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A. Policy Statement

Antipsychotic medications have had well-demonstrated success in the clinical management of psychotic disorders. Nonetheless, a number of different movement disorders have been associated with the use of antipsychotic medications. Some of these movement disorders, such as parkinsonian-like extrapyramidal symptoms, are easily identified, controllable with medication which treats the symptoms, and are ultimately reversible upon discontinuation of the antipsychotic medication.

However, tardive dyskinesia and tardive dystonia are potentially irreversible movement disorders which often do not emerge until months or years after initiation of medication. Tardive dyskinesia and tardive dystonia have been associated with use of traditional antipsychotic medications (often referred to as neuroleptic medications). The newer atypical antipsychotic medications, or second generation antipsychotic medications, may carry less risk of tardive dyskinesia. Thus, the primary goal related to antipsychotic treatment is to maximize clinical efficacy while minimizing the risk of adverse side effects, particularly tardive dyskinesia.

The guiding philosophy of the Office of Mental Health, reflecting in part the recommendations of the American Psychiatric Association, is the judicious use of antipsychotic medication. Assessment for the presence of medication-related movement disorders is an integral part of ongoing clinical assessment of the patient. Such assessment includes both a comprehensive medication history (including history of movement difficulties) and an assessment of the patient's current clinical status. Because of the slowly developing nature of tardive dyskinesia, tardive dystonia, and tardive akathisia, it is important to document this assessment in a consistent and objective fashion, so that changes can be noted and addressed in a timely fashion.

The purpose of this policy directive is to ensure that each State operated psychiatric center has a written plan regarding the prevention, early detection, and treatment of tardive dyskinesia for both inpatient and outpatient populations. Accordingly, this directive shall apply to all State operated inpatient and outpatient programs.

B. Relevant Statutes and Standards:


Mental Hygiene Law §7.17

Tardive Dyskinesia: A Task Force Report of the American Psychiatric Association (*American Psychiatric Association Task Force on Tardive Dyskinesia, February 1992*).

C. Definitions

(1) *Antipsychotic Medication* means a drug used to treat psychotic symptoms.

(2) *Atypical Antipsychotic Medication, or Second Generation Antipsychotic*


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Medication means an antipsychotic medication from a newer class which, on the basis of current knowledge, is thought to have less effect on the autonomic and/or extrapyramidal systems.


- (3) *Neuroleptic or Traditional Antipsychotic Medication* means an antipsychotic drug that often exerts an effect upon the autonomic and extrapyramidal nervous systems.
- (4) *Tardive akathisia* means a late developing drug induced disorder characterized by persistent inner restlessness, producing an inability to sit still or remain in one place or position.
- (5) *Tardive dyskinesia* means a late or slow evolving movement disorder associated with use of antipsychotic drugs and manifested by a wide variety of involuntary movements, including abnormal oral-lingual-facial movements.
- (6) *Tardive dystonia* means a late or slow evolving movement disorder involving sustained muscle contraction, often causing twisting, repetitive movements or abnormal sustained postures.

D. Body of the Directive

- (1) General Principles:
 - (a) Prior to the initiation of medication therapy for any patient, including antipsychotic treatment, the following factors must be assessed:
 - (i) an objective and accurate diagnosis of the illness to be treated;
 - (ii) review of the patient's clinical history and response to treatment;
 - (iii) analysis of the risk/benefit ratio of the proposed treatment for the individual patient; and
 - (iv) education of the patient concerning the risks and benefits of treatment.
 - (b) Upon establishing antipsychotic therapy as one treatment of choice, the safest effective drug and lowest effective drug dose must be utilized.
- (2) Written Plan: Each facility shall develop a written plan consisting of 5 components:
 - (a) **Prescription of Antipsychotic Medications;**
 - (b) **Monitoring System;**

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- (c) **Treatment of Tardive Dyskinesia, Tardive Dystonia, and Tardive Akathisia;**
 - (d) **Patient and Advocate Education;** and
 - (e) **Quality Assurance Activities.**
- (3) Requirements for Plan Components:
- (a) **Prescription of Antipsychotic Medications:** The written plan shall reaffirm certain basic clinical principles related to the prescription of antipsychotic medications. At a minimum, the plan must address the following:
 - (i) The short-term indications versus the long-term indications for use of antipsychotic medications; (i.e., treatment of less than six months duration versus that of more than six months).
 - (ii) The choice of drug, considering risk of tardive dyskinesia, or other serious side effects, while weighing other relevant clinical factors such as patient acceptance and effectiveness of medication.
 - (iii) The need to prescribe the lowest effective dose.
 - (iv) The need for continued use of the medication after stabilization of symptoms.
 - (v) Justification for doses beyond usual therapeutic range.
 - (b) **Monitoring System:** The plan shall identify a mechanism to develop, implement, and periodically evaluate a system for monitoring the onset of tardive dyskinesia, tardive dystonia, and tardive akathisia, and the need for continued antipsychotic treatment. At a minimum, this system must include detection, documentation, reporting and evaluation provisions. To facilitate the integration of the monitoring system within the facility's operations, the detection procedures must be developed in cooperation with the Drug Monitoring Committee, the documentation procedures must be developed in cooperation with the Medical Records Department, and the reporting and evaluation procedures must be developed in cooperation with the Quality Assurance Department.
 - (i) Detection
 - A. The written plan developed by each facility must delineate the minimum standards for the detection component of the monitoring

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system. These standards shall include, at a minimum, assessments of tardive dyskinesia using the Abnormal Involuntary Movement Scale (AIMS), Form 99 MED. The initial AIMS must be completed for each newly admitted patient who is prescribed anti-psychotic medications at the time of completion of the initial psychiatric assessment, (i.e., within 60 hours after admission), for baseline information.

- B. Patients, regardless of age or diagnosis, who are currently receiving antipsychotic medications are considered to be at increased risk of developing tardive dyskinesia and should receive screening at a minimum annually using the AIMS. Patients with a diagnosis of tardive dyskinesia that is non-changing, regardless of medication regimen, shall be reevaluated at least annually.
 - C. The facility's written plan must provide for clinical situations in which evidence demonstrates that the frequency of AIMS testing should be increased, such as when medication type or dosage is changed and when new onset or progression of tardive dyskinesia is identified.
 - D. As part of the detection component of the monitoring system, each facility must identify those professional staff members who may administer the AIMS. It is the responsibility of the Clinical Director to ensure that such staff members receive appropriate training in the administration of the scale.
 - E. If a patient is uncooperative or unable to participate in the AIMS evaluation, the staff person conducting the assessment must describe the circumstances in the clinical record (including the patient's condition) that hinder the completion of the assessment. Such situations do not preclude the completion of global, unobtrusive assessments of the patient's movements which shall be documented in the clinical record. In these situations, the treating physician must ensure that future attempts at completing the AIMS are made, particularly for patients who are considered to be at high risk of developing tardive dyskinesia.
- (ii) Documentation

Each facility shall develop, implement, and evaluate a system to document the tardive dyskinesia monitoring process. At a minimum, this system shall represent the inclusion of the completed AIMS forms in the patient's Uniform Case Record, and documentation of the risks and benefits of the continued use of antipsychotic medication, if that is the treatment of choice.

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(iii) Reporting

As part of each facility's monitoring system, a reporting process shall be developed and implemented. This process must include procedures whereby appropriate persons are notified when a patient receives an abnormal score on the AIMS (i.e., a score of 2 or more in any body area). At a minimum, the treating physician must be notified to ensure the initiation of a comprehensive case review if the assessment is completed by someone other than the treating physician.

Confirmed cases of tardive dyskinesia, tardive dystonia and tardive akathisia should be reported to the facility's Drug Monitoring Committee.


(iv) Evaluation

Each facility's monitoring system must include evaluation procedures, including procedures for periodic reviews of cases of abnormal AIMS scores. At a minimum, monitoring shall include the following:

- A. Periodic review of the possible relationship between the occurrence of tardive dyskinesia and individual physician prescribing practices, the occurrence of new cases of tardive dyskinesia and their relationship to hospital prescribing patterns by the Drug Monitoring Committee; and
- B. Periodic analyses, when requested, of facility trends related to tardive dyskinesia and other medication-related movement disorders by the Quality Assurance Monitoring Department.

(c) **Treatment of Tardive Dyskinesia, Tardive Dystonia, and Tardive Akathisia**

- (i) The occurrence of a score of two or more (i.e., "mild") in any body area on the AIMS shall generate a comprehensive review of the case by the treating physician. Such a review shall include the following:
 - A. The differential diagnosis of the abnormal involuntary movement disorder;
 - B. An assessment of the appropriateness of ongoing antipsychotic treatment and the management of tardive dyskinesia or other tardive disorder;
 - C. Consideration of the appropriateness of a trial of other medications and/or nutritional supplements for which there is

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evidence in peer-reviewed journals of potential efficacy in palliating symptoms or modifying the course of the dyskinesia; and

D. In severe cases of tardive dyskinesia or tardive dystonia, consideration of referral to neurologists specializing in the treatment of movement disorders.

- (ii) Through the Office of the Clinical Director, each facility must ensure that tardive dyskinesia issues are addressed by the Drug Monitoring Committee or other comparable standing committee. This committee shall provide a mechanism whereby clinical consultation is provided, upon request, regarding issues related to tardive dyskinesia, including differential diagnosis and treatment. Such consultation may be provided by facility staff members, outside experts, the OMH Clinical Consultation Service, or other arrangements, depending on the needs of the patient population and the expertise available in the facility and professional community.

(d) **Patient and Advocate Education**

- (i) Educating patients about the nature of their illnesses and the potential risks and benefits of available treatments is an integral part of the treatment process. Patients and their advocates need to be provided with appropriate information about any medication therapy, including antipsychotic treatment that is being considered as part of their treatment plan. To the extent that patients' families are involved in the treatment planning process, appropriate information should also be made available to them, along with appropriate written material. For children and adolescents, parents/guardians must also be provided with complete information about medications. Furthermore, since tardive dyskinesia may not be noticed in their early stages by patients themselves, it is essential that their families and/or advocates be informed about how to recognize early symptoms of these movement disorders.
- (ii) Whenever a new medication is started, patients should be given information about the medication, in language comprehensible to the patient. The frequency, nature and extent of information provided about medication therapies should be based upon an assessment of the patient's clinical condition, patient interest, the degree of potential risks and benefits of treatment and other pertinent factors.
- (iii) Each facility's written plan, at a minimum, must address the following patient and advocate education processes:

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A. Ongoing Discussion

Patient education regarding medication therapy should be an ongoing process from the time of admission (or initiation of medication therapy). The frequency of discussions about the potential risks and benefits of medication therapy is a clinical decision which will vary for each patient according to the patient's degree of cognitive impairment, the medication regimen, and the the patient's preferences. At a minimum, the appropriateness of such discussions should be determined at the time of the AIMS evaluation and any change in the patient's medication regimen.

B. Nature and Extent of Information

The nature and extent of information conveyed should be determined on the basis of each patient's degree of cognitive impairment and preference for information. Early in treatment, this information may be limited to a discussion of the type, dose, purpose, and short-term side effects of the medication. As treatment progresses, more in depth information may be necessary, including but not limited to, potential drug interactions and potential risks of prolonged medication therapy such as tardive dyskinesia. Any discussion should also address the potential benefits of medication therapy and what will be done to monitor and reduce any potential risks.

C. Responsible Staff


The treating physician is responsible for initiating and directing the process of patient education. At the direction of the physician, designated staff may provide adjunctive education as appropriate to their qualifications, experience and training.

D. Approaches to Patient Education

Each facility must provide patient education in a manner that best serves the needs and preferences of the patient population.

E. Documentation

Staff who provide patient education must document its provision in an appropriate section of the patient's clinical record (e.g., progress notes, treatment plan). At a minimum, documentation by responsible staff must address the nature and extent of information provided to the patient and/or the family. Additionally, during the

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AIMS evaluation, the treating physician must document the status of patient education on the AIMS form.

(e) **Quality Assurance Activities**

As part of the facility's quality assurance program, the Quality Assurance Department shall monitor the implementation of the facility's written plan. In addition, the quality and appropriateness of patient care services related to antipsychotic treatment shall be monitored and evaluated, and steps taken to resolve identified problems. Such quality and appropriateness activities shall incorporate the results of any analyses conducted by the Drug Monitoring Committee or other comparable committee which are related to tardive dyskinesia.