A. Policy Statement

Each State operated psychiatric facility shall have a fully operational OMH pharmacy, licensed by the State Education Department, which is compliant with applicable laws, rules and regulations. The operation of the pharmacy shall be directed by a Pharmacy Manager, a full-time New York State licensed and registered pharmacist.

The pharmacy plays an important role in helping patients achieve their therapeutic goals by promoting a safe medication use process that ensures optimal selection of medications, dose, dosage form, frequency, route, duration of therapy and that substantially reduces or eliminates adverse drug events and duplication of treatment. The purpose of this policy directive is to identify the major principles and practices that facilitate the provision of quality pharmaceutical care for patients and to ensure a safe and efficient program for the distribution of medication. This directive also contains provisions intended to address the storage and administration of medications in residential and outpatient programs.
This policy directive does *not* apply to:

- Department of Correctional and Community Services (DOCCS) based pharmacy services, which are subject to the provisions of a Memorandum of Agreement between OMH and DOCCS.

B. Relevant Statutes and Standards

Code of Federal Regulations, Title 21 Sections 1301-1316
Education Law, Article 130 General Provisions
Education Law, Article 137 Pharmacy
Public Health Law, Article 33 Controlled Substances Therapeutic Research Act
8 NYCRR Part 3, State Education Department
8 NYCRR Part 16, Rules Relating to Attendance
8 NYCRR Part 28, Proceedings to Determine Good Moral Character and to Evaluate Prior Disciplinary History for Authorization to Practice the Licensed Professions
8 NYCRR Part 29, Unprofessional Conduct
8 NYCRR Part 59, General Provisions
8 NYCRR Part 63, Pharmacy and Registered Pharmacy Technicians
10 NYCRR Part 80, Rules and Regulations on Controlled Substances
14 NYCRR Part 524, Incident Management Programs
The Institute for Safe Medication Practices, http://www.ismp.org/
The Joint Commission, Comprehensive Accreditation Manual for Hospitals,

Public Officers Law Section 74, Code of Ethics
OMH Official Policy Manual, QA-510, Clinical Risk Management and Incident Management Plans OMH Official Policy Manual, PC-605, Emergency Medical Services System
OMH Official Policy Manual OM-740, Record Retention
Guidelines: Adverse Drug Reaction Monitoring and Reporting Overview (Appendix A)

C. Definitions

1. Administration of Medication means the act of identifying and removing an individual dose from a previously dispensed, properly labeled container, verifying it with the prescriber's order, giving the individual dose to the proper patient, promptly recording the time, dose, and initials of the person giving the dose, and documenting verification of ingestion of oral doses.

2. Adverse Drug Reaction means any response to a medication that is unintended, undesired, unexpected or excessive, and that occurs at doses normally used in patients for prophylaxis, diagnosis or therapy of disease, or for the modification of physiologic function.[1] Such a response is considered a Severe Adverse Drug Reaction if it:

    a) results in transfer to an emergency room, admission to a medical facility or a longer hospital stay;
    b) requires intervention to prevent permanent impairment,
    c) results in permanent disability,
    d) results in congenital anomaly
    e) is life threatening, or
    f) results in death.

3. Dispensing means the practice by a New York State licensed pharmacist or physician of interpreting, evaluating, and implementing of a prescription medication order, including the preparation and delivery of a medication or device to a patient or a patient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient.

4. Drug Monitoring Committee (DM) means a facility committee established to review quality and trends related to individual and facility wide prescribing practices, develop guidelines for medication use, and identify performance improvement opportunities and the need for educational programs.

5. Drug Monitoring means a manual or electronic documentation method used by each facility to monitor patients on medication regimens or doses of medication that fall outside of agency or facility guidelines.

[1] See Appendix A of this policy directive for details.

6. Investigational Drugs means medications which have not been released or approved by the Federal Food and Drug Administration (FDA) for general use.

7. Medication Error means any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling; packaging and nomenclature; compounding; dispensing; distribution; administration; education; monitoring and use.[2]

8. Good Catch means an unplanned event that did not result in injury, illness, or damage to the patient but had the potential to do so. An example is a medication event that did not reach the patient/recipient.

9. Medication Information Specialist is a person employed by a pharmaceutical or pharmacy equipment vendor for the following purposes:

    a) developing and maintaining a relationship with medical leaders for the purpose of providing research and educational information to clinicians;

    b) to provide literature searches, presentations, and continuing education activities to clinicians.

    c) to conduct and participate in clinical trials, and provide scientific support for company products.

10. Medical Service (Pharmaceutical Sales) Representative is a pharmaceutical sales representative, i.e., a person employed by a pharmaceutical or pharmacy equipment vendor for the following purposes:

    a) visiting health care professionals and presenting information on new products and new FDA approved uses for old products;

    b) to provide information on patient assistance programs and provide samples as appropriate; and

    c) developing and implementing clinical sales presentations for both health care professionals and the general public in health fairs and support groups.

11. Medications or Pharmaceuticals means drugs intended for use in the diagnosis, alleviation, treatment or prevention of illness.

[2] The term "medication error" is defined according to the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP), 2012 National Coordinating Council for Medication Error Reporting and Prevention, all rights reserved.

12. New York State Licensed Pharmacist means an individual who is currently licensed as a registered pharmacist by the New York State Education Department.

13. Pharmaceutical Care means the direct responsible provision of medication-related care for the purpose of achieving definite outcomes that improve a patient's quality of life while minimizing patient risk.[3]

14. Pharmacokinetics means the characteristic interactions of a drug and the human body in terms of its absorption, distribution, metabolism, and excretion.

15. Pharmacy Aide means an unlicensed person who performs duties under the direct supervision of a pharmacist as permitted by law and regulation.

16. Pharmacy and Therapeutics Committee (P&T) means a facility committee established to serve an administrative, advisory, and educational role in clinical matters related to pharmaceuticals.

17. Pharmacy Intern is an individual who currently holds a valid New York State pharmacy intern certificate and performs pharmacist duties under the close supervision of a pharmacist, while completing pharmacy school or pending licensure.

18. Registered Pharmacy Manager means a managerial New York State Civil Service title for a New York State licensed and registered pharmacist who is responsible for supervising all pharmacy staff, overseeing the general operation of the facility pharmacy, and developing and issuing policies and procedures.

19. Registered Pharmacy Supervisor means a supervisory New York State Civil Service title for a New York State licensed and registered pharmacist who is responsible for maintaining pharmacy standards and supervising pharmacists and other staff of the facility pharmacy.

20. Prescriber means an individual authorized by law to order the use of medications or devices for the diagnosis, alleviation, treatment, or prevention of illness, relative to thier practice (e.g. physician, dentist, physician's assistant, nurse practitioner).

21. Protected Health Information (PHI) means individually identifiable information relating to past, present or future physical or mental health or condition of an individual, provision of health care to an individual, or the past, present or future payment for health care provided to an individual.

22. Supervising Pharmacist means full time (employed for more than 30 hours per week) New York State licensed and registered pharmacist employee whose name appears on the New York State Pharmacy Registration to fulfill New York State Board of Pharmacy requirements.

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[3] Further information. (https://www.ashp.org/-/media/assets/policy-guidelines/docs/statements/pharmaceutical-care.ashx )

23. Telephone Order means the communication of a medication order by telephone from an authorized prescriber to an authorized nurse or registered pharmacist. Use of a telephone order is limited to circumstances where the patient's medical needs necessitate care and should not be delayed until the prescriber is available on the unit to write orders. A registered pharmacist may receive a clarification from an authorized prescriber via the telephone.

24. Unit Dose System means a pharmacy-controlled method of dispensing medications that are contained in, and administered from, single unit or unit-dose packages.

25. Verbal Order means the face-to-face communication of a medication order by an authorized prescriber directed to and in the presence of an authorized nurse during an emergency.

D. Body of the Directive

This policy directive consists of thirteen components:

1. Administrative Requirements for the Facility Pharmacy
2. Pharmacy Management and Staff Requirements
3. Procurement, of Pharmaceuticals
4. Storage, Preparation and Disposal of Pharmaceuticals
5. Dispensing Pharmaceuticals
6. Administration of Pharmaceuticals
7. Medications Brought to the Facility by Patients
8. Investigational Drugs (FDA Non-approved)
9. Infection Control in the Pharmacy
10. Education and Training
11. Documentation and Reporting
12. Monitoring and Medication Safety
13. Medication Use Committees

**1) Administrative Requirements for the Facility Pharmacy**

(a) *Licensure*

i. The facility's pharmacy must be currently licensed and registered with the State Board of Pharmacy, State Bureau of Narcotics Enforcement and the Federal Drug Enforcement Agency (DEA). If the facility is involved in pharmaceutical alcohol distribution, a license and registration must also be on file with the Federal Bureau of Alcohol, Tobacco and Firearms.

ii. To fulfill requirements for licensure of the facility pharmacy, the Pharmacy Manager in each facility, as well as any pharmacy supervisors or staff pharmacists, must be currently licensed and registered as pharmacists by the New York State Education Department.

iii. The name of the Supervising Pharmacist must appear on the facility pharmacy license.

(b) *Pharmacy Management*

The Supervising Pharmacist is responsible for developing, supervising, and coordinating all the activities of the pharmacy service. The Pharmacy Manager generally serves as the Supervising Pharmacist for purposes of the requirements of the State Board of Pharmacy (Education Law Section 6808 and 8 NYCRR Section 63.6).[4]

(c) *Support*

To support the professional and administrative functions of the facility pharmacy, sufficient space, sufficient personnel, equipment, supplies and clerical services shall be provided.

(d) *Provision of Pharmaceutical services.*

i. Pharmacy staff must be sufficient in types, numbers, and training to provide quality services. To ensure that pharmaceutical services are adequately available to meet the needs of facility patients, each facility pharmacy shall provide services for at least one shift per weekday. Weekend staffing shall be scheduled as necessary to accommodate the pharmaceutical needs of patients, provided, however, that each facility pharmacy shall provide for no more than one shift per weekend day.

ii. To meet emergency or other pharmaceutical service needs when the pharmacy is closed or a pharmacist is not available, each facility must have an arrangement to provide emergency pharmacy services, as determined by the needs of patients and as specified by facility clinical leadership. The arrangement may include approaches such as an after- hours medication cabinet, extra service, flexible scheduling, contracts with pharmacies that are open 24 hours a day, or the maintenance of an automated dispensing device such as a Pyxis® machine that contains a limited subset of formulary medication.

iii. Pharmaceutical services must be administered in accordance with accepted professional principles, including compliance with applicable Federal and State laws, regulations, and Office of Mental Health guidelines.

[4] For purposes of compliance with regulations of the Center for Medicare and Medicaid Services, any professional, competent, licensed and registered pharmacist who is thoroughly knowledgeable about facility pharmacy practice and management at the facility can serve as the Supervising Pharmacist.

**2) Pharmacy Management and Staff Requirements**

(a) *General Requirements for Pharmacy Staff*

i. Each pharmacist on the staff of a facility must be currently licensed and registered as a pharmacist by the New York State Education Department.

ii. Pharmacists and pharmacy staff must perform their duties within the scope of their license and education.

iii. Facility pharmacists are responsible for all of the following:

(1) safely dispensing medication and other pharmaceuticals to all patients cared for by the facility in accordance with New York State and federal laws and regulations, and facility policy;

(2) providing input, including information regarding pharmacokinetic dosage calculation, interpretation of medication levels, optimization of medication dosage, and product selection;

(3) monitoring all medication regimens and bringing to the attention of the prescribers any clinically significant potential medication interactions or incompatibilities;

(4) making him/herself available to provide medication information for all facility patients and their care givers in accordance with applicable laws and regulations;

(5) maintaining accurate patient records;

(6) exerting appropriate control over all medications to prevent diversion, including maintaining accurate inventory records;

(7) assisting in supervising and directing ancillary pharmacy staff; and

(8) performing duties and responsibilities identified in the title of Pharmacist.

iv. All pharmacy staff must be, and remain, eligible to provide services for New York State Medicaid and Medicare.

(1) The Supervising Pharmacist must annually review restricted and exclusion lists provided by the Office of Medicaid Inspector General (OMIG) and the Office of Inspector General of the U.S. Dept. of Health & Human Services to verify pharmacy staff eligibility. (See: https://oig.hhs.gov/exclusions/index.asp).

(2) If a staff member's name appears on an exclusion list, necessary action shall be taken by the Facility Director or designee, in consultation with the facility human resource department and OMH Counsel's Office, to ensure such person does not perform excluded tasks until he or she is removed from the list(s).

(b) *Management of the Pharmacy*

i. Pharmacy Manager

Each facility shall have a Pharmacy Manager, as defined in this policy directive. The Pharmacy Manager serves as the leader of pharmacy staff and is the Director of the Pharmacy Department.

(1) The Pharmacy Manager is responsible for both short and long term planning, directing the services provided by the Pharmacy Department in collaboration with other departments, implementing and coordinating the pharmacy services with those of other departments, and directing the improvement of pharmacy services to the patients.

(2) The Pharmacy Manager sets standards for professional performance within the department and leads the department in carrying out its mission of providing quality pharmaceutical care which meets the patients' needs.

(3) The Pharmacy Manager is responsible for the appropriate procurement, storage, and preparation of all drugs, pharmaceutical chemicals, and vaccines, (unless otherwise provided in this policy directive).

(4) The Pharmacy Manager reports to the Clinical or Medical Director or executive staff as designated by the facility Executive Director. S/he will supervise the Pharmacy Supervisor (if the Pharmacy Manager is not also serving as the Pharmacy Supervisor) and all pharmacy staff.

(5) The Pharmacy Manager provides for pharmacy staff development and ensures staff are adequately trained and competent to perform their responsibilities. S/he ensures that all pharmacy staff complete all OMH mandated training as is required by the Bureau of Education and Workforce Development training grid.

(6) The Pharmacy Manager assesses staff, space and equipment necessary to provide high quality pharmaceutical services and will bring any perceived needs to the attention of the facility administration.

(7) The Pharmacy Manager and staff pharmacists, as consultant treatment team members, shall be available to confer with prescribers and other members of the treatment team on drug therapy issues, and participate in facility-wide

committees, as appropriate. The Pharmacy Manager will provide medication education for health care staff when requested or as needed.

(8) The Pharmacy Manager is expected to stay abreast of current trends in hospital pharmacy practice and to introduce and implement programs for the pharmacy that support state-of-the-art practice.

ii. Pharmacy Supervisor

(1) The Pharmacy Supervisor is responsible for supervising the day-to-day operations of the department, including delegating areas of responsibility to members of staff according to their qualifications and abilities, as well as reporting any concerns to the Pharmacy Manager.

(2) The Pharmacy Supervisor shall ensure that all pharmacy operations are in compliance with OMH and facility pharmacy policies and requirements regarding the handling of medications, including but not limited to ensuring that controlled substances are purchased, secured, distributed, and documented correctly and accurately as required by state and federal law.

(3) The Pharmacy Supervisor is responsible for maintaining an adequate medication supply and ensuring that medication storage areas throughout the facility are maintained according to professional standards.

**3) Procurement of Pharmaceuticals**

(a) Procurement of pharmaceuticals is the responsibility of the Pharmacy Manager, except at facility-operated dental clinics authorized to procure their own products by the facility Pharmacy and Therapeutics Committee.

(b) In cooperation with Central Supply staff and the facility business office, all medications and medical-surgical supplies, as available, must be purchased through the services of a Group Purchasing Organization and a Prime Vendor wholesaler in order to maximize both best purchase price and efficiency.

i. The Prime Vendor must utilize a computer ordering system and offer facilities a five day a week delivery service. Therapeutically equivalent generic drug products shall be purchased when available.[5]

ii. Ethics Requirements Related to Pharmaceutical Procurement

(1) Facility staff must abide by the State Ethics Laws, including the regulations of the Ethics Commission, with regard to the acceptance of gifts, meals, honoraria and reimbursement for travel related to official duties from

[5] The Office of General Services is the current contract holder for Group Purchasing and Prime Vendor services, which are available statewide to all state and local government health care facilities.

pharmaceutical and pharmacy equipment companies, which are "disqualified sources" for OMH employees.

(2) Gifts: In accordance with Public Officers Law Section 74 and Ethics Commission Advisory Opinion No. 94-16, no OMH employee, including pharmacists, may accept gifts of any value in any form (including but not limited to meals, goods, services, favors, or other remuneration from contractors, providers or other persons or entities) if it could reasonably be inferred that the gift was intended to influence or reward official action by the employee.

(3) Disqualified Source: The Ethics Commission has determined that pharmaceutical companies are disqualified sources for all OMH employees. A "disqualified source" means an individual or organization which is: regulated by, does business with, appears before or negotiates with OMH or any of its facilities; lobbies or has litigation adverse to OMH or any of its facilities; applies for or receives funds from OMH or any of its facilities; or contracts with OMH, any of its facilities or another agency when OMH receives the benefit of the contract. Under no circumstances may an employee accept gifts in any form which exceed $75 in value from a so- called "disqualified source."

(4) Honoraria and Travel Reimbursement: Unless specifically exempt pursuant to Ethics Commission regulations, employees may not accept honoraria (which includes travel for off-duty activities) or travel reimbursement related to official duties if the payment is funded directly or indirectly by a disqualified source.

(5) Employees should seek advice from Counsel's Office or the Ethics Commission in any instance where the propriety of a proposed activity is in question.

iii. Medical Service Representatives and Medical Information Specialists: These guidelines have been developed because of growing concern, nationally and internationally, about the potential conflict of interest between health care professionals and the pharmaceutical industry. While all relationships involve differing priorities and interests, the concern is that the duality of interests can become conflicts which compromise patient care, science, or the integrity of the field. While this duality has been recognized for many years, decreasing sources of other funding for research, educational and social activities have led many physicians and administrators to seek assistance from the pharmaceutical industry. In return, the pharmaceutical sales representatives may receive easy access to clinicians to promote new drugs.

(1) Medical Services Representatives/ Medical Information Specialists will not be permitted on any Office of Mental Health facilities grounds including

Psychiatric Centers, residential or outpatient programs, for the purpose of detailing or providing samples of pharmaceuticals.

(2) No OMH facilities or programs may accept pharmaceutical samples for distribution to patients.

(3) Medical Services Representatives/ Medical Information Specialists are not permitted to distribute educational or promotional materials on the grounds of any OMH facility or program either to healthcare providers or patients.

(4) Medical Services Representatives/ Information Specialists should not have individual meetings with Residents or other trainees.

(5) OMH facilities should not accept the provision of food from pharmaceutical company representatives.

(6) Promotional items (e.g., clocks, pens, notepads) shall not be distributed or displayed in OMH facilities or in facility-operated programs.

(7) All requests for drug information from manufacturers should go through the pharmacy manager.

(8) All educational programs should receive prior approval from the Clinical Director, Education and Training Department and/or the Pharmacy Director as appropriate, and be CME approved and screened for relevance. Facilities should fund Continuing Medical Education Programs through the OMH Bureau of Psychiatric Services and Research Institute Support, and not from pharmaceutical company support.

(9) Facility staff members are obliged to abide by the New York State Ethics Laws including regulations of the Ethics Commission, regarding acceptance of gifts and honoraria from pharmaceutical and pharmacy equipment companies.

**4) Storage, Preparation, and Disposal of Pharmaceuticals**

(a) In order to provide patient safety, medications and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with federal and state laws and regulations.

(b) The Pharmacy Manager, in consultation with appropriate facility staff and committees, shall develop and implement policies and procedures for the provision of pharmaceutical services that ensure patient safety through the appropriate control and distribution of medications, medication-related devices, and biologicals. Such policies and procedures shall address, at a minimum, all of the following:

i. Safe storage. To ensure that all medications are stored under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security, procedures must be developed that clearly delineate locked storage areas and identify personnel who will have access to such areas. The procedures must include a diversion risk management plan.

ii. Emergency carts and boxes. The contents of all emergency carts and boxes utilized by the facility shall be based on a standard list developed in consultation with the Pharmacy and Therapeutics Committee, and approved by the Clinical or Medical Director. Such list must be consistent with OMH Official Policy PC-605, Emergency Medical Services System, and must specify that the pharmacy is promptly notified when the contents of an emergency cart or box is utilized so that it may be replaced.

iii. Floor stock/STAT medications. Floor stock/STAT medications must be approved by the Pharmacy and Therapeutics Committee and reviewed periodically. A limited supply of these medications may be stocked at the inpatient medication administration areas/stations. Injections shall be supplied in single use containers whenever possible.

iv. Inspections. Inspections of all inpatient nursing medication stations, emergency kits and automated dispensing cabinets must be conducted monthly by a pharmacy staff member to ensure that proper drug storage conditions are met. Such inspections must be documented, kept on file in the pharmacy and posted in the nursing medication station. Inspections of all outpatient treatment medication storage areas must be performed at least periodically by a pharmacy staff member or designated employee. At a minimum, a pharmacy staff member must conduct such inspections quarterly.

v. Control and Accountability. Procedures must include measures designed to control and account for all medication products and for removing and destroying or returning outdated medications to the manufacturer. Such procedures may include developing and maintaining a log of lot numbers and expiration dates for diversion prevention and so that medications which are being recalled or are expiring may be retrieved and returned. Facilities must use a returned goods service to obtain vendor credit when available.

vi. Emergency Drug Recalls. Procedures must address how to handle emergency drug recalls. All pertinent recall reports from manufacturers, prime vendors, online services or other sources, must be documented as to action taken and kept on file in the pharmacy.

vii. Product Defects. Procedures shall be developed for reporting medication product defects in accordance with the FDA MedWatch Program, https://www.accessdata.fda.gov/scripts/medwatch/.

viii. Poison Control. The telephone number of the regional poison control center must be conspicuously posted or easily available to all staff in drug preparation and storage areas in all wards, in the pharmacy, and in appropriate areas in outpatient and residential programs. In addition, a drug information source shall be available at each nursing station. OMH provides electronic access to a pharmacology database.

ix. Outdated or Unusable Medications. Procedures shall be developed for storing outdated or unusable medications, prior to their disposition, in clearly quarantined storage areas.

x. Sterile products. Sterile products must be handled or prepared according to United States Pharmacopeia Chapter 797.

xi. Storage of medication in outpatient and residential programs. As appropriate, procedures shall be developed for the limited storage of patient specific prescription medication in outpatient day treatment and residential programs. Procedures must include the following:

(1) Outpatient programs must store completed prescriptions which are awaiting patient collection. If such medications have not been collected within a reasonable period of time, the prescribing physician must be notified.

(2) Outpatient programs must not store stock controlled substances unless in possession of appropriate licensure from the State Department of Health. Facility permits do not extend to outpatient programs.

(3) Completed prescriptions that have previously been dispensed by a pharmacist may be stored in residential programs. If storage is offered, such storage must be in a locked cabinet.

(4) Facilities will establish a policy and procedure for patients who self administer medications in outpatient or residential programs.

**5) Dispensing Pharmaceuticals**

(a) *Role of Pharmacist*

A pharmacist is responsible for the safe and accurate dispensing of all pharmaceuticals in conformance with the prescribers' medication order.

(b) *Policies and Procedures*

The Pharmacy Manager must facilitate development of policies and procedures for completing and filling such medication orders. These policies and procedures must address at least the following:

i. Medication orders must include at minimum:

(1) patient name
(2) date of birth
(3) height
(4) weight
(5) diagnosis
(6) drug allergies,
(7) drug name (preferably generic),
(8) drug dosage, route, and frequency of administration,
(9) start date and time,
(10) stop date and time, and
(11) prescriber name.

ii. In addition to the information identified in subparagraph (i) above, PRN orders must include a maximum daily dose and rationale for use. [6]

iii. Outpatient prescriptions require patient demographic information, the drug name and product strength, the dosage, route, and frequency. Outpatient prescriptions must be written on a prescriptions form that meets applicable State regulations.

iv. All orders for new medications must include a rationale for use, i.e., target symptom. All orders for discontinuation of a therapy must include reason for discontinuation.

v. If medication orders are handwritten, all information must be legible.

vi. Medication orders shall be written or provided by telephone only by individuals who are on an authorized list of prescribers.

vii. Every inpatient medication order must include specific start and stop dates or the duration of therapy, as specified by the prescriber. The duration shall not exceed the maximum order duration as described for that specific drug in the facility Formulary or policy, up to a maximum of 30 days.

viii. Medication orders cannot be filled if they contain unfamiliar or non-approved abbreviations. There will be access to a facility approved published reference or a facility generated list which is approved by the local Pharmacy and Therapeutics Committee in consultation with the facility Health Information Management Department. Consistent with current Joint Commission standards each facility shall also have a short list of abbreviations that must never be used because of the potential of being misunderstood, which includes the Joint Commission "DO NOT USE" abbreviations as well as clarifies any

[6] As a clinical best practice, rationale for use should be included in the PRN order. However, an acceptable alternative is to include rationale for use in the clinical record.

abbreviations with multiple meanings.

ix. A pharmacist must review all new medication orders before the initial dose of medication is dispensed to ensure proper dosage and to identify potential drug-drug, drug-disease state or drug-food interactions. If a potential problem is noted, the pharmacist shall contact the prescriber for discussion. A record of such discussion and the resolution of the problem shall be documented. The pharmacist shall then enter these orders in the pharmacy computer, which shall generate a patient profile.[7]

x. All prescribers writing orders for OMH patients must be credentialed as per Medical Staff Organization guidelines. Under appropriate supervision, unlicensed residents and limited permittees, may prescribe **only** for dispensing within the facility pharmacy.

xi. Each facility shall develop and maintain a means of identifying the signature of all authorized prescribers, and shall maintain a list of their DEA numbers. This file must be reviewed and updated whenever there is a change in status of employees who are authorized prescribers (e.g., employees are newly hired, prescribing status is suspended, or employment is terminated), or annually, whichever occurs first.

xii. For patients of OMH outpatient facilities who are not eligible for Medicaid/Medicare Part D and/or cannot obtain their medications from a community pharmacy, facility pharmacies may dispense up to a month's supply of medication upon receipt of a valid facility authorized prescriber's prescription.

xiii. All outpatient prescriptions filled pursuant to a legal prescription must be labeled in accordance with NYS Education Law Section 6810 and shall contain a label bearing the name and address of the pharmacy, the date it was filled, the number of the prescription, the name of the prescriber, the name and address of the patient, the directions for use as given on the prescription. The dispensing of a drug which is a controlled substance is subject to additional requirements of Article 33 of the NYS Public Health Law. The filled prescriptions must be accompanied by a patient education handout, which includes the FDA toll free number for reporting adverse events.

xiv. Medications shall be distributed to the inpatient population by a manual or automated unit dose system. Clinical units conducting supervised self administration programs may be issued fully labeled individual prescription

[7] For OMH facilities, the exception to this review is the use of the After Hours Cabinet when the pharmacy is closed. The expectation is that the Cabinet will be accessed by a licensed independent practitioner who will control the ordering, preparation and administration of the medication or when a delay in treatment would harm the patient. In these instances, a pharmacist shall review the order during the next working day. A properly permissioned Pyxis machine will meet the definition of the Afterhours Cabinet for purposes of this paragraph.

packaging designed for use in outpatient patient settings.

xv. All inpatient medications dispensed from an OMH pharmacy for the patient medication cart are required to be labeled in a standard format in accordance with law and standards of practice. At a minimum, the label shall include the generic medication name, strength, amount (if not apparent from the container), expiration date, and lot number. For inpatient medications dispensed between cart fills, the package must also include the patient's name, location and directions for use (when appropriate) and any cautionary labels a needed.

xvi. Each facility must develop procedures for providing pharmacy services to inpatients when a pharmacist is not available. If these procedures include the maintenance of a use of an after- hours cabinet, such procedures must include a periodic review process of medications available within the limited subset and the record of use.

xvii. As technology changes, facilities will develop policy and procedure in regard to electronic physician order entry.

(c) *Telephone Orders*

Procedures must be established for the use of telephone orders, which shall include at least the following provisions:

i. The person taking the order must read back to the prescriber to verify accuracy and document the action by the addition of the phrase "RBO" or equivalent in the order. Telephone orders shall be limited to urgent situations. These orders shall be accepted by an authorized nurse.

ii. Telephone orders regarding clarification of written orders may be accepted by an authorized nurse, or pharmacist. All telephone orders shall be included in the patient's clinical record and must be signed by the prescriber or another physician in keeping with current standards and regulations and as specified in facility policy.

iii. A counter signature must indicate the original prescriber. Telephone orders must be signed within a time frame designated by the facility.[8]

(d) *Verbal (face to face) Orders*

Each facility must have procedures for issuing verbal orders, which include at least the following provisions:

i. Verbal orders must be limited to emergency situations, either medical or psychiatric, when it is impossible or impractical for the authorized prescriber to

[8] Based on previous Joint Commission surveys, this time frame should be 24 hours or less.

write the order.

ii. Only an authorized nurse can accept verbal orders. A nurse may not accept a verbal order for a Schedule II controlled substance.

iii. Verbal order procedures shall be as follows:

(1) In an emergency, facility code procedures shall be followed; Basic first aid and/or life support efforts must begin immediately.

(2) A nurse may accept verbal orders only when the authorized prescriber is present and both are at the site of the emergency. The administering nurse will repeat the prescriber's verbal order back to the prescriber and obtain active confirmation from the prescriber prior to administering the medication. This order will be reduced to writing, authenticated by the nurse and countersigned by the prescriber as soon as the situation is resolved.

**6) Administration of Medications or Pharmaceuticals**

Each facility shall have written policies and procedures for the administration of pharmaceuticals, which address at least the following:

(a) Licensed independent practitioners and clinical staff that are authorized to administer medication, with or without supervision, in accordance with law and regulation, shall be identified.

(b) All drug products administered to inpatients must be labeled and dispensed through the facility pharmacy, provided, however, that facility policy can include limited exceptions. In accordance with OMH guidelines, if drug products are ordered by the Dental Clinic, such clinic will record the drug product, the manufacturer, lot and expiration date, and will forward a copy of this record to the pharmacy. When a medication is needed after hours, it may be dispensed and labeled from an off grounds licensed pharmacy in accordance with facility policy.

(c) Drugs to be administered to patients shall be verified against the written order on a regular basis. Facilities shall implement a system for checking medication administration record transcription with original orders.

(d) Supervised self-administration of medication for inpatients shall be permitted only when ordered by a facility prescriber. The patient must be deemed competent at medication administration before being allowed to self-administer. The pharmacy must receive an order for self-administration and medication counseling must be provided either directly to the patient or through the patient's primary care giver.

(e) Methods to monitor the response of patients to new medications must be developed, along with procedures for detecting adverse reactions following administration of

pharmaceuticals.[9]

(f) The administration of medications shall be adequately documented by nursing and other involved staff in accordance with applicable law and regulations.

(g) If inpatients attending off-site programs require administration of medication, the facility pharmacy shall prepare a complete prescription and issue it to the program for administration by a nurse as directed by a physician's order and current policies. If specifically ordered by an authorized prescriber, supervised self-administration of medication is permissible. Completed prescriptions shall not be altered by program staff or placed in alternate containers.

(h) Procedures shall be developed for notifying responsible prescribers of the impending expiration of a drug order. Facility pharmacies are encouraged to provide prescribers with the pharmacy computer system's medication order renewal report or a similar tool.

**7) Medications Brought Into the Facility by Patients**

(a) Procedure Upon Admission

i. Whenever possible, facilities shall provide referring facilities or hospitals with prior notice that OMH will not accept medications, including controlled substances that are brought by a patient who is to be admitted for services.

ii. In the rare instance that family members are not available to retain the patient's medication, medications will be stored, in a manner that protects the integrity of the medications' stability and prevents diversion.

iii. Facilities shall develop a local procedure to facilitate safe storage of these medications.

(b) Procedure for the use of medications brought into the facility by a patient. If an attending physician prescribes a non-formulary drug that is unavailable through established pharmacy procurement processes but is available from the patient's own drug supply that is being stored in accordance with the admissions procedure described in this section, the policies governing the ordering and use of non-formulary drugs shall apply. In addition:

i. The medication must be examined, visually inspected for crumbling, discoloration, and other signs of deterioration. It shall also be confirmed that the medication is, in fact, the medication that has been requested.

ii. In the event that a positive identification cannot be made, or if the drug is not in a usable condition, the patient's nurse and prescribing physician shall be informed

[9] See appendix A for additional guidance in regards to Adverse Drug Reactions Reporting.

and the medication will be held for destruction (if unusable), returned to the patient's family, or stored securely in the accordance with the provisions of this policy directive.

**8) Investigational Drugs (FDA Non-approved)**

The pharmacy shall control the storage, dispensing, labeling, and distribution of investigational medications  Investigational medications are those drugs that have not yet been released by the Federal Food and Drug Administration (FDA) for general use.

(a) All research uses of investigational medications must be approved for use by the Institutional Review Board (IRB).

(b) Prior to initiating a study, the Principal Investigator shall provide a copy of the protocol and documentation of IRB approval to the licensed pharmacist or physician responsible for oversight of the medication tracking, accountability, storage and dispensing.

(c) Investigational medications must be stored in a secured, designated area of the facility in containers labeled with the IRB#, Principal Investigator name, drug name and storage conditions.

(d) Investigational medications shall only be dispensed following receipt of a properly completed prescription that includes the IRB#, and patient study ID number, in addition to all other required items.

(e) Investigational medications shall be used only under the direct supervision of the authorized Principal Investigator or physician listed on the FDA form 1572, who shall also be responsible for obtaining the patient's informed consent in accordance with the IRB approved protocol, consent process and consent document (See http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM074728.pdf).

(f) Registered nurses may administer investigational medications only after the drugs have been approved and the nurses instructed by the Principal Investigator or authorized prescriber listed on FDA form 1572.

(g) Each facility must have written processes addressing the use of investigational medications that includes, review, approval, supervision and monitoring.

**9) Infection Control in the Pharmacy**

Pharmacy policies and procedures shall include the following provisions:

(a) Personnel must wash hands following the Center for Disease Control (CDC) guidelines prior to leaving washrooms.

(b) Personnel preparing unit dose or otherwise handling medication shall be instructed to

wash hands prior to handling and wear protective gloves when repackaging solid dosage forms.

(c) Counting trays and spatulas must be cleaned according to professional standards of practice and used for transferring all bulk medications which require direct handling to prescription vials.

(d) The pharmacy must be cleaned and dusted routinely by cleaning personnel in the presence of a pharmacist. The medication refrigerator in the pharmacy shall be cleaned as required. The facility will ensure that the medication carts and drawers are clean and that they meet infection control standards.

(e) The pharmacy environment will be maintained according to infection control and environment of care standards.

**10) Education and Training**

The Pharmacy Manager and members of the pharmacy staff shall participate in the facility's education and training programs. Such participation shall include receipt of training, as well as provision of training and/or educational materials. Education and training shall address, at the minimum, the following:

(a) Staff education

i. All pharmacy staff shall receive orientation in the general functions of the facility and the overall needs of the patient population being served, as well as participating in in- service and continuing education programs, as appropriate. Staff must complete all facility and agency required programs and updates. Such participation must be documented in the employees' records.

ii. Facility policy and procedures that address medication use -- such as order writing, drug use guidelines, drug serum level monitoring and the facility drug monitoring process -- must be made available to all physicians, pharmacists, nurse practitioners, registered nurses, and licensed practical nurses at the time of their orientation. These policy and procedures must be written to address the requirements of the facility, taking into consideration the Central Pharmacy and Therapeutics Committee guidelines and advisories.

iii. Members of the pharmacy staff may participate in educational programs which consist of updating clinical staff who are involved in prescribing, dispensing, and administering pharmaceuticals.

iv. All New York State Registered Pharmacists are required to have 45 hours of approved continuing educations (CE) every three years to meet re-licensure requirements. OMH pharmacists should be encouraged and allowed to attend qualifying CE programs, including grand rounds, agency psychopharmacology programs, industry sponsored accredited programs as allowed and academic CE

presentations, in order to fulfill this requirement.

v. All pharmacy staff shall be trained in proper disposal of hazardous pharmaceutical waste, initially upon employment, and then annually thereafter. Such training shall be based on facility policy and procedure.

(b) Patient education

i. As an integral part of the treatment process and consistent with federal and state regulations, all patients must be counseled about their medications. Such counseling may consist of the pharmacist speaking directly with the patient, (alone or together with a caregiver, such as a nurse or case manager), or by providing information to the caregiver who will then share it with the patient. Patient information, both written and verbal, should be appropriate to the patient's level of understanding. Upon request, medication information may also be provided to families involved in the patient's care. As part of the facility patient medication education plan, Pharmacists should play a role in patient medication education as a part of the facility patient medication education plan.

ii. When a patient is prescribed medications that are to be administered at home, such as pass or discharge prescriptions, the patient and their family shall receive instructions from the prescriber, nurse or pharmacist. These instructions must include written material that reinforces verbal directions and explanations. These documents and information should be made available consistent with OMH Official Policy Directive PC502, Cultural and Linguistic Competence.

(c) Public education

i. As appropriate, a pharmacist shall participate in the facility's family and public education and information programs. Facility pharmacists should also be encouraged to participate voluntarily in professional activities as speakers and pharmacology consultants.

ii. To meet the additional medication information needs of the patients and families, as well as the need of the professional staff, each facility's pharmacy department shall maintain current reference materials, which shall be accessible to all appropriate requesters. These materials shall address topics including, but not be limited to: pharmacology, pharmacokinetics, toxicology, alternative therapies and microbiology. These topics may be hard copy reference or established websites.[10]

[10] Suggested library references include Facts and Comparisons, Drug Interaction Facts; or Hansten's Drug Interactions and Updates; AHFS Drug Information; Harrison's Principles of Internal Medicine; and Coe's Preparing the Pharmacy for a Joint Commission Survey and Goodman and Gilman's Pharmacological Basis of Therapeutics.

**11) Documenting and Reporting**

(a) Consistent with applicable law and OMH Official Policy OM-740 (Record Retention Periods) and as necessary to maintain adequate control and accountability of all medications, records of pharmacy transactions shall be maintained. At minimum, such records shall include, but are not limited to, controlled substance administration records, monthly medication use areas inspections, cart fill logs, prescription files and logs, pertinent drug recall records, and controlled substance requisitions, wholesaler invoices, returns service invoices and biennial controlled substance inventory. In addition, the Drug Supply Chain Security Act (DSCSA) requires document retention for 6 years. The more stringent requirement will prevail in any discrepancy for maintenance requirements.

(b) The pharmacy department in each facility shall maintain an individual electronic profile of each patient receiving medication.

i. In addition to a record of all medications dispensed, each patient profile must include medication allergy information, patient diagnoses, patient weight, height, and access to the results of pertinent laboratory tests that could affect drug therapy.

ii. Lab data shall be made available either by means of a pharmacy lab computer system interface or the use of software, such as the Cerner Millennium System. The patient profile may also contain record of any physician and pharmacist consultations, and any other pertinent information, such as patient medication preferences.

iii. All patient records will be maintained and managed in accordance with applicable state and federal laws and regulations, including but not limited to Mental Hygiene Law Section 33.13. and 45 CFR Parts 160, 164 (HIPAA).

(c) All medications administered shall be documented in the patient's clinical record by the staff member who administered the medications.[11]

(d) *Reporting*

i. Each facility shall categorize, report, monitor and analyze good catches and medication errors (both actual and potential medication errors), in a form and format designated by the Bureau of Quality Management, in accordance with the following categorizations, based on the level of harm to the patient:

(1) Category A means situations wherein circumstances or events that have the capacity to cause error were detected and corrected, but no error occurred;

[11] Preferably, the facility will make use of the pharmacy computer system which generates a Medication Administration Record, based on medication order entry.

(2) Category B means an error occurred, but the error did not reach the patient;

(3) Category C means an error occurred that did reach the patient but did not result in harm;

(4) Category D means an error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm;

(5) Category E means an error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention;

(6) Category F means an error occurred that may have contributed to or resulted in temporary harm to the client and required initial or prolonged hospitalization;

(7) Category G means an error occurred that may have contributed to or resulted in permanent patient harm; and

(8) Category H means an error occurred that required intervention necessary to sustain life.

a. All medication errors that reach a patient are considered incidents and must be reported in accordance with 14 NYCRR Part 524 and OMH Policy QA-510.

   There shall be a multidisciplinary program at each facility to monitor and analyze medication error types (both actual and potential), severity, and outcomes and implement performance improvement projects based on the findings. The findings from this program should be reported up on a regular basis to the facility Pharmacy and Therapeutics Committee, should ensure that based upon findings, the program implements performance improvement projects and fully implements indicated recommendations to reduce and eliminate errors.

b. Adverse drug reactions shall be documented and reported to the facility's Pharmacy and Therapeutics Committee. The Committee shall review the event and, if appropriate, report the event to the Federal Food and Drug Administration through its MEDWATCH program (https://www.accessdata.fda.gov/scripts/medwatch/).

   All severe adverse drug reactions shall be reported to the FDA, and are also reportable as incidents pursuant to 14 NYCRR Part 524 and OMH Policy QA-510.

c. All adverse reactions to newly marketed drugs shall be reported to the FDA, as part of its post marketing surveillance. To facilitate this process,

each facility Pharmacy and Therapeutics Committee must develop, implement and maintain an appropriate reporting system based on agency recommendations.[12]

**12) Monitoring and Medication Safety**

(a) As part of the facility's performance improvement program, each Pharmacy Manager is responsible for developing and implementing a plan for monitoring and evaluating the quality and appropriateness of patient care services that are related to the use of medications.

(b) Such plan must provide for the routine collections and assessment of information regarding the operation of the pharmacy.

i. The Pharmacy Manager shall be a part of all review processes related to incident reports of medication errors and adverse drug reactions. Such review may take place in the facility Incident Review Committee, Medication Error Committee, Pharmacy and Therapeutics Committee and/or Drug Monitoring Process Committee.

ii. All new medication orders for both inpatients and outpatients must be screened for appropriateness of dose, route, potential drug interactions, allergy checking, drug-food and drug-disease state interactions at the time of order entry into the pharmacy computer system.

iii. A monthly review of all medication orders must be completed by the responsible prescriber, which shall result in the renewal, discontinuation or modification of the orders, depending on the patient's condition.

iv. The Pharmacy Manager is responsible for reviewing and reporting to the facility leadership, on a yearly basis, the results of all pharmaceutical department monitoring activities. The facility pharmacy shall provide drug monitoring data to the appropriate hospital committees and shall participate in analysis and reporting of the data in accordance with facility medication use policy and procedures, which should be guided by the agency's Central Pharmacy and Therapeutics Committee.

This shall include the provision of drug utilization data to enable the facility to derive some conclusions about frequency, appropriate use, outcome and costs of specific medications.[13]

[12] See Appendix A for agency guidelines for the reporting of adverse drug reactions.
[13] An analysis of this information will set a baseline for the development and implementation of clinical practice guidelines. Guideline adoption, implementation and outcome assessments will become a national standard for identifying, evaluating and managing clinical care. OMH has developed best practice models which should be consulted by the facilities for all stages of the guidelines performance improvement project.

**13) Medication Use Committees**

(a) *Pharmacy and Therapeutics Committee (P&T)*

Each facility shall have a Pharmacy and Therapeutics Committee that serves as administrative, advisory, and educational role in clinical matters related to pharmaceuticals.

i. The primary functions of this Committee shall be the development and maintenance of a current formulary based on facility needs and cost effectiveness principles. The Committee shall also oversee the development of policies and procedures for selecting, procuring, prescribing, and dispensing medication.

ii. Membership of the Committee shall include, at minimum, the Clinical Director or designee, Medical Specialist, Pharmacy Manager, Chief Nursing Officer or designee, and additional members of pharmacy, nutritional services, medical, dental, administrative, quality assurance and nursing staff, as appointed by the Facility Director or designee.

iii. The Pharmacy Manager, in consultation with the Clinical Director or designee, shall schedule, plan, and coordinate all meetings. At minimum, the Pharmacy and Therapeutics Committee must meet four times per year.

iv. Responsibilities

(1) *Use of FDA Approved Drugs for Indications Not in the Approved Labeling* - The P & T Committee shall ensure that the use of any FDA approved drug for an off label indication or by an off label route of administration is properly monitored.

(2) *High Risk/Alert Medications* - The P & T Committee shall be responsible for creating and updating at least annually, a list of High Risk/Alert Medications and corresponding policy. High risk medications are agents whose safety profiles present a significant risk to patients. This may be due to the potential these medications have for serious side effects (possibly life threatening) and/or narrow therapeutic range which may be close to the dosage range known to trigger adverse events.

(3) *Sound Alike/Look Alike Medications* - The P & T Committee shall be responsible for creating and updating, at least annually, a list of sound alike/look alike medications and corresponding policy, in order to minimize medication errors that may result from use of these medications.[14] When creating this list, the facility shall consult resources from the Joint

[14] Some strategies for preventing errors regarding these medications may be by using both brand and generic names when ordering and transcribing, physically separating problematic pairs of medications, tall man lettering and using indications when ordering.

Commission and the Institute of Safe Medication Practices.

(4) *Pharmaceutical Hazardous Waste* - The P & T Committee shall develop a facility policy and procedure for the proper disposal of hazardous pharmaceutical waste, which shall be included as part of the facility's comprehensive waste plan. Such policy and procedures shall conform with federal Environmental Protection Agency (EPA) regulations for hazardous chemicals and medications requiring special disposal and shall be designed to prevent harm to human health and the environment through the proper management of hazardous pharmaceutical waste.

(5) *National Institute of Occupational Safety and Health Medications* - Hazardous drug evaluation is a continual process. In order to prevent workplace exposure to hazardous drugs, the P & T Committee shall assess the use within the facility of drugs identified by the National Institute of Occupational Safety and Health Medications as hazardous and shall provide guidance on handling these medications.[15]

(6) *Nutritional (Nutraceutical) Therapy* - It is recognized that a large number of products approved by the FDA as food products or nutritional supplements are often used for medicinal purposes, for purposes not intended by the manufacturer, or for indications not approved by the FDA. The P&T Committee is responsible for promoting the rational use of medications, including herbal, homeopathic or other alternative products. As such, the Committee shall develop clinical guidelines to be used by the facility to address the use of nutraceuticals on a case by case basis.

(7) *Time Critical Medication* - Time-critical medications are those for which an early or late administration of greater than thirty minutes might cause harm or have significant, negative impact on the intended therapeutic or pharmacological effect. The P&T Committee will assist in developing policies and procedures which address the timing of medication administration, i.e., identifying which medications need to be administered at a scheduled time and the duration of the administration window around said time.

(b) *Drug Monitoring Committee (DM*)

Each facility shall have a Drug Monitoring Committee to review quality and trends related to individual prescribing practices, identify associated problems and issues, and review exceptions to OMH/facility prescribing guidelines.

[15] Drugs considered hazardous include those that exhibit one or more of the following six characteristics in humans or animals: carcinogenicity, teratogenicity or other developmental toxicity, reproductive toxicity, organ toxicity at low doses, genotoxicity, structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria. Physical characteristics of the agents also need to be considered in determining the potential for occupational exposure.

i. The DM Committee, with advisory guidance from Central Office and identified consultants, shall develop guidelines for the use of medications and conduct surveys to assess safety and efficacy of medications as prescribed within the facility.

ii. The DM Committee shall consist of, at minimum, the Pharmacy Manager, Clinical Director or designee, Chief Nursing Officer or designee, Medical Director and other physicians, as appointed by the Facility Director or the Clinical Director.

iii. The DM Committee may be a subcommittee of the P & T Committee or integrated within the P & T Committee. The DM Committee shall meet at least four times a year.

**Appendix A:**

**Guidelines: Adverse Drug Reaction Monitoring and Reporting**

**Overview**:

The Joint Commission (TJC) requires health care organizations to develop a definition for Adverse Drug Reactions (ADR) and to have a program in place for the identification, monitoring, reporting, review and follow-up of all significant ADRs.

In addition, Severe ADRs, as defined in this guideline, should be reported to the FDA through MEDWATCH and to OMH via the current Incident Reporting Mechanism.

**Definitions**:

An Adverse Drug Reaction (ADR) is any response to a medication that is unintended, undesirable, unexpected or excessive, and that occurs at doses normally used in patients for prophylaxis, diagnosis or therapy of disease, or for the modification of physiologic function.

A clinically significant ADR results in one or more of the following:

- requires discontinuation or decreasing the dose of a medication
- requires a change in drug therapy
- requires a longer length of stay or in transfer to an emergency room or admission to a medical facility.
- requires treatment with another prescription drug
- complicates current diagnosis or negatively affects prognosis
- is life threatening
- results in congenital anomaly
- results in disability or requires intervention to prevent permanent impairment
- results in death

A Severe ADR is a clinically significant ADR that is further defined by the FDA MEDWATCH Program, as a reaction to a drug or drugs that results in one or more of the following:

- permanent disability
- a longer length of stay or a transfer to an emergency room or admission to a medical facility.
- is life threatening
- results in congenital anomaly
- requires intervention to prevent permanent impairment
- results in death

Adverse Drug Reactions are also classified as to *type* and *causality.*

**Type**: There are three major types of ADRs: hypersensitivity reactions (allergic event), idiosyncratic reactions (rare and unpredictable), and predictable effects of a greater severity than generally observed.

**Causality**: A determination should be made as to the probability that an observed reaction is actually an ADR.

A **definite** ADR is a reaction that follows a reasonable temporal sequence from the time of drug administration or from the time the drug level has been established in the body fluids or tissues; and/or follows a known response pattern to the suspected drug; and/or is confirmed by improvement on stopping the drug (de-challenge) and reappearance of the reaction on repeat exposure, when feasible (re-challenge).

A **probable** ADR is a reaction that follows a known response pattern to the suspected drug or is confirmed by de-challenge and/or cannot be reasonably explained by the known characteristics of the patient's clinical state.

A **possible** ADR is a reaction that follows a reasonable temporal sequence from administration of the drug and/or follows a known response pattern to the suspected drug and/or could be produced by the patient's clinical state or by other modes of therapy administered to the patient.

A **doubtful** ADR is a reaction where the causal relationship between the suspected drug and the event is doubtful when the temporal association is such that the drug would not have any reasonable association with the observed event.

**Monitoring and Reporting Requirements**

The benefits of a strong ADR Monitoring and Reporting program are that it provides a positive risk management tool and that it allows a facility to assess the safety of drug therapy in its population. Reporting of all suspected ADRs should be encouraged by the facility. ADR monitoring also provides an outcome measure and the prevention of ADRs is cost-effective, as more than 25% of all hospital admissions are the result of drug misadventures.

- An ADR program should be a <u>non-punitive, multi-disciplinary surveillance system.</u> When an ADR is suspected, the attending physician should be notified at once and the patient should receive the appropriate care. Pharmacy should be alerted as to the event and the facility reporting process should be initiated. ADR forms should be reviewed by the facility Pharmacy and Therapeutics Committee or its equivalent and evaluated for type, severity, causality and preventability. Severe ADRs will also be reviewed by the facility Incident Review Committee.

- Severe ADRs should be reported to the FDA on a MEDWATCH form and to OMH via the current Incident Reporting Mechanism.

- ADR programs should include mechanisms for feedback to clinical staff, continuing monitoring of prescribing practices within the facility, and educational activities stressing detection and prevention.

**Detecting Adverse Drug Reactions**

The following areas highlight key processes which should be used to detect ADRs:

- Patient self report of adverse effects after starting new medication or receiving dose increase of current medication
- Unexplained change in symptoms, both physical and mental, not suggested by working diagnosis, e.g. falls, movement disorders, ataxia, vomiting, severe constipation
- Unexplained change in mental status, such as confusion, psychosis
- Symptoms consistent with an allergic reaction, such as rash, shortness of breath, tongue swelling
- Hematologic changes, such as neutropenia, eosinophilia
- Changes in laboratory values, such as electrolytes, hepatic enzyme levels, glucose values, lipid levels
- Investigational Drugs: If an ADR occurs when a patient is on an investigational drug, the study facility must alert the IRB.

**Adverse Drug Reactions: References**


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**Appendix B:**

**Naranjo (Naranjo et.al, 1981) ADR Probability Scale**

| Question | Yes | No | Don't Know | Score |
|---|---|---|---|---|
| 1. Are there previous conclusive reports on this reaction? | +1 | 0 | 0 | |
| 2. Did the adverse event appear after the suspected drug was administered? | +2 | -1 | 0 | |
| 3. Did the adverse reaction improve when the drug was discontinued, or a specific antagonist was administered? | +1 | 0 | 0 | |
| 4. Did the adverse reaction reappear when the drug was re-administered? | +2 | -1 | 0 | |
| 5. Are there alternative causes (other than the drug) that could on their own have caused the reaction? | -1 | +2 | 0 | |
| 6. Did the reaction reappear when a placebo was given? | -1 | +1 | 0 | |
| 7. Was the drug detected in the blood (or other fluids) in concentrations known to be toxic? | +1 | 0 | 0 | |
| 8. Was the reaction more severe when the dose was increased, or less severe when the dose was decreased? | +1 | 0 | 0 | |
| 9. Did the patient have a similar reaction to the same or similar drug in any previous reaction? | +1 | 0 | 0 | |
| 10. Was the adverse event confirmed by any objective evidence? | +1 | 0 | 0 | |

Score: <0 Doubtful, 1-4 Possible, 5-8 Probable, >9 Highly Probable