STATE OF FLORIDA
DEPARTMENT OF
CHILDREN AND FAMILIES
TALLAHASSEE, October 15, 2018

CF OPERATING PROCEDURE
NO. 155-1

Mental Health/Substance Abuse

# GUIDELINES FOR THE USE OF PSYCHOTHERAPEUTIC MEDICATIONS IN STATE MENTAL HEALTH TREATMENT FACILITIES

1. Purpose. This operating procedure provides a structured framework for psychiatric, medical, pharmacy and nursing services in state mental health treatment facilities that are involved with the use of psychotherapeutic medications. In addition to the primary purpose, the intent of this operating procedure is to instruct staff with respect to documentation of methodology to stabilize or improve mood, mental status, behavioral symptomatology, or mental illness and to facilitate recovery of the resident.

2. Scope. This operating procedure applies to state mental health treatment facilities, whether operated by the Department of Children and Families or by contract with private entities, and the Florida Civil Commitment Center.

3. References.

a. Chapter 394, Florida Statutes (F.S.), Mental Health [Part I, Florida Mental Health Act (ss. 394.455, 394.459, 394.4598, 394.922)].

b. Chapter 395, F.S., Facility Licensing and Regulation [Part 1, Facilities and other Licensed Facilities (ss. 395.0193)].

b. Chapter 916, F.S., Mentally Deficient and Mentally Ill Defendants (ss. 916.106, 916.107).

c. Chapter 59A-3, Florida Administrative Code (F.A.C.), Facility Licensure (ss. 59A-3.110).

d. Rule 64B8-9.003, F.A.C., Standards for Adequacy of Medical Records.

e. Chapter 65E-5, F.A.C., Mental Health Act Regulation (ss. 65E-5.100, 65E-5.110, 65E-5.140, 65E-5.160, 65E-5.1602, 65E-5.170, 65E-5.1703, 65E-5.180, 65E-5.230, 65E-5.2301, 65E-5.602).

f. Chapter 65E-20, F.A.C., Forensic Client Services Act Regulation (ss. 65E-20.002, 65E-20.004, 65E-20.005, 65E-20.009).

g. Code of Federal Regulations (CFR), Title 42, Public Health, Chapter IV, Centers for Medicare and Medicaid Services, Department of Health and Human Services, Part 482, *Condition of Participation for Facilities, Subpart B Administration, Section 482.13: Residents' rights,* [71 FR 71426, Dec. 8, 2006].

h. American Psychiatric Association: Practice Guidelines at http://www.psychiatry.org/practice.

This operating procedure supersedes CFOP 155-1 dated August 15, 2013.
OPR: SMF
DISTRIBUTION: X: OSGC; ASGO; SMS; Region/Circuit Mental Health Treatment Facilities.

i. Centers for Medicare and Medicaid Services (CMS), *Medication Regimen Review, Instructor's Guide*, CFR § 483.60(c)(1)(2) F428, prepared by: American Institutes for Research, 1000 Thomas Jefferson St, NW, Washington, DC 20007, 2006, http://www.aging.pitt.edu/professionals/resources/S&C-06-29-11-F428MedRegReviewInstructorGuide.pdf.

j. American Pharmacists' Association (APhA), comments to CMS re: Draft Formulary Review Criteria, December 30, 2004, http://www.pharmacist.com/AM/Template.cfm?Section=Home2&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=2770.

k. American Society of Consultant Pharmacists (ASCP), Guidelines for Assessing the Quality of Drug Regimen Review in Long-Term Care Facilities, July 21, 1999. http://www.ascp.com/resources/policy/upload/Gui99-%20Quality%20DRR.pdf.

l. American Society of Health-System Pharmacists (ASHP) Guidelines on Adverse Drug Reaction Monitoring and Reporting, *Medication Misadventures – Guidelines,* Copyright © 1995, American Society of Health-System Pharmacists, Inc., all rights reserved.

m. Commission on Accreditation of Rehabilitation Facilities: Behavioral Health Standards Manual, 2017.

n. Agency for HealthCare Research and Quality (AHRQ), Patient safety network: Medication reconciliation, http://psnet.ahrq.gov/primer.aspx?primerID=1.

o. Food and Drug Administration (FDA) 2009, FDA's safe use initiative: Collaborating to reduce preventable harm from medications, U.S. Department of Health and Human Services.

4. Definitions. For the purposes of this operating procedure, the following definitions shall mean:

a. Adverse Drug Reaction (ADR).

(1) The ASHP defines a significant ADR as any unexpected, unintended, undesired, or excessive response to a drug that:

(a) Requires discontinuing the drug (therapeutic or diagnostic);

(b) Requires changing the drug therapy;

(c) Requires modifying the dose (except for minor dosage adjustments);

(d) Necessitates admission to a facility;

(e) Prolongs stay in a health care facility;

(f) Necessitates supportive treatment;

(g) Significantly complicates diagnosis;

(h) Negatively affects prognosis; or,

(i) Results in temporary or permanent harm, disability, or death.

(2) Consistent with this definition, an *allergic reaction* (an immunologic hypersensitivity, occurring as the result of unusual sensitivity to a drug) and an *idiosyncratic reaction* (an abnormal susceptibility to a drug that is peculiar to the individual) are also considered ADRs.

b. Drug Regimen Review. A thorough systematic evaluation of a person's medication therapy conducted by a pharmacist and viewed within the context of person-specific data. The goal of the review is promoting positive outcomes and minimizing adverse consequences associated with medications. The review includes preventing, identifying, reporting, and resolving medication-related problems, medication errors, or other irregularities and collaborating with other members of the interdisciplinary team.

c. Emergency Situation. A circumstance in which a resident poses imminent and substantial danger of hurting self or others.

d. Emergency Treatment Order (ETO). A physician's order for psychotherapeutic medication that supersedes the person's right to refuse psychotherapeutic medication when, based upon the physician's assessment, the person is not capable of exercising voluntary control over his or her own symptomatic behavior and the uncontrolled symptoms and behaviors are an imminent and substantial danger to the resident and/or to others in the facility.

e. Express and Informed Consent (hereafter referred to as consent) (form CF 1630, available in DCF Forms [or facility-specific version]). Permission voluntarily given in writing by a capable person, after sufficient explanation and disclosure of the subject matter involved to enable the person to make a knowing and willful decision without any element of force, fraud, deceit, duress, or other form of constraint or coercion.

f. Loss of Functional Status. A measurable loss of a resident's previously possessed ability to function in one or more of the following:

(1) Activities of daily living (e.g., locomotion, bathing, dressing, eating, etc.);

(2) Cognition or thinking (e.g., memory or orientation);

(3) Communication (e.g., ability to communicate in one's native language);

(4) Continence of bladder or bowel; and,

(5) Motivation and interest in preferred activities.

g. Medication Error. 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 or the resident. Such events may be related to professional practice, health care products, transfer of relevant handoff information, procedures and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.

h. Medication Reconciliation. The multidisciplinary team (resident, physician, nurse, pharmacist) process of confirming the medications a resident had been taking at the sending facility or unit with the medications to be ordered upon admission to the facility or transfer to a new unit or level of care, to avoid medication errors such as omissions, duplications, dosing errors. All medications must be continued, discontinued, or modified whenever a resident is involved in a transition of care.

i. Non-Routine Medication Prescribing Practice. Prescribed psychotherapeutic medication treatment plans that are not evidence based practices and residents receiving these medications are

followed more closely to ensure intended therapeutic outcomes are achieved. This may include such practices as dosage prescribing for a medication for a specific illness higher than the recognized range for the illness, prescription of inter- and intra-class polypharmacy, etc.

j. Pharmacy and Therapeutics (P&T) Committee. An advisory group that considers all the matters related to the use of medications in a facility including evaluation of medications and dosage forms and safe use of medications.

(1) The committee is responsible for framing policies and procedures for selection, procurement, dispensing, labeling, availability, administration, and control of medications throughout the facility.

(2) This committee is composed of physicians, pharmacists and other health care professionals selected with the guidance of the medical staff. It is a policy recommending body to the medical staff and the administration of the facility on matters related to the therapeutic use of medications.

(3) The role of the P&T Committee, as it relates to this operating procedure, will be to address the responsibility of planning, reviewing, and establishing guidelines for the therapeutic and cost effective use of psychotherapeutic medication within the facility.

k. Pro Re Nata (PRN) Order. An individualized treatment order based on the presence of predetermined specific criteria established by the prescribing practitioner which is administered by the nurse who has, by means of an assessment, determined the need for the medication. A PRN is a time limited written order not to exceed thirty (30) days for the first three (3) months of prescribed PRN treatment, then once a month thereafter. The PRN may be administered by a Licensed Practical Nurse (LPN), under the direction of an RN, based on the RNs assessment.

l. Psychiatric Evaluation. A psychiatric examination which shall include:

(1) Medical history, including psychiatric history, developmental abnormalities, physical or sexual abuse or trauma, and substance abuse;

(2) Examination, evaluative or laboratory results, including mental status examination;

(3) Working diagnosis, ruling out non-psychiatric causes of presenting symptoms of abnormal thought, mood, or behaviors;

(4) Course of psychiatric interventions including:

(a) Medication history, trials and results;

(b) Current medications and dosages;

(c) Other psychiatric interventions in response to identified problems;

(5) Course of other non-psychiatric medical problems and interventions;

(6) Identification of prominent risk factors including physical health, psychiatric and co-occurring substance abuse; and,

(7) Discharge or transfer diagnoses.

m. Psychotherapeutic Medication. Any drug prescribed with the primary intent to stabilize or improve mood, behavioral symptomatology, or mental illness. The medications include, but are not limited to, the following major categories:

(1) Antipsychotics;

(2) Antidepressants;

(3) Anxiolytics;

(4) Mood stabilizers;

(5) Cerebral or psychomotor stimulants; and,

(6) Other medications commonly used which may include but are not limited to beta blockers, anticonvulsants, antihistamines, opiate blockers and medications to control side effects. These medications are considered psychotherapeutic medications when used to stabilize or improve mood, behavior, or mental illness, or to induce sleep.

(7) Cognitive enhancers and medications used solely for the treatment of dementia shall not be considered psychotherapeutic medications and shall not require an informed consent.

(8) Diphenhydramine and melatonin, being over the counter medications, shall be specifically excluded from the requirements for psychotherapeutic medications when used for sleep.

n. Psychotherapeutic Medication Treatment Plan. A treatment plan developed after evaluation of the resident by the psychiatrist or psychiatric advanced registered nurse practitioner (ARNP). This plan includes specific subjective and/or objective target symptoms for each psychotherapeutic medication ordered with expected outcomes documented as measurable objectives. The psychotherapeutic medication treatment plan is an essential part of the overall recovery plan.

o. Recovery. A process by which a person with mental illness and/or emotional disturbances overcomes the negative impact of such conditions despite their continued presence and which incorporates hope, personal responsibility, education, self-advocacy, and developing and maintaining of a support system.

p. Recovery Plan. A written plan developed within 30 calendar days of admission by the resident and his or her recovery team (also referred to as the “plan”). This plan is based on assessment data, identifying the resident’s clinical, rehabilitative and quality of life/enrichment service or recovery needs, the strategy for meeting those needs, documented treatment and recovery goals and objectives, criteria for terminating the specified interventions, and documented progress in meeting specified goals and objectives. The recovery plan is reviewed at least every 30 calendar days during the first 24 months the resident is in the facility, and at least every 60 calendar days when the resident’s length of stay exceeds 24 months.

q. Recovery Team. An assigned group of individuals with specific responsibilities identified on the recovery plan including the resident, psychiatrist, guardian/guardian advocate (if resident has a guardian/guardian advocate), community case manager, family member, and other treatment professionals commensurate with the resident’s needs, goals, and preferences.

r. Side Effect. An action or effect that is usually regarded as an undesirable secondary effect which occurs in addition to the desired therapeutic effect of a medication. Side effects may vary for each individual and can occur when commencing, decreasing/increasing dosages, maintenance, or ending a medication regimen. Side effects may also lead to non-compliance with prescribed treatment.

When side effects of a medication exist, the dosage of the medication may be adjusted or a second medication may be added. Lifestyle or dietary changes, including access to hydration, may also help to minimize side effects.

s. Statewide P&T Committee. A statewide advisory group chosen from the State Mental Health Treatment Facilities and Program Office to oversee the safe and therapeutic use of psychotherapeutic medications in State Mental Health Treatment Facilities through external monitoring of the activities of the facilities P&T Committees. This group will be comprised of a professional team that will include, at a minimum: the Statewide Chief Medical Officer, one facility psychiatrist; one facility psychiatric ARNP; one facility pharmacist; a facility medical physician; a facility Chief of Nursing Services; one facility Quality Assurance staff member; one Risk Manager; one Infection Prevention and Control Practitioner; the RN Consultant from the Program Office, one Resident/Peer Specialist/Advocate and a Dentist. The group will be chosen by the Assistant Secretary for the Substance Abuse and Mental Health or his/her designee and led by the Statewide Chief Medical Officer.

5. General.

a. It is the intent of the Department to provide the most effective, safe, fiscally responsible, evidence based treatment for the residents receiving treatment in the state mental health treatment facilities. Treatment will be consistent with current psychiatric and medical diagnoses and treatments.

b. Psychotherapeutic medication will not be used for punishment, discipline, coercion, or retaliation; to compensate for inadequate staffing; for staff convenience; as a substitute for meaningful psychosocial or rehabilitative services; or in quantities that lead to a loss of functional status.

6. Clinical Services.

a. Psychiatric Services.

(1) The admitting psychiatrist or psychiatric advanced registered nurse practitioner (ARNP) will complete a psychiatric evaluation within sixty (60) hours of admission and provide a working diagnosis and initial orders.

(a) The diagnosis will be clinically justifiable in accordance with the criteria contained in the most current Diagnostic and Statistical Manual of Mental Disorders (DSM).

(b) Differential diagnoses, “deferred” or “rule-out” diagnoses, and diagnoses listed as “NOS” (“Not Otherwise Specified”) will be addressed within 90 days through documented clinical assessments and resolution in a clinically justifiable manner. Any diagnosis that cannot be justified will be discontinued no later than the next review.

(2) Within five days following the psychiatric evaluation, a psychiatric treatment plan including a psychotherapeutic medication plan will be developed by the psychiatrist or psychiatric ARNP with input from the resident (unless he or she is clinically or cognitively unable to participate), the guardian/guardian advocate (if one has been appointed), and the recovery team. The psychiatrist or psychiatric ARNP will discuss the following:

(a) Target symptoms will be identified for each psychotherapeutic medication prescribed.

(b) The recovery plan will include specific baseline data on frequency and intensity of symptoms or behaviors and functional abilities and limitations.

(c) Short term goals will be written in objective and measurable terms.

(3) Monthly reviews by the psychiatrist or psychiatric ARNP will include the resident's response to treatment (progress toward short term goals), changes in the patient's condition which may indicate the presence of possible side effects from the medications, and the plan to continue or adjust treatment.

(4) Monthly documentation by the psychiatrist or psychiatric ARNP shall include psychiatric progress notes that indicate the psychiatrist has reviewed the need for anticholinergic medications, the medications are needed, and there are no contraindications for their use.

(5) The psychiatrist or psychiatric ARNP will update the psychiatric evaluation annually, within 30 days surrounding the admission anniversary date. The timeframe for the evaluation to be completed is 30 days prior to the admission anniversary date or 30 days after the admission anniversary date. Barriers to discharge will be documented and addressed with the recovery team.

b. Medical Services.

(1) Each resident shall receive a physical examination which shall include screening for communicable disease by a health practitioner authorized by law to perform such examinations within twenty-four (24) hours of admission. The medical examination will include a summary of findings and a medical care plan for each acute or chronic medical illness identified. A comprehensive medical history and physical examination conducted within 30 calendar days prior to admission will be acceptable if a legible copy is provided and updated within 24 hours of admission and a current medical care plan is added.

(2) Each resident will receive timely preventive, routine, specialized, and emergency medical care as needed and consistent with prevailing accepted professional standards.

(3) Residents with medical problems will be promptly identified, assessed, diagnosed, treated, and receive follow-up care consistent with prevailing accepted professional standards.

(4) Initial and ongoing medical assessments will include, but are not limited to preventative health screenings, gynecology examinations for women, vision care, dental care, and laboratory and consultative services.

(5) Chronic medical/health problems will be identified and added to the Recovery Plan with specific measurable outcomes, planned interventions, and timeframes for treatment completion.

(6) At a minimum, the medical practitioner will complete a physical examination annually. Annual physical exams may be completed within 30 days surrounding the admission anniversary date. The timeframe for the annual physical exam to be completed is 30 days prior to the admission anniversary date or 30 days after the admission anniversary date.

c. Nursing Services.

(1) Upon admission, each resident shall receive a professional nursing assessment of information obtained in a systematic manner through observation, interviews, and resident examination.

(2) Following the nursing assessment, the registered nurse will identify needs and expected outcomes of nursing services that are mutually agreed upon with the resident (unless he or she is clinically or cognitively unable to participate). The ultimate goal is to influence health outcomes and improve the resident's health status.

(3) A registered nurse will assess the resident prior to administration of a PRN psychotherapeutic medication intervention. The nurse will document the assessment of the resident,

presence of the specific symptoms or behavioral criteria defined by the prescribing practitioner, the time of administration, and the effect of the medication on the resident's symptoms in a progress note.

(4) If the resident presents a threat of imminent and substantial harm to self or others, de-escalation will be attempted as per the person's safety plan if the situation allows. If de-escalation is not effective, the physician will be notified. The nurse will document the situation, the physician's orders, and the outcome of intervention provided in a progress note.

(5) The registered nurse will document monthly reviews of nursing services provided, a review of medical/psychiatric health care objectives, the resident's progress toward his/her therapeutic goals of psychotherapeutic medication therapy, the status of any side effects present, and any noted changes/trends in the resident's health status.

(6) The registered nurse/licensed practical nurse will inform the prescribing practitioner of any changes in the resident's condition such as incidence of constipation, progression of weight gain or loss, restlessness, increased salivation, increased fluid intake, lethargy, frequency of falls, location and intensity of tremors, abnormal involuntary movements, etc. which may indicate the presence of possible side effects from the medications.

(7) At a minimum, the registered nurse will update the nursing assessment within 30 days surrounding the admission anniversary date. The timeframe for the annual nursing assessment to be completed is 30 days prior to the admission anniversary date or 30 days after the admission anniversary date. Potential health care issues that may impede a resident's transition to a less restrictive environment will be documented and addressed with the recovery team.

d. Pharmacy Services.

(1) Upon prescription of a new medication, the dispensing pharmacist will review the resident's medication profile and, as needed, notify the prescribing practitioner of any warnings, possible drug/drug interactions, potential side effects, and needs for laboratory testing.

(2) The drug regimen of each individual will be reviewed by a pharmacist consistent with State Rule and Federal Regulation, every six (6) months. The pharmacist will report findings to the prescribing practitioner and other disciplines as required.

(3) The pharmacist will review the record of any resident as requested by the prescribing practitioner if the goals of the medication therapy are not being achieved.

(4) The pharmacist may chair a subcommittee of the facility Pharmacy and Therapeutic Committee that will review non-routine medication prescribing practice and report on the outcomes of these treatment modalities at least quarterly to the Statewide P & T Committee.

7. Express and Informed Consent for Use of Psychotherapeutic Medication.

a. Informed consent shall be obtained from a resident who has the capacity to consent to treatment (form CF 1630, available in DCF Forms [or facility-specific version]). The consent process includes the person's right to ask questions about the proposed medication, to receive complete and accurate answers to those questions, and to discuss medication options.

b. The resident's capacity to provide express and informed consent will be assessed and documented by the physician or ARNP upon admission and every time psychotherapeutic medication consent is obtained. For the consent to be valid, the physician or ARNP will note on the consent form that, in their clinical opinion, the individual who provided consent understood the information provided.

c. In determining capacity to consent to treatment, three (3) factors will be considered: 1) resident is aware of his/her situation/condition; 2) resident is able to understand the benefits and the risks of, as well as the alternatives to, the proposed medication; and 3) resident is able to understand and to negotiate treatment options. Incompetence may not be presumed because the individual has been evaluated or treated for a mental disorder or because of a diagnosis of being mentally ill, disordered, abnormal, or mentally challenged.

d. Before express and informed consent is obtained, the following information shall be provided and explained in plain language to the resident or the resident's legal or chosen representative:

(1) The proposed medication and purpose;

(2) The proposed dose, dosage range, and titration plan;

(3) The frequency and route of administration;

(4) The approximate length of treatment, probability of success, and the amount of time for benefits to occur;

(5) Expected outcome and benefit of the planned treatment;

(6) The recognized potential short-term and long-term common side effects and potential adverse reactions;

(7) Any contraindications which may exist;

(8) Clinically significant interactive effects with other medications resident is taking;

(9) How the treatment will be monitored;

(10) Similar information on alternative medications or treatments which may have less severe or serious side effects;

(11) The results of medication refusal such as the expected prognosis if treatment is not implemented, emergency procedures, court actions, and potential discharge of voluntary residents;

(12) That consent given for treatment may be revoked orally or in writing before or during the treatment period by the resident or by the person who is legally authorized to make mental health care decisions on behalf of the resident;

(13) Explanation of all other treatments or treatment alternatives recommended for the resident; and

(14) The name of the prescribing practitioner and how to contact him/her at the facility.

e. The information must be provided in the person's native language or mode of communication that is understandable to the individual before consent will be considered valid.

f. Oral consent may only be obtained in the civil facilities. The consent must be signed by both the prescribing practitioner and the staff witness to the oral consent. Oral consent will be followed by pursuit of written consent.

g. The signed consent form will be filed in the current medical record and will not be purged from the record for at least two years.

h. If the resident does not have the capacity to make an informed decision regarding psychotherapeutic medication treatment, consent shall be obtained from a duly authorized substitute decision-maker for the resident before psychotherapeutic medication is initiated.

i. If the resident has been adjudicated incapacitated and has a court appointed guardian or guardian advocate, a copy of the court order of appointment will be obtained and filed in the medical record with documentation confirming the guardian/guardian advocate has received the required training.

j. If the resident has a living will that has a chosen surrogate identified to make healthcare decisions for the resident, the facility will honor the documented wishes of the resident.

k. Psychotherapeutic medication will not be initiated until consent is obtained from the resident or a person legally authorized to provide consent except in the following situations:

(1) Civil Facilities.

(a) When a resident is admitted, and has a current prescription for psychotherapeutic medication(s) but has been determined by the admitting physician to lack the capacity to provide informed consent, if it is determined by the admitting physician to be medically necessary to continue the prescribed psychotherapeutic medications, the medications may be continued while an alternative decision maker is being pursued through the court.

(b) The sending facility will be contacted and requested to fax the physicians' order sheet and the current consent to be placed in the resident's medical record until informed consent or court order is obtained.

(c) The facility will expeditiously pursue the new consent.

(2) Forensic Facilities.

(a) In a situation, other than an emergency situation, the administrator or designee of the facility shall petition the court for an order authorizing necessary and essential treatment for the resident. The order shall allow such treatment for a period not to exceed 90 days following the date of the entry of the order. Unless the court is notified in writing that the resident has provided express and informed consent in writing or that the resident has been discharged by the committing court, the administrator or designee shall, prior to the expiration of the initial 90-day order, petition the court for an order authorizing the continuation of treatment for another 90-day period. This procedure shall be repeated until the client provides consent or is discharged by the committing court.

(b) When a resident is admitted, and has a current prescription for psychotherapeutic medication(s) but has been determined by the admitting physician to lack the capacity to provide informed consent, if the resident wants to continue the medication while a court order is pursued, the admitting psychiatrist will:

1. Complete and document a risk assessment of the potential effect an abrupt withdrawal may have for the resident based on the resident's current treatment medications and psychiatric condition.

2. Continue the medication as indicated.

3. Immediately pursue a court order for psychotherapeutic medication as needed.

8. Emergency Intervention Using Psychotherapeutic Medication.

a. Civil Facilities.

(1) In an emergency situation, a physician may initiate an Emergency Treatment Order (ETO) that is considered to be the least restrictive treatment to address a person's uncontrolled symptoms and behaviors.

(2) An ETO is provided for immediate administration of rapid response psychotherapeutic medications to expeditiously treat symptoms, that if left untreated, present an immediate and substantial danger to the safety of the resident or others in the facility.

(3) A psychotherapeutic medication ETO supersedes the resident's right to refuse the medication if based upon the physician's assessment that the individual is not capable of exercising voluntary control over his or her own symptomatic behavior.

(4) The physician's initial order for emergency treatment may be by telephone but such a verbal order must be reduced to writing upon receipt and signed by a physician within 24 hours. Each emergency treatment order shall only be valid and shall be authority for emergency treatment only for a period not to exceed 24 hours.

(5) The need for each ETO must be documented in the resident's medical record in the progress notes and in the section used for physician's orders and must describe the specific behavior which constitutes an imminent danger to the resident or to others in the facility, and the nature and extent of the danger posed. An ETO may authorize multiple interventions encompassing multiple administrations, for a period of 24 hours. If after 24 hours, the resident continues to present with symptoms and behaviors that are imminent danger to the resident or others requiring an additional ETO be written, this would constitute a separate and additional ETO event. Additionally, if later in a single 24 hour period, further clinical assessment reveals the need for additional or different treatment (different dose or different medication), this would constitute a separate order and separate ETO. In this instance, it is possible to have more than one ETO in a single 24 hour period.

(6) The issuance of an ETO requires a physician's review of the resident's condition within 24 hours to rule out medical factors that may be contributing to the emergent situation, such as insufficiency of psychotherapeutic medication blood levels, as determined by laboratory test findings; medication interactions with psychotherapeutic or other medications; side effects or adverse reactions to medications; organic, disease or medication based metabolic imbalances or toxicity; or other biologically based or influenced factors.

(7) Upon the initiation of an ETO, the facility shall, within two court working days, petition the court for the appointment of a guardian advocate to provide express and informed consent, unless the resident voluntarily withdraws a revocation of consent or requires only a single emergency treatment order for emergency treatment. If a second emergency treatment order is issued for the same resident within any 7 day period, the petition for the appointment of a guardian advocate to provide express and informed consent shall be filed with the court within 1 court working day.

(8) While awaiting court action, treatment may be continued without the consent of the resident, but only upon the daily written ETO of a physician who has determined that the resident's behavior each day during the wait for court action continues to present an immediate and substantial danger to the safety of the resident or others and who documents the nature and extent of the emergency each day of the specific danger posed. Such orders may not be written in advance of the demonstrated need for same.

(9) To assure the safety and rights of the resident, and since ETOs by a physician are absent of express and informed consent and permitted only in an emergency, any use of psychotherapeutic medications, other than rapid response psychotherapeutic medications, requires a detailed and complete justification for the use of such medication. Both the nature and extent of the imminent emergency and any orders for the continuation of that medication must be clearly documented daily as required above.

(10) Residents in civil facilities committed pursuant to Chapter 916, F.S. share the same rights as those committed pursuant to Chapter 394, F.S., including the administration of psychotherapeutic medication in emergency situations.

b. Forensic Facilities. If a resident refuses such treatment as is deemed necessary and essential by the resident's psychiatrist and recovery team for the appropriate care of the resident, such treatment may be provided under the following circumstances:

(1) In an emergency situation in which there is immediate danger to the safety of the resident or others, such treatment may be provided upon the written order of a physician for a period not to exceed 48 hours, excluding weekends and observed holidays (i.e., two business days).

(2) If, after the 48-hour period, the resident has not given express and informed consent for the treatment initially refused, the administrator or designee of the facility shall, within 48 hours, excluding weekends and observed holidays, petition the committing court or the circuit court serving the county in which the facility is located, at the option of the facility administrator or designee, for an order authorizing the continued treatment of the resident.

(3) In the interim, the need for treatment shall be reviewed every 48 hours and may be continued without the consent of the resident upon the continued written order of a physician who has determined that the emergency situation continues to present a danger to the safety of the resident or others.

(4) A single ETO may authorize multiple interventions encompassing multiple administrations, for a period up to 48 hours; if after 48 hours, the resident continues to present with symptoms and behavior that are imminent danger to the resident or others requiring an additional ETO be written, this would constitute a separate and additional ETO event. Additionally, if later in a single 48-hour period, further clinical assessment reveals the need for additional treatment, this would constitute a separate ETO. In this instance, it is possible to have more than one ETO in a single 48-hour period.

9. PRN Orders for Use of Psychotherapeutic Medication

a. Consent must be obtained for PRN psychotherapeutic medication orders and consent can be revoked orally or in writing at any time. PRN Orders are to be used when the resident's condition warrants individualized non-scheduled dosing.

b. All PRN orders should specify:

(1) Specific dose (not a dose range).

(2) Frequency medication can be administered.

(3) Form of the medication (pill, liquid, injection)

(4) Maximum dose in 24 hours (include the regular dose with the total dose if applicable).

(5) Specific indication for use of the medication.

(6) Duration of the order, not longer than thirty (30) days.

c. The order may include one or two medications to be given at the same time but the order must clearly state what is to be given and for what reason. It is not in the scope of nursing practice to decide to administer one medication or another or both at the same time.

d. If a PRN psychotherapeutic medication is renewed, a progress note must be written at the time of renewal.

e. If the PRN psychotherapeutic medication is ordered repeatedly, the prescribing practitioner will document the ongoing plan and rationale for not changing a daily PRN medication to a regular scheduled prescription.

f. If the PRN psychotherapeutic medication is unnecessary, or has not been administered in the preceding month, and the physician has not documented a thirty-day review, the pharmacist will consult and review with the prescriber to determine the patient's continued need for the medication.

g. When a PRN psychotherapeutic medication is administered, the nurse must document the date and time of the administration on a medication administration record (MAR) and must write a progress note indicating the date and time of the administration, the reason for the administration, the alternative interventions attempted, the target symptoms/behavioral parameters which resulted in the drug being administered, the name of the medication administered, the dose and route, and the resident's response to the medication administered. The documentation shall include the behavior or symptoms/indication for the use of the medication and any change or lack of change in the behavior or symptoms of the resident.

h. An LPN may administer PRN psychotherapeutic medication as directed by a RN, based on the RN's assessment.

10. Monitoring and Managing Medication Side Effects and Adverse Drug Reactions (ADR).

a. Team members, to include physicians, ARNPs, nursing, direct care staff and other team members, will receive new employee orientation and annual updated competency based training to identify potential side effects and/or behavior changes that may be attributed to psychotherapeutic medication.

b. Staff will monitor and immediately report any observed changes in behavior to the nurse on duty.

c. Every resident receiving psychotherapeutic medication will be evaluated upon admission by medical staff and nursing and at least monthly thereafter as part of the monthly review process, for potential side effects.

d. An Abnormal Involuntary Movement Scale (AIMS) rating will be completed on admission; semiannually for residents receiving antipsychotic medications. The facility will ensure that each staff member who completes the AIMS rating tool has been trained to complete this assessment.

e. The nurse will document in a progress note any emergent potential side effect or adverse drug reaction and will report it in a timely manner to the prescribing practitioner. The nurse will record the status of any side effect present at least monthly.

f. Monthly documentation by nursing and medical of "*no side effects present*" does not demonstrate that the requirement for standardized monitoring has been met.

g. Side effect history will be maintained on the current medical record in the admission and updated psychiatric evaluation.

h. The prescribing practitioner will routinely (at a minimum monthly) document an assessment of each resident for potential medication side effects. Documentation will include confirmation and management of emergent side effects or adverse drug reactions in a progress note with the expected outcomes and a clinical rationale for continued treatment or change in the medication treatment plan.

i. The recovery team will be informed of medication side effects, risks and benefits of continued treatment, and planned management and the discussion will be documented. Persistent side effects will be added to the resident's problem list and management of side effects will be monitored monthly by the recovery team.

j. The prescribing practitioner will document discussion of the risks and benefits of continued psychotherapeutic medication treatment with the resident or his/her legal representative when side effects are present and the resident's or legal representative's decision regarding the treatment plan will be documented by the prescriber or designated recovery team member in the progress note.

k. The prescribing practitioner will report all adverse drug reactions to the pharmacist.

l. All efforts will be made to recognize side effects as soon as possible to minimize the impact.

11. Facility Quality Assurance, Utilization Review, and Cost Accountability.

a. Each facility will develop and implement a comprehensive review process to evaluate medication use and foster medically appropriate and cost effective psychotherapeutic medication treatment to meet the needs of the resident. Areas of review will include:

(1) Compliance with the requirements set forth in this operating procedure;

(2) Congruence between prescribed medication, diagnosis and expected outcomes including the extent to which expected resident outcomes are achieved; and,

(3) Cost effective psychotherapeutic medication treatment and process.

b. Continuous Quality Improvement (CQI) will be achieved through internal quality assurance monitoring, peer review, and the facility and statewide P&T Committee process.

c. CQI will be accomplished by Quality Assurance focused reviews as requested by the Statewide Chief Medical Officer, Statewide Facilities Administrator, the Facility Administrator, the facility Medical Executive Director, the Chief of Nursing Services, or the Pharmacy Director.

d. Peer Review.

(1) The office of the Statewide Chief Medical Officer and/or the Medical Executive Director of each facility will implement a peer review process. The process will include the use of Quality Indicators approved by the Statewide Medical Directors Group to encourage use of evidence-based, cost effective, nationally recognized prescribing standards.

(2) The Peer Review process will be confidential.

(3) Pursuant to § 395.0193(2)(g), F.S., the focus of the peer review process at the facility will be to reduce morbidity and mortality and to improve resident care.

(4) At a minimum, Peer Review will include review of psychiatrists' prescribing practices that may have contributed to patient morbidity or adverse outcomes;

e. Residents who have extended length of stay and are not progressing toward desired outcomes and discharge will be reviewed by facility Medical Executive Director. The reviews will be conducted monthly under the direction of the Statewide Chief Medical Officer or designee.

f. Facility P & T Committee.

(1) The Facility P&T Committee will be responsible for ensuring standards of medication practices outlined in this operating procedure are met. Each Facility P & T Committee will develop and maintain a facility formulary.

(2) The committee will ensure that practice protocols are in place at the facility to ensure safe and effective treatment and that the protocols are followed. At a minimum, protocols will be in place for the use of clozapine, lithium, and valproic acid. As outlined in paragraph 6d(2) of this operating procedure, the pharmacists will conduct a drug regimen review of each patient every six months. The committee will ensure these reviews are accomplished and assist pharmacy as needed.

(3) The committee will meet at least quarterly and oversee prescribing practice, adverse drug reactions, medication error reports, action planning, and required or requested reporting to the Statewide P&T Committee.

(4) Evidence based practice will be used for the majority of residents; however, in some situations, medication therapy may evolve beyond what is in the current literature.

(5) The outcomes of complex, non-standard treatment plans will be monitored monthly by the facility P&T Committee (or assigned designee).

(6) A minimum amount of data to be collected and reviewed by the committee will be determined, modified and maintained by the Statewide P & T Committee. Additional data may be collected by the committee at their discretion.

(7) The committee (or assigned designee) will review and report on:

(a) Non-routine medication prescribing practice;

(b) Incidents of significant medication side effects including, but not limited to, tardive dyskinesia, metabolic syndrome, neuroleptic malignant syndrome, akathisia, and agranulocytosis;

(c) Serum medication levels above therapeutic range with presenting symptoms of toxic levels as with, but not limited to, lithium, valproic acid, and clozapine for absolute neutrophil counts (ANC's); amd ,

(d) All reportable adverse medication reactions and medication error data.

(8) The committee will review the data and will determine if any actions are needed.

(9) The committee with the assistance of the designated Quality Assurance staff will follow-up on all corrective actions until completed.

(10) The committee will prepare the data as required by the Statewide P&T Committee.

12. Statewide P & T Committee. The responsibilities of the Statewide P & T Committee include:

a. Review the activities, as reflected in the meeting minutes, of each facility P & T Committee.

b. Review each facility formulary and any standards and protocols set by the facility for psychotherapeutic medication use.

c. Review standards of practice and non-standard practices at the facilities.

d. Convene (via VTC, conference call or face to face) on a semiannual basis to provide analysis and trending of the facilities P & T Committee data, review facility action plans, and make any necessary recommendations to the Statewide Chief Medical Officer and the Statewide Medical Executive Directors' Group.

13. Program Office Staff. Program office staff will:

a. Monitor facilities progress. The Director of Policy and Programs will conduct on-site reviews of each facility to determine compliance with DCF Operating Policies and Procedures. These reviews will be scheduled by the Program Office staff and will include the use of Quality Indicators approved by the Director of Policy and Programs. There will be a written report to each facility outlining the findings of the review. A review of all activities outlined in this operating procedure will be included.

b. Validate corrective actions should on-site reviews indicate a need for follow-up of identified concerns.

c. Ensure Department clinical policies, procedures, and protocols related to the use of psychotherapeutic medications are maintained current.

d. Function as a liaison between the Statewide Medical Executive Directors' Group and the Statewide Pharmacy and Therapeutics Committee.

14. The Statewide Medical Executive Directors' Group. The Statewide Medical Executive Directors' Group will:

a. Review the use of psychotherapeutic medications in the state mental health treatment facilities.

b. Set standards and protocols for psychotherapeutic medication use.

c. Review standards of practice and non-standard practices at the facilities.

BY DIRECTION OF THE SECRETARY:

*(Signed original copy on file)*

WENDY SCOTT
Director, State Mental Health Treatment Facilities, Policy and Programs

SUMMARY OF REVISED, DELETED, OR ADDED MATERIAL

References updated.
- Medication Exception Request (MER) definition deleted.
- Medication Exception Request (MER) process deleted.
- PRN Orders for Psychotherapeutic Medication changed from maximum of 14 to maximum of 30 days.
- Definition of and membership of the Statewide P & T Committee was revised;
- Language regarding ETO changed to provide more detailed information.
- Language change throughout from “Psychiatrist or Prescriber” to “Psychiatrist/Psychiatric ARNP.”
- Language in ETO section changed to clarify and standardize with F.A.C and F.S. Example added.
- Peer review process revised.
- Statewide and Facility P & T Committee responsibilities revised. Data collection requirements revised.

Deleted the following:
- Appendix A: Effects of Abrupt Withdrawal;
- Appendix B: Tardive Dyskinesia (TD) Information Sheet;
- Appendix C: Metabolic Syndrome Information Sheet;
- Appendix D: Neuroleptic Malignant Syndrome (NMS) Information Sheet;
- Appendix E: Quarterly Review of P & T Committee Data and Review Findings by the Clinical Advisory Committee;
- Appendix F: Lithium Monitoring Guidelines;
- Appendix G: Mental Health Treatment Facilities State Formulary.