**Section 325.APPENDIX A** **Guidelines for the Utilization of Psychotropic Medications for Children in Foster Care**

**Introduction**

With few exceptions, children and youth in State custody have experienced abuse and/or neglect and often have chaotic caretaking histories with disrupted attachments and multiple placements. Additionally, they may be genetically predisposed to mental illness and may have been exposed in utero to substances of abuse. Not surprisingly, children in foster care are at higher risk for developing emotional and behavioral disturbances and mental illness, utilize mental health services at higher rates, and are more likely to receive psychotropic medications than children from comparable backgrounds.

The utilization of psychotropic medications, defined as drugs used to affect psychological functioning, perception, behavior or mood, for the treatment of children and youth in foster care with severe emotional and behavioral disturbances, has increased dramatically over recent years. The increased utilization of psychotropic medications is paralleled by an equally dramatic increase in the rate of polypharmacy, the co-administration of two or more psychotropic medications. Data on the safety and efficacy of many of the psychotropic medications used in children and youth and research supporting the practice of polypharmacy in this population is limited.

As a result of the increased use of psychotropic medications in children and youth, several highly publicized cases of seemingly inappropriate prescribing, and the recent FDA warnings on the psychostimulants (such as Adderall, Ritalin and Concerta) and the SSRIs (e.g., Prozac, Zoloft, Celexa, Lexapro and Luvox), the treatment of children and youth in State custody with psychotropic medications has come under intense scrutiny from the press, child advocacy groups, and State and federal regulatory agencies.

The provision of psychiatric care for children and youth in the child welfare system faces several hurdles. Not uncommonly, children in foster care are treated in multiple settings, including psychiatric hospitals, residential treatment centers, juvenile detention facilities, outpatient clinics and therapeutic day schools. Communication between providers in each of the settings is often quite poor resulting in fragmented psychiatric care. Additionally, the dependable, ongoing therapeutic and caregiving relationships these children desperately need are hampered by the high turnover among child welfare caseworkers and child care providers. Furthermore, unlike mentally ill children from intact families, often no consistent interested party is available to coordinate treatment planning and clinical care, provide informed consent for treatment, or provide longitudinal oversight of a foster child's treatment.

By law, the Illinois Department of Children and Family Services (DCFS) is responsible for consenting to the medical, surgical and psychiatric care for children and youth in its custody. To meet these guardianship responsibilities, DCFS established the Centralized Psychotropic Medication Consent Program in the Office of the Guardian to provide consent for the prescription of psychotropic medications. To support the consent process, DCFS has contracted with the University of Illinois at Chicago to provide an independent review of all consent requests from clinicians to prescribe psychotropic medications for children in its care.

In June 2006, DCFS convened an Expert Panel to provide consultation to the Department to establish a set of treatment guidelines for these children and youth. It was the consensus of the participants in the Expert Panel that children in the child welfare system present with such complicated clinical pictures that the formation of rigid treatment algorithms that clinicians must rigidly adhere to is unrealistic. Instead, the Expert Panel recommended principles to guide prescriptive practices. The guidelines that follow serve to inform the practice of pediatric psychopharmacology in this population and to provide a framework to assure the provision of quality psychiatric services to DCFS wards. These guidelines are not meant to supersede clinical judgment.

**Guidelines**

1. **This Part requires that written consent from the DCFS Guardian must be obtained prior to prescribing a psychotropic medication to a child or youth under 18 years of age.** In addition the child should give informed assent prior to starting the medication. In order to be effective, informed assent should be based on an honest discussion of risks versus benefits and potential side effects of the proposed treatment, availability of alternative treatments, prognosis with and without the proposed medication treatment, and potential for drug interactions. The treating clinician should document this discussion in the patient's medical record.

2. **The prescription of psychotropic medications is just one component of a comprehensive treatment plan that includes psychosocial and behavioral interventions.** Psychotropic medications are not to be used in place of psychosocial or behavioral interventions that the child or youth requires. Furthermore, 89 Ill. Adm. Code 384 (Behavioral Treatment in Residential Child Care Facilities) specifically prohibits the use of psychotropic medications for chemical restraint. Chemical restraint is defined as the use of any psychoactive medication that is not a part of the patient's treatment plan during a behavioral crisis or psychiatric emergency that results in the sedation of the child for the express purpose of restricting an individual's freedom of movement.

3. **All children and youth must receive a diagnostic assessment prior to starting a psychotropic medication.** A diagnostic assessment should include, at minimum:

a. history of the present illness;

b. past psychiatric history, including medication history;

c. medical and surgical history;

d. allergies;

e. current medications;

f. family history (when available and relevant);

g. mental status examination;

h. DSM-IV1 diagnosis; and

i. treatment plan.

In addition, a physical examination should be done. Baseline laboratory studies and/or an EKG should be obtained if medically indicated and in accordance with accepted standards of care and in congruence with the prescribing clinician's medical judgment.

4. **It is strongly recommended that the prescribing clinician communicate with other clinicians involved in the child's care, particularly other prescribers. The clinician must document that attempt in the medical record.** The purpose of this recommendation is to obtain collateral information to enhance continuity of care and to facilitate the monitoring of the outcome of the medication trial. This communication is particularly important in the treatment of wards hospitalized on a psychiatric unit. According to the Illinois Department of Healthcare and Family Services, 50% of all medications prescribed to patients discharged from State operated psychiatric facilities are discontinued and alternative medications initiated within 2 weeks after discharge. Communication among prescribers is also important when a ward moves from one treatment setting to another (i.e., a lateral move from one residential treatment facility to another) or from one level of care to another (e.g., discharge from a psychiatric hospital back to a foster home). Treatment summaries from the treating clinician should follow the patient detailing the treatment course with particular emphasis on results of psychotropic medication trials.

5. **Prescription of a psychotropic medication should be based on research showing it to be safe and effective for the disorder being treated. Medications that have been approved by the Federal Drug Administration (FDA) for the treatment of a specific disorder in children or youth meet this requirement by definition and should be used preferentially over non-FDA approved medications when they are available.** Exceptions can be made when a patient has had a history of a successful trial of an off-label medication, if a first degree relative has responded to the medication being requested, if the patient is allergic to the FDA approved medication, or if the patient is on other medications that react unfavorably with the preferred medication. Few medications used to treat psychiatric disorders in children and youth are approved by the FDA for use in this age group; however, off-label use of drugs by prescribers is not only legal, but may represent the standard of care. Prescribers have the responsibility to be well informed about the product, to base its off-label use on firm scientific rationale and sound medical evidence, and to maintain records of the product's use and effects. If data supporting the use of the medication in children and youth are not available, data can be extrapolated from the adult literature, though caution is advised.

6. **Medications prescribed should be appropriate to the patient's diagnosis and target symptoms and must be part of the treatment plan.** For patients in whom the diagnosis is not clear or there is no appropriate DSM-IV diagnosis, the decision to prescribe a psychotropic medication may be based on the presence of target symptoms that are likely to be responsive to psychotropic medications.

7. **Existing medication algorithms should be consulted when making the decision about which medication to use for a specific disorder.** Algorithms designed for use by the consultants to the DCFS Centralized Psychotropic Medications Consent Line are based on the Children's Medication Algorithm Project (ADHD and depression), the American Academy of Child and Adolescent Psychiatry (AACAP) Practice Parameter for the Assessment and "Treatment of Children and Adolescents with Bipolar Disorder, and various AACAP Practice Parameters all available from the American Academy of Child and Adolescent Psychiatry, 3615 Wisconsin Avenue, NW, Washington DC 20016-3007, (202)966-7300 or AACAP's website at http://www.aacap.org and the American Academy of Pediatrics Attention Deficit Hyperactivity Disorder diagnostic guidelines available from the American Academy of Pediatrics, 141 Northwest Point Blvd., Elk Grove Village IL 60007-1098, (847)434-4000 or AAP's website at http://www.aap.org.

8. **The decision to utilize polypharmacy (more than one psychotropic medication) or copharmacy (more than one psychotropic medication in the same medication class) should be based on a solid clinical rationale and accepted medical practice.** Research supports the use of polypharmacy in the treatment of certain co-morbid conditions, for augmentation for partial responders, for treating the adverse effects of other psychotropic medications, and for treating multiple symptoms of a single disorder. The following guidelines should be followed when considering polypharmacy or copharmacy:

a. Unless otherwise indicated in published treatment algorithms for children and youth, monotherapeutic options should be exhausted before considering polypharmacy or copharmacy.

b. When polypharmacy is necessary, the fewest medications should be used as possible.

c. Clinicians should be ready to support their use of polypharmacy or copharmacy should DCFS request a review of the case.

d. The concurrent use of slow-release and immediate-release formulations of the same chemical (e.g., Concerta and methylphenidate) is not considered to be polypharmacy or copharmacy.

e. To the extent possible, medications should be started and titrated one at a time. Copharmacy with antipsychotic medications has little evidence to support its use in adults and no quality data to support that practice in children and youth. All requests for concurrent pharmacotherapy with two or more antipsychotic medications will be closely scrutinized.

9. **The prescription of psychotropic medications should be accompanied by education for the patient, his or her foster family or treatment team, and (when indicated) his or her family of origin.** The nature of the diagnosis, the prognosis, and the risks and benefits of treatment, as well as non-treatment, and alternative treatment options should be discussed in detail.

10. **Pharmacotherapy with psychotropic medications must be monitored closely. The frequency of visits depends on the phase of treatment.**

a. Initiation phase − the initiation phase of treatment warrants frequent visits, weekly for some treatments, to monitor early treatment emergent side effects, the development of suicidal ideation in patients treated with antidepressant medications, and the effectiveness of treatment. Clinicians should not implement treatment with psychotropic medications that cannot be monitored closely.

b. Acute treatment phase – this phase is defined as the period of time between initiation of treatment and remission of symptoms and is characterized by frequent visits. The duration of the acute duration phase of treatment is variable.

c. Continuation phase – once the symptoms have remitted, treatment continues to prevent relapse. This phase of treatment lasts between four and six months and is characterized by regular visits.

d. Maintenance phase – treatment after the continuation phase is for the prevention of recurrence of the underlying disorder. Not all pharmacotherapy requires maintenance treatment. For example, successful treatment of a single episode of depression in a child does not require maintenance treatment. In contrast, treatment of ADHD with stimulants often requires a long maintenance phase. Visits during the maintenance phase can be less frequent. Depending on the stability of the patient, visits could be as infrequent as two to three times per year.

e. Discontinuation phase – the prescribing clinician should consider discontinuation of the psychotropic medications when the patient has recovered from the underlying episode and is no longer at risk for relapse. Medication discontinuation requires a separate treatment plan with increased frequency of visits to monitor for signs of relapse. Medications should be tapered slowly to prevent withdrawal effects.

11. **Response to treatment should be monitored through the use of standardized symptom severity scales and instruments to measure treatment emergent side effects.** Follow-up may also include height, weight, abdominal girth, blood pressure, pulse, CBC with differential, thyroid function studies, lipid profile panels, liver function tests, EKGs and drug levels as indicated by the patient's medication regimen.

12. **In order to be effective, medication trials must be adequate in terms of dosage and duration.** A medication may be falsely characterized as ineffective if the trial is inadequate. Inadequate medication trials frequently occur due to changes in treatment setting. For example, admission to and discharge from an inpatient unit is often accompanied by a change in medication, often before an adequate trial has been completed. When available, blood levels of medications should be followed to assure an adequate dosage. At times the dose of a medication needed to maintain a therapeutic blood level may exceed the maximum recommended dosage for that medication. In those cases, the blood levels, not the dosage, should inform treatment.

13. **If a child does not respond to the medication trial despite adequate dosage and duration, the prescribing clinician should assess patient compliance, reassess the diagnosis, rule-out the presence of co-morbid conditions, including substance abuse and general medical disorders, and evaluate the influence of psychosocial stressors.**

14. **DCFS specifically prohibits the use of pro re nata (PRN) medications.** Prior consent for the one-time administration of a psychotropic medication is not necessary when an emergency exists. However, all administration of emergency medications must be reported to DCFS.

**Case Review**

The following situations will trigger a closer review of a patient's care and possible denial of psychotropic medication requests:

1. Four or more psychotropic medications prescribed concomitantly (three or more for children six years of age or younger).

2. Prescription of psychotropic medications, with the exception of stimulants, for children under the age of four.

3. The concomitant prescription of:

a. two or more antidepressants2;

b. two or more antipsychotic medications;

c. two or more stimulant medications3; or

d. three or more mood stabilizer medications.

4. Frequent changes of psychotropic medications without a clear rationale, such as adjusting medication dosages or in response to treatment emergent side effects.

5. The requested psychotropic medication is not consistent with the patient's diagnosis or the patient's target symptoms.

6. Polypharmacy is utilized before exhausting monotherapeutic options.

7. The psychotropic medication dose exceeds usually recommended doses for weight and age.

8. The prescription of psychostimulants to an actively psychotic child.

9. Children for whom emergency medications are used more than twice a day for three or more consecutive days.

**End Notes:**

1 "DSM-IV" means the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (American Psychiatric Association, 1400 K Street NW, Washington DC 20005 (1994)) or most current edition.

2 The prescription of trazodone or mirtazepine as a sleep aid in addition to another antidepressant does not constitute concomitant prescribing.

3 The prescription of a long-acting stimulant and an immediate release stimulant of the same chemical entity (e.g., Concerta and methylphenidate) does not constitute concomitant prescribing.

(Source: Added at 36 Ill. Reg. 3846, effective February 24, 2012)