

*Provider Bulletin # 10-03*  
**Philadelphia Behavioral Health System**  
**Community Behavioral Health**  
**Use of Psychotropic Medications in Children and Adolescents (FDA  
approved and Off-label)**  
*January 11, 2010*

**Background**

It is the intent of the DBH/MRS to provide the Children and Youth of Philadelphia who are receiving behavioral health services, safe treatments that are consistent with best practice standards. This bulletin will increase the likelihood that youth, who are prescribed psychotropic medication, and their guardians will participate in a more comprehensive and rational informed consent process. In addition, youth who are receiving off-label medications will be more closely monitored for adverse effects as a result of this policy.

It is understood that this practice standard will necessitate collaboration with the youth's primary care physician.

DBH/MRS recognizes that even though pediatric psychopharmacology research has grown significantly in the last decade, physicians still have a limited database with which to guide evidence-based practice.

While it would be ideal for all psychiatric medications to be studied in youth before they are used, research is lacking for many of the medications on the market today. Until such studies are completed, it may sometimes be necessary for practitioners to prescribe medications off-label.

Off-label drug use is defined as the use of a drug to treat a condition, target symptoms or a population of patients even though the drug is not specifically approved for an indication by the US Food and Drug Administration (FDA). The use of non FDA-approved medications requires a higher standard of informed consent and closer clinical monitoring.

**General Procedures of Bulletin**

**Consent:**

The consent process includes providing information to the legal guardian, the child/youth, engaging in an interactive discussion regarding the purpose, risks, benefits of medication (as well as specific points noted below) and the documentation of such discussion in the chart as well as a separate informed consent document signed by the appropriate parties.

A mechanism to obtain assent for psychotropic medication from minors must be established.

It is the responsibility of the prescribing psychiatrist to identify the parties who are legally empowered to consent for medication treatment of children and youth. In particular, careful attention must be paid to children and families with child welfare involvement as well as to custody arrangements that specify who is the legal guardian for medical care.

When medication is being considered as part of the treatment plan, there should be an interactive, well-documented discussion with the patient (or the person authorized to make medical decisions on the patient's behalf) regarding:

1. The rationale for an initial prescription of medication, including the condition or targeted symptoms
2. The risks specifically associated with the proposed use
3. If the selected medication is off-label, the nature of off-label use and the reasons for choosing a non-FDA-approved medication.
4. If the medication also has a black box warning about its use, the clinician must discuss the nature of the black box warning as well as the regulatory requirements and monitoring schedules set forth by the FDA for these uses.
5. Proposed strategy for tapering and or discontinuing the prescribed medication

The recommendations from the article Dell, et al *Ethics and the Prescription Pad* published in *Child Adolescent Psychiatric Clinics of North America*, Vol 17 (2008) constitute guidelines that can be followed in developing this policy and procedure as it relates to the informed consent process

### **Documentation, Informed consent document, psychoeducational materials, and medication information sheets**

Documentation of the discussion, informed consent document, along with any written materials provided to the patient, must be included in the child/adolescent's chart.

**Psychoeducational Materials, Medication Information Sheets:** There are a number of resources available that provide information about behavioral health disorders and medication. The following are examples of such resources:

Below can be found [www.aacap.org](http://www.aacap.org), under Families

- Facts for Families
- [Psychiatric Medication for Children and Adolescents Part I: How Medications are Used](#) (2004)
- [Psychiatric Medication for Children and Adolescents Part II: Types of Medications](#) (2004)
- [Psychiatric Medications for Children and Adolescents Part III: Questions to Ask](#) (2004)
- [Comprehensive Psychiatric Evaluation](#) (2005)
- [Preventing and Managing Medication-Related Weight Gain](#) (2008)

Dulcan, MK. Helping Parents, Youth, and Teachers Understand Medications for Behavioral and Emotional Problems. A resource book of medication information handouts, third edition, APPI, 2007.

**Monitoring:** There are several evidence-based strategies to manage the screening and monitoring of adverse effects. Contracted providers are required to develop and implement a policy and procedure to monitor adverse events for each class of psychotropic medication prescribed.

Comprehensive recommendations from the article Zito et al *Off-label psychopharmacologic prescribing for children: History supports close clinical monitoring* published in Child and Adolescent Mental Health Vol 2, 2008 can be useful in developing provider procedures. Please refer to DBH/MRS bulletin # 07-07 released 11/01/2007 for requirements regarding the procedures for monitoring of Metabolic Syndrome in youth who are prescribed antipsychotics.

The articles referenced above are only examples of ways in which consent processes and close clinical monitoring can be accomplished.

Effective February 11, 2010 CBH will review these policies and procedures as well as their implementation during the Credentialing and Re-credentialing process.