

Guidelines for Psychotropic Medication Use in Children and Adolescents

Psychotropic Medication Advisory Committee
Department of Children and Families
State of Connecticut
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Foreword

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 and we look forward to working collaboratively with you in the future.

Over the past fifteen years, the DCF Psychotropic Medication Advisory Committee (PMAC) composed of Child Psychiatrists, Pediatricians, Pharmacists, Advanced Practice Registered Nurses, and Family Advocates, from both the private sector and the State system, has been reviewing the psychiatric and mental health treatment needs of children in the DCF system, while working to refine and standardize the processes related to the use of psychotropic medications in DCF-committed children. Using multiple resources, we have formulated guidelines to improve and systematize psychotropic medication treatment. Additionally, these guidelines 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 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 guidelines are reviewed and revised by PMAC on a regular basis to reflect the latest in state-of-the-art, evidence-based practice. 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.

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 3000 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. 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. One study found that nearly 90 percent of young children entering the foster care system had physical health problems, and 55% have two or more chronic conditions. (Leslie, L; Gordon, J.; Meneken et al; *"The Physical, Developmental, and Mental Health Needs of Young children in Child Welfare by Initial Placement Type"* Journal of Developmental and Behavioral Pediatrics, June 2005). 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. In other words, not only the trauma associated with abuse and/or neglect that led to their initial removal from their family, , but traumatic experiences within the foster care system has the potential to create a set of circumstances that may lead to behavioral difficulties and the need for psychiatric consultation. Medicaid data demonstrates that children in foster care represent only 3 percent of children in Medicaid, but 15 percent of children using behavioral health services. Furthermore, these children represent 13 percent of those in Medicaid receiving psychotropic medications, and are four times more likely to receive these medications than children in Medicaid overall. (Allen, K; and Hendricks, MS; *Medicaid and children in Foster Care*, Center for Health Care Strategies, March 2013)

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.

Along with the identification of the vulnerabilities of this population is the recent focus on concerning 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 medication for treatment of aggression and psychosis when new studies show first generation antipsychotic medication for psychosis may be equally effective with fewer side effects; and overall concerns that lack of community –

based, evidence-informed psychosocial 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 well to the “quick-fix” approach or to work done by providers working in isolation. Given that many behavioral symptoms within the foster care population may be related to trauma, it is vital when evaluating and treating these children to consider the ways development can be affected by traumatic experiences. Many of the symptoms related to chronic exposure to trauma are not especially medication-responsive, although medication may be necessary to help the child to improve functioning and to participate actively in trauma-informed treatment modalities. Close collaboration between mental health providers, primary care providers, school systems, families, community-based support systems, 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).

The following protocols and procedures were recommended by the Psychotropic Medication Advisory Committee and adopted by DCF. The recommendations were 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 are important.

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 and monitoring therapeutic effects of the medication.

The **assessment of a medication trial** is facilitated by the initial identification of target symptoms and the regular evaluation of those target symptoms. 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. Compliance may also need to be investigated through pharmacy 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 regimen, 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 diagnoses and at times, the successful treatment of one disorder may then expose an underlying co-morbid disorder that also 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 for Psychotropic Medication Treatment

In order to further safeguard prescribing practices for this vulnerable population, the following safety guidelines 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 reviewed and not approved by the Psychotropic Medication Advisory Committee and thus not listed as approved for use in DCF-involved youth -- based on a lack of safety and/or efficacy data -- should be avoided.
5. Medications should only be prescribed in compliance with the PMAC recommended dosing guidelines which are available on the DCF CMCU website.
6. 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 children and youth who are committed to the agency. To facilitate this process DCF has established a **Centralized Medical Consent Unit (CMCU)**, comprised of APRNs, RNs and Child Psychiatrists. The CMCU staff is authorized to review all recommended psychotropic medications for DCF-committed children, and to make the final decision to approve, modify or deny the recommended medication

When this process was started in 2007, it represented a major change and paradigm shift from a model that had relied on medication consent being granted by Social Work Program Supervisors in each area office, to a more streamlined process in which providers interact directly with medical/nursing staff who are trained and board certified in psychiatric/behavioral health care. The current process increases the level of expertise in psychopharmacology used in making such decisions, and also increases the overall efficiency of the decision-making process. A database has been developed that collects information about each child's medication history in a centralized location. This medication database is 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 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 which can be completed online or faxed to the CMCU**.

Toll free fax: 1-877 323-3784 (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; all psychiatric and medical diagnoses and medications with dosages: plans to taper, cross-taper, discontinue other medications as part of the treatment plan; and labs, vitals signs, etc.** Providing sufficient information about the child's clinical condition and needs on the request form 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 committed to DCF, the **CMCU** will process the medication request according to CMCU procedures.
 - If the child is on an Order of Temporary Custody (OTC) or 96hr hold, the CMCU notifies the Social Worker so that reasonable efforts can be 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 seek 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. The DCF Social Worker is also informed of the request.

- 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. The DCF Social Worker is also informed of the request.

3. CMCU Notification is necessary for all STAT medications given in the context of an emergency situation when prior authorization had not been received. Using the DCF-465 form, the name, doses and target symptoms of all previously unauthorized STAT medications must be submitted to the CMCU within 12 hours of their use. If the provider has previously requested and received approval for the medication that was used in an emergency, a new DCF-465 does not have to be submitted.

Response Time

The **response time** for medication requests is often dependent upon the request form being properly completed. **The goal is to complete each request within one business day of receipt, however when outdated or incomplete forms are submitted for review, the processing time is extended as the CMCU has to obtain the missing information from the prescriber.**

Appeal Process

Any medication decision can be appealed.

When the initial request was completed by an APRN or RN, the first-level appeal is heard by a CMCU Child Psychiatrist. If second-level of appeal is made the request is reviewed by the DCF Medical Director/designee.

When the initial request was completed by a Child psychiatrist the appeal is heard by the DCF Medical Director/designee.

An appeal may be submitted by informing the CMCU APRN, RN or Child Psychiatrist of the request to file an appeal. The request will be submitted to the appropriate physician who will contact the prescribing provider to discuss the case and make a decision. The final decision will be recorded by the CMCU RN in the CMCU database and any modification in the decision will be provided in writing to the prescribing provider and DCF Social Worker. The decision of the DCF Medical Director is 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 DCF-465A, 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 at least semi-annually. The Protocols contain required and suggested baseline and follow up labs and other monitoring interventions that are based on the latest in evidence-based practice and research literature. Prescribing Providers 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 require review by a CMCU Child Psychiatrist.

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 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 completes the form and rates the level of significance of the adverse drug reaction. The aggregated data are forwarded to the DCF Psychotropic Medication Advisory Committee in order to examine quantitative and

qualitative trend analysis and make recommendations to resolve identified issues and/or act on opportunities to improve patient care

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.