

**GUIDELINES FOR PSYCHOTROPIC
MEDICATION USE IN CHILDREN AND
ADOLESCENTS**

DCF Psychotropic Medication Advisory Committee
Department of Children and Families
State of Connecticut January 2010

**Guidelines for Use of Psychotropic Medications with
Children and Adolescents
Department of Children and Families
State of Connecticut**

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Dear Fellow Practitioner:

Thank you for your commitment and dedication in caring for children under the care of the Department of Children and Families (DCF). We understand that you will face special challenges in treating these children and their families.

Over the past decade, the DCF Psychotropic Medication Advisory Committee (PMAC), a group of Child Psychiatrists, Pediatricians, Pharmacists, Advanced Practice Registered Nurses, and Family Advocates, from both the private sector and the State system, has been meeting to review the psychiatric treatment of children and adolescents in the DCF system. As well as reviewing the psychiatric and mental health treatment needs of children in the DCF system, we have been working to refine and standardize the processes related to the use of psychotropic medications in DCF-involved children. Using multiple resources, we have formulated guidelines to improve and systematize psychotropic medication treatment. Additionally, these guidelines will aid DCF personnel who work diligently to advocate for children under their care. **While these guidelines are not meant to dictate standards of care in your practice, they should provide a consistent consent process for the use of psychotropic medications as well as serve to improve the overall level of care for DCF children.**

These new guidelines will doubtless stimulate many thoughts and questions, which we welcome and encourage. The associated protocols will be reviewed and updated every six months to reflect the latest in state-of-the-art, evidence-based practice.

Once again we thank you for your dedicated work with children in the care of the Department of Children and Families, and we look forward to working collaboratively with you in the future.

Respectfully,

Janet E. Williams, MD DCF Medical Director Chair, DCF
Psychotropic Medication Advisory Committee

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Chapter One: Introduction

The children and adolescents in the care of the Department of Children and Families (DCF) offer special challenges to the practitioner. There are approximately 6000 Connecticut children at any one time whose guardian is the Commissioner of DCF. In addition, there are many other children who are entering and leaving the system, through orders of temporary custody, 96-hour holds, commitment for the purpose of placement, or by turning age 18 and reaching the age of consent. Many of these children cycle between foster homes, group homes, residential treatment centers, and hospitals, often with incomplete medical records and no consistent primary practitioner overseeing their care. There is now widespread acknowledgement among healthcare professionals that these children represent a very vulnerable sub-population. According to one study (Farmer, Burns, Chapman, Phillips, Angold, and Costello, 2001) serious emotional disturbance, as defined by the presence of a diagnosable psychiatric condition and significant functional impairment, was present in 78 percent of the children in foster care. The authors also noted rates of behavior problems, developmental delays, and need for mental health treatment of between 39 and 80 percent of the foster care population. The high rate of psychiatric and behavior problems in the population of children in foster care are costly, both in human and financial terms. For example, in California foster children make up 4% of the Medicaid population, but account for more than 40% of child mental health expenditures (Rosenfeld, Pilowsky, Fine, Thorpe, Fein, Simms, Halfon, Irwin, Alfaro, Saletsky, & Nickman, 1997).

Not only may children/adolescents in state care present with complex psychiatric diagnostic issues, but also reliable and comprehensive medical history on the child may not be available to help clarify complex medical and behavioral health issues. The child may have had multiple caretakers; disruptions and trauma within the foster care system itself, and may currently be in transition from one home setting to another.

As a result of these findings, many agencies (Child Welfare League of America – CWLA; American Pediatrics Association- APA; American Association of Child and Adolescent Psychiatrists – AACAP) have published guidelines, readily available on their websites, for treatment of children for whom the state is their guardian. These guidelines focus on the importance of a complete diagnostic work-up, and the establishment of a “medical home” for overall preventative care. The AAP guidelines call for mandatory health evaluations for children entering foster care, including an initial health screen within a week and a comprehensive examination within 30 days. (Pediatrics 2003; 112;134-142)

Along with the identification of the vulnerabilities of this population is the recent focus on alarming trends in psychotropic medication use in children and youth. Examples include articles citing the lack of an evidence-base for pediatric psychopharmacology; growing concern about side effects of SSRIs; medication use linked to increased susceptibility to diabetes, metabolic syndrome and obesity; the rapid increase in use of second generation antipsychotic for aggression when new studies show first generation antipsychotic for psychosis may be more effective; and overall concerns that lack of

community –based treatment options have led to an over-reliance on medications. Now more than ever there is reason for caution and prudence in prescription writing for this population, and states as diverse as Arizona, Texas, and Florida have begun publishing their own guidelines for this process. **Responding to growing concern, Connecticut legislation was passed in 2005, requiring DCF to set up a state-of-the-art medication management system for children and youth in the care and custody of the Commissioner.**

A third major development in the understanding of needs of this population has been the acknowledgement of the pervasive effects of trauma (which is often the reason for the change in guardianship) in this population, including effects on brain development, attachment, cognitive development, educational readiness, physical health, and last but not least the development of long-term behavioral and psychological difficulties. The overlay of exposure to trauma during critical periods of development in infancy and childhood often leads to long-term, complicated treatment problems that do not respond to the “quick-fix” approach, nor do they respond to work done in silos. In general, the resulting symptoms fit best with the “developmental trauma diagnosis” which is currently in field trials for DSM-V. These symptoms are not specifically medication-responsive, although medication may be necessary to help the patient be more available for other treatment modalities. Close collaboration between mental health providers, primary care providers, school systems, families and extended families, residential/foster home/group home/ hospital staff, and DCF is presumed to be a key ingredient to a successful outcome (i.e., a healthier child in the least restrictive setting available).

In summary, the following guidelines and protocols based on clinical evidence, clinical judgment, and research, represents a community standard in the use of psychotropic medications in children and adolescents under DCF’s care. Their purpose is to support practitioners who work with this complex, ever-changing, ever-moving population and to guide rational treatment of these patients.

Chapter Two: Psychiatric Assessment of DCF Children and Adolescents

Assessment

The baseline assessment of a child or adolescent prior to initiating psychopharmacological treatment is complex. It must involve the evaluation of a myriad of biological, psychological and social variables. The actual purpose of the assessment is multifaceted and includes: 1) the establishment of a therapeutic relationship with the patient and parent/guardian; 2) the formulation and establishment of a working diagnosis; 3) the identification of target symptoms; and, 4) the development of a comprehensive treatment plan.

It is important to note that co-morbid medical and psychiatric disorders are often present in children and adolescents who require our care. **All children should have a thorough health evaluation and identification of acute medical problems prior to the administration of psychotropic medications. In some cases, medical problems mimic and/or occur co-morbidly with psychiatric disorders.** In those cases, the identification of target symptoms is most critical. When pharmacologic intervention is identified as part of the treatment plan, considerations such as diagnostic medical evaluations, drug-drug interactions, polypharmacy, treatment compliance, informed consent, and the safe storage and administration of medications become key.

The administration of psychotropic medication should involve appropriate education of the patient and caretaker, an adequate trial, and careful monitoring by the prescribing practitioner along with other treatment providers. An **adequate trial** refers to an appropriate dose of the medication being given over a reasonable period of time needed to obtain benefit. **Adequate treatment** must be offered in order to clearly determine therapeutic efficacy; however, the practitioner must be ever mindful of possible adverse reactions, which might necessitate a careful discontinuation of the medication. Regular and frequent follow-up with the patient and guardian is important in enhancing compliance, providing ongoing psycho-education about side effects and medical monitoring, monitoring therapeutic effects of the medication, and assessing effectiveness of the medication intervention.

The **assessment of a medication trial** is facilitated by the initial identification of target symptoms and the regular evaluation of those target symptoms. Secondly, the consideration of intercurrent life events, particularly in children and adolescents, is also essential in assessing benefits of medication. The start of school, a change in living situation, physical illness, parental functioning, issues of loss, a birthday, etc., can all impact functioning and can confound the evaluation of a medication trial. Thirdly, compliance may need to be investigated through pharmacy records or medication administration records in order to clearly assess efficacy of a medication trial. Once an informed decision is made about a particular medication, changes in the treatment plan may be necessary including changes in medication regime, adjustment in non-pharmacologic treatment strategies, and re-evaluation of the diagnosis.

In children and adolescents, **re-evaluation of the working diagnosis** is useful not only when there is a lack of treatment response but in other situations as well. By nature, children and adolescents are developing and changing during their treatment. Longitudinal information may become available revealing temporal patterns of functioning that may alter diagnosis. And, at time, the successful treatment of one disorder may then expose an underlying co-morbid disorder that requires treatment. Ultimately, the resolution of a disorder or the ineffectiveness of a medication requires the medically supervised discontinuation of medications. Because withdrawal or discontinuation effects may arise and confound the clinical picture, **close monitoring is vital to sort out the illness from medication effects. Polypharmacy can be avoided or minimized if these issues are considered.**

Safety Guidelines

In order to further safeguard prescribing practices for this vulnerable population, the following safety guidelines (many adopted from the Texas Utilization Parameters and the JAACAP Practice Parameters for Psychotropic Medication Use in Children and Adolescents) are utilized with DCF-involved children and youth who receive psychotropic medication treatment:

1. Monotherapy regimens for a given disorder or specific target symptoms should be tried before polypharmacy regimens.
2. One medication change should be made at a time (except for cross-tapers).
3. Polypharmacy (i.e., the use of two or more medications for the same indication or specific mental disorder) is discouraged and requires specific justification (except for different forms of the same medication).
4. Medications can only be prescribed according to their published recommended daily maximum doses.
5. In addition to informed consent by the DCF Centralized Medication Consent Unit and/or DCF Regional Medical Director and assent by patients over the age of 8, psychotropic medications must be prescribed in collaboration with other treatment providers and with the primary care physician.

Chapter Three: Psychotropic Medication Consent Process

DCF Policy 44-5-2.1 Psychotropic Medications: Informed Consent

The Department has developed a streamlined process for requesting and obtaining consent to treat DCF children and youth with psychotropic medications. These guidelines will summarize this process, including how the prescribing provider will interface with the Department to obtain required informed consent for the use of psychotropic medications in treatment of children and adolescents who are under the care and custody of DCF. These guidelines, along with the attached appendices, are revised on a regular basis and reviewed by the Psychotropic Medication Advisory Committee. Revisions will be available to prescribing providers on an ongoing basis accessible on the DCF website.

The procedure for informed consent is based in DCF policy. Per the policy, the DCF Commissioner and/or designees shall authorize consent to administer psychotropic medication in a timely manner. To facilitate this process, the DCF area offices have been divided into three **Medical Regions**. Each region is assigned a DCF Regional Medical Director, who is a board-certified child and adolescent psychiatrist. In addition, DCF has established a **Centralized Medical Consent Unit (CMCU)**, comprised of three Psychiatric-Mental Health APRN's, who will receive all medication requests and make decisions or triage to the appropriate Regional Medical Director. The Regional Medical Directors and CMCU APRN's, act as the designees of the DCF Medical Director and the DCF Agency to authorize consent to use psychotropic medications for this DCF population.

This represents a major change and paradigm shift from a model that relied on medication consent being granted by Social Work Program Supervisors in each area office, to a more streamlined process in which providers will interact directly with medical/nursing staff who are trained and board certified in psychiatric/behavioral health care. The goal is to increase both the DCF level of expertise in psychopharmacology used in making such decisions and also to increase the overall efficiency in how consents are granted. In addition, this new process corresponds with the future development of database capability that will allow the collection of information about each child's medication history in a centralized location. This medication history will then be available to DCF staff and prescribing providers in the ongoing assessment and treatment of each child's individual needs.

Contacting DCF for Psychotropic Medication Consent

The prescribing provider who wishes to prescribe psychotropic medications to children/adolescents who are under the care and custody of DCF must obtain informed consent from the Agency, who acts as the legal guardian for the child. The first point of

contact with DCF to request this consent is with the **Centralized Medication Consent Unit (CMCU)**. Providers may contact the CMCU to request psychotropic medication consent either by fax or email (See Appendix I for contact information).

Medication Consent Process

The Process for Obtaining Medication Consent is as follows:

1. Requests for psychotropic medications are to be submitted to the **CMCU**, using the **DCF-465, Request for Psychotropic Medications Form**. Toll free fax: 1877 323-3784 (1 877 DCF-DRUG) or Email: Getmeds.dcf@ct.gov. It is important to **complete the information requested on the form in its entirety, including target symptoms, listing of all medications (including for medical diagnoses, such as asthma), plans to taper, cross-taper, discontinue other medications as part of the treatment plan, and labs, vitals signs, etc.**

Providing complete information that provides a clear “picture” of the child’s current condition and need will decrease time delays that could occur if inadequate baseline information is provided.

2. The **CMCU** receives the DCF Form 465 and verifies the child’s demographic information, assigned Area Office, and Legal Status in the LINK database system. Based on the child’s legal status, the CMCU will use an algorithm to triage and communicate appropriate information regarding the medication request:

- If the child is on an Order of Temporary Custody (OTC) or 96hr hold, the CMCU contacts the Social Worker to determine that reasonable efforts have been made to locate the parent/guardian and acquire parental/guardian consent. If the parent/guardian is located, the Social Worker will call the provider to inform him/her of this fact so that they can request consent from the parent/guardian. If the parent/guardian can not be located, the DCF Social Worker may apply for the Court’s consent to medicate a child, in which case the request would be returned for approval by the CMCU.
- **If the child is not committed to DCF**, the CMCU will call the prescribing provider to inform him/her of this fact so that he/she can request consent from the parent/guardian.
- If the child is a committed delinquent or is receiving Voluntary services, the CMCU will call the prescribing provider to inform him/her of this fact so that consent can be requested from the parent/guardian.
- If the child is committed to DCF, the **CMCU** will process the medication request according to CMCU procedures.

3. CMCU notification is necessary for all intramuscular administration of psychotropic medication including stat medications and those given in the context of an emergency situation. CMCU Notification, using the DCF- 465, must occur within 12 hours of a child receiving medications on an emergency basis.

Turn-around/Response Time

The **turnaround time** for medication requests will be **12 hours for urgent** requests and **24 hours for routine** requests.

Appeal Process

The decision of the Regional Medical Director is final, unless there is strong disagreement. In this case, the DCF Medical Director may be asked to make a final determination if the Provider submits a written or verbal appeal to the DCF Medical Director. An appeal may be submitted to the DCF Medical Director by informing the CMCU APRN or Regional Medical Director of the request to file an appeal. The CMCU APRN or Regional Medical Director will forward the request for an appeal to the DCF Medical Director. The DCF Medical Director will then contact the prescribing provider to discuss the case and make a decision. The final decision will be recorded by the CMCU APRN in the MEDLINK database and notify the prescribing provider of the final outcome. The decision of the DCF Medical Director is absolute and final.

Notification of Psychotropic Medication Discontinuation Process

It is important that DCF be kept apprised of any changes in psychotropic medication treatment, including discontinuation of medications and/or changes in dosage/frequency of a medication previously approved with a defined dosage range. The prescribing provider is requested to notify the CMCU of such changes by submission of **Form DCF465A, Notification of Discontinuation or Dosage Change of a Psychotropic Medication** either by fax or email. Please note: consent is not required to discontinue a medication or change the dosage within a previously approved dosage range.

Chapter Four: DCF Psychotropic Medication Protocols and DCF Formulary

DCF Psychotropic Medication Protocols

The DCF Psychotropic Medication Advisory Committee publishes the DCF Psychotropic Medication Protocols, with revisions made on a semi-annual basis. The Guidelines contain suggested baseline and follow up labs and other monitoring interventions that are based on the latest in evidenced-based practice and research literature. Prescribing Providers are requested to utilize the Guidelines and may be asked to provide clinical information and follow-up based on this document.

DCF Approved List of Psychotropic Medications

The DCF Psychotropic Medication Advisory Committee publishes the DCF Approved List of Medications that contains a comprehensive listing of medications (generic and brand) approved for use with DCF Children/Adolescents. Requests for medications that are not listed on the formulary require review by the DCF Regional Medical Director.

Please note, that the DCF Approved List of Medications is separate from and unrelated to any Formulary that may be published by any insurance company, including the HUSKY/Medicaid Managed Care Organizations (i.e., Blue Care Family Plan, Connecticut Health Network, Inc., Wellcare/Preferred One, Health Net/ Healthy Options). It is the prescribing provider's responsibility to seek prior authorization from the child's health plan for any medication that is subject to the health plan's prior authorization process.

Chapter Five: Reporting Adverse Drug Reactions

Purpose

DCF has established an ongoing Adverse Drug Reaction (ADR) monitoring and reporting program that focuses on psychotropic medications used in the treatment of DCF-involved children/youth. The purpose of this monitoring program is four-fold:

1. To provide an anonymous mechanism for collecting ADR data;
2. To evaluate the data in aggregate to identify system problems;
3. To implement non-punitive actions to resolve identified problems; and
4. To insure proper reporting of ADR's to the FDA and manufacturer when indicated.

Definition

Within DCF, **a reportable, significant ADR includes any unintended, unexpected, undesired or excessive response to a medication that:**

1. Requires discontinuing the drug (therapeutic or diagnostic);
2. Requires changing the drug therapy;
3. Requires modifying the dose (except for minor dosage adjustments);
4. Necessitates admission to a hospital;
5. Prolongs stay in a health care facility;
6. Necessitates supportive treatment;
7. Significantly complicates diagnosis;
8. Negatively affects prognosis; or
9. Results in temporary or permanent harm, disability, or death.

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 ADR's.

Process

All reporting shall be anonymous as to who reported the ADR and who prescribed the medication suspected of causing the ADR. All licensed medical professionals who interact with DCF clients are encouraged to report any observed adverse event that may be related to psychotropic medication therapy by completing Section I of the **DCF-465B Suspected Adverse Drug Reaction Reporting Form** and faxing it to the DCF ADR Center, located on the form.

The ADR Reporting Center then completes the form, using whatever resources are available, and rates the level of significance of the adverse drug reaction. DCF will then be able to use aggregate data that is compiled from the ADR Reporting forms to examine quantitative and qualitative trend analysis and make or implement

recommendations to resolve identified issues and/or act on opportunities to improve patient care. In addition, significant events will be forwarded to the DCF Psychotropic Medication Advisory Committee Chairperson who will schedule a further case review.

As a collaborative process, timely completion of the ADR reporting process allows DCF the opportunity to improve quality of care via data analysis, and communication with providers regarding trends or findings that are significant for the DCF child/adolescent population.

Chapter Six: Conclusion/ Request for Feedback

It is the hope of the Department of Children and Families that this psychotropic medication consent process will increase not only the efficiency and level of expertise of the decision making process, but that ultimately, communication and collaboration between the Department and providers for our children/youth will result in enhanced continuity of care and positive long-term outcomes for the children/youth in our care.

We welcome any feedback or suggestions as to how to change/improve this process over time, and encourage you to complete and send back the Feedback Page with your comments and suggestions.

FEEDBACK PAGE

Please Return to : Janet E. Williams, MD,
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505 Hudson Street Hartford, CT
06106 or Fax (860) 560-7066

Name: _____

Address: _____

Comments:

Suggestions: