy policy.

2. TPN After-hours Handling (Weekends/Holidays)

- For **New Orders/New Starts**
  - After receiving the TPN order, the pharmacist is responsible for writing a recommendation using clinical judgement for a standard TPN recommendation until the custom compounded TPN becomes available (infusion rate is generally the same as TPN):
    - D10W [1000 mLs] with infusion rate of 60- 100ml/hr **OR**
    - Clinimix E 4.25%/5% [1000 mLs] with infusion rate of 60- 100ml/hr **OR**
    - Kabiven [3:1] TPN [1540 mLs] with infusion rate of 60 – 100 ml/hr.
  - Fax the recommendation back to the facility.
  - The nursing facility is responsible for contacting the prescribing M.D. with the pharmacist's recommendations.
  - **After** the pharmacist has received the physician-signed recommendation sheet, the processing technician is responsible for processing the order as written (for D10% or Clinimix or Kabiven).
  - The pharmacist is responsible for charting the resident's course of dosing and/or monitoring services in accordance with pharmacy policy.

Note: For information on infusion of TPN therapies please refer to Section 8 of the IV Policy and Procedure Manual found in the Resource Center of ViewMasteRx.

HAZARDOUS DRUG HANDLING

USP Chapter <800>: Hazardous Drug

Background:

USP General Chapter <800> provides standards for safe handling of hazardous drugs to minimize the risk of exposure to healthcare personnel, patients, and the environment. Standards are not enforceable until adopted by the appropriate state regulatory agencies. Facilities are recommended to check with local and state regulatory agencies to verify requirements for Hazardous Drug handling.

The National Institute for Occupational Safety and Health (NIOSH) considers a drug to be hazardous if it exhibits one or more of the following characteristics in humans or animals: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity, organ toxicity at low doses, genotoxicity. If a new drug is structurally similar to a drug on the NIOSH list, it will also be classified as hazardous.

USP General Chapter <800> describes requirements including responsibilities of personnel handling hazardous drugs, facility and engineering controls, procedures for deactivating, decontaminating and cleaning, spill control, and documentation. These standards apply to all healthcare personnel who receive, prepare, administer, transport or otherwise come in contact with hazardous drugs and all the environments in which they are handled (USP General).

Hazardous Drug Handling

- **Purpose:** To establish safe handling of hazardous drugs (HDs), promote patient safety, worker safety, and environmental protection. Handling HDs includes, but is not limited to, the receipt, storage, compounding, dispensing, administration, and disposal of sterile and nonsterile products and preparations. This system shall include policies and procedures to prevent the unintentional entry of HDs into the body due to the handling of HDs and/or touching contaminated surfaces.

- **Scope**: The facility must develop and maintain a health and safety management system which shall, at a minimum, include the following:
    1. List of Hazardous Drugs (HDs);
    2. Facility and engineering controls;
    3. Competent personnel;
    4. Safe work practices;
    5. Proper use of appropriate Personal Protective Equipment (PPE); and
    6. Policies for HD waste segregation and disposal

HAZARDOUS DRUG HANDLING

This policy applies to all healthcare personnel who handle HD preparations and all entities that store, prepare, transport, or administer HDs.

Procedures

A. List of Hazardous Drugs (HDs)
   1) The facility shall designate a responsible person who will act as "Program Director" and oversee the facility Hazardous Drug processes, procedures and personnel education.
   2) The facility, along with the consultant pharmacist, shall be responsible for determining which drugs will be included on the facility's list of HDs.
      a. The facility's list of HDs shall include any drugs identified as Category 1 drugs on the most current list of drugs established by the National Institute for Occupational Safety and Health (NIOSH) that the facility handles.
      b. Drugs identified in Categories 2 and 3 on the most current list of drugs defined by NIOSH, and final dosage forms of conventionally manufactured drugs that do not require any further manipulation other than administration are not required to be handled as specified in this section if the facility performs or adopts an assessment of risk (AoR) for the drug(s).
         1. The facility shall maintain documentation of any AoR of such drugs.
         2. AoRs must be reviewed annually and signed and dated by the Program Director.
   3) For a drug that enters the market after the most recent version of the NIOSH list is established, the facility shall evaluate the drug using the criteria found in the NIOSH list to determine whether the drug is to be added to the facility's list of HDs. If the information available on a drug is deemed insufficient to make an informed decision, the drug shall be considered hazardous until more information is available.

B. Occupational Safety and Hazard Communication Program
   1) The facility Program Director shall designate a qualified and trained personnel member or team to review and implement policies and procedures appropriate for the facility for the safe handling of HDs.
   2) The designated person or team must thoroughly understand:
      a. Risk prevention policies
      b. Risks to individuals
      c. Risk of noncompliance; and
      d. Responsibility to report potentially hazardous situations to appropriate parties
   3) All personnel who handle HDs are responsible for understanding and implementing the practices and precautions outlined in this policy and

HAZARDOUS DRUG HANDLING

procedure and must document this understanding by signing a Hazardous Drug Risk Acknowledgement.

C. Designation of HD areas
   1) HDs that are appropriately packaged and designated as hazardous, not requiring any additional manipulation beyond administration to a patient, can be stored with other drugs in a shared storage space if the facility deems this appropriate in the facility policy and procedures for drug storage and as allowed by local, state and federal regulation.
   2) Designated areas must be available if administration of a HD requires manipulation (e.g. cutting, crushing, or mixing) in order to minimize patient and worker exposure. HDs that have been determined through an AoR to have negligible risk may continue to be crushed in a contained system using proper manufacturer's procedures on the medication cart positioned in the hallway.

D. Personal Protective Equipment
   1) General
      a. Appropriate PPE must be worn when handling HDs in keeping with the AoR during:
         i. Receipt
         ii. Storage
         iii. Transport
         iv. Compounding (sterile and nonsterile)
         v. Administration
         vi. Deactivation/decontamination, cleaning and disinfecting
         vii. Spill control; and
         viii. Waste disposal
      b. Reusable PPE must be decontaminated and cleaned after use.
      c. The facility must describe the appropriate PPE to be worn based on its occupational safety plan and AoR performed for each HD
      d. The use of PPE is based on the risk of exposure and activities performed when handling each HD and should be provided to all personnel.
      e. All PPE worn when handling HDs shall be considered to be contaminated with, at minimum, trace quantities of HDs.
      f. PPE must be placed in an appropriate waste container and further disposed of per local, state, and federal regulations.
      g. PPE worn during HD manipulation shall be disposed of in the proper waste container before leaving designated HD area.
   2) Gloves
      a. When chemotherapy gloves are required, they must meet American Society for Testing and Materials (ASTM) standard D6978 (or its successor).

HAZARDOUS DRUG HANDLING

b. Chemotherapy gloves must be powder-free because powder can contaminate the work area and can adsorb and retain HDs.
c. Gloves must be inspected for physical defects, such as pin holes or weak spots, before each use. Defective gloves shall not be used.
d. Hands should be washed with soap and water after removing gloves.

3) Gowns
   a. When gowns are required, they must be disposable and shown to resist permeability by HDs.
   b. Gowns must be selected based on the HDs handled.
   c. Gowns must close in the back (i.e., no open front), be long sleeved, and have closed cuffs that are elastic or knit.
   d. Gowns must not have seams or closures that could allow HDs to pass through.
   e. Washing of non-disposable clothing contaminated with HD residue shall only be done according to facility policy as drug residue may be transferred to other clothing.
   f. Potentially contaminated clothing must not be taken home under any circumstances.
   g. Gowns must be changed per the manufacturer's information for permeation of the gown. If no permeation information is available for the gowns used, change them every 2–3 hours or immediately after a spill or splash.
   h. Gowns worn in HD handling areas must not be worn to other areas in order to avoid spreading HD contamination and exposing other healthcare workers.
4) Eye and face protection
   a. Appropriate eye and face protection must be worn when there is a risk for spills or splashes of HDs or HD waste materials.
   b. Goggles must be used when eye protection is needed. Eyeglasses alone or safety glasses with side shields do not protect the eyes adequately from splashes.
   c. Face shields in combination with goggles provide a full range of protection against splashes to the face and eyes. Face shields alone do not provide full eye and face protection.
   d. All requirements in the Occupational Safety and Health Administration (OSHA) respiratory protection standard (29 CFR 1910.134) shall be followed.

E. Hazardous Communication Program
1) The facility must implement a Hazardous Communication Program that must include:
   a. Identification method of HD
   b. How to accesses a Safety Data Sheet (SDS) and AoR for each HD

HAZARDOUS DRUG HANDLING

c. Process for notification and training to personnel who may be exposed to HD when working
d. Confirmation documented and maintained by the facility, for personnel of reproductive age that they understand the risks of handling HDs (see Hazardous Drug Risk Acknowledgement)
e. PPE needed for administering hazardous drugs to patients
f. Identification of potential cleaning requirements associated with spills and disposal

F. Personnel training
1) All personnel who handle HDs must be trained based on their job functions including the receipt, storage, compounding, repackaging, dispensing, administering, and disposing of HDs.
2) Training must occur before the employee independently handles HDs. All trained employees must sign the Hazardous Drug Risk Acknowledgement.
3) Employees who handle or come into contact with HDs will be evaluated for competency in the specific HD handling techniques which apply to their job.
4) Personnel competency must be reassessed at least every 12 months.
5) Personnel must be trained prior to the introduction of a new HD or equipment and prior to a new or significant change in process or SOP.
6) All training and competency assessment must be documented. The training must include at least the following:
a. Overview of facility's list of HDs and their risks
b. Review of the facility's SOPs related to handling of HDs
c. Proper use of PPE
d. Proper use of equipment and devices
e. Response to known or suspected HD exposure
f. Spill management
g. Proper disposal of HDs and trace-contaminated materials

G. Receiving
1) HDs shall be received from the pharmacy or alternate supplier in closed, packaging and can be placed with other non-hazardous medications if AoRs and processes are adopted to support this method and it is in compliance with local, state and federal laws and regulations.

H. Administering
1) The facility should provide all PPE needed and monitor use according to established policies and procedures that minimize employee and patient exposure

I. Deactivating, decontaminating, cleaning and disinfecting
1) All areas where HDs are handled and all reusable equipment and devices must be deactivated, decontaminated, and cleaned.

HAZARDOUS DRUG HANDLING

a. The facility shall use procedures for decontamination, deactivation, and cleaning HD areas per manufacturer's specifications and in compliance with local, state and federal laws and regulations. These procedures must be readily accessible to personnel.
    i. Written procedures for cleaning must include procedures, agents used, dilutions (if used), frequency, and documentation requirements.
b. All personnel who perform deactivation, decontamination, cleaning, and disinfection activities in HD areas must be trained in appropriate procedures to protect themselves and the environment from contamination.
    i. The products used must be compatible with the surface material.
    ii. Agents used for deactivation, decontamination, and cleaning shall be applied through the use of wipes wetted with appropriate solution and not delivered by a spray bottle to avoid spreading HD residue.
c. All personnel performing these activities must wear appropriate PPE resistant to the cleaning agents used as outlined in the facility policy.
    i. Eye protection and face shields should be used if splashing is likely
d. If warranted by the activity, respiratory protection may be used.
e. The deactivating, decontaminating, cleaning, and disinfecting agents selected must be appropriate for the type of HD contaminant(s), location, and surface materials.
f. All disposable materials must be discarded to meet local, state, and federal regulations, including Environmental Protection Agency (EPA) requirements regarding hazardous waste disposal as well as any other facility policies
g. Cleaning shall be performed in areas that are sufficiently ventilated.

2) Disposal of all HD waste, including, but not limited to, unused HDs and trace-contaminated PPE and other materials, must comply with all applicable local, state and federal laws and regulations.

J. Spill control

1) All personnel who may be required to clean up a spill of HDs must receive proper training in spill management and the use of PPE and cleaning equipment.
2) Spills must be contained and cleaned immediately only by qualified personnel with appropriate PPE. Qualified personnel must be available at all times while HDs are being handled.
3) Signs must be available for restricting access to the spill area.

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4) Spill kits containing all of the materials needed to clean HD spills must be readily available in all areas where HDs are routinely handled.
5) If HDs are being prepared or administered in a non-routine healthcare area, a spill kit must be available.
6) All spill materials must be disposed of as hazardous waste.
7) The circumstances and management of spills must be documented.
8) The facility should develop a policy for handling personnel who are potentially exposed during the spill or spill clean-up or who have direct skin or eye contact with HDs.
9) Non-employees exposed to an HD spill shall follow facility policy, which may include reporting to the designated emergency service for initial evaluation and completion of an incident report or exposure form.

Definitions:

- Assessment of risk: Evaluation of risk to determine alternative containment strategies and/or work practices.
- Cleaning: The process of removing soil (e.g., organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products.
- Compounded preparation: A nonsterile or sterile drug or nutrient preparation that is compounded in a licensed pharmacy or other healthcare-related facility in response to or anticipation of a prescription or a medication order from a licensed prescriber.
- Compounding personnel: Individuals who participate in the compounding process.
- Deactivation: Treatment of an HD contaminant on surfaces with a chemical, heat, ultraviolet light, or another agent to transform the HD into a less hazardous agent.
- Decontamination: Inactivation, neutralization, or removal of HD contaminants on surfaces, usually by chemical means.
- Doff: To remove PPE.
- Don: To put on PPE.
- Disinfection: The process of inhibiting or destroying microorganisms.
- Engineering control: Primary, secondary, and supplemental devices designed to eliminate or reduce worker exposure to HDs.
- EPA-registered disinfectant: Antimicrobial products registered with the Environmental Protection Agency (EPA) for healthcare use against pathogens specified in the product labeling.
- Final dosage form: Any form of a medication that requires no further manipulation before administration.
- Goggles: Tight-fitting eye protection that completely covers the eyes, eye sockets, and facial area that immediately sur-rounds the eyes. Goggles provide protection from impact, dust, and splashes. Some goggles fit over corrective lenses.
- Hazardous drug (HD): Any drug identified by at least one of the following criteria:
    - Carcinogenicity, teratogenicity, or developmental toxicity

HAZARDOUS DRUG HANDLING

  - Reproductive toxicity in humans
  - Organ toxicity at low dose in humans or animals
  - Genotoxicity or new drugs that mimic existing HDs in structure or toxicity
- Personal protective equipment (PPE): Items such as gloves, gowns, respirators, goggles, face shields, and others that protect individual workers from hazardous physical or chemical exposures.
- Repackaging: The act of removing a product from its original primary container and placing it into another primary container, usually of smaller size.
- Safety data sheet (SDS): An info Safety data sheet (SDS): An informational document that provides written or printed material concerning a hazardous chemical. The SDS is prepared in accordance with the HCS [previously known as a Material Safety Data Sheet (MSDS)].
- Spill kit: A container of supplies, warning signage, and related materials used to contain the spill of an HD.
- Standard operating procedure (SOP): Written procedures describing operations, testing, sampling, interpretation of results, and corrective actions that relate to the operations that are taking place.

References	
Federal: Regulatory Reference	United States Pharmacopeia (USP) Chapter <800>
Federal: Survey Tag Numbers	F759/F760
State	Reference State Regulations
Related Documents	National Institute for Occupational Safety and Health (NIOSH), CDC
Policy Revised	Date: _____ By: _____ Date: _____ By: _____ Date: _____ By: _____ Date: _____ By: _____

12.4 COLLECTION RECEPTACLES FOR MEDICATION DISPOSITION-MEDSAFE

Use of Collection Receptacles will be in Accordance with Both State and Federal Regulations.

1. Collection Receptacles- Medsafe

a. Pharmacies will request modification of their DEA registration to be authorized Collectors per State and Federal requirements including the facility location of the receptacle.

b. Only those controlled substances listed in Schedule II, III, IV, or V that are lawfully possessed by the resident may be collected. Controlled and non-controlled substances may be collected together and be comingled, although comingling is not required.

c. Only the following may dispose of controlled substances in the medication receptacle:
   1) Resident for whom the controlled substance is prescribed
   2) Facility Staff authorized by the state to dispose of controlled substances on behalf of the resident
   3) Any persons lawfully entitled to dispose of the resident's or decedent's property (family member, attorney, etc.)

   Note the employee of the pharmacy is not allowed to dispose of controlled substances on behalf of the resident under any circumstances.

d. Once a substance has been deposited into a collection receptacle, the substance shall not be counted, sorted, inventoried, or otherwise individually handled.

e. Once an item has been disposed of in the receptacle, then it may not be removed, even if accidently deposited, by anyone other than law enforcement.

f. **At a long-term care facility**: A collection receptacle shall be located:
   1) In a locked, controlled access room; OR
   2) If the receptacle is located in a secured, publicly accessible area then it must be regularly monitored by long term care staff.

g. A controlled substance collection receptacle shall meet the following design specifications:
   1) Be securely fastened to a permanent structure so that it cannot be removed;
   2) Be a securely locked, substantially constructed container with a permanent outer container and a removable inner liner;
   3) The outer container shall include a small opening that allows contents to be added to the inner liner, but does not allow removal of the inner liner's contents;
   4) The outer container shall prominently display a sign indicating that only Schedule II-V controlled and non-controlled substances, if a collector chooses to comingle substances, are acceptable substances (Schedule I controlled substances,

controlled substances that are not lawfully possessed by the ultimate user, and other illicit or dangerous substances are not permitted); and

5) The depository door is to be locked if there is no staff to monitor the receptacle that is publicly accessible or if the inner liner is full and unable to be removed.

2. Receptacle Installation and Keys

a. Sharps Compliance will ship Receptacle directly to Facility. One Liner will be included.

b. Facility will be responsible for selecting location and installing by mounting to floor or wall per section 1.5 above.

c. The MedSafe receptacle will have 6 keys
   1) Two (2) keys are for the depository drop-down door. These keys are to be kept by supervisory level employees at the Facility (DON, Administrator, etc.).
   2) Two (2) padlocks with keys two (2) keys each will be in the inner liner that is shipped with the MedSafe. These are for the bottom MedSafe Door. The Facility is to keep the keys to the top padlock (with stamped "T" on the back) and provide the keys to the second lock (with stamped "U" on the back) to the Pharmacy.
   3) Pharmacy is to maintain their key to the locked receptacle. The key should be kept in a safe place with knowledge of only the Pharmacy Director, PIC, or other associates as determined by Pharmacy Director. The Pharmacy Director may also assign the Consultant Pharmacist as the contact to maintain key.

3. Disposing of Medications in the Collection Receptacle- Controlled Substances

a. When disposing of such controlled substances by transferring those substances into a collection receptacle, such disposal shall occur immediately, **but no longer than three business days** after the discontinuation of use by the resident/ ultimate user. Discontinuation of use includes a permanent discontinuation of use as directed by the prescriber, as a result of the resident's transfer from the long-term care facility, or as a result of death.

b. The following persons in lawful possession of a controlled substance in Schedules II, III, IV, or V may dispose of medications for the purpose of disposal as follows:
   1) An ultimate user (resident) in lawful possession of a controlled substance;
   2) Any person lawfully entitled to dispose of a decedent’s property if that decedent was an ultimate user who died while in lawful possession of a controlled substance; and
   3) A long-term care facility on behalf of an ultimate user who resides or resided at such long-term care facility and is/was in lawful possession of a controlled substance.

c. Disposition of Controlled Medication into the receptacle should only be completed by two staff as authorized by the state. Upon discontinuation of a patient's controlled substance medication, two authorized staff must document the removal of the patient's

dangerous drugs from the medication cart or storage area and record the transfer of the drugs to the medication receptacle (MedSafe).

d. The record of the controlled substances removed from the medication cart, or other area of storage, for disposal shall be made on a controlled substance proof-of-use sheet.

e. Two authorized staff are required to deposit controlled medications into the depository door. Liquids should be placed in a ziplock bag. See below for additional information.

f. Once a substance has been deposited into a collection receptacle, the substance shall not be counted, sorted, inventoried, or otherwise individually handled. If a substance needs removed from the receptacle prior to sealing the liner, it must be done by law enforcement

4. Receptacle Liners - Responsibilities of Pharmacy and Facility/Community

a. An inner liner shall meet the following requirements:
   1) The inner liner shall be waterproof, tamper-evident, and tear-resistant;
   2) The inner liner shall be removable and sealable immediately upon removal without emptying or touching the contents;
   3) The contents of the inner liner shall not be viewable from the outside when sealed;
   4) The size of the inner liner shall be clearly marked on the outside of the liner (e.g., 5-gallon, 10-gallon, etc.); and
   5) The inner liner shall bear a permanent, unique identification number that enables the inner liner to be tracked.

b. The inner liner shall be sealed immediately upon removal from the permanent outer container and the sealed inner liner shall not be opened, x-rayed, analyzed, or otherwise penetrated.

c. The installation, removal, transfer, and storage of inner liners shall be performed either:
   1) By or under the supervision of one employee of the authorized collector (Employee of the Pharmacy) and one supervisor-level employee of the long-term care facility (e.g., a charge nurse or supervisor) designated by the authorized collector; or
   2) By or under the supervision of two employees of the authorized collector (Pharmacy).

d. The MedSafe receptacle will arrive at the Facility with a liner ready to use.
   1) Replacement liners should be ordered on demand by contacting Sharps Compliance:
   Edniecia Rogers
   Key Account Representative
   Office: 800-772-5657
   Direct: 770-726-9152
   Email: erogers@sharpsmws.com

2) When the Facility receives a new liner, they should contact the Pharmacy or consultant pharmacist to schedule their visit to unlock the MedSafe for liner removal.
3) Once the Facility knows when Pharmacy is scheduled to be at the Facility, the facility will schedule a pick-up by calling Sharps Compliance directly at 800-772-5657, or via the following link, https://upspickup.sharpsinc.com

e. The Facility should let the front desk know that UPS is coming and be prepared to instruct UPS as to where the liner is.

f. As the liner is jointly being sealed, the Facility and the Pharmacy should keep a record of the UPS tracking # of the liner being returned. This will help verify pick-up, transfer and delivery of the sealed, returned liner back to Sharps

g. Upon removal, sealed inner liners may only be stored at the long-term care facility for up to three business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer to UPS carrier for delivery to Sharps Compliance Inc for incineration.

h. Pharmacy will receive login for online portal to view shipment calendar, access tracking, reporting and proof of destruction of MedSafe liners. Sharps Tracer will show date received at the destruction facility, weight, condition and proof of destruction.

i. See video https://player.vimeo.com/video/116675520 with instruction on how liner will arrive and video on how to replace liner.

j. Documentation of the change in liner should be completed on the provided Destruction log (Inner Liner Step Log) to include required DEA information (new log provided with each new liner. **Pharmacy should retain log and provide copy to community for their records.**

k. Sharps Compliance will periodically provide reports listing all liners that have been shipped to a facility and if they have been returned to Sharps for incineration. Consultant Pharmacists should use this report to reconcile the liners that are in the Binder to ensure unused liners are accounted for and that returned liners have been accounted for. Any missing unused liners should be reported to Consultant Supervisor. Any returned liners that do not document receipt by Sharps Compliance should be reported to Pharmacy Director and Consultant Pharmacist Supervisor immediately to determine next steps including contacting local authorities and Sharps Compliance.

l. **Sharps Compliance to obtain and maintain DOT Permit 20284 Common Carrier Special Permit.** A copy of the DOT Special Permit is required to be kept on-site at the generation facility. A copy is sent with every inner liner though the community only needs to keep a single copy on hand and not every copy sent to them. Recommend keeping the current copy in your MedSafe Binder.

5. Documentation Binder and Inner Liner Step Log

The following process is recommended to insure necessary documentation is readily available for any inspections.

a. Facility to maintain a Binder for MedSafe Inspections. Recommend dividing the binder into 4 sections to show status of each liner at any given time:
   1) **Delivered /Awaiting Use**
      a) Maintain **MedSafe Liner Receipt Log** documenting each Date a liner is delivered and Liner Number
      b) Place a copy of **MedSafe Liner Step Log** with Date Delivered, Liner Number and location address completed in this section until you are ready to use the liner. Move the Step log into the appropriate section of the binder with
   2) **In Use**
   3) **Awaiting UPS/ In Storage**
   4) **Destruction Process Complete**
      a) Pharmacy will keep the completed Step Log when Liner is shipped with UPS and Provide a copy for facility to keep on file.
      b) Pharmacy staff/ consultant pharmacist should send the completed original step log to the Pharmacy Director to complete verification of destruction process and maintain on file.

b. Other items to keep in Documentation Binder:
   1) Med Safe Details
   2) Copy of **MedSafe Policy and Procedure** and **MedSafe Customization page**
   3) Copy of Department of Transportation Permit from Medsafe supplied with each liner (keep most current copy)

   While they do not need to be stored in this binder, recommend having Disposal documentation on facility Perpetual Inventory Sheets readily available.

c. **Liner Step Log Documentation**
   1) Installation:
      a) Receipt and Installation dates, Liner number and address
      b) Pharmacy Registration number
      c) Names and signatures of 2 Employees
      (Two pharmacy employees or One pharmacy employee and One Supervisory Nurse)
   2) Removal:
      a) Date removed and Sealed
      b) Names and Signatures of 2 Employees
      (Two pharmacy employees or One pharmacy employee and One Supervisory Nurse)
   3) Storage (transfer to storage)
      a) Date transferred to storage

b) Names and Signatures of 2 Employees
(Two pharmacy employees or One pharmacy employee and One Supervisory Nurse)

4) Destruction (Shipped for Destruction)
   a) Date liner transferred/ shipped for destruction
   b) Names and Signatures of 2 Employees
   (Two pharmacy employees or One pharmacy employee and One Supervisory Nurse)

Reference: Medications that Can Be Placed into MedSafe and Personnel

1. **Who May Dispose of Medications into MedSafe:**
   a. Ultimate Users – those whom the medication was prescribed
   b. Any person lawfully entitled to dispose of a decedent's property
   c. LTCF staff may dispose of meds ON BEHALF of their resident or former resident
2. **What Medications May Be Placed into MedSafe in Original Containers:**
   a. OTC medications
   b. Non-controlled prescription medications
   c. Controlled Substances Schedule II – V
   d. Liquid Medicines sealed in Original Containers up to 4oz in zip lock baggie with paper towel.
      1) If greater than 4oz, split into two containers, seal and zip lock baggie with paper towel.
   e. P-Listed and U-Listed (e.g. Coumadin and Warfarin) disposal in MedSafe is dependent on states' adoption of the EPA regulations.
   f. This Includes
      1) Pills, tablets, capsules
      2) Ointments
      3) Creams
      4) Lotions
      5) Powders
3. **What Medications MAY NOT Be Placed into MedSafe:**
   a. Illegal / Illicit Drugs (Schedule I)
   b. No batteries, mercury containing devices or medical devices
   c. No needles / syringes or sharps containers
   d. No aerosol cans / gas inhalers or chemicals -
   e. No liquid chemotherapy drugs

4. **Disposal of Inhalers:**
   a. Empty inhalers (gas or dry powder) can be put into the trash (solid waste).
   b. Partially filled dry powder inhalers may be placed in the Collection Receptacle.
   c. Partially filled gas inhalers MAY NOT BE placed in the Collection Receptacle
      1) Partially filled gas inhalers have a separate collection device.

Use of Collection Receptacles for Hazardous Waste Pharmaceuticals

1. Use for HWP must be in accordance with State Regulation and Adoption of 2019 EPA HWP Management Rule
2. Only applies to SNFs. Per EPA, ALFs are not medical facilities, therefore disposal of HWP falls under RCRA household hazardous waste exemption and all meds may be disposed of in collection receptacles **EXCEPT** inhalers.
3. SNFs must qualify as VSQGs in order to utilize MedSafe for disposal of HWPs:
   a. IF SNF has < 20 beds, they are automatically a VSQG – no documentation required. Some states have not adopted this and require all communities to prove generator status if allowed per state regulation.
   b. IF SNF has > 20 beds, then have to prove your monthly HW generation falls within the VSQG limits – cannot have more than 2.2 lbs (1 kg) of P-listed waste on-site per 30-day period (approx. 447 Coumadin pills).
4. EPA believes 99% of all SNFs are VSQG regardless of bed number.

SAMPLE OF DOT PERMIT PROVIDED BY SHARPS COMPLIANCE:

October 29, 2018

U.S. Department of Transportation

Pipeline and Hazardous Materials Safety Administration

DOT-SP 20284
(SECOND REVISION)

EXPIRATION DATE: 2022-09-30

(FOR RENEWAL, SEE 49 CFR 107.109)

1. GRANTEE: Sharps Compliance, Inc. of Texas
Houston, TX

2. PURPOSE AND LIMITATIONS:

a. This special permit authorizes the manufacture, mark, sale and use of non-DOT specification packaging for the transportation in commerce of certain materials authorized to be disposed of under 21 CFR Part 1317, Subpart B. This special permit provides no relief from the Hazardous Materials Regulations (HMR) other than as specifically stated herein. The most recent revision supersedes all previous revisions.

b. The safety analyses performed in development of this special permit only considered the hazards and risks associated with transportation in commerce. The safety analyses did not consider the hazards and risks associated with consumer use, use as a component of a transport vehicle or other device, or other uses not associated with transportation in commerce.

c. In accordance with 49 CFR 107.107(a) party status may not be granted to a manufacturing permit. These packagings may be used in accordance with 49 CFR 173.22a.

3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180.

4. REGULATIONS FROM WHICH EXEMPTED: 49 CFR Parts 171-180, except as specified herein.

Storage of Ophthalmic Products Facility-Specific Policy

Facility Name: _____

The following guidelines for storage of Ophthalmic Products (Solutions, Suspensions, Ointments) shall be followed:

☐ Manufacturer's Guidelines for expiration should be followed.

☐ When no shortened expiration date is listed by the manufacturer, the facility will follow the policy listed below:

Once the ophthalmic product (solution, suspension, ointment) is opened, the date opened shall be added to the product and the expiration of such product shall be _____ days after the open date.

Represented by:

Administrator _____ Date: _____

Director of Nursing: _____ Date: _____

Medical Director: _____ Date: _____

Consultant Pharmacist: _____ Date: _____