

Pennsylvania Department of Public Welfare Child and Adolescent Psychotropic Medication Workgroup Report January 2012

Introduction

In 2009 the Secretary of the Pennsylvania Department of Public Welfare (DPW) directed the Office of Mental Health and Substance Abuse Services (OMHSAS) to convene a diverse group of stakeholders to address key issues related to pediatric psychotropic medication, with the goal of generating recommendations for providers, DPW, and other stakeholders.

Participants included providers, a range of professionals, youth and families, and representatives of behavioral health managed care organizations, state and county government, various child-serving systems, and others. Initially, there were four subcommittees – Informed Consent, Youth and Family Education, Prescribing Practices, and Special Populations. For the final report, the recommendations of the Special Populations Subcommittee have been incorporated into the Informed Consent and Prescribing Practices reports.

Over the past 20 years there has also been a dramatic increase in the prevalence and severity of psychiatric disorders in childhood and adolescence (hereafter referred to as *children*). Childhood psychiatric disorders may cause significant impairment in functioning, and disrupt the psychosocial development for many youth. In response to these concerns, with the goal of intervening early, there has been increased use of psychotropic medication in the pediatric population (Olfson et al, 2002; Zito, J et al, 2003).

For some stakeholders, the increased use of psychotropic medication in the pediatric population appears justified, given how rapidly change occurs during childhood and the long-term impact on development if the youth's psychiatric symptoms remain unabated. Others, however, take a different perspective, pointing out that there have been relatively few outcome studies of pediatric psychotropic medication use, as compared to adult use. They also indicate that most psychotropic medications for youth have not been approved for use by the Federal Drug Administration (FDA). Moreover, they argue out that there have been few studies on the long-term effectiveness of psychotropic medications for youth. They may cite examples of some youth who have developed significant side effects from the use of psychotropic medication, and the uncertain outcomes of longer term use.

Complicating the issue about the appropriateness of psychotropic medication for children is the fact that there are many potential prescribers of pediatric psychotropic medication. These may include child and adolescent psychiatrists, general psychiatrists, primary care

pediatricians and other primary care physicians, developmental pediatricians, pediatric neurologists, certified registered nurse practitioners (CRNPs), and physician's assistants (PAs). At the clinical level, there is need to ensure that prescribers of pediatric psychotropic medication, regardless of specific discipline, are knowledgeable about normal child and adolescent development, child and adolescent psychiatric disorders, psychosocial interventions for psychiatric disorders, indications for use of pediatric psychotropic medications, potential side effects, and methods for effective medication monitoring. The prescriber also needs to be familiar with the variable effects of medication based on the age and developmental level of the youth. In some instances, psychosocial interventions alone may be indicated, with use of psychotropic medication either deferred or determined not to be indicated. In other instances, it may appear that the youth needs to receive psychotropic medication as soon as possible.

This report addresses these issues, drawing together the ideas of participants and the work of the subcommittees. The report identifies best practices related to pediatric psychotropic medication use and offer recommendations for further action. The following assumptions have guided the development of this document:

- First, psychotropic medication for youth and their families, as with all behavioral health treatment, needs to be family-driven and youth-guided. The best outcomes are achieved through the blending of professional expertise and the lived experience and priorities of youth and families. Such an approach benefits both parties, as an educated, informed youth and family actively collaborate with the psychotropic medication prescriber in all medication decisions.
- Second, psychotropic medication, when prescribed appropriately and monitored carefully, represents one way to promote the positive development of youth and help them make effective use of existing resources and opportunities. In particular, psychotropic medication can help a youth benefit from services that might otherwise be ineffective.
- Third, despite the potential benefits of psychotropic medication, such medication also carries risks, and the decision to use psychotropic medication in the pediatric population is not easy. For this reason, psychotropic medication should be used only after the youth has received a mental health evaluation that offers diagnostic clarity, helps youth and family better understand what is going on, and provides an overall direction to treatment.
- Finally, since the goal of treatment involves the promotion of youth adaptation and resilience and not just symptom reduction, psychotropic medication should be part of an integrated treatment process and only rarely used alone.

We believe that the discussion and recommendations within this document are relevant to youth and families, psychotropic medication prescribers, human service providers,

representatives of multiple child-serving systems, public sector managed care, and state government. We hope that this document stimulates dialogue and, more importantly, positive change.

Background

Over the past 25 years, there has been increasing concurrence among those working in human services with children and youth (*youth*) and their families that effective treatment and care involves collaborating with the youth and family and promoting their active participation in all aspects of service provision. Such an approach, with the goal of empowering youth and families and partnering with them, promotes hopefulness and engagement, leading to positive, cost effective outcomes.

Themes of partnership and empowerment are evident within Pennsylvania, at the national level, and among professional organizations, including the American Academy of Child and Adolescent Psychiatry. Examples include the following:

- Pennsylvania's Child and Adolescent Service System Program (CASSP) Principles uphold the importance of what is referred to as child-centered, family-focused care ("Pennsylvania Child and Adolescent Service System Program Principles," 1995). CASSP Principles also highlight the need for professionals to respect family beliefs and values, and their culture.
- The federal government has strengthened the language of family and youth empowerment, identifying the expectation that care for families be *family-driven* and not just family-focused, and that care for youth be *youth-guided* and not just child-centered.
- The core concept of person-directed care has been strongly endorsed by the Institute of Medicine (2002) and by the President's New Freedom Commission (2003). More recently (2009), Kathryn Power, Director of the Center for Mental Health Services (CMHS) within the Substance Abuse and Mental Health Services Administration (SAMHSA) highlighted the need for practitioners to have the capacity for "engaging with consumers and family members," in support of "service recipients direct(ing) their own care."
- Within the field of child and adolescent psychiatry, the American Academy of Child and Adolescent Psychiatry (AACAP), has formally endorsed the need for family and youth participation in treatment ("Policy Statement: Family and Youth Participation in Clinical Decision-Making," 2009).
- The National Federation for Children's Mental Health (the National Federation), with chapters in all 50 states, advocates for family participation and empowerment.

- More recently, the national youth organization known as Youth MOVE (Youth Motivating Others through the Voice of Experience), with support from the federal government and the National Federation, has begun to promote youth empowerment at both the clinical and policy levels.

Within Pennsylvania, there are many tangible ways that youth and families participate at the state level, providing policy-makers with invaluable input. Examples include the following:

- Youth and families participate in the bimonthly Children's Advisory Committee, helping the Office of Mental Health and Substance Abuse Services (OMHSAS) identify priorities and guiding OMHSAS on a range of policy issues.
- In addition, there is now a Youth Advisory Subcommittee, and youth participate in both the Children's and the Adult Advisory Committees.
- Family members and youth are members of the Pennsylvania Youth and Family Training Institute's (YFTI) Advisory Board.
- With the support of the YFTI, a nationally recognized, individualized planning process known as *high fidelity wraparound* actively and creatively builds on the principles and practices of family empowerment.
- The goals of collaboration and partnership guide not only Behavioral Health but, increasingly, Child Welfare, Juvenile Justice, Education, Physical Health (in particular, primary care medicine), and other child-serving systems. For example, the Pennsylvania System of Care Partnership, a federally funded initiative, involves the use of high fidelity wraparound for youth with mental health challenges who are involved with Child Welfare or Juvenile Justice. In addition, another youth and family empowerment approach known as family group decision-making is being used in both Child Welfare and Juvenile Justice.

As a result of developments such as these, significant changes in perspective and action are occurring at multiple levels to benefit youth and families. For example, rather than being blamed for their child's behavioral challenges, families are increasingly embraced by providers and systems. There is an expectation that family members are present and will participate actively in interagency service planning team meetings and treatment team meetings. Youth and families are encouraged to provide information about their strengths, needs, and culture and identify their priorities for treatment. The planning, implementation, and monitoring of treatment all require their active input.

Ironically, the prescribing and monitoring of psychotropic medication have been less influenced by CASSP than other aspects of behavioral health and human services. Too

often, meetings with the psychiatrist or other psychotropic medication prescriber afford the youth and family relatively little opportunity to discuss issues of concern and raise important questions. Given that psychotropic medication use in a pediatric population is typically a complex process, youth and family education, informed decision making, and open communication among all parties are especially important. Partnerships involving the use of psychotropic medication are at least as important as other aspects of treatment and care.

I. Family and Youth Education Subcommittee Report

Subcommittee Mission Statement

To obtain the perspectives of parents, legal guardians, and other caregivers (“families”), and children and youth (“youth”), and the perspectives of pediatric psychotropic medication prescribers (“prescribers”), regarding the core elements of family and youth education, in order to identify best practices for achieving a collaborative process, with active family and youth participation, when pediatric psychotropic medication is used.

Subcommittee Vision Statement

When psychotropic medication is recommended and prescribed for youth, a collaborative process is pursued between prescriber, family, and youth that involves mutual exchange of information, education about medication options and other alternatives, and the use of youth- and family-friendly information about relevant treatment issues. Youth and family participate actively during such meetings, asking questions, identifying priorities and engaging in dialogue with the prescriber. Other members of the treatment team actively support this process, through direct participation when appropriate or as part of ongoing treatment.

Note: *Family* is used to refer to the youth’s parents, legal guardians, or other (substitute) caregivers.

Youth is used to refer to children up to age 21.

Prescriber refers to all practitioners licensed in Pennsylvania to prescribe psychotropic medication to children and adolescents. Such individuals include child and adolescent psychiatrists, general psychiatrists, primary care physicians, developmental pediatricians, and certified registered nurse practitioners (CRNPs).

Need for Biopsychosocial Treatment

Youth resilience – the ability to “bounce back” and be successful in life despite adversity – is promoted when a biopsychosocial perspective is used to understand the strengths and needs of youth and family, in order to help the youth overcome specific challenges to positive functioning and adaptation. Attention to the three domains of biopsychosocial care – biological, psychological, and social factors – allows strategies to be comprehensive and holistic (Engel, 1977, 1980, 1997).

Consistent with the biopsychosocial perspective, psychotropic medication should always be *considered* for youth with behavioral health problems, within a context that also includes appropriate treatment services and supports. In some cases, psychotropic medication will be deemed appropriate and begun immediately, while in other cases, medication will be deferred or postponed in favor of non-pharmacological interventions. Even when it is indicated, psychotropic medication as the sole intervention should be the exception, given the need to address the youth's psychological- and social- as well as biologically-based needs.

Holistic care involves not only attention to the biopsychosocial triad of biology, psychology and social context, but also collaboration among all those supporting the youth's wellbeing and involved in any of these three domains. For example, information should be shared between psychiatric and primary care practitioners about the use of psychotropic and physical health medications, so that adverse interactions can be minimized or avoided. In like manner, provision of formal services should not obscure the importance of natural supports and the need for ongoing collaboration among professionals, support persons, and youth and family.

As in all behavioral health treatment, positive, trusting relationships are essential when psychotropic medication is recommended or prescribed. Building on this trust, effective behavioral health treatment for youth involves a combination of education and active participation by youth and family (Hodas, 1998, 2006). With the decision resting with family and youth, the prescriber has a critical, facilitative role as consultant:

Education should be ongoing, so that caregivers and child are informed and the physician becomes a consultant to the family, and learns about a particular youth's strengths and needs in an ongoing manner (1998).

Need to Understand and Respect the Culture of the Youth and Family

It is important that the prescriber understand, and if necessary learn about, the culture of the youth and family. In this way, discussions and recommendations can be culturally competent. The term "culture" refers not only to a person's ethnicity but also includes language, religion, spirituality, gender, gender identity, sexual orientation, age, economic status, physical ability, cognitive ability, and type and level of other capabilities. Medication-related issues that may be influenced by culture are broad and include the following:

- Readiness to accept a psychiatric diagnosis.
- Receptivity to accepting the use of psychotropic medication.
- The nature of family supervision and oversight of youth adherence to prescribed medication.
- Ability to understand information being provided.

The prescriber should also appreciate that cultural beliefs and practices may vary within a single family, depending in part on the age and degree of acculturation of various family members.

Empowerment – Contributions from “Recovery”

Although the focus of this report is on youth and their families, approaches to empowerment in the adult literature on recovery have relevance to the current discussion, particularly for older youth. The work of Pat Deegan, a mental health professional and a consumer is especially relevant.

Deegan strongly advocates for shared decision-making in mental health treatment, which she identifies as being “an ethical imperative” (2009). In order to “put the person back at the center of person-centered care,” mental health treatment should “empower a person to collaborate with his or her psychiatrist in making informed medical decisions that lead to the best treatment outcomes” (2009).

Deegan has developed pilot peer-run programs to help empower consumers who are taking psychotropic medication. Deegan’s peer-run programs involve the use of what is called a Decision Support Center, to help individuals be better informed about medication issues and interact collaboratively with the psychiatrist or other prescriber during medication visits (Deegan et al, 2008). With the assistance of a clinic-based peer specialist in a welcoming environment, the individual uses a special software program, approximately 30 minutes in advance of a medication appointment, to prepare for the meeting with the prescriber. Prior to meeting with the psychiatrist or nurse, the individual has access to health-related information via the Internet and to decisional aids that can help in addressing potential “areas of decisional conflict related to medication use” (2008). Ultimately, the computer generates a one-page report, highlighting areas of concern and progress, which the individual can use during the medication meeting.

One behavioral health managed care company in Pennsylvania (Community Care Behavioral Health) has engaged Deegan as a systems consultant, and has established Decision Support Centers for adults in conjunction with a Learning Collaborative with over 50 behavioral health providers. These providers are implementing recovery-focused, consumer-driven, decision-support toolkits that promote empowerment.

Deegan also identifies ways for individuals to become empowered with their prescriber during medication appointments, which may be particularly helpful when peer-run programs and Decision Support Centers are not available. The theme involves “reclaiming your power during medication appointments with your psychiatrist” (2006). Drawing on personal experience, Deegan explains that “recovery means taking an active stance towards (one’s) problems and challenges...,” consistent with a focus on education and active participation during psychotropic medication meetings (2006). Medication is viewed as one of many recovery tools, so that its use becomes practical and pragmatic,

helping to reduce potential feelings of stigma. Deegan encourages individuals to record their own medication history, organize their thoughts and concerns, and write questions down, in order to develop and implement a recovery-oriented agenda to follow during medication meetings.

Developmental Differences Among Youth

When it comes to youth of various ages, chronological age and developmental level help determine the amount of education and participation that can be expected. Youth who are young or developmentally immature will generally be less active in learning and participating, but they can still be engaged by the prescriber in a manner that is developmentally appropriate. In what follows, we summarize the progression from preschoolers to adolescents, in terms of typical developmental abilities and limitations.

With very young children (ages 0-5 years), there is primary reliance on the parents, legal guardians, or other caregivers, who need to be educated, ask questions, and participate actively with the prescriber. School age youth (5-10) can be more active than preschoolers, but here too the primary responsibility lies with the caregivers. The prescriber should provide information that helps the caregiver become informed about psychotropic medication for a youth aged 5-10, while also engaging the youngster directly.

Youth from approximately age 10 to 14 years, although not yet of age to formally consent to the use of psychotropic medication, can be educated about medication and encouraged to participate in discussions, ask questions, and offer meaningful opinions. Such youth should be asked to describe their understanding of medication being discussed, and to identify their concerns. When these concerns are effectively addressed, their anxiety decreases and their motivation increases. A youth under age 14 who is informed about and agrees to use specific psychotropic medication is considered to have offered his or her “assent.” Obtaining assent from a youth under 14, while not a legal requirement, is considered part of best practice, so long as formal consent is also obtained from the parent or legal guardian, or from the court in instances where there has been a transfer of legal custody to a county children and youth agency.

Beginning at age 14, the age in Pennsylvania when formal consent to psychotropic medication is required, the youth becomes an even more significant participant. As a result, there is greater balance in the roles of the youth and his or her parents, legal guardian, or other caregiver. All involved parties need to be engaged, educated, and active. Medication will likely be taken regularly only when both family and youth have agreed to its use. A prescriber, to be effective, needs more than scientific knowledge about medications. He or she needs to have an understanding of the changing balance of responsibility for participation and decision-making between youth and family, based on the youth’s age and developmental level. The prescriber also needs skills to engage youth

and family and to mediate disagreements that may arise within the family, so that an appropriate resolution can occur.

The Role of the Family and Youth Subcommittee

Key decisions made by the subcommittee involved 1) actively recruiting youth for the Subcommittee, in order to ensure their participation during conference calls, 2) gathering input from key, external stakeholders through focus groups and surveys, 3) drafting youth-and family-friendly references, and 4) drafting recommendations based on the literature, subcommittee input, and the input of diverse, participating stakeholders.

In October 2009, Ms. Valarie Oulds-Dunbar, family co-chair of the subcommittee, conducted a focus group with family members of the Philadelphia Compact Family Member Committee, to obtain their input regarding the prescribing of psychotropic medications to youth. On December 12, 2009, with the support and assistance of leadership of the Pennsylvania Youth and Family Training Institute (YFTI), Ms. Oulds-Dunbar also conducted a focus group with family members of the YFTI Advisory Board. On that same date, Dr. Gordon Hodas, Professional Subcommittee co-chair, conducted a separate focus group with youth members of the YFTI Advisory Board. Specific questions for these focus groups had been previously developed and vetted by the subcommittee.

An additional survey was developed for completion by child and adolescent psychiatrists and other prescribers of pediatric psychotropic medication. This survey was distributed by the Pennsylvania Psychiatric Society and the Southeast Regional Council of Child and Adolescent Psychiatry for individual completion. Collection of data from youth, families, and prescribers was intended to identify areas of concurrence among stakeholders, as well as disagreements and potential barriers to the implementation of best practices.

Results of Subcommittee Focus Groups

Focus Group with the Philadelphia Compact Family Member Committee

Seven parents/family members from the Philadelphia Compact Family Committee participated in the focus group. They were asked to respond to the following two questions:

- 1. What are the some of the questions/issues that should be addressed by the prescribing physician with parents/family members of children and adolescents who are considering psychotropic medication?*
- 2. What would parents/family members like to see happen at the initial appointment with the prescribing physician?*

The following responses, addressing both of the above questions, were given:

- Discuss whether or not my child needs to be on medication at all.
- Provide a description of the medication being recommended, and whether the medication is primarily an “adult” medication or also appropriate for children.
- Identify the recommended dose, and why this dose is being recommended.
- Identify the potential side effects, both short-term and long-term. Discussion of potential side-effects should include physical health issues as applicable, including effect of medication on growth, sexual functioning, and on skin and hair.
- Indicate if and how side-effects can be addressed.
- Address the possible parental concern that youth who take psychotropic medications might be at greater risk of self-medicating later in life.
- Identify the entire range of medications that could be prescribed for the disorder in question, rather than just recommending one specific medication.
- Discuss information from current research about the medication.
- Discuss how long the child will likely need to remain on the medication.
- Discuss the sensitivities of certain groups of children to medication.
- Discuss what the parent can expect to see in the child, if the medication is changed or discontinued.
- Discuss possible non-medication options, including dietary options and complementary-alternative interventions.
- Provide written literature on the research, including side effects, of medication **before** it is prescribed.
- Provide referrals for peer-to-peer family support and education.

Focus Group with Family Members of the Youth and Family Training Institute (YFTI) Advisory Board

The YFTI Family Focus Group was facilitated on December 9, 2009 by Ms. Valarie Oulds-Dunbar. Specific discussion questions were posed to the five participating parents/guardians, all of whom are family members of the YFTI Advisory Board. Following are their responses to the four questions.

1. *What kind of information do you need about psychotropic medication that is recommended or prescribed for your child?*
 - Information about side effects—“not just what is listed on the medication insert, but real-world side effects, such as weight gain.”
 - What other families have reported as possible experiences with this medication.
 - Alternatives to the recommended medication.

- Information on the best practices based on research, presented in a way parents can understand.
- Possible changes and effects to look for when the child begins the medication, changes dose, or is coming off a medication.
- A nurse or other practitioner whose role is to provide information and support on medications, diagnosis, etc. to families.

2. *Questions about family participation:*

a. *In what ways would you like to participate actively during your meetings with the psychiatrist or other prescriber?*

- Family members want to be present and included with their child, even if their child is 18 or older, in the discussion of medications.
- Family doctors and pediatricians also need to be included with psychiatrists in knowing how to partner with families around prescribing psychotropic medications. Family doctors are more commonly involved in rural areas of the state than pediatricians or psychiatrists.
- Prescribers should allocate sufficient time so that families can ask questions and obtain necessary information.
- Written information should be provided related to the child's diagnosis and the medications being recommended.

b. *If your child is receiving psychotropic medication, have you been able to participate in desired ways?*

3/5 participants = Yes

2/5 participants = No

c. *If not, what keeps this from happening?*

- One parent feels discounted by the doctor, with the impression that her opinion does not count.
- One parent was made to feel that she is the reason for the child's issues.
- One parent feels like "the doctor really does not want to hear from me, because I will have lots of questions about things and they don't want to hear it."
- There is lack of choice in selecting a provider.

3. *What could the psychiatrist or other prescriber do to make it easier for you to participate actively during meetings around the use of medication for your child?*

- Value the detailed information and real input parents provide (e.g., what life at home is like on a typical day).

- Promote mutual respect between family member and physician.
 - View family members as part of the solution, not the problem.
 - Acknowledge that the family loves their child and cares about what happens (and is not just acting out of a sense of obligation).
 - Encourage and welcome questions.
 - Be knowledgeable about the particular diagnosis. If not, then refer child and family to a more knowledgeable prescriber.
 - Educate the child, along with the family, on the medications.
 - Arrange appointment times so that they are convenient for the family.
4. *What other things could the psychiatrist or other prescriber do to better educate you and your child about medication, work together with you during visits, and support your child's doing well?*
- Provide information about what might happen if medication is not taken, or is not taken correctly.
 - Discuss the role of therapy in conjunction with the medication, based on the needs of the child and family.
 - Provide information to families on nutritional strategies and a holistic approach.
 - Direct youth and families to peer support groups, so they can get needed support and feel connected.
 - Use terminology that is not illness based (e.g., the child has a “mental health issue,” rather than a “mental illness”).

Focus Group with Youth Members of the Youth and Family Training Institute (YFTI) Advisory Board

The Youth Focus Group was facilitated by Dr. Gordon R. Hodas. Seven youth – five males and two females – participated, including six who are youth members of the YFTI Advisory Board, and one who was a visitor to the YFTI meeting. The same discussion questions were posed to the seven participating youth, with language specific to the youth's experience.

Input from the youth focus group is organized around two issues that were addressed by participating youth: the initial youth reaction to the recommendation of psychotropic medication, and the nature of desired prescriber efforts to provide education and promote youth participation:

1. Initial youth reaction to recommendation of psychotropic medication:

Since most of the youth had previously been on psychotropic medication or had it recommended, their responses were based on personal experience. Specific comments involved the following:

- One youth's response to the recommendation of psychotropic medication involved passive acceptance. He did not feel there was much choice. The doctor did not explain the rationale or the potential side effects. The diagnosis also was not discussed or explained.
 - Several youth indicated that their reaction, and that of their parents, had been influenced by earlier experience when their siblings had been placed on psychotropic medication. Most of the siblings did not seem to benefit from medication.
 - Two youth indicated that their parents were more opposed to the use of psychotropic medication than they were. One youth had taken psychotropic medication once before and it had helped, and so was willing to go back on it. The other youth was ready to accept the recommendation, but ended up "not needing it" at that time.
 - Many of the youth had an overall positive view of the use of psychotropic medication. Their statements included the following:
 - "It makes sense to take meds if it can help you."
 - "You don't have to let it run your life."
 - "Information and support from peers can be helpful."
 - "I'm not overly concerned with stigma – many things help me, and I can determine if it works and go from there."
 - An overall theme was that youth in general are capable of being open-minded and making an appropriate decision.
2. *Types of information needed during meetings with the psychiatrist, and how the psychiatrist or other prescriber can best promote youth education and participation:*
- a. *Types of desired information:*
- A clear explanation of the diagnosis.
 - Reasons for taking psychotropic medication.
 - Alternatives to psychotropic medication.
 - The expected benefits of recommended psychotropic medication.
 - Possible side effects, including both psychological and physical side effects.
 - How to avoid becoming over-medicated.
 - Next steps, if the medication proves ineffective.
 - How to prevent health problems.
- b. *How doctors can promote active youth participation:*
- Be clear in what you say.

- Be honest and truthful.
- Accept who I am.
- Talk to me, not just my parents.
- See me alone part of the time, without my parents.
- Don't see my parents without me (stated by one youth).
- Offer a plan – “Here's what we can do”
- Give me some of the control.
- Allow peers to actively participate and share their experiences with youth.

Additional Youth Input from Within the Subcommittee

One youth subcommittee member identified additional questions that could be used to promote youth education and participation during psychotropic medication meetings. These questions involve the following:

- *Do you know what psychotropic medication is?*
- *Are you aware of the side effects to look for, and what to do if you think you are experiencing any?*
- *Do you know how prescribed medications interact with drugs and alcohol and herbal products?*
- *What does your psychiatrist or other prescriber ask about during meetings?*
- *How much time do you spend face-to-face with your psychiatrist or other prescriber at meetings?*
- *Do you feel there is enough time?*
- *Does the psychiatrist or other prescriber talk to you in language that is easy for you to understand?*

Responses by Child and Adolescent Psychiatrists and Other Prescribers to Survey Questions

The other major subcommittee outreach activity was directed at those prescribing psychotropic medication, with particular attention to child and adolescent psychiatrists. The goal involved learning what responding child psychiatric prescribers regard as important for youth and families to know about psychotropic medication, and how they believe they can promote youth and family participating during medication meetings. Responses to six questions follow:

1. *What kind of information would you want parents or legal guardians and youth to have, when you are recommending or monitoring psychotropic medication for a youth?*
 - Nature of youth's diagnosis, and what this diagnosis means.

- The rationale for recommended medication, and how the medication corresponds to the youth's diagnosis and psychiatric needs.
 - Written handouts providing relevant information for youth and parent or legal guardian.
 - Expected therapeutic effects of recommended medication.
 - Possible side effects of recommended medication.
 - Risk/benefit ratio regarding use of medication, use of other treatments, and no treatment at all.
 - Potential risks of not treating with medication.
 - If medication is "off label," explaining what this means and identifying the evidence for use of this medication.
 - If medication has a Black Box warning, explaining what this means in non-technical, family-friendly language.
 - Likely time needed for therapeutic effects to take effect.
 - The plan for monitoring the effects of medication, including medication visits, information from ancillary sources, and periodic blood work.
 - What to do if side effects of concern occur, who to call, and when to call.
 - The specific dose of medication, and the dosing pattern (how much, when/time of day, and timing of medication to food, if relevant).
 - Need to call the psychiatrist if wanting to make medication changes, and not doing this on their own.
 - Need to be cautious about information on the internet, given possible lack of reliability or balance.
 - Need to have reliable, trusted sources of information, such as NIMH, FDA, APA, AACAP, Mayo Clinic, or university medical center web sites. Caution regarding consulting unbalanced web sites, or those advocating interventions without evidence.
 - Need for a long-term plan, including likely duration of medication use.
 - When, and how, medication can be tapered and then discontinued.
 - Dissemination of information as guided by, and consistent with, information provided in Mina Dulcan, M.D.'s American Psychiatric Association publication (2007).
2. *What kind of information do you want to have from parents or legal guardians and from youth, when psychotropic medication is being considered or being prescribed?*
- Residential status – where and with whom the youth lives.
 - Who has custody of the youth, and who has legal authority to sign for treatment.
 - Specific, involved child-serving systems.
 - Why youth and family are presenting for help now.
 - Nature of the target symptom – the primary area of concern.

- Youth and family expectations about the use of the medication.
 - Full and complete biopsychosocial information on youth and family – e.g., “everything.” “Information is the single most important factor in my evaluations and management. I wish that I could get more and better.”
 - Past medication history, including response to specific meds, allergies, serious adverse effects.
 - Family history of use of, and response to, specific psychotropic medications.
 - The youth’s previous record. Lack of previous record is common, and is “a major obstacle to good care.”
 - Nutrition, exercise, and sleep-related information.
 - Identification of the responsible adult for obtaining, storing, administering, renewing, and supervising use of medication by youth.
 - Where medication is stored, and who dispenses it.
 - Safety practices in the home, including whether or not medications are kept in a locked box and whether or not there are weapons in the home.
 - Responsible adult(s) for monitoring and reporting child’s response to med.
 - Information from youth and family about youth’s response to the medication, side effects, and possible questions and concerns.
3. *Under what circumstances do you provide written material on psychotropic medication to parents/guardians and youth, or others?*
- “I provide written material whenever a new medication is prescribed, at the time it is prescribed.”
 - “I provide written material every time I prescribe.”
 - “I provide written material any time a new medication is being started or considered.”
 - “I provide written material when starting a new medication or when the client/family requests it.”
 - “Written material should be easy to understand, and in the primary language of the family.”
4. *In what ways can parents/guardians and youth participate actively during their meetings with you? How often does this happen now? If not, what prevents this?*
- I welcome active participation during the initial evaluation, and at every visit thereafter.
 - I try to “create an atmosphere where questions and comments are welcome.”
 - I ask youth and family what they already know the medication first, and then address any gaps in knowledge or myths.
 - I share information.
 - I maintain a healthy, supportive relationship with patient.
 - Youth and family should ask questions.

- Youth and family should read handout information on medication given to them, to inform the current and/or future visit.
 - Youth and family should write down their concerns or questions prior to the next appointment. If urgent, they can call the psychiatrist.
 - Youth and family should bring a sleep diary, if sleep is a concern.
 - Youth and family bring a record of food intake and activity.
 - Youth and family should bring in rating scales filled out by them and/or by others (teachers).
5. *What could you along with other prescribing physicians do to make it easier for parents and legal guardians and youth to participate actively during meetings involving the use of psychotropic medication?*
- Prescribers can provide information that is simply stated, which is customized for each youth.
 - Prescribers can make themselves available to families to contact me between visits.
 - Prescribers should give youth and families appropriate handouts. A centralized handout bank would be helpful.
 - Prescribers can ask the youth and family to summarize information discussed in written form, “to ensure understanding and to cover any serious concerns.”
6. *Are there any other things that you and other physicians could do to better educate parents or legal guardians and youth about medication, help them collaborate more actively with you during visits, and support their wellbeing?*
- Ask open-ended questions, and ask for feedback at each visit.
 - Wait for a response, and then listen to it.
 - Get good information, seeking many sources.
 - Encourage accurate and honest exchange of information.
 - Create rapport between youth and family and treating prescriber.
 - Encourage all providers to work together and to keep information flowing.
 - Work to achieve a good working relationship between prescriber and “all professionals interacting with the client and family...”
 - Longer visits are needed.
 - “Enough time to adequately address questions” – a minimum of 30 minutes and sometimes more (up to 45 – 60 minutes). “Medication prescribing is a complex task.”
 - Direct youth and family to reputable web sites for information, and to make use of a computer as an accessible source of information.
 - Encourage the use of family groups that address similar medication issues, for those families that are open to sharing their concerns with other families.

- A depot for medical information, as with vaccination records, would make information accessible and updated.

Discussion

In considering the nature of stakeholder input, the subcommittee is struck by the compatibility and complementary nature of input from family members, youth, and child and adolescent psychotropic medication prescribers. The collective input is also consistent with key issues addressed in the American Academy of Child and Adolescent Psychiatry's recent Practice Parameter related to the use of psychotropic medication for children and adolescents, discussed elsewhere in this document, and with expert consensus in the field of children's mental health. In general, youth want to be treated with dignity and respect, and not pathologized. Parents and other caregivers want to be recognized as caring about their child, and not blamed for their child's difficulties. Both groups seek information on psychotropic medication when it is recommended and used. Both groups want to experience a trusting relationship with the psychotropic medication prescriber, and be able to participate actively during medication meetings. Understandably, parents and other caregivers want an opportunity to be included in the process, even with an older youth. Youth, in turn, want their own relationship with the prescriber, consistent with their increasing developmental thrust toward autonomy.

Child and adolescent prescribers, in turn, actively seek to partner with youth and families. They identify frustration regarding frequent time limitations that constrain medication visits and often lead them and the families they serve to feel rushed. There is frustration as well with the limited information, and the challenges in obtaining parental consent, for some youth in substitute care.

As with any meaningful process, the possibility of disagreement exists. From the youth's point of view, there might be disagreement with the parent or other caregiver regarding the family's desire to meet with the prescriber without the youth being present. From the family's point of view, depending on the age of the youth and the specific circumstances, there might be reluctance to have the prescriber meet with the youth without the caregiver present. Beyond this, there may be differing perceptions about the presenting concern and whether or not to pursue the use of psychotropic medication. All of these are important issues, and they can only be addressed and resolved on an individual basis. We believe, however, that positive resolution of such issues is most likely when there is trust and collaboration between youth and family and the prescriber.

Subcommittee Recommendations

Subcommittee recommendations have been organized according to those that are practice-based and those that are system-based.

A. Practice-Based Recommendations

1. Stakeholders – including youth and families, psychotropic medication prescribers, professional organizations, and representatives of various child-serving systems – are encouraged to carefully review the comments of participants in the subcommittee’s focus groups and surveys, as discussed above. We believe that participant comments reflect practices that can empower youth and families, and increase their ability to collaborate with psychotropic medication prescribers.
2. All prescribers of psychotropic medication are encouraged to talk with youth and families in an open, respectful manner that engages them as full partners in the psychotropic medication prescribing and monitoring process. This includes recognizing that parents, legal guardians, other caregivers and youth can participate actively during meetings when given the opportunity and support.
3. Prescribers should welcome initiative on the part of youth and family members, as reflected in their use of a written agenda or written set of questions, since such initiative reflects motivation and offers opportunities for collaboration among prescriber, youth, and family.
4. Prescribers are encouraged to provide youth and families with information on the full range of possible psychotropic medication for the youth’s specific disorder, and explain the rationale for any medication being recommended. The evidence base for all relevant medications should be reviewed.
5. Prescribers should discuss the expected therapeutic effects of recommended psychotropic medication, possible side effects, and how to manage them. Side effects should be explained as being short-term and/or long-term, with the warning signs identified. When psychotropic medication is prescribed off-label and/or when it has a Black Box warning from the Federal Drug Administration, this should be discussed.
6. Prescribers should discuss non-medication options, including psychosocial interventions and complementary and alternative medicine as applicable, not just psychotropic medication. Discussion of these interventions should include review of potential benefits and risks, and the existing evidence base.
7. Prescribers should provide youth-and family-friendly articles, brochures, and website references relevant to psychotropic medication being considered, at the time of initial discussion of the use of medication and during subsequent meetings.
8. Prescribers should consider, whenever possible, family responsibilities and youth preferences, in developing schedules for the administration of prescribed psychotropic medication. This includes accommodating the work schedule of the

parent, legal guardian, or other caregiver, and the preferences of the youth (for example, avoiding medication administration at school, if possible).

9. Prescribers should become knowledgeable about, and provide treatment that is informed by, the culture of the youth and families they serve. Exchange of information should take place in the family's primary language, through the use of language interpreters or sign language interpreters for families or youth who are deaf or hard of hearing.
10. Prescribers should offer evening and weekend appointments whenever possible, in order to accommodate the school and work schedules of youth and family.
11. The family should be told whom to contact, if concerns arise between appointments regarding side effects or other issues in need of immediate attention.
12. Prescribers should reinforce the potential benefits of informal, natural supports (e.g. church, coaches, youth groups) and offer to make referrals to such resources, or identify individuals who with the expertise to make such referrals. Similarly, prescribers should provide information on potential sources of support and advocacy for the youth and the family.
13. Prescribers should use psychotropic medication visits as an opportunity to support youth and family strengths, and to promote healthy lifestyle choices and wellness.
14. Prescribers should be prepared to address potential youth and family concern regarding the possible addictiveness of prescribed psychotropic medication, or the possibility of addiction to drugs later on, as a result of psychotropic medication use during childhood or adolescence.
15. Consistent with youth and family wishes and with signed consents, prescribers should collaborate with other members of the youth's treatment team and with those involved from other child-serving systems. This includes but is not limited to collaboration with the youth's primary care physician and medical home, so that behavioral health and physical health care can effectively address youth needs, promote healthy development, and support the family.

B. Systems-Based Recommendations

1. DPW should ensure that youth and families are key members of advisory committees and advisory boards that develop, or provide oversight for, guidelines and policies related to the prescribing of psychotropic medication for youth. Such guidelines or policies should be subject to ongoing youth and family input during implementation and monitoring.

2. DPW should ensure that prescribers of psychotropic medication for youth are reimbursed for time spent implementing the best practices identified in this report, during evaluations and medication visits. Time spent responding to questions and concerns that arise between scheduled meetings should also be subject to reimbursement.
3. Similar to initiative by the Department of Health (DOH) related to issues of physical health and safety, it is recommended that DPW, in collaboration with youth and families, promote public awareness of the potential benefit of psychotropic medication, when used as part of comprehensive behavioral health treatment.
4. DPW, in collaboration with DOH, should sponsor trainings for psychotropic medication prescribers that address ways to promote youth and family education and active participation.
5. Youth and family advocacy groups in Pennsylvania are encouraged to develop technical assistance documents that guide prescribers and providers on how to engage, educate, and empower both youth and families during evaluations and medication visits.
6. Prescriber promotion of education and engagement of youth and families during psychotropic medication visits should be periodically assessed by counties and their applicable HealthChoices managed care plans, via use of anonymous questionnaires. Data can be used to promote quality improvement. Youth and families should be reassured that their participation is voluntary and will not jeopardize their access to services.
7. Implementation of Pat Deegan's peer-run Decision Support Center in Pennsylvania should be expanded over time, to include other communities and counties. Use of Decision Support Centers for transition age youth and their families should be considered.
8. The Family and Youth Education Subcommittee report should be disseminated to all applicable psychotropic medication prescribers, via applicable statewide professional organizations and by managed care plans within HealthChoices.
9. DPW, in conjunction with the counties, should provide a central clearinghouse of information about psychotropic medication and alternative treatment interventions, for youth, families, providers, and support and advocacy organizations. A process should be developed for the ongoing review of material submitted for addition to the clearinghouse.

Attachment 1

Annotated Bibliography of References Relevant to Psychotropic Medication for Youth and Families

Note: This list of articles and books represent some, but not all, of the relevant resources for youth and families related to psychotropic medication, mental health, and wellness.

Recovery and Shared Decision-Making

Adams, J, Drake, R, Wolford, G (2007): Shared decision-making preferences of people with severe mental illness. *Psych. Services* 58 (9), 1219-1221.

Adults with severe mental illness expressed a desire for greater participation in decisions about psychiatric care, including use of psychotropic medication, than they were experiencing. Shared decision-making in psychiatric care is more important than in general medical care. There is clear endorsement of the need for need for shared decision-making between psychotropic medication prescribers and individuals receiving treatment, which by extension would include youth and families.

Deegan, P et al (2008): A program to support shared decision making in an outpatient psychiatric medication clinic. *Psych. Services* 59 (6), 603-605.

The article defines and amplifies the concept of shared decision-making and its relevance in psychiatric treatment. A 12 month pilot program involving shared decision-making was viewed favorably by both patients and professionals. A key element involves a peer-run Decision Support Center, with patients completing a one-page, computer generated report for use in the medication visit.

Diamond, R (2009): Taking Issue – How to support recovery for people with mental illness. *Psych. Services* 60 (9), 1155.

Psychiatrists need to promote recovery – the best life possible, despite illness and symptoms – for every person. Doing so involves promoting hopefulness, celebrating small victories and strengths, viewing psychotropic medication as a recovery tool, supporting the person’s goals, and promoting positive activities.

Drake, R & Deegan, P (2009): Taking Issue: Shared decision making is an ethical imperative. *Psych. Services* 60 (8), 1007.

This editorial highlights the importance, and the ethical imperative, of shared decision-making, which does not involve unilateral decisions by patients but

rather “empower(s) a person to collaborate with his or her psychiatrist in making informed medical decisions that lead to the best treatment outcomes.” The concept is also clearly applicable to children’s mental health.

Mojtabai, R (2009): Americans’ attitudes toward psychiatric medications, 1998-2006. Psych. Services, 60 (8), 1015-1023).

A comparison of samples of adult participants in the US General Social Surveys of 1998 and 2006 shows that there has been an increase in public perception of the benefits of psychotropic medication, a greater willingness to take it when needed, and no change regarding the degree of risk involving in using it. Since adults with a positive view of psychotropic medication may often be parents of children in need of such medication, this survey of changing attitudes has direct relevance to the use of psychotropic medication with children & adolescents.

Salyers, M et al (2009): The role of patient activation in psychiatric visits. Psych. Services 60 (11), 1535-1539.

A study of adults in which psychiatric visits were audiotaped, transcribed, and analyzed for themes, and patients also rated their own level of participation (patient activation). Patients who believed they were active in visits were more involved in the self-management of their disorder and less likely to use substance. However, patients tended to rate their level of involvement in visits as greater than actually occurred. This study is important because it focuses on patient involvement during psychotropic medication visits.

Evidence-Based Treatments for Youth

Burns, B & Hoagwood, K (eds.) (2002): Community treatment for youth: Evidence-based interventions for severe emotional and behavioral disorders. New York: Oxford (paperback).

The compendium of evidence-based treatments changes over time. Currently, this is likely the most comprehensive and reliable book. It is edited by two highly respected psychologists, and encompasses systems of care as an organizing basis for understanding and implementing evidence-based treatments for youth.

Mental Health Disorders and Treatment

Greene, R & Ablon, J (2006): Treating Explosive Kids: The Collaborative Problem-Solving Approach. New York: Guilford.

The authors present a humanistic approach to children who are vulnerable to having explosive episodes, which may include children with a variety of

psychiatric diagnoses. The focus is on understanding the specific needs of the child and recognizing that much of the behavior results from cognitive and skill deficits, not willful disregard of others. The authors propose a respectful, collaborative approach to help the child and family.

Jensen, P (2004): Making the system work for your child with ADHD. New York: Guilford (paperback).

This book addresses the needs of children with ADHD, but it is equally focused on helping families be informed about mental health challenges and being able to advocate effectively for their child. Many of the topics discussed are relevant for parents with a child with a variety of mental health disorders.

Koplewicz, H (1996): It's nobody's fault: New hope and help for difficult children. New York: Times Books (paperback).

This book is included, despite its 1996 publication date, for several reasons: It is reader-friendly, compassionate, and clearly indicates the inappropriateness of blaming parents for their child's mental health challenges. There is a very helpful chapter on the use of psychotropic medication (Chapter 6).

Papolos, D & Papolos, J (1999): The bipolar child: The definitive and reassuring guide to childhood's most misunderstood disorder. New York: Broadway Books.

*This book is written for parents, and is clear, reader-friendly, and non-blaming. It addresses psychosocial interventions as well as the use of psychotropic medication. It can be usefully read along with Greene and Ablon's book, *The Explosive Child*.*

Psychotropic Medication

Dulcan, M (ed.) (2007): Helping Parents, Youth, and Teachers Understand Medications for Behavioral and Emotional Problems: A Resource Book of Medication Information Handouts, 3rd Edition. Washington, DC: American Psychiatric Publishing, Inc.

Clear discussions of psychotropic medications used in youth, with separate discussions for parents and teachers, and for youth. Each medication has a complete discussion, which can be used as part of family and youth education and in promoting informed consent.

Gorman, J (2007): The Essential Guide to Psychiatric Drugs, 4th Edition. New York: St. Martin's Griffin (paperback).

This book addresses psychotropic medication use in adults, but much of the basic information applies, and it is written in a reader-friendly way by a respected psychiatrist. Over 400 pages long, it is a good reference book, discusses every class of medications, and addresses many relevant questions.

Wilens, T (2004): *Straight Talk about Psychiatric Medications for Kids*, Revised Edition. New York: Guilford (paperback).

This reader-friendly book addresses the use of psychotropic medication in children and adolescents. It covers the common disorders and specific medications used, and as such is a good reference book, less comprehensive than the Gorman book above but specific for the pediatric population. The Q&A format is engaging.

Complementary and Alternative Medicine (CAM)

Rey, J, Walter, G, & Soh, N (2008): Complementary and alternative medication (CAM) treatments and pediatric psychopharmacology. *J. Am. Acad. Child Adolesc. Psych.*, 47 (4), 364-368.

This article offers a brief overview of the most common complementary and alternative medication (CAM) agents used for mental health purposes. There is recognition that CAM may be beneficial, but evidence is largely limited to adult studies. Psychiatrists need to be familiar with these products, and ask patients if they are using them. The strongest evidence in adults involves the use of omega-3 essential fatty acids. There have been mixed results with St. John's Wort, and possible interactions with other prescribed medications.

National Center for Complementary and Alternative Medicine (NCCAM) – recommended as a resource by Ray, Walter, and Soh, for both practitioners and consumers: <http://nccam.nih.gov/>

Wellness Approaches

Williams, M, Teasdale, J, Segal, Z, Kabat-Zinn, J (2007): *The mindful way through depression: Freeing yourself from chronic unhappiness*. New York: Guilford (paperback).

Written for adults but applicable to adolescents, this book is an example of many books that address the promotion of wellness and self-help. Mindfulness is wellness approach that has been gaining increasing attention. This book involves a collaboration among individuals from England, Canada, and the US, is available in paperback, and includes an instructive CD.

Seligman, M (2006): *Learned optimism: How to change your mind and your life*. New York: Vintage.

This reissued classic represents the beginnings of positive psychology, a strengths-based approach toward human behavior and relationships that is now 10 years old. The book describes ways that individuals can overcome pessimism and create a better quality of life.

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Family and Youth Subcommittee Participants

OMHSAS Facilitators: Lydia Sacavage and Shaye Erhard.

Co-Chairs: Gordon R. Hodas (professional co-chair) and Valarie Oulds-Dunbar (family co-chair).

Additional Subcommittee participants: Barbara Altenburger, Doris Arena, Kathleen Cantwell, Jess Curtis, Dan DeLucey, Mary Diamond, Judy Dogin, Judy Green, Paulette Hunter, Debi Johnson, Wendy Luckenbill, Corey Ludden, Sherry Peters, Victoria Pham, and Jake Vandall.

Additional individuals agreed to participate in focus groups and complete questionnaires for youth, family members, and prescribers, respectively.

II. Informed Consent Subcommittee Report

Mission Statement

To provide an overview of the concepts and core practices related to informed consent and informed assent for pediatric psychotropic medication by children and youth (hereafter ,youth) and their families, and to make recommendations that promote the provision of informed consent and informed assent for youth and families, including youth in substitute care, in Pennsylvania.

Vision Statement

Informed consent and informed assent are regular practices when psychotropic medication is prescribed for youth in Pennsylvania. In addition, prescribers of psychotropic medication for youth and their families are supported in implementing these practices and all human service professionals involved with the child are knowledgeable about and supportive of these practices.

Introduction

The Office of Mental Health and Substance Abuse Services (OMHSAS) has the responsibility to create a behavioral health system that includes access to appropriate and quality psychopharmacology services. For the pediatric population and their families, this includes ensuring, when psychotropic medication is recommended and prescribed, that the risks and benefits of psychotropic medication are understood and accepted by the family and youth, based on provision of adequate information and subsequent discussion. When a youth, ages 14-18 years, and the parents or legal guardians engage in such informed decision making and decide in favor of the use of psychotropic medication, this is referred to as *informed consent*. For a youth under age 14, the parents or legal guardians make the decision about psychotropic medication use. When the parents or legal guardians of a youth under age 14 decide in favor of the use of psychotropic medication and the youth under age 14, based on age-appropriate discussion, also indicates agreement with the medication decision, this agreement by the youth is referred to as *informed assent*.

Informed consent by a youth between the ages of 14-18 and by the parents or legal guardians is a legal concept, and is part of a larger concept involving informed consent for behavioral health treatment and, most broadly, for medical treatment. Informed assent by youth under the age of 14, in contrast, is a best practice concept rather than a legal requirement.

The Subcommittee has identified challenges related to informed consent that may compromise the treatment of youth in need of psychotropic medication. These challenges involve the following:

- Many parents, legal guardians and youth do not understand informed consent and informed assent, and therefore do not know what to expect during meetings with prescribers of psychotropic medication for youth.
- Within many child-serving systems, there is lack of clarity regarding who has the right of consent and under what circumstances. In addition, applicable laws, regulations, and policy in Pennsylvania may not be understood.
- As a result of the above factors and others, practices consistent with informed consent do not always occur when pediatric psychotropic medication is prescribed.
- For youth involved in out-of-home placement, where the birth parent retains the right of informed consent but is not easily contacted, access to needed psychotropic medication may be delayed. In addition, due to multiple moves and other factors, continuity of care for these youth may be disrupted.

In what follows, the Informed Consent Subcommittee addresses the need for prescribing physicians and other authorized psychotropic medication prescribers to obtain informed consent for pediatric psychotropic medication from the parent or legal guardian and the youth age 14 or older, and to obtain informed assent from youth under age 14. Families need to understand the applicable concepts and practices, as do providers and representatives of behavioral health and other child-serving systems involved with the youth and family. The discussion that follows should be reviewed in conjunction with the report of the Family and Youth Education Subcommittee, which considers how families and youth can be effectively educated on pediatric psychotropic medication and supported in participating actively in psychotropic medication meetings, and the Prescribing Practices Subcommittee report..

The Broader Concept: Informed Consent for Treatment

Informed consent for psychotropic medication is a specific application of the broader concept of informed consent for treatment. Informed consent for treatment is defined by Frank et al (2008) as “an interactive process culminating in an agreement between a patient and a healthcare provider on a course of treatment.” In contrast, informed consent is absent “when a (healthcare provider) does not provide adequate information to the patient to make an informed decision.” Essential to informed consent is meaningful communication between the healthcare provider and the youth and family. Thus, “[while] a signed consent form may help validate that the patient and provider have reached an agreement...it is not a substitute for a meaningful discussion between the clinician and the patient.”

Informed consent for treatment is both an ethical and a legal concept. It involves ethical considerations in that youth and families have a right to be informed about, and agree to, a course of medical treatment, which by its nature entails some level of uncertainty and risk. Professional organizations also require adherence to this ethical standard, including the American Medical Association, which has established informed consent as an ethical obligation of physicians. Legally, although it is defined and operationalized with variability, all 50 states require the provision of informed consent for patients.

Informed Consent for Psychotropic Medication

Informed consent for psychotropic medication for the pediatric population entails the active involvement of the parent or legal guardian and the youth age 14 or older in discussions and decisions related to the use of a new psychotropic medication, as part of ongoing behavioral health treatment. The psychotropic medication prescriber is a licensed physician or other designated professional with expertise in child and adolescent behavioral health disorders with the legal authority to prescribe medication. When the dose of an existing psychotropic medication is changed and when a medication is discontinued, informed consent of the parent or legal guardian is not required. Instead, from a legal perspective, notification of the parent or legal guardian is sufficient.

Active involvement by parent or legal guardian and youth consistent with informed consent entails 1) a clear explanation by the psychotropic medication prescriber of key information related to the recommended medication, 2) the likely comprehension of the information by parent or legal guardian and the youth, and 3) an affirmative decision in favor of the medication by the parent or legal guardian, the youth age 14 or older, and ideally by both parties. These three elements are considered further below.

1. Clear Explanation of Recommended Medication

- Informed consent involves the provision of a clear explanation by the prescriber of the following psychotropic medication issues:
 - The nature of the disorder, or specific symptoms, for which medication is being recommended or prescribed. This is part of identifying the diagnosis, and discussing the prognosis.
 - The rationale for the recommended medication, or for the types of medication being considered.
 - The expected benefits and potential side effects of medication being recommended or considered.
 - Potentially serious side effects requiring immediate medical attention, and how to obtain such medical attention.
 - Potential alternative, non-pharmacological treatments, as applicable, or the combined use, as applicable, of psychotropic medication and non-pharmacological treatments (psychotherapy and other interventions).

- The overall risks of using the medication in relation to the risks of not using the medication – e.g., the risks of treating vs. not treating the disorder with psychotropic medication.

2. The Likely Comprehension of Information

- Informed consent entails that the parent or legal guardian and the youth age 14 or older understand the above information. Therefore, information needs to be given in a manner that is clear and family-and youth-friendly.
- In some instances, a youth's capacity to understand information may be compromised by developmental delays, mental illness, and other factors. The prescriber should always seek to offer information in a clear, developmentally appropriate manner for the youth.

3. An Affirmative Decision in Favor of the Medication

- Informed consent entails a voluntary decision in favor of psychotropic medication being recommended or considered. This decision may be made by the parent or legal guardian, youth age 14 or older, and ideally by both parties.
- Individuals consenting to psychotropic medication indicate that all of their questions have been addressed satisfactorily.
- The agreement regarding psychotropic medication is manifested in a consent form that is signed by the individual or individuals who are agreeing to the use of the medication. The consent form is maintained in the youth's medical record, along with a progress note by the prescriber indicating that discussion has occurred and agreement reached.

Thus, informed consent for medication involves a voluntary agreement by parents or legal guardians to accept the use of psychotropic medication for the youth, and by the youth age 14 or older, to accept medication treatment. The decision is based upon knowledge of facts, risks, costs, implications and future consequences associated with a particular course of treatment, and entails understanding the benefits and risks of the medication and the alternative treatment options that are available.

The practice of obtaining informed consent for psychotropic medication use is consistent with the evolution of medicine “from medical paternalism to patient autonomy” (Frank, 2008), a shift that is relevant for youth and their families, not just to adults. In addition, by promoting knowledge and autonomy, ensuring the practice of informed consent is consistent with both youth resiliency and the recovery process.

Informed Assent

In Pennsylvania, youth under the age of 14 years cannot formally consent to the use of psychotropic medication, and the concept of informed consent is not legally applicable.

Informed assent is the term used to indicate that a youth under the age of 14 has been given age-appropriate and developmentally-appropriate information on prescribed psychotropic medication by the medical prescriber. While not a legal requirement, the obtaining of informed assent from a youth under age 14 is nevertheless important, and is consistent with quality care.

Informed assent thus represents willingness by a youth under age 14, consistent with his or her developmental level, to accept treatment, specifically psychotropic medication treatment. Informed assent is based on the presumption that youth under the age of 14 are too young to provide informed consent, but are old enough to understand basic aspects of the proposed treatment. Informed assent can usefully be viewed “as a continuum ranging from mere affirmation in the youngest children to the equivalent of the informed consent process in the mature adolescent” (Rossi, Reynolds, & Nelson, 2003).

Ethically, obtaining informed assent reflects respect for the developing autonomy and right for meaningful participation of the youth under age 14 in the treatment process. Pragmatically, obtaining informed assent likely increases the youth’s level of engagement and readiness for treatment.

Since it is not a legal requirement, informed assent by a youth under age 14 cannot stand alone as the basis of consent for psychotropic medication, and is legally insufficient in the absence of informed consent by a parent or legal guardian. Permission for treatment by the parent or legal guardian protects the youth under 14 from assuming unreasonable risk.

Informed Consent to Psychotropic Medication and Act 147

In 2004, the Pennsylvania legislature passed Act 2004-147 (Act 147), which modifies part of the Minor’s Consent Act and addresses the age of consent for mental health treatment in Pennsylvania. Consent for mental health treatment applies to youth only between the ages of 14 and 18 years. As discussed earlier, for youth under age 14, there is no right of consent, only the best practice of obtaining assent, with the legal right of consent belonging to the parents or legal guardians. In turn, beyond age 18, the youth is, for purposes of consent, regarded as an adult in Pennsylvania, and the parental right of consent for mental health treatment is no longer legally relevant, although parental involvement remains a best practice.

Act 147 identifies which parties have the right of consent for mental health treatment, when a youth ages 14-18 is involved. It also makes clear that consent to mental health *treatment* legally entails consent to psychotropic *medication*, unless a specific exclusion of medication is identified by the consenting individual(s). Act 147, in addressing who has the right to consent for both outpatient and inpatient mental health treatment, builds on the provisions of Pennsylvania’s Mental Health Procedures Act (MHPA) without altering it.

It should be understood that the legislation for Act 147 was passed without identification of which program office is responsible for its interpretation and implementation. As a result, there is an absence of clear operational guidelines for its implementation. In part to address this limitation, the Pennsylvania Psychiatric Society (PPS), in association with an attorney with legislative expertise, released a document, "Effects of Act No. 2004-147," in 2005, and this document has served as a useful source of reference for Pennsylvania (Hoffman, 2005)

Key elements of Act 147 related to consent for mental health treatment and for psychotropic medication include the following:

- Both a youth ages 14-18 and the parent or legal guardian have the legal right to consent to mental health treatment in an outpatient setting.
- Both a youth ages 14-18 and the parent or legal guardian have the legal right to consent to inpatient mental health treatment.
- If, in either setting, the youth ages 14-18 consents and the parent or legal guardian does not, the consent by the youth takes precedent. Thus, the youth's consent overrides the absence of consent by the parent or legal guardian.
- If, in either setting, the parent or legal guardian consents and the youth ages 14-18 does not, the consent by the parent or legal guardian takes precedent. Thus, the parent or legal guardian's consent overrides the absence of consent by the youth.
- The consenting party controls release of the medical record.
- If one party withdraws consent for treatment (for example, the youth ages 14-18) and the other party (the parent or legal guardian) provides what is known as a replacement consent, then treatment can continue without interruption.
- If the youth ages 14-18 objects to inpatient mental health treatment initiated by the consent of the parent or guardian, the youth can file a petition and request a hearing in the county in which the facility is located.
- If the parent or legal guardian objects to inpatient mental health treatment that is initiated by the consent of the youth ages 14-18, they can object to the treatment and request a court hearing.
- While Act 147 is silent regarding which consent applies when both the youth ages 14-18 and the parent or legal guardian consent to mental health treatment, according to the PPS document, it likely that consent of the youth would take precedence over the consent by the parent or legal guardian (Hoffman 2005).

Three other aspects of Act 147 should be recognized:

- First, Act 147 addresses issues of informed consent and voluntary treatment only, not involuntary treatment, as delineated in the Mental Health Procedures Act (MHPA). As a result, even though the consent of a parent or legal guardian for mental health treatment can lead to the provision of treatment for a youth ages 14-18 who has not consented, from a legal perspective this does not constitute "involuntary treatment" of the youth. Involuntary treatment applies only when the

- criteria of the MHPA, based primarily on dangerousness, are met, and Act 147 does not alter the provisions of the MHPA.
- While Act 147 confers the legal right of a youth ages 14-18 to consent to treatment in the absence of consent by the parent or legal guardian, it remains best practice, with permission from the youth, to involve the family in the treatment. Such family involvement includes the family's participation in a decision to use psychotropic medication. Thus, ideally the prescriber and facility obtain informed consent for medication from both the youth and the parent or legal guardian. In situations where the youth chooses to consent to the use of psychotropic medication alone, notification of the parent or legal guardian is encouraged, consistent with the youth's permission.
 - Certain key elements of the Minor's Consent Act are unaffected by Act 147. In particular, a parent or legal guardian does not have a right of consent to mental health treatment of a youth ages 14-18 under the following three conditions:
 - The youth has graduated from high school.
 - The youth has married.
 - The youth has been pregnant.

Other Relevant Concepts

Consent for psychotropic medication can only be made by a youth age 14 and older and by a parent or legal guardian. At the same time, when a youth is in out-of-home care, the foster parent or other caregiver has an extremely important role even though he or she has no legal authority, and therefore this individual should be included in the treatment process. Caregiver attitudes about psychotropic medication can influence those of the youth, so it is essential that the substitute caregiver be informed about psychotropic medication, including the specific medications being taken or considered for the youth. A substitute caregiver who is informed about and supportive of the use of psychotropic medication can in turn promote the youth's understanding of the need for the medication and a willingness to take it. Depending on the age and developmental level of the youth, the caregiver may also have a direct role in the youth's medication adherence, by administering, overseeing, and supervising the youth's use of medication. Thus, the caregiver needs as much information about the youth's strengths, needs, and treatment as possible, and should always be included as a member of the treatment team.

In the provision of psychotropic medication, the expectation of informed consent by the youth, family, or both, reflecting a voluntary decision in favor of the use of psychotropic medication, is the rule. However, in accordance with the MHPA, there are specific circumstances involving acute risk of harm, in which psychotropic medication may be given on an involuntary basis over the objection of the youth or family. It should be understood that, even when medication is being given involuntarily consistent with Pennsylvania law, every effort should be made to educate and inform the youth and family about the medication in question.

Implementation of Informed Consent

In Pennsylvania, the right of informed consent differs, depending on the age of the youth, where the youth is living, and whether parental rights of the birth family remain intact or have been terminated. For purposes of clarity, the discussion of informed that follows considers whether youth is living with a birth parent or legal guardian, or is in out-of-home care and living with a substitute caregiver.

Youth Living with Parent or Legal Guardian

For youth living with their birth parent or legal guardian, the right to consent to treatment, and to psychotropic medication in particular, belongs to the parent or legal guardian alone, if the youth is younger than age 14. In contrast, if the youth is age 14 or older, then the right to consent to psychotropic medication belongs to both the parent or legal guardian and the youth. Thus, when a youth is age 14 or older, either the parent or legal guardian, or the youth, may consent to psychotropic medication for the youth. While both parties – parent or legal guardian and youth – can jointly consent to the use of psychotropic medication, consent by either party, from a legal perspective, stands alone and is sufficient for the medication to be given.

Youth Living in Substitute Care with a Foster Family

Youth younger than age 14 in substitute care are not able to consent to their own medication, and the foster parent does not have a right to consent either. The child welfare worker needs to obtain consent for medication from the birth parent, so long as the birth parent continues to maintain parental rights. If good faith efforts to find the birth parent are unsuccessful, or if the birth parent refuses to consent to medication for the youth under age 14 when the prescriber and team regard the medication as medically necessary, then court permission is needed in order to proceed. The child welfare worker arranges for a judge to determine whether or not use of psychotropic medication for the youth under age 14 is medically necessary and likely to benefit the child. If the judge approves the request, then the youth can receive psychotropic medication, in the absence of consent by the birth parent. It is usually appropriate for the child welfare worker to make efforts to inform the birth parent of the outcome, once the judge has made a decision.

For youth younger than age 14 in out-of-home care when there has been termination of parental rights, it is the judge who determines whether or not the youth is able to receive psychotropic medication as recommended by a physician or other prescriber. The decision will be based on information provided by the prescriber regarding the nature of the need and the likely benefit.

For youth ages 14-18 in out-of-home care, the right to consent to psychotropic medication belongs to both the parent or legal guardian and the youth. So long as the

birth parent continues to maintain parental rights, the child welfare worker needs to try to contact the birth parent regarding possible use of psychotropic medication by the youth. If the parent objects to the use of medication or cannot be located, the youth's consent is sufficient. Unless the youth objects or parental rights have been terminated, the birth parent should be informed of the decision of the youth regarding psychotropic medication. In instances where parental rights have been terminated, the birth parent will not be contacted by the child welfare worker regarding medication decisions made by the youth age 14 or older, because the biological parent does not have a right to consent to the youth's medication.

An additional out-of-home care arrangement in Pennsylvania is known as permanent legal custodianship. Unlike usual out-of-home care, this is a permanency arrangement for youth, who are expected to remain with the permanent legal custodian until age 18. Youth may be placed in a permanent legal custodianship when parental rights of the biological parents have been terminated. However, permanent legal custodianship may also occur when parental rights remain intact. Typically, for youth under age 14, the right of consent is identified within the custody order. Thus, the right of consent may in some instances remain with the birth parent, while in others it may reside with the permanent legal custodian. When parental rights have been terminated, the right of consent may reside with the permanent legal custodian or the court.

Subcommittee Recommendations

Recommendations Applicable to all Youth

1. Access to the information contained in this report should be made available to parents and legal guardians, youth, and all human service professionals involved with youth and families. This could be part of a website to inform stakeholders of issues relevant to the use of pediatric psychotropic medication including informed consent, or could be achieved in other ways.
2. Behavioral health and other agencies who have licensed, pediatric psychotropic medication prescribers need to ensure that the process of informed consent – “an interactive process culminating in an agreement between a patient and a healthcare provider on a course of treatment” – occurs whenever psychotropic medication is recommended and prescribed. The results of this discussion should be documented in writing, to include the signature and date by a consenting parent or legal guardian and the youth between the ages of 14-18, as applicable. Similar considerations related to the need for informed consent apply to individual psychotropic medication prescribers not affiliated with an agency.
3. A written informed consent form should be obtained for each psychotropic medication used, signed and dated by the appropriate parties. Similar

- considerations apply to individual psychotropic medication prescribers not affiliated with an agency.
4. Written, informed consent forms should be reader-friendly, minimizing the use of technical terms to the extent possible.
 5. The following are specific elements subject to an informed consent discussion and written documentation by the provider:
 - a. The rationale, purpose, nature of the disorder, and/or symptoms giving rise to the decision to use psychotropic medication. The above information should be individualized to the specific needs of the youth.
 - b. The intended benefits of the psychotropic medication.
 - c. The potential side effects and risks of the psychotropic medication.
 - d. If the medication is being used off-label (discussed in “Prescribing Practices” report), acknowledgement that this has been discussed with youth and family.
 - e. If the medication has Black Box warning, acknowledgement that this has been discussed with youth and family.
 - f. Additional information related to the use of the psychotropic medication as identified in the body of this report, should be part of the informed consent discussion and addressed within the written informed consent form.
 6. As part of the informed consent process, agencies and providers should disseminate reader-friendly fact sheets on psychotropic medication to youth and families. Alternatively, information on the psychotropic medication in question may be part of the written informed consent form.
 7. The above elements of informed consent can be subject to a checklist by the provider, or the consent form can contain each of these elements, which are discussed and documented prior to obtaining relevant signatures.
 8. At the time of referral to the pediatric psychotropic medication prescriber, professionals from behavioral health and other child-serving systems should explain the informed consent process. This will help orient the youth and family, and allow the psychotropic medication prescriber to use available time to move directly to the core clinical tasks – engaging youth and family, gathering information, and discussing treatment options.
 9. Psychotropic medication prescribers should ensure that information about psychotropic medication and the informed consent process is offered in a culturally sensitive manner. This may entail asking questions about the family’s culture and beliefs. Mechanisms for cultural and linguistic competence may include written or verbal communication, use of language interpreters, communication boards, sign language, and whatever else is needed.

10. Child-serving agencies should ensure that their staff is knowledgeable about issues of informed consent for psychotropic medication, and about the appropriate use of psychotropic medication as well. Active staff support of psychotropic medication use, when indicated, can help youth and family overcome concerns about stigma and be more receptive to psychotropic medication recommendations.
11. DPW and behavioral health managed care companies should ensure that there are adequate units of time available to psychotropic medication prescribers, so that they can properly implement the identified elements of informed consent when working with youth and families.
12. Given continuing uncertainty regarding implementation of Act 147, the Workgroup recommends that authority to interpret Act 147 and provide implementation guidelines be formally assigned to a Commonwealth Department or Program Office.
13. For all youth receiving psychotropic medication, the behavioral health system and other involved child-serving systems should ensure that there is overall coordination of services and continuity of care.

Additional Recommendations Applicable to Youth in Out-of-Home Care

1. When a youth is placed in out-of-home care, birth parents need to be identified and contacted in a timely manner. They should be provided a clear explanation of their right to consent to medical care for their child, and the limitations to their right of consent.
2. Professionals involved in the child welfare and juvenile justice systems should receive training on informed consent and on psychotropic medication commonly prescribed for youth. Training should also be provided for judges and others in the juvenile court system.
3. Out-of-home caregivers, including foster parents, should be educated about informed consent and the use of psychotropic medication. Substitute caregivers should also be advised as to how to promote the youth's medication adherence.
4. When a youth is in out-of-home care, the youth's treatment team should help ensure that the necessary elements of informed consent are met.
5. Given the need for continuity of medical information over time, a protocol for a comprehensive electronic health record for youth, which documents the youth's longitudinal medical and mental health information, should be developed through

collaboration the Departments of Public Welfare and the Department of Health. This is especially important for youth identified as being at high risk.

6. The youth's electronic health record should be available to consenting youth and to the consenting parent or legal guardian. In addition, with appropriate youth and family releases, the electronic health record should be available to representatives of involved child-serving systems and to psychotropic medication prescribers, promoting informed decision-making by youth and family in collaboration with the prescriber..

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Relevant Pennsylvania Legislation and Regulations

1. Minor Consent Law (Act 147)
2. Mental Health Procedures Act
3. 55 Pa Code, Chapter 3130 (related to Administration of County Children and Youth Social Service Programs). 3130.91. Consent to treatment.
4. 55 Pa. Code, Chapter 3800 (related to Child Residential and Day Treatment Facilities). 3800.19, Consent to treatment.
5. OCYF Policy Clarification under 55 Pa Code, 3800.19(a)(2), regarding consent for treatment in residential and day treatment facilities. #3800-05-02
6. OCYF Policy Clarification under 55 Pa Code 3800.19 and 20, regarding the process of attempting to obtain parental signature. #3800-02-09
7. OCYF Policy Clarification, under 55 Pa Code, 3800.19(a)(2), regarding the circumstances under which consent to treatment is obtained for children residing in residential and day treatment facilities. #3800-05-02
8. OCYF Policy Clarification, under 55 Pa Code, 3800.19 and 3800.20, regarding consent for treatment for youth in the custody of the county agency, whose parental rights have been terminated or who are without a court specified legal guardian. 3800-02-09

Informed Consent Subcommittee Participants

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III. Prescribing Practices Subcommittee

Mission Statement

To develop general recommendations for psychotropic medication prescribing practices for children and adolescents (youth) in Pennsylvania, in order for medication prescribers to maximize the benefits of such medication and minimize the potential risks, and to develop recommendations that ensure that individuals with specialized expertise in psychotropic medication for youth more fully participate in policy-related decisions about such medication at the state and local levels.

Vision Statement

Every youth in Pennsylvania for whom psychotropic medication is considered or prescribed will have access to informed medication prescribers who follow appropriate prescribing guidelines that ensure high quality, safe use of such medication. In addition, policy-related decisions related to psychotropic medication at the state and local levels will be guided in part by a committee consisting of child and adolescent psychiatrists and others with this specialized expertise.

Introduction

Prescribing practices for pediatric psychotropic medication in the public behavioral health system in Pennsylvania can be usefully viewed as involving two different levels. The first level is a clinical one, involving a licensed prescriber of psychotropic medication and a specific youth, who is receiving such medication in conjunction with his or her family, or for whom such medication is being considered or recommended. The second level involves policy considerations at the state level that influence prescribing practices. These policy considerations are under the jurisdiction of the Office of Medical Assistance Programs (OMAP), within the Pennsylvania Department of Public Welfare (DPW), and also the specific physical health managed care organizations under HealthChoices, the managed care program within Pennsylvania. Even though the use of psychotropic medication is closely related to behavioral health, with a few exceptions, policy regarding psychotropic medication at the state level for the Fee-for-Service Program within DPW is under the jurisdiction of OMAP and not the Office of Mental Health and Substance Abuse Services (OMHSAS). In like manner, policy regarding psychotropic medication within managed care under HealthChoices is under the jurisdiction of the physical health plans, not the behavioral health plans.

A second area of importance involves decision-making at the policy level regarding psychotropic medication use in youth. Some stakeholders, especially family members, child and adolescent psychiatrists, and other professionals working with youth, seek to have policy decisions involving psychotropic medication for youth made by individuals with specialized expertise in youth and in pediatric psychotropic medication, along with family members and advocates. Specific policy issues include the determination of which medications can be prescribed for a Medicaid member and filled by the pharmacy without the need for prior authorization by the funding source, whether Fee-for-Service or a specific physical health managed care plan, and how such policies are determined. In what follows, we consider relevant aspects of the above two issues – clinically-based prescribing practices, and policy-based prescribing practices – in greater depth.

Part 1: Clinically-Based Prescribing Practices

Consideration of clinically based prescribing practices begins with a discussion of foundational principles, and then is followed by identification of potential, practical issues related to pediatric prescribing.

Foundational Principles

Discussion of clinically-based prescribing practices needs to begin with consideration of foundational principles, with particular attention to their applicability to youth and their families. These foundational principles involve Child and Adolescent Service System Program (CASSP) Principles, and the biopsychosocial approach to assessment and treatment.

Pennsylvania's CASSP Principles were adopted by multiple child-serving systems in 1995, the result of sustained dialogue among stakeholders under the sponsorship of the OMHSAS Children's Advisory Committee. CASSP Principles were formulated in Pennsylvania and in other communities as a result of the creation, in 1984, of the Child and Adolescent Service System Program at the federal level, which focused on how to best address the needs of youth and families in public systems of care. This early beginning served as a catalyst for a national movement that continues to the present.

Pennsylvania's CASSP Principles are well-known to many statewide stakeholders. They direct all child-serving systems to provide services that are: 1) child-centered, 2) family-focused, 3) community-based, 4) multi-system, 5) culturally competent, and 6) least restrictive/least intrusive. The first two principles have been strengthened at the federal level by the Center for Mental Health Services and by the Federation of Families for Children's Mental Health, to now connote care that is "family-driven" and "youth-guided" (Osher et al, 2006), which also includes care that is strengths-based. Along with other aspects of behavioral health, pediatric medication prescribing should be linked to CASSP Principles ((Hodas 2006).

The biopsychosocial perspective is a holistic, integrative approach to assessment and treatment in behavioral health. Formulated by an internist (Engel, 1997), it avoids potential ideological polarization by moving away from simplistic notions of care, including that of “the medical model.” Instead, understanding of an individual is achieved through holistic attention to three component dimensions: 1) biologically-based factors, 2) psychologically-based factors, and 3) socially-based factors, reflective of the individual’s social context.

The biopsychosocial perspective is congruent with CASSP Principles, and together these two formulations can guide quality behavioral health treatment, including pediatric psychotropic prescribing. However, a potential barrier sometimes involves insufficient time for psychiatric evaluations and medication visits. It has been noted that the ability of a prescriber to spend adequate time with the patient and family is a critical determinant of quality and satisfaction (Malik et al, 2010). It is further stated:

Patients too often feel as though they are merely “the next appointment” unless the doctor listens to the personal and unique elements of their story.

When the biopsychosocial perspective and CASSP Principles are implemented, and when there is adequate time available for evaluations and medication visits, the prescriber is in a position to develop a positive relationship with the youth. This in turn has important implications, because “among adolescent psychiatric patients, the quality of the therapeutic alliance with the psychiatrist can mediate treatment effectiveness” (DeLallo and Weiss, 2009). The authors point out that the therapeutic alliance can be enhanced through the use of motivational interviewing, which helps the prescriber convey empathy toward the youth and then promote youth self-efficacy and a positive attitude toward prescribed medication.

Recognizing What is at Stake

The developmental process for youth is highly significant, in that each stage of development builds on the ones that precede it. As a result, early and severe disruption of typical development, as occurs with child psychiatric disorders and trauma, has the greatest potential consequences, during childhood and over the lifespan. In addition, the concept of sensitive and critical periods – specific developmentally-based timeframes during which certain capacities need to be achieved – reinforces the importance of promoting normal development as much as possible. Given their impact on development, childhood psychiatric disorders and the consequences of these disorders tend to persist over time. Attachment, the capacity for self-regulation, interpersonal and problem-solving skills, learning, attitudes and beliefs, lifestyle choices, and physical as well as emotional and behavioral health – all related to quality of life – may be affected. Ultimately, even life expectancy itself is often affected (Angold, 2009, Jokela et al, 2009).

A further consideration involves the severity of childhood disorders. As articulated by one leader in child psychiatry, “Psychiatric disorders with childhood onset are generally thought to be more severe and more impervious to treatment than adult-onset disorders...” (Rockhill, 2010). This is especially the case with childhood-onset mood disorders, “such that many patients will have persistent symptoms after recommended intervention.”

These sobering considerations lead us as professionals, parents, and others who care about children to appreciate the need to intervene early and effectively. Perhaps in an ideal world, interventions would be strictly educational and psychosocial, without recourse to psychotropic medication. Unfortunately, this ideal world does not exist, and there is need for careful consideration of all biopsychosocial interventions, including the use of medication.

Specific Practical Issues Related to Psychotropic Prescribing

While the use of psychotropic medication for youth may at times be life-saving and greatly improves the youth’s functioning and quality of life, there are issues related to the use of psychotropic medication that need to be identified and discussed.

Medication Side Effects

All prescription medications may be associated with undesired side effects. Many of these are not considered to be serious in nature. Some side effects are only temporary, and disappear after the body gets used to the medication and the dose remains stable. In some cases, the individual learns to tolerate a specific side effect, while in other cases the dose may be decreased until the side effect decreases or disappears. Such circumstances are extremely common, whether the medication is prescribed for adults or youth.

Some side effects are potentially more serious, and in these cases a more intentional strategy may be followed. For example, since bupropion (Wellbutrin) may decrease the seizure threshold, this agent is typically not chosen for an individual with a pre-existing seizure disorder. For an individual with sleep disturbance, efforts are made to avoid the use of a medication associated with increased arousal as a side effect. Instead, another medication with neutral or sedative qualities might be preferentially selected.

Given the broad range of potential side effects for various medications, it is not always possible to predict which side effects will develop for a specific individual. Thus, the use of medication, including psychotropic medication, often entails uncertainty, which makes ongoing monitoring of therapeutic effects and side effects essential.

It has become clear that, while newer classes of medication may in some respects avoid some of the side effects of their predecessors, they may nevertheless have their own side effects of concern. In like manner, while newer medications may have a broader range of

potential therapeutic effects, they may also have certain side effects that were less of a concern with the earlier agents. For example, some of the newer antipsychotic medications, referred to as atypical neuroleptics, are believed to be more effective in the treatment of adolescent schizophrenia than the older, so-called typical neuroleptics. However, many of the atypical agents may also be associated with greater weight gain as a side effect. Weight gain, in turn, is associated with a series of risk factors for heart disease referred to as the metabolic syndrome:

According to the National Heart Lung and Blood Institute, the metabolic syndrome consists of at least 3 of the following 5 risk factors: abdominal obesity, a high triglyceride level, a high fasting blood glucose level, a low HDL cholesterol level (the so-called “good” cholesterol), and high blood pressure (Revised 2010).

The metabolic syndrome may be a precursor to secondary diabetes mellitus (also known as Type 2 diabetes). In addition, metabolic syndrome in adults increases the risk of coronary artery disease. Although the metabolic syndrome was first identified in adults, there is evidence that it can occur in the pediatric population as well, perhaps with greater severity than in adults. However, there is evidence that not all atypical agents are associated with the same degree of metabolic abnormality, and this can influence the specific choice of medication selected (Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes, 2004).

Certain side effects raise sufficient concern that the federal Food and Drug Administration (FDA) requires the pharmaceutical company to identify the side effect in question within what is referred to as a “black box warning.” The requirement of a black box warning as part of the marketing of a specific medication is relatively uncommon, and is usually reserved for those side effects that can be associated with high risk of serious damage, especially the risk of death. Some black box warnings are presumed to be applicable to all age groups, while others are age-specific. For example, there is now a black box warning for atypical antipsychotics related to the risk of death when given to the elderly. Specific to children, one very prominent, and also controversial, black box warning is now required for the marketing of antidepressant medication for children, identifying the association of such medication with potential suicidality. While many experts argue that the benefits of antidepressant use in childhood depression greatly outweigh the potential risks – and that the studies on which the black box warning are based include no completed suicides – the point here is that black box warnings represent a prioritized concern of the FDA related to the use of a specific medication or class of medications in one or more targeted groups.

“Off Label” Use of Many Pediatric Psychotropic Medications

When medication is prescribed in a manner other than as approved by the FDA, such medication is said to be used “off label.” Medication is used off-label when it is prescribed for an age group other than as approved by the FDA, and for a purpose or indication other than as approved by the FDA. In this section, we discuss off-label prescribing due to use of medication in an age group other-than-approved – in particular, the use in youth of psychotropic medication approved for use in adults. In the next section, we consider off-label prescribing due to use of medication for an indication other than approved by the FDA.

In general, pharmaceutical products developed by drug companies can be marketed only after they receive approval by the FDA. FDA approval is necessary for the drug to be placed on the market and to remain there. The FDA approves a drug when research demonstrates that it is effective for a specific purpose, and when the benefits outweigh the potential risks. FDA drug approval is specific to an identified population, usually adults. Yet psychotropic medication effective for adults may also be prescribed for use in youth. Given the absence of research, such use is considered off-label. However, “off-label” prescribing, as discussed below, does not necessarily mean that its use is inappropriate.

In general, the use of medications (physical health medication and psychotropic medication) not approved by the FDA in youth is quite common. In fact, it has been observed that “the lack of childhood safety and efficacy data for medications developed and tested principally in adults...applies to 75% of all medications (antibiotics, anesthetics, etc.) currently available in the United States” (Jensen 2001).

There are reasons why medications are often not FDA-approved for use in youth, and these are often unrelated to the medication’s effectiveness and safety. Most drug company research of psychotropic medication begins with adults, because this is where the vast majority of sales come from. Once the drug company receives FDA approval for use of a psychotropic medication in adults, there may be little financial incentive to conduct additional studies to obtain FDA approval for use of the medication in youth. Despite increased use of pediatric psychotropic medication in recent years, the overall financial gain is limited. Exceptions to this involve those medications used primarily by youth, in particular those used to treat ADHD. When the target group is youth, the pharmaceutical companies will actively seek FDA approval for use in youth and conduct the necessary studies on the medication’s impact on this population.

For the most part, then, the pharmaceutical industry has not funded studies to determine the outcomes of psychotropic medication used in the pediatric population. While this situation has begun to change as a result of incentives for drug companies to conduct research on medication use in youth (and also due to research from other sources now taking place), for the vast majority of psychotropic medication, the research with youth

has not taken place. The lack of research accounts for lack of FDA approval of pediatric medication much more than specific evidence that the medication is ineffective or harmful. Thus, the absence of FDA approval of a psychotropic medication for use in children does not signify that there has been FDA *disapproval*, or that such use is inappropriate or unsafe. Rather, the research has not occurred, and the drug company has not submitted a formal request to the FDA for approval of the medication in question for children. The pediatric use of psychotropic medication that is not FDA-approved for use in youth, if guided by other research or by expert consensus, may be clinically sound.

The above considerations have led Dulcan, in a resource book on pediatric psychotropic medication, to make the following generalization:

Many medications have not been approved by the U.S. Food and Drug Administration (FDA) for use in children. For this reason, use of this medication for a particular problem or age group is not listed in the Physician's Desk Reference. This does not necessarily mean that the medicine is dangerous or does not work, only that the company that makes the medicine has not received permission to advertise the medicine for use in children (2007).

At the same time, in the interests of safe prescribing, there is need to ensure that off-label prescribing is pursued in accordance with appropriate criteria. A consensus group in Australia has developed such criteria (Gazarian et al, 2006). When a medication is being considered for off-label use, there are two key clinical rationales. The first involves the presence of high quality evidence supporting its use. Thus, the critical element is not formal approval of the medication, but the degree of evidence of its efficacy and safety. The second rationale involves an exceptional need in an individual with a serious disease or condition, where the evidence is limited but standard treatment has been ineffective and the potential benefits outweigh the potential risks. Until medication use in youth is subject to regular research so that FDA approval can be given, the above two criteria are appropriate for the off-label use of psychotropic medication for youth.

To some extent, the research landscape is now beginning to change, and there is more research on pediatric psychotropic medication and greater opportunities to demonstrate the benefits of such medication in the pediatric population. Research to date has demonstrated support for the use of psychotropic medications for youth with mental health disorders, and for those with a combination of mental health and developmental disorders engaging in aggressive or self-injurious behavior. Nevertheless, it is clear that youth and families have a right to be informed about whether or not a recommended medication has been approved by the FDA for use with youth for a particular psychiatric disorder, and discussion of this information with the family is now becoming part of the standard of care.

A few examples will illustrate the current status of FDA approval of pediatric psychotropic medications. Currently, for the treatment of depressive disorder, only two of

the many available Selective Serotonin Reuptake Inhibitors (SSRIs) are approved for use in youth: fluoxetine (Prozac), for those age 8 years and older, and, more recently, escitalopram (Lexapro), for those ages 12-17. SSRIs approved for use in specific pediatric anxiety disorders are sertraline (Zoloft), for youth 6 years and older with Obsessive Compulsive Disorder (OCD), and fluvoxamine (Luvox), for those age 8 or older with OCD. Other SSRI agents, FDA-approved for use in individuals age 18 and older, are also used in the treatment of pediatric depression, when approved agents prove ineffective. The rationale is that SSRIs as a group tend to be similar in clinical effects but potentially different in side effects.

The situation is less complicated with medications for the treatment of ADHD, since it is primarily regarded as a pediatric disorder. Methylphenidate (Ritalin) and methylphenidate derivatives, including such long acting agents as Concerta, are approved for youth age 6 and older. Amphetamine salts, known as Adderall, are approved for youth age 3 and older, while extended release amphetamine salts, Adderall XR, are approved for those age 6 and older. The newer non-psychostimulant medication for ADHD, atomoxetine (Strattera), is also FDA-approved for youth age 6 and older. A complete listing of psychotropic medications, with identification of the FDA-approved age, as compiled by the National Institute of Mental Health, can be found at the following website:

www.nimh.nih.gov/health/publications/mental-health-medications/alphabetical-list-of-medications.shtml.

Use of Medication for a Purpose Not FDA-Approved

A related issue in the off-label use of psychotropic medication involves the use of medication for a purpose that may not be approved, at least initially, for either youth or adults. For example, valproic acid (Depakote) is FDA-approved for seizures for anyone 2 years and older. This is because valproic acid was originally developed for the treatment of seizures, and was approved by the FDA for this purpose. In addition, it was later discovered that valproic acid can also stabilize mood, and psychiatrists often prescribe valproic acid for this purpose with good effect. Nevertheless, since valproic acid is not FDA-approved to treat unstable mood, its use in this manner is regarded as “off-label” prescribing. Even though valproic acid is often effective for mood instability and is commonly prescribed in this manner, its use for mental health reasons is still off-label.

With youth, atypical neuroleptic medications may at times be used off-label for high risk youth, particularly when there are safety concerns due to anger. For example, an atypical may be used to decrease aggression in children, in the absence of schizophrenia or bipolar disorder. Clinical experience suggests that such off-label use can have significant benefit for appropriately chosen youth, who might otherwise end up being arrested and incarcerated.

Use of More than a Single Psychotropic Medication

Ideally, every youth in need of psychotropic medication would respond to one carefully chosen medication, so that use of more than a single medication would not be necessary. In reality, however, this is not always the case. Youth may have more than a single psychiatric disorder for which medication is indicated, and there is no assurance that disparate disorders will respond to the same medication. In addition, some children with severe symptoms may require more than one medication to treat a single psychiatric disorder.

However, it is also clear that the use of multiple medications increases the possibility of undesired side effects, as well as potential drug-drug interactions. In addition, use of more than a single medication to address the same target symptom is problematic when the primary medication has not been maximized appropriately or used for an appropriate length of time. Further, multiple medications may alter the effect of the specific agents used, creating uncertain outcomes.

Ultimately, it is important to distinguish between the appropriate and inappropriate use of more than one psychotropic medication, based on the profile of the youth and the history. In general, psychotropic medication prescribing should be based on a comprehensive evaluation of the youth, not just a collection of symptoms viewed in isolation. In addition, medication should be used in a systematic, sequential manner, with careful monitoring of outcomes. For example, the simultaneous initiation of two or three different psychotropic medications by a prescriber would constitute a source of concern. Such an approach is quite different from a prescriber who begins the youth on a single medication, carefully increases the dose as needed over time in order to maximize its use while monitoring for side effects, and then determines need to add a second medication to treat the same or a different psychiatric disorder.

Need for Outcome Studies of Pediatric Psychotropic Medication

Given limited research on pediatric psychotropic medications by the pharmaceutical companies and the need for data on the effective treatment of psychiatric disorders in youth, in 1997, the National Institute of Mental Health set up and began funding Research Units for Pediatric Pharmacology, known as RUPPs. These involve federal-university partnerships, with the goal of developing data about the best treatment approaches to various childhood disorders, including depression, bipolar disorder, obsessive compulsive disorder, other anxiety disorders, and autism spectrum disorders. The RUPP studies, which are in multiple sites with rigorous research protocols, are increasing knowledge in the field regarding the treatment of both common and treatment-resistant disorders. Specific psychotropic medications already on the market are part of the research design, but for the most part the RUPP studies do not focus on comparative effectiveness of various medications or even the use of medication in isolation. Instead, most of the pilots compare the effectiveness of a specific medication intervention with a

specific psychosocial intervention, as well as the impact of the combination of these two modalities (Vitiello 2005). The RUPP studies have provided the field with valuable information about psychotropic medication use in youth. However, this information is not as comprehensive as that obtained, for example, from pharmaceutical company research on new medications for adults when a specific FDA approval is being sought..

For more than a decade now, the federal government has made efforts to increase industry research on pediatric medications, which includes pediatric psychotropic medication. For example, in 1997, the Food and Drug Modernization Act gave the FDA the authority to extend drug exclusivity for an additional six months to pharmaceutical companies, in return for their conducting studies of the medication in youth. Further information can be obtained at:

www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAct/SignificantAmendmentstotheFDCAct/FDAMA/default.htm.

Further momentum for obtaining data on all medications used in pediatrics was strengthened with the passage by Congress of the Best Pharmaceuticals for Children Act (BPCA) in 2002. The BPCA, which was reauthorized in 2007, is intended to improve the level of information about medications used to treat youth. The legislation, which is not restricted to psychotropic medication, calls for research to learn more about the efficacy and safety of pediatric medications. Further information can be obtained at:

www.fda.gov/opacom/laws/pharmkids/contents.html.

Yet another initiative by Congress involves the Pediatric Research Equity Act (PREA) of 2003, which builds on the BPCA. Unlike BPCA, which was voluntary, PREA is mandatory, and involves studies specifically directed to a medication under development for a specific pediatric indication. In particular, a Pediatric Assessment is required for formal applications for approval under this act of a new medication, a new indication, a new dosage form, a new dosing regimen, and a new route of administration. The Pediatric Assessment, in turn, must contain data adequate to assess the safety and effectiveness of the medication or biological product. The Act also gives the FDA the authority to require the pharmaceutical industry pediatric investigations as a condition for approving new medications for adults, when off-label use in youth can be anticipated (Vitiello 2005). Further information can be obtained at:

www.fda.gov/ohrms/dockets/ac/04/slides/4006S1_01_Murphy.ppt.

The combined impact of the above developments is that there is now more research related to specific medications, and types of medications, as applied to specific pediatric populations, including youth with psychiatric disorders. While these studies have not yet significantly increased the number of FDA approved pediatric psychotropic agents, there nevertheless is an increasing amount of research that can guide, and in many cases help

justify, the use of psychotropic medication for youth in the absence of formal FDA approval.

Need for Clinical Guidelines for the Use of Pediatric Psychotropic Medication

Given the multiple issues related to pediatric psychotropic medication prescribing, there is need for a set of clinical guidelines for prescribers. Fortunately, in 2009, the American Academy of Child and Adolescent Psychiatry (AACAP) issued such guidelines, in the form of a “Practice Parameter on the Use of Psychotropic Medication in Children and Adolescents” (AACAP, 2009). This practice parameter consists of 13 principles to guide the prescribing of pediatric psychotropic medication. The specific principles are identified below. Discussion under each principle, with the exception of direct quotes from the Practice Parameter document, is by the subcommittee:

1. Initiating Pharmacotherapy, a Psychiatric Evaluation Is Completed.

Completion of a psychiatric evaluation ensures that psychotropic medication is not prescribed prematurely or frivolously, without first obtaining a comprehensive understanding of the youth. The latter includes delineation of the strengths and needs of the youth and family, the current functioning of the youth, the past history, consideration of possible drug and alcohol-related problems, and identification of an appropriate mental health diagnosis. In addition, the psychiatric evaluation should distinguish “symptoms best addressed pharmacologically and (those) best addressed with psychosocial treatments,” thereby ensuring that treatment is biopsychosocial in nature, with psychotropic medication used only when indicated. During the psychiatric evaluation, both the youth and the parents or legal guardians should be interviewed.

2. Before Initiating Pharmacotherapy, a Medical History Is Obtained, and a Medical Evaluation Is Considered, When Appropriate.

The medical history and the medical evaluation can rule out physical health disorder as the basis of the youth’s symptoms, and also establish that the youth can likely participate in a medication trial “with minimal risk.” Family medical history is obtained, along with baseline information about the youth’s growth, routine blood chemistry and medical conditions, as applicable. Information about the use of physical health medications, and about the possible use of over-the-counter products, is also obtained. Such medical information can help safely guide psychotropic medication use, and provides a framework for ongoing medication monitoring. When the youth has a significant physical health disorder or is taking physical health medication that could interact adversely with psychotropic medication being taken or considered, direct communication among psychiatric and physical health practitioners can be particularly helpful.

- 3. The Prescriber Is Advised to Communicate With Other Professionals Involved With the Child to Obtain Collateral History and Set the Stage for Monitoring Outcome and Side Effects During the Medication Trial.*

Communication with other professionals adds to the information base available to the prescriber. Equally important, such communication can serve to educate non-medical team members and promote the buy-in of psychotropic medication use. Over time, communication with team members helps promote a unified approach, and provides multiple sources of information regarding the youth's progress.

- 4. The Prescriber Develops a Psychosocial and Psychopharmacological Treatment Plan Based on the Best Available Evidence.*

This principle further reinforces the need for balanced treatment, rather than sole reliance on psychotropic medication. The choice of treatment, both psychosocial and medication, should be based, whenever possible, on the existing evidence base. It is important that the youth and family be informed about what to expect and what to look for, when psychotropic medication is used. Based on careful monitoring and collaboration between prescriber and youth and family, medication is pursued during three phases: the acute or initiation phase, the maintenance phase, and the discontinuation phase.

- 5. The Prescriber Develops a Plan to Monitor the Patient, Short and Long Term.*

This principle further reinforces the importance of education for the youth and family. Monitoring needs to involve the youth and family, not just the prescriber. Others on the team can also contribute to monitoring. The nature of the monitoring plan should be clearly identified, in this way increasing the likelihood of its full implementation. The frequency of contact between the youth and the prescriber is determined on an individualized basis, in general with greatest contact during the initiation phase. Monitoring should include information about the physical health status of the youth and the impact of physical health medications in use, as obtained from the physical health provider or others in the medical home. It is important that monitoring of the youth continue after the discontinuation of psychotropic medication, in order to document continued progress or identify possible signs of relapse.

- 6. Prescribers Should Be Cautious When Implementing a Treatment Plan That Cannot Be Appropriately Monitored.*

Potential barriers to the effective use of psychotropic medication should be identified, so that they can be addressed by the prescriber and team. Such barriers may involve limited access to medication, inconsistent medication adherence, and a need for greater adult supervision. Without consistent medication adherence, the prescriber may mistakenly assume that there is need to increase the medication dose or add another medication.

Such responses complicate the youth's treatment, and may create unnecessary safety risks,

7. The Prescriber Provides Feedback About the Diagnosis and Educates the Patient and Family Regarding the Child's Disorder and the Treatment and Monitoring Plan.

This principle also identifies the need for youth and family education. Education is a prerequisite to informed consent, and also facilitates active participation and collaboration by youth and family. Education is needed regarding the youth's disorder, its treatment, and the approach to treatment monitoring. The prescriber needs to ensure that there is clarity and agreement about the specific responsibilities of youth, family and team members regarding psychotropic medication adherence and monitoring. In addition, youth and family need to understand the responsibilities, and the nature of the availability, of the prescriber.

8. Complete and Document the Assent of the Child and Consent of the Parents Before Initiating Medication Treatment and at Important Points During Treatment.

This principle explicitly identifies the need for informed consent – in Pennsylvania by parents and legal guardians and youth age 14 and older – and also informed assent by youth younger than age 14. Informed consent is necessary at the initiation of psychotropic medication use and whenever there is a change in type of medication or an addition of medication.

9. The Assent and Consent Discussion Focuses on the Risks and Benefits of the Proposed and Alternative Treatments.

Discussion of risks and benefits is part of youth and family education, and is also integral to obtaining informed consent. Such discussion applies to both psychotropic medication and psychosocial interventions, and includes consideration of the risks associated with not implementing an intervention, not just the risks of implementing it.

10. Implement Medication Trials Using an Adequate Dose, and for an Adequate Duration of Treatment.

Initiation of psychotropic medication should be guided by agreement at the outset to pursue a complete medication trial. The two key parameters of a medication trial are dose and duration. Given the desire to avoid unnecessary side effects, psychotropic medication may be started at a low dose, with upward titration until there is a clinical response, the target dose is reached, or there are side effects requiring a decrease of the medication or its discontinuation. Understanding the strategy of medication titration enables the youth and family to experience greater mastery and control during this period of transition. The duration of a medication trial depends on the length of time needed for the medication at

the appropriate dose to take effect, plus additional time based on the time span during which a positive response may occur.

11. The Prescriber Reassesses the Patient if the Child Does Not Respond to the Initial Medication Trial as Expected.

Assessment is an ongoing process, and adjustments are necessary when the youth does not respond to an adequate medication trial. At times, change to a different medication is indicated, while at other times there may be specific indications to add another medication. At other times, the diagnosis needs to be reconsidered, and there may be a need to implement psychosocial interventions to address issues not responsive to psychotropic medication. Reinforcing the need for a balanced approach to treatment, the Practice Parameter indicates that “the prescriber who does not appreciate the need for combined psychosocial and psychopharmacological treatment for children with concomitant psychosocial problems...may unnecessarily expose the child to increasingly complex pharmacological treatment strategies.”

12. The Prescriber Needs a Clear Rationale for Using Medication Combinations.

Psychotropic medication use should be guided by the principle of economy, ideally by using only one medication. There are, however, circumstances where more than a single medication may be indicated and appropriate. These include the presence of multiple disorders in the same youth, the need for more than one medication to address a single disorder of severe intensity, and the need to use a new medication to treat the side effect of an effective psychotropic medication. Prescribing practices should be guided by the presence of a clear rationale for each medication used, typically with only one medication change at a time.

13. Discontinuing Medication in Children Requires a Specific Plan.

Psychotropic may be appropriately discontinued as a response to progress, the failure of progress, or a side effect of concern. Whatever the reason, it is important that discontinuation be pursued in a careful, planned manner, tapering one medication at a time. In addition, the youth should be followed following medication discontinuation, so that expected and unexpected needs can be addressed.

Ultimately, the decision of whether to maintain or discontinue psychotropic medication rests with the youth and family. Nevertheless, it is extremely important that collaborative discussion occurs with the prescriber, and that the decision to discontinue medication not be made unilaterally by the youth or family. Sudden medication discontinuation creates unnecessary risks. Thus, the agreement to begin psychotropic medication should also include an agreement that the youth and family will contact the prescriber if concerns arise, rather than discontinue medication on their own.

The above principles, while written primarily for child and adolescent psychiatrists, are in fact applicable for all medical professionals who are licensed to prescribe psychotropic medication to children and adolescents. Attachment 1 discusses the applicability of the AACAP principles to primary care physicians and other pediatric prescribers, and indicates how the principles can be implemented in non-psychiatric settings.

Need for Individualized Prescribing of Pediatric Psychotropic Medication

The above considerations reflect that the decision to recommend or prescribe psychotropic medication for a child is not one to make lightly. Each recommendation needs to take into account the unique characteristics of the youth, including strengths, needs, culture, past history, family preferences, and family history and response to medication. The use of psychotropic medication for youth, and the specific choice of agents, must always be individualized. Prescribers need to be familiar with the literature, research, expert consensus, and current trends. At the same time, prescribing for an individual youth and their family should be based on that youth's unique clinical profile. Ultimately, medication decisions should be based on a strategic decision, sometimes referred to as a decisional balance, in which the expected benefits of use (the "pros") are weighed against the potential risks (the "cons"). Part of this determination involves considering the risks of using medication, as compared to the risks of *not* using medication.

Clinically appropriate, ethically based prescribing practices require that child and family are educated about treatment options, including both psychosocial interventions and medication interventions. Regarding the latter, the pros and cons of each medication should be discussed, including expected therapeutic effects and medication-specific side effects. In general, the psychotropic medication prescriber should serve as a source of information, facilitation, and consultation, with the family as the final arbiter of the decision.

Need for Culturally Competent Prescribing Practices

Cultural competence is one of the previously identified CASSP Principles, and it deserves additional discussion here, since it is an important component of psychotropic medication prescribing practices for youth and their families.

Cultural competence has been defined as:

a set of congruent behaviors, attitudes, practices, and policies that come together in a system or agency or among professionals and enable that system or agency or those professionals to work effectively in cross-cultural situations (Isaacs-Shockley et al, 1996).

Culturally competent care, then, involves both a healthcare system and a workforce that are “capable of delivering the highest quality care to every patient regardless of race, ethnicity, culture, or language proficiency” (Betancourt, J et al 2005). Although issues of culture frequently arise as part of clinical work with racial and ethnic minorities, cultural considerations are relevant for all youth and families, including those within the dominant culture in society. It is also important to recognize that “there are as many variations *within* cultures as *between* cultures (Isaacs-Shockley et al, 1996), and that a family’s culture is dynamic rather than “fixed or static” (Carpenter-Song et al, 2007).

Cultural competence involves the presumption of multiculturalism, a broadly based concept of culture that includes “the variable values, attitudes, beliefs, and behaviors shared by a people, (which) is transmitted between generations” (Pumariega and Joshi, 2010). The authors identify, from a multicultural perspective, three major tasks for clinicians:

(1) developing a broad knowledge base about cross-cultural variations in child development and childrearing; (2) integrating this knowledge in a developmentally relevant way to make more informed clinical assessments and case formulations; and (3) developing a culturally sensitive attitude and therapeutic stance in all interactions with patients and families...

Consistent with the broadly based framework of multiculturalism, culturally competent prescribing can be usefully divided into understanding 1) the meaning of psychotropic medication for a youth and family, and 2) the specific physiological effects of such medication on the youth, which may be influenced by race and ethnicity. Attending to both dimensions within a respectful helping relationship promotes the development of trust and a positive therapeutic alliance.

Malik et al refer to the provision of culturally competent medication as “culturally adapted pharmacotherapy” (2010). Prescribing practices that are “culturally adapted” seek to understand the cultural meaning of taking medication for the youth and family and, when relevant, to diminish associated stigma and shame. In addition, the selection of medication and decisions on dosing take into account such variables as response rate, side effects, and metabolism among different racial and ethnic groups. Such group-specific considerations are likely to become increasingly important in the future, when there is additional research on medication differences in the pediatric population. At present, familiarity with existing research on such differences in adults is recommended, since “there is a paucity of empirical evidence to guide ethno-pharmacologic practices in children and adolescents” (Malik et al, 2010).

Need for Informed and Respectful Approaches to Special Populations

There are many special populations within child and adolescent behavioral health, in addition to those organized around race, ethnicity, religion, and other variables typically

regarded as part of culture. Each of these special populations also has unique strengths, needs, beliefs, and practices, and so should receive informed, respectful approaches from professionals that also comprise cultural competence.

One significant special population involves youth in substitute care, and the needs of this group are discussed within the Informed Consent Subcommittee report. Other special populations include youth with co-occurring psychiatric and substance use disorders, youth with a mental health disorder and an intellectual disability, and youth with a mental health disorder and significant physical health challenges. The attuned prescriber becomes familiar with the culture of other involved service systems, whether drug and alcohol, intellectual disability, physical health, or a combination of these. The prescriber also needs to understand all of the health challenges of the youth, separately and in relation to each other, not just those related to mental health. Only in this way can psychotropic medication prescribing practices be safe, informed, and coordinated with the youth's overall health care. Any of the above youth may also have experienced trauma, and an informed prescriber understands the potential impact of trauma on the youth's neurobiology, beliefs and attitudes, and overall functioning.

Other special populations include youth with mental health challenges who are blind, and those who are deaf and hard-of-hearing. The attuned prescriber needs to understand both the common and the unique experiences of such youth and their families.

Another special population involves adolescent females who are pregnant. The prescriber needs to be familiar with the possible effect of specific psychotropic medications on fetal development, as well as the negative effects of prenatal alcohol, drug use, and smoking. Careful discussion with youth and family is essential, when deciding whether to prescribe a psychotropic medication during pregnancy. For female youth of child-bearing age who are sexually active, discussion and care are needed when psychotropic medication is prescribed.

A final group involves youth with mental health challenges who are lesbian, bisexual, gay, transgender, questioning, and intersex (LBGTQI). There are significant differences among the types of individuals included within the above global category. However, as a group they may experience discrimination in the community and in the healthcare system. OMHSAS, in collaboration with the Keystone Pride Recovery Initiative, has developed two bulletins applicable to the LBFTQI population, one to ensure non-discrimination toward Lesbian, Gay, Bisexual, Transgender, Questioning, and Intersex people (2010) and the other to ensure affirmative environments and clinically appropriate services (2010). All of the core elements of these bulletins are applicable to psychotropic medication prescribers.

Part II: Policy-Based Prescribing Practices

General Considerations

Pennsylvania as a state requires that there be “an open formulary” for all individuals enrolled in the Medical Assistance program. This means that members can potentially have access to all medications that are on the market in the United States for all types of disorders, physical health and behavioral health, and that the pharmacies of the state and the physical health managed care programs cannot exclude specific medications from their formularies based on cost or other considerations unrelated to safety. Within its open formulary, Pennsylvania then classifies its medications into three categories: 1) those brand name medications that require a formal review and approval as medically necessary (a prior authorization) by the funding source; 2) those brand name medications that are on a Preferred Drug List (PDL) and are referred to as “preferred drugs,” which usually do not require a prior authorization; and 3) generic medications, which are less costly and usually not subject to a prior authorization process. Prior authorization for drugs on the PDL may at times occur, due to specific safety concerns regarding the use of the drug with a particular population. For example, prior authorization is required for all neuroleptic medications prescribed for youth under age 6, due to safety concerns. Prior authorization for drugs on the PDL may also occur when there is limited evidence for use, or limited evidence for use for a specific indication.

A number of considerations enter into the decision of which brand name medications are included in the state’s PDL. These include the evidence of effectiveness of a specific medication, its safety profile, its cost, and the number of medications within the same class already in the PDL. It should also be understood that some medications on the PDL for one indication may be subject to a prior authorization when used for another indication. For example, Abilify, which is on the PDL, does not require a prior authorization when prescribed for schizophrenia or bipolar disorder. However, prior authorization may be required when Abilify is prescribed for depression.

Policy based prescribing issues at the state and local levels include the specific rules governing the availability of, and access to, psychotropic medication, when prescribed for Medicaid members by a physician or other licensed prescriber, as well as issues related to the quality and safety of medication prescribing. Also at issue are the formal mechanisms for determining which brand name medications are placed on a Preferred Drug List (PDL), and which brand name medications are not on the PDL. Yet another issue involves the nature of the appeal process that is to be followed, when a member appeals denial of a medication requiring prior authorization. Of particular importance is the composition of the decision-making bodies that determine formularies, prior authorization and appeal processes, as well as other medication-related policies.

In Pennsylvania, decision-making related to psychotropic medication use for MA-enrolled members follows parallel tracks, depending on whether the member is being

served directly through the Fee-for-Service (FFS) system or through mandatory physical health managed care under HealthChoices. (The Children's Health Insurance Program (CHIP) is not under the jurisdiction of DPW, and therefore the policies and procedures discussed in this document do not apply).

Within MA, both FFS and managed care are ultimately under the jurisdiction of the Department of Public Welfare, since DPW directly manages the Fee for Service (FFS) system and is the contractor for HealthChoices managed care. In addition, there is a general expectation that individuals served by the physical health plans under HealthChoices have comparable access to the same medications as individuals served within FFS. Operationally, however, there are differences in how the systems work, depending on whether a member is in FFS or in physical health managed care under HealthChoices.

Concerns may arise for Medicaid members and their prescribers in relation to the following circumstances: 1) limitations of access to specific medications that are subject to prior authorization requirements; 2) authorization requirements that may be lengthy and time-consuming, and associated with delays in medication access, at times associated with delays in decisions; and 3) denials of prior authorization requests, and the nature of the appeal process. Additional, clinical issues involve the policies and procedures that determine the composition of Preferred Drug Lists, those that determine the nature of the prior authorization process, and those that determine the composition of stakeholders who make these important policy decisions.

Fee for Service (FFS)

Within FFS, overall oversight and decision-making regarding medication-related decisions for FFS members resides within the Office of Medical Assistance Programs (OMAP). Under the direction of OMAP, a Pharmacy and Therapeutics (P&T) Committee is the designated body that determines the nature of member access, for all ages, to all medications, both physical health and behavioral health medications. The P&T Committee also is responsible for developing the procedures that guide the addition of new medications to the PDL. Behavioral health medications include psychotropic medications for children. The P&T Committee consists of physicians and others with both general medical and specialty expertise. Due to the broad scope of responsibility of P&T Committee, the vast majority of its members do not have specialized expertise in pediatric behavioral health.

Also within FFS, a separate decision-making body, known as the Drug Utilization Review (DUR) Board, creates policy related to prior authorization requirements and procedures, as well as those pertaining to the appeal process following prior authorization denials. The DUR Board also focuses on issues related to quality, safety, and best practices in the prescribing of medication, including psychotropic medication. As with

the P&T Committee, due to its broad scope, the vast majority of members of the DUR Board do not have specialized expertise in pediatric behavioral health.

Physical Health Managed Care Under HealthChoices

Within physical health managed care under HealthChoices, each plan has its own Pharmacy and Therapeutics Committee (P&T) Committee. As in FFS, the physical health plan's P&T Committee is the designated body that determines the nature of member access to all medications, both physical health and behavioral health medications, for all age groups. The P&T Committee also is responsible for developing the procedures that guide the addition of new medications to the PDL.

Physical health managed care plans under HealthChoices have their own decision-making structures to determine prior authorization policies. These policies, however are subject to OMAP review, first by OMAP's internal Prior Authorization Review Panel (PARP) and then by OMAP's Chief Medical Officer.

Within the current HealthChoices structure, each physical health plan develops its own set of procedures related to medication access. This means that families need to be familiar with the formularies and procedures of available physical health plans, so that they can choose the plan that most closely meets their needs.

Challenges with FFS and Managed Care

In considering the needs of MA members of all ages with psychiatric needs, the Pennsylvania Community Providers Association (PCPA) has made specific recommendations intended to better meet their psychotropic medication needs ("Pharmacotherapy: Often Critical to Recovery," June 30, 2008). One recommendation is that all denials of behavioral health medications be made "by board eligible/board certified psychiatrists with expertise in (applicable) fields, e.g., child, addictions, geriatrics, etc." This recommendation highlights the need for specific expertise in medication decisions involving individuals with behavioral health challenges.

Moreover, many professionals and families involved in children's behavioral health believe that the needs of youth, given their vulnerability and their rapid developmental trajectory, require highly specialized attention and expertise. For example, psychiatric disorders in youth are less easily treated than most physical health disorders of childhood. Similarly, psychiatric disorders present differently in youth than in adults, often have different courses over time, and may require different psychotropic medication approaches.

Within FFS, important decisions, for example involving the specific medications to be made available as Preferred Drugs in formularies, are being made by a large body of P&T

Committee members, most of whose expertise is limited with regard to medications for the treatment of childhood psychiatric disorders.

At the local level under HealthChoices, the responsibility for psychotropic medication decisions resides with the physical health managed care plans, even though most behavioral health expertise is located in the county-based, behavioral health managed care system. Within children's mental health, this arrangement creates challenges for both prescribers of pediatric psychotropic medication and families, because decisions on medication access are being made by decision-making bodies whose members as a whole have limited experience and expertise in the treatment of childhood psychiatric disorders.

Thus, there is concern that the current decision-making processes in FFS and HealthChoices physical health lack the necessary overall expertise in pediatric behavioral health to formulate the best policies related to youth with behavioral health needs. As an alternative, it has been proposed that specific decision-making entities be developed to address the unique challenges related to the prescribing of psychotropic medication for youth.

Additional Issues Related to Quality in Prescribing Practices

Nationally, the use of antipsychotic medications in youth, particularly young children, has been an area of interest and concern (Eggar 2010). In Pennsylvania under FFS and with some physical health plans, prior authorization is required in order to access atypical antipsychotic medications for youth under age 6 years. The link to the 2009 reference from the Medical Assistance Handbook is as follows:

www.providersynergies.com/services/medicaid/Pennsylvania/form.asp?content=LookupPDLSearch

The approach of 16 states to the issue of pediatric antipsychotic use can be found in a recently published monograph (*Antipsychotic Medication Use in Medicaid Children and Adolescents: Report and Resource Guide from a 16-State Study*, 2010).

Another area of interest nationally involves psychotropic prescribing practices for children in substitute care, since such youth typically lack active family members who can advocate for their needs. A discussion of various statewide approaches to this issue can be found in a recently published report (*Multi-State Study on Psychotropic Medication Oversight in Foster Care*, 2010).

In general, states take a variety of approaches to quality improvement activities and oversight related to psychotropic medication prescribing. Until recently, DPW had a contract with an external organization to oversee psychotropic medication prescribing practices within FFS. Individual prescriber practices were analyzed according to specific prescribing standards regarded as consistent with industry standards. Those prescribers

whose practices consistently deviated from the industry standards were sent letters that provided education and offered additional technical assistance. This approach was used by DPW in order to change provider practices where indicated, while avoiding a primary reliance on the more restrictive denial process.

Currently, the approach being used for oversight of prescribing practices within DPW does not involve the involvement of an external organization. The HealthChoices behavioral health plans receive pharmacy utilization data for each of their credentialed prescribers from the various HealthChoices physical health plans serving their members. Following careful analysis of this data, the behavioral health plans identify and contact those individuals whose prescribing practices raise concerns about safety. These prescribers can then receive clinical consultation from the medical staff of the behavioral health plan. Such clinical consultation is also available to any credentialed prescriber within a behavioral health plan who requests it.

Subcommittee Recommendations

A. Recommendations Related to Clinically-Based Prescribing Practices

1. Pediatric psychotropic medication prescribing should occur in a manner consistent with CASSP Principles, including recognition of the need for all behavioral health treatment to be family-driven and youth-guided.
2. Psychiatrists, primary care physicians, and other prescribers of psychotropic medication should all be familiar with and adhere to the 2009 document entitled, “Practice Parameter on the Use of Psychotropic Medication in Children and Adolescents,” as developed by the American Academy of Child and Adolescent Psychiatry (AACAP):
 - a. The AACAP Practice Parameter is applicable to all pediatric psychotropic medication prescribers, not just child and adolescent psychiatrists.
 - b. The Prescribing Practices Subcommittee endorses this Practice Parameter, and recommends its implementation by pediatric prescribers in Pennsylvania.
 - c. Attachment 1, developed by the Subcommittee, discusses the applicability of each principle to primary care prescribers and other non-psychiatric, pediatric medication prescribers.
3. Agencies and individual prescribers that provide pediatric psychotropic medication should provide family and youth education, and actively promote family and youth participation during meetings with the prescriber, consistent with the specific recommendations in the report on Family and Youth Education.
4. Agencies and individual prescribers that provide pediatric psychotropic medication should have a written policy on informed consent and informed

- assent. This policy should be consistent with the specific recommendations on informed consent presented under “Recommendations Applicable to All Youth,” in the report on Informed Consent.
5. Agencies and individual prescribers that provide pediatric psychotropic medication should have written policies addressing the following clinical issues:
 - a. Children under age 6 years receiving antipsychotic medication.
 - b. Children receiving more than one antipsychotic medication.
 - c. Children receiving more than three different psychotropic medications.
 - d. Screening of, and response to, metabolic syndrome.
 - e. Monitoring of other psychotropic medication side effects.
 6. Pediatric psychotropic medication prescribers should be guided by the current evidence base regarding the use of psychotropic medication in the pediatric population, recognizing that there are risks as well as potential benefits associated with the use of psychotropic medication for this age group. In addition, in recognition of developmental considerations, prescribers should understand and be guided by potential differences in the use of psychotropic medication in preschoolers, school age children, and adolescents, respectively.
 7. Potential psychosocial interventions should be identified, to be considered for use concurrently with psychotropic medication or used as an alternative.
 8. All use of psychotropic medication for the pediatric population should be informed by the child’s clearly established diagnosis, and based on the following: a comprehensive biopsychosocial evaluation and determination of strengths and needs; the child’s prior response to psychotropic medication; the family history of mental health disorder and response to psychotropic medication; and the child’s age and developmental level.
 9. Children prescribed psychotropic medication should receive appropriate medical screening prior to the initiation of such medication. In addition, medical monitoring and determination of blood levels of medication, where applicable, should occur periodically during the course of psychotropic medication use.
 10. Recommended guidelines regarding the selection of specific pediatric psychotropic medications include the following:
 - a. In all situations involving use of psychotropic medication, a clear clinical rationale should be identified, and child and family should be informed of potential benefits and side effects. A signed consent should be obtained from both parents or guardians and children age 14 years and older.

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- b. The preferred choice is medication with an evidence base that is also FDA-approved.
 - c. Medication that is evidence-based but without FDA approval should be considered next. This might involve non-approved medication in the same class as a medication that is FDA-approved for use in this population. Medications in an unrelated class with an evidence base may also be clinically appropriate.
 - d. Medication with a developing evidence base, or medication for which there is expert consensus regarding potential benefit, should be considered next.
 - e. When there is limited evidence that a psychotropic medication effective for adults is effective for children, a clear rationale should be established for use of such medication. In addition, the level of monitoring for side effects should be consistent with the established level of risk
 - f. Caution should be exercised in prescribing psychotropic medication for the pediatric population, when serious side effects are common. Whenever possible, medications less likely to lead to such side effects should be used instead.
 - g. Caution is indicated in prescribing psychotropic medication to children under the age of 6 years of age, particularly regarding the use of neuroleptic medication. We support the current requirement in Fee-for-Service that a comprehensive evaluation be completed by a board-certified child and adolescent psychiatrist, developmental pediatrician, or pediatric neurologist as part of the prior authorization requirement, when antipsychotic medication is being recommended for a child under 6 years.
 - h. Regarding the use of psychotropic medication other than antipsychotic agents for children under age 6, prescribers should be guided by current guidelines and expert consensus.
 - i. Caution is indicated in the use of multiple psychotropic medications at the same time, even though this practice is sometimes clinically indicated. There should be a clear rationale for the use of each medication. Each medication should be added sequentially based on a clearly identified need, and two or more medications should not be initiated at the same time. The child's response to prescribed medications and the possible emergence of side effects should be carefully monitored.
11. Pediatric psychotropic medication prescribing should be closely coordinated with the involved physical health physician or the certified registered nurse practitioner (CRNP) or physician assistant (PA), when involved:
- a. Primary care physicians or designated others in the child's medical home should be informed of psychotropic medication being taken by the child.
 - b. The psychotropic medication prescriber within behavioral health should be aware of any physical health medications being taken by the child.

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- c. Coordination and collaboration between behavioral and physical health practitioners should occur, especially when the use of multiple medications might exacerbate existing medical or psychiatric conditions or interact adversely with one another, and when the child has a combination of physical and behavioral health challenges in need of joint planning.
 12. Pediatric psychotropic medication prescribing should occur within a context of respect for multiculturalism, with adherence to the principles and practices of cultural competence.
 13. Pediatric psychotropic medication prescribing should also involve cultural competence in working with special populations and their families, taking into account the common strengths, needs, and culture of the group and the individualized differences among specific youth and families within each group.
 14. Behavioral and physical health providers should ensure that training in cultural competence is made available to pediatric psychotropic medication prescribers.

B. Recommendations Related to Policy-Based Prescribing Practices

1. DPW and the behavioral health managed care plans should ensure that there is sufficient time available for pediatric medication prescribers to develop a therapeutic alliance, provide needed education, promote active youth and family participation, and answer treatment-related questions.
2. The remaining recommendations of this Subcommittee address the need for system change in the structure of decision-making about psychotropic medication for the pediatric population in the public system. However, rather than recommend broadly based changes in the entire system at this time, we focus instead on selected pilot projects, as a possible precursor to broader system change in the future.
3. We recommend the creation, on a pilot basis within FFS, of a separate Pharmacy and Therapeutics Committee (P&T) Committee for children's behavioral health. This dedicated Children's P&T Committee would have the authority to determine the Preferred Drug List for children's behavioral health, and the process for modifying the formulary.
4. Appropriate members of the dedicated Children's P&T Committee should include child and adolescent psychiatrists along with others having specific expertise in pediatric psychopharmacology – e.g., primary care physicians with psychotropic expertise, developmental pediatricians, pediatric neurologists, CRNPs, PAs, and a pediatric pharmacist. Additional members should include a representative of the OMHSAS Children's Bureau, the Office of the OMHSAS Psychiatric Director,

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- OMAP's Chief Medical Officer or designee, and representatives from FFS and the PARP.
5. We also recommend the creation, on a pilot basis, of a separate, dedicated, Children's Drug Utilization Review (DUR) Board for psychotropic medication, which incorporates representatives from both the OMAP PARP and from FFS. A Children's DUR can most effectively focus on quality, safety, and medication access for the pediatric population.
 6. Implementation and monitoring of these pilot structures should be implemented collaboratively within DPW by OMAP and OMHSAS. The pilot project structures should be maintained for a 3-year period, with data on outcomes and satisfaction obtained and reviewed. Specific outcomes to be tracked can be determined by involved stakeholders.
 7. Based on the outcomes and "lessons learned" from the above pilot projects, parallel pilots projects could then be pursued within the HealthChoices physical health plans.
 8. In order to simplify the process of prior authorization for prescribers and for all members of the public behavioral health system, it is recommended that a uniform, statewide prior authorization process, to include both Fee-for-Service and the physical health managed care plans under HealthChoices, be developed.
 9. The following additional recommendations pertain to the desired prior authorization process within both FFS and HealthChoices:
 - a. Prior authorization requirements should be clear, concise, and easily completed. This should include an efficient, automated prior authorization process than can be accessed and completed online.
 - b. If denials occur, the appeal process should also be clear, concise, and easily completed.
 - c. The time required to complete requests for prior authorizations and for appeals should be reasonable – e.g., no longer than 10 minutes for each.
 - d. The processing of prior authorizations and appeals should make use available technology, in order to facilitate timeliness of processing.
 10. In the interest of quality improvement and collaboration, DPW and physical health plans, respectively, should develop and disseminate information on a clear mechanism for families and youth, mental health and other child-serving agencies, and psychotropic medication prescribers to communicate concerns about the current system of accessing psychotropic medication. This includes such issues as prior authorization requirements, time required to make phone contact regarding prior authorization requests, turnaround time for a prior

authorization decision, implementation of five-day emergency prescription fills, denial of continued authorization for medication after primary authorization has been established, the appeal of medication denials, and other systemic issues related to psychotropic medication. Information should be provided as to how stakeholder concerns will be addressed, and how appropriate operational improvements can be achieved.

11. The HealthChoices Medical Directors, under the leadership of the OMHSAS Medical Director, should make recommendations to DPW regarding how to best achieve oversight of psychotropic medication prescribing practices for MA members.

Attachment 1

AACAP Principles of Practice

Note: The document below, developed by the Prescribing Practices Subcommittee, is based on the specific 13 principles identified in the 2009 AACAP “Practice Parameter on the Use of Psychotropic Medication in Children and Adolescents.” The discussion under each principle pertains to how the standards identified by AACAP can be applied to primary care settings. The child and adolescent psychiatrists are referred to as “CAPs,” while primary care physicians as referred to as “PCPs.”

Principle 1 – Before Initiating Pharmacotherapy, a Psychiatric Evaluation Is Completed:

It is easier for a CAP to have access to, and complete, a psychiatric evaluation, than it is for a PCP. In fact, a CAP should never initiate use of psychotropic medication in the absence of a current or recent psychiatric evaluation. For PCPs the most relevant psychosocial and treatment history can be obtained directly or by another member of the medical team.

A core set of questions should be asked, and relevant information obtained by either the physician or a member of his staff, prior to the start of psychotropic medication. Such questions should include the following:

- a) *information consistent with ruling in or out the diagnosis of a suspected psychiatric disorder;*
- b) *consideration of possible comorbid psychiatric disorders or co-occurring substance use problems;*
- c) *family history of psychiatric disorders and response to treatment;*
- d) *child’s psychiatric treatment history, including currently active or planned treatment modalities;*
- e) *child psychotropic medication history;*
- f) *questions related to possible traumatic experiences of child;*

- g) *information about child and family strengths, and other relevant psychosocial information.*

Principle 2 – Before Initiating Pharmacotherapy, a Medical History Is Obtained, and a Medical Evaluation Is Considered, When Appropriate:

A medical history and evaluation are easier for PCPs to achieve than CAPs, so there is no barrier to achieving this with PCPs.

Principle 3 – The Prescriber Is Advised to Communicate With Other Professionals Involved With the Child to Obtain Collateral History and Set the Stage for Monitoring Outcome and Side Effects During the Medication Trial:

Identifying and obtaining information from collateral contacts is appropriate for any prescriber of any medication, and is particularly relevant with use of psychotropic medication.

Principle 4 – The Prescriber Develops a Psychosocial and Psychopharmacological Treatment Plan Based on the Best Available Evidence:

Developing a treatment plan that incorporates both psychopharmacological and psychosocial components is easier to achieve for CAPs than PCPs, and this task is best achieved through the use of a team, not a physician in isolation. PCPs managing a psychiatric disorder who are part of a medical home have access to such a team and are positioned well to address Principle 4. All physicians who prescribe psychotropic medication should be aware of psychosocial interventions to pursue either concurrent with, or before or after a trial of psychotropic medication. All physicians also should address issues of wellness and ways to achieve it with child and family.

Principle 5 – The Prescriber Develops a Plan to Monitor the Patient, Short and Long Term:

Development of a short- and long-term plan to monitor the child is appropriate for any prescriber of any medication, and is particularly relevant with use of psychotropic medication. As with pharmacological prescriptions for physical illnesses, medication trials for mental illnesses in children are most likely to be successful when the child and parents feel themselves heard and understood by their physician. Listening to the family and scheduling follow-up visits convey this empathic concern, enhancing trust and cooperation.

Principle 6 – Prescribers Should Be Cautious When Implementing a Treatment Plan That Cannot Be Appropriately Monitored:

Caution in implementing a treatment plan that cannot be adequately monitored is indicated for all physicians who prescribe psychotropic medication, whether a CAP or a PCP. However, such monitoring may often be more easily achieved by a CAP, who typically sees children at a greater frequency than PCPs. Nevertheless, the PCP who chooses to provide psychotropic medication for a child needs to be prepared to increase the frequency of contact with child and family, particularly at the beginning. With both CAPs and PCPs, monitoring and the communication of medication effects can also be provided by others – in particular, parents or guardians, teachers, school counselors, and therapists, if involved. It is therefore essential that the physician guide others providing supplementary monitoring of the key issues and potential side effects to consider (e.g., the emergence of suicidality, in response to the use of SSRI medications).

Principle 7 – The Prescriber Provides Feedback About the Diagnosis and Educates the Patient and Family Regarding the Child’s Disorder and the Treatment and Monitoring Plan:

Providing feedback to child and family about the child’s mental health diagnosis and educating them regarding the child’s disorder is equally relevant for a CAP and a PCP. A PCP needs to have this information at hand before undertaking to treat a child psychiatric disorder.

Principle 8 – Complete and Document the Assent of the Child and Consent of the Parents Before Initiating Medication Treatment and at Important Points During Treatment:

This is equally relevant for a CAP and a PCP.

Principle 9 – The Assent and Consent Discussion Focuses on the Risks and Benefits of the Proposed and Alternative Treatments:

Obtaining family and youth consent, and child assent, by focusing on risk and benefits of a proposed psychotropic medication, is equally relevant for a CAP and a PCP. A PCP should be sufficiently informed about a psychiatric disorder for which he or she might prescribe medication to also offer child and family an overview of potential alternative, or supplements, to psychotropic medication. Distribution of written material to the family and on-line references can also be helpful.

Principle 10 – Implement Medication Trials Using an Adequate Dose and for an Adequate Duration of Treatment:

This is an area where PCPs may sometimes have difficulties. It is important for the PCP to obtain current information about appropriate dosing, both at the start and over time. In like manner, the PCP needs to know what constitutes an

adequate trial, for a specific dose and for a specific medication as a whole. Such information can be obtained through the PCP professional organization, AACAP, child psychiatry newsletters, and formal and information consultation with CAPS.

Principle 11 – The Prescriber Reassesses the Patient if the Child Does Not Respond to the Initial Medication Trial as Expected:

As with implementation of Principle 10, this is an area where PCPs may sometimes have difficulty. Such information can be obtained through the PCP professional organization, AACAP, child psychiatry newsletters, and formal and information consultation with CAPS.

Principle 12 – The Prescriber Needs a Clear Rationale for Using Medication Combinations:

Some PCPs may feel comfortable to prescribe and oversee specific medication combinations for a single disorder, such as the use of psychostimulant medication with an alpha adrenergic agent for their synergistic effect on ADHD. However, PCPs should typically defer to a CAP or obtain CAP consultation if medication combinations are needed to treatment two or more separate psychiatric disorders.

Principle 13 – Discontinuing Medication in Children Requires a Specific Plan:

This knowledge is needed equally by CAPs and PCPs. Since PCPs have knowledge and expertise in planning for the tapering and discontinuation of physical health medications, the same skill can be applied to the tapering and discontinuation of psychotropic medication, once the appropriate information has been obtained.

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Additional Websites

The Best Pharmaceuticals for Children Act (BPCA) of 2002:

www.fda.gov/opacom/laws/pharmkids/contents.html

Food and Drug Administration approved psychotropic medications, by age of approval:

www.nimh.nih.gov/health/publications/mental-health-medications/alphabetical-list-of-medications.shtml.

Food and Drug Administration Modernization Act (FDAMA) of 1997:

www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAAct/SignificantAmendmentstotheFDCAAct/FDAMA/default.htm.

Pediatric Research Equity Act (PREA) of 2003:

www.fda.gov/ohrms/dockets/ac/04/slides/4006S1_01_Murphy.ppt.

Pennsylvania Office of Medical Assistance prior authorization requirements for use of antipsychotic medications in children under age 6 years:

www.providersynergies.com/services/medicaid/Pennsylvania/form.asp?content=LookupPDLSearch

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Websites on Psychotropic Medication and Resources

Note: The list of websites that follow represent some, but not all, of the relevant resources for youth and families related to psychotropic medication and mental health.

Family and Youth Information and Advocacy Organizations

National Organizations

Mental Health America (Children) www.mentalhealth.org/child/childhealth.asp

A national organization for education and advocacy, with over 200 affiliates in 41 states and the District of Columbia. Formerly known as the National Mental Health Association, Mental Health America is “dedicated to promoting mental health, preventing mental and substance use conditions, and achieving victory over mental illnesses and addictions through advocacy, education, research and services.”

Mental Health America has a website known as the “mpower web site,” which is a resource list for children’s mental health, developed specifically for adolescents and young adults and providing information on a range of issues related to mental health and wellness.

National Alliance on Mental Illness (NAMI) www.nami.org

A national organization that advocates for and supports individuals with mental illness and their families. Has useful information sheets on psychotropic medications, including a fact sheet for families on dealing with adolescent depression, entitled “The Use of Medication in Treating Childhood and Adolescent Depression: Information for Patients and Families.” Go to: www.parentsmedguide.org

NAMI also publishes, “A Family Guide – Choosing the Right Treatment: What Families Need to Know about Evidence-Based Practices,” and “A Family Guide-What Families Should Know About Adolescent Depression and Treatment Options.”

For information on mental health diagnoses (alphabetical listing). Go to: http://www.nami.org/Template.cfm?Section=By_Illness

National Federation of Families for Children’s Mental Health www.ffcmh.org

A national, parent-run organization that advocates for family education and family leadership in systems policies that affect children’s mental health. The Federation arose over twenty years ago from a grass roots organization, and now encompasses more than 120 chapters and state organizations throughout the country. The Federation has provided leadership to the federal government and states as well as to families and youth.

Information is provided on the website related to the definition of “family-driven” care, and there are links to other resources for families. Power points on the annual conference are available for downloading.

Youth Motivating Others through the Voice of Experience (Youth MOVE National)
<http://youthmove.us>

A youth-led national organization devoted to improving services and systems that support positive growth and development by uniting the voices of youth who have been served by various child serving systems, including mental health, juvenile justice and foster care.

Youth MOVE National is now a subsidiary of the National Federation of Families for Children’s Mental Health, and receives funding from the Substance Abuse and Mental Health Services Administration (SAMHSA). The organization was able to define for SAMHSA what it means to have a youth-guided system. There are now an increasing number of state chapters, increasing the voice of youth throughout many communities.

Pennsylvania-Specific Organizations

Family Training & Advocacy Center (FTAC) (www.pmhcc.org)

The Family Training & Advocacy Center (FTAC), a Philadelphia Mental Health Care Corporation (PMHCC) agency, provides a variety of training and advocacy efforts regarding behavioral health and/or addictions issues. These efforts and trainings are for or with: a. families and family groups through the Family Resource Network (www.frnfamilies.org), b. providers interested in family inclusive efforts, especially those working with the City of Philadelphia (www.frnfamilies.org), c. Philadelphia graduate social work and psychology students through Philadelphia Connections (www.philaconnect.org), d. state-wide community psychiatry stakeholders through the Pennsylvania Psychiatric Leadership Council (www.pmhcc.org), e. law enforcement through police and correctional officer training (www.pmhcc.org).

Parents Involved Network of Pennsylvania (PIN) www.mhasp.org

One of the first family advocacy programs in the country, PIN is part of the Mental Health Association of Southeastern Pennsylvania. PIN assists parents and other caregivers of children and adolescents with emotional or behavioral disorders, by providing information, advocacy, and support

Among its many online resources are its “E-Mental Health Kit,” and a “Children’s Interactive Web Site” for school age children with mental illness.

Pennsylvania Families Incorporated (PFI) www.pafamiliesinc.org

PFI is “a statewide network that shares the common concerns about children and their special needs, brings groups together and uses the power of all families to bring about change in the community, county and state.” PFI is a diverse family network that empowers families of children with special needs by linking them to support and information. PFI is funded by SAMHSA, and since 2007 has had a partnership with the Youth Outreach Union.

Youth Outreach Union www.youthoutreachunion.com

Initially formed in 2001 to address issues of transition for the Allegheny County Department of Human Services, the Youth Outreach Union is now an independent advocacy organization for youth, funded by SAMHSA and in partnership with Pennsylvania Families Incorporated. The Youth Outreach Union strives to “utilize the strengths and experiences of its youth leaders and members to assure that present and future generations of youth within child serving systems get the support and education needed to become empowered adults.”

The Federal Government

National Child Traumatic Stress Network Center (NCTSN) www.nctsn.org

Established by Congress in 2000, the NCTSN is funded by the Center for Mental Health Services within the Substance Abuse and Mental Health Services Administration (SAMHSA). NCTSN operates through a collaboration of academic and community service centers, to improve access to care for children and adolescents exposed to traumatic events and their families.

A broad range of childhood trauma resources and links can be found at the website, and relate to the mental health consequences of trauma, its impact on children in various child-serving systems, and information on trauma informed care and trauma specific treatments.

National Institute of Mental Health (NIMH) www.nimh.nih.gov/

NIMH is part of the National Institutes of Health (NIH), which in turn is a component of the U.S. Department of Health and Human Services. NIMH funds research across the country and its own internal research program. NIMH has developed a broad range of educational materials, including mental health information and information on coping with traumatic events.

For child and adolescent publications on specific diagnoses or medication, go to:
<http://www.nimh.nih.gov/health/publications/children-and-adolescents-listing.shtml>

Substance Abuse and Mental Health Services Administration (SAMHSA)
www.samhsa.gov/

SAMHSA, established by Congress in 1992, works to improve the quality and availability of substance abuse prevention, alcohol and drug addiction treatment, and mental health services. SAMHSA funds prevention and treatment grants, and sets national policy related to mental health and substance abuse. The Center for Mental Health Services (CMHS) within SAMHSA focuses on prevention and treatment of mental health disorders. The Child, Adolescent and Family Branch of CMHS addresses issues specific to children's mental health.

For information on child mental health diagnoses:
<http://mentalhealth.samhsa.gov/publications/allpubs/CA-0006/default.asp>

Resource guide – families and youth: Family-driven and youth-guided systems.
<http://www.systemsofcare.samhsa.gov/ResourceGuide/systems.html>

National Websites on Specific Mental Health Disorders

Anxiety Disorders Association of America (ADAA) www.adaa.org

Information includes, “Anxiety Disorders in Children: A Test for Parents,” and also fact sheets for parents on anxiety disorders.

Child and Adolescent Bipolar Foundation (CABF) www.cabf.org

CABF is committed to improving the lives of families raising children and adolescents with bipolar disorder and related conditions. CABF provides information, support and resources for children and teens with Bipolar Disorder. Resources include online support groups for parents, and podcasts for adolescents and young adults.

Children and Adults with Attention Deficit/Hyperactivity Disorder (CHADD)
www.chadd.org

Information, support, and resources for individuals with Attention Deficit Hyperactivity Disorder and parents of children with ADHD. One of CHADD's educational resource is Attention Magazine, which addresses coping strategies for individual of all ages with ADHD.

Depression and Bipolar Support Alliance (DBSA) www.dbsalliance.org

Includes a brochure for youth about depressive illnesses, "Just a Mood . . . or Something Else?" that includes a checklist. There is also a similar packet for parents.

International Mental Health Research Organization (IMHRO). www.imhro

IMHRO sponsors a separate website on schizophrenia, which includes information on treatment and medication for childhood-onset schizophrenia.
<http://www.schizophrenia.com/family/FAQchild.htm#presmeds>

Obsessive Compulsive Foundation (OCF) www.ocfoundation.org

Information on Obsessive Compulsive Disorders (OCD) in children & adolescents, and on related disorders and treatment components. Resources include a video on "How to Recognize and Respond to Obsessive-Compulsive Disorder in School Age Children."

Tourette Syndrome Association, Inc. (TSA) www.tsa-usa.org

Information, support, and resources for individuals, including teens, with Tourette Syndrome

Psychiatric Organizations

American Academy of Child and Adolescent Psychiatry (AACAP) www.aacap.org

AACAP, established in 1953, is the leading national professional medical association dedicated to treating and improving the quality of life for children, adolescents, and families affected by mental, behavioral, or developmental disorders. AACAP has a broad range of advocacy activities and educational materials. Educational materials include family-friendly fact sheets for parents and family members ("Facts for Families") on a variety of topics, including psychotropic medication, diagnosis, and resources for families. Another relevant

document involves “Practice Parameter on the Use of Psychotropic Medication in Children & Adolescent,” cited in this report.

In 2008, AACAP facilitated a children’s mental health coalition that developed a “Bill of Rights for Families Living with Mental Illnesses.”

American Psychiatric Association www.psych.org

The lead organization for psychiatrists as a profession in the United States, the APA has developed a range of resources for psychiatrists, patients, and families.

Two online publications, developed in partnership with the American Academy of Child and Adolescent Psychiatry (AACAP), are medication guides for parents. These resources are: 1) “ADHD Parents Medication Guide,” and 2) “The Use of Medication in Treating Childhood and Adolescent Depression: Information for Patients and Families. Both are available at www.psych.org/share/parents-medguide.aspx (Parents Med Guide).

Pennsylvania Department of Public Welfare (DPW) Publication

*“Guidelines for Best Practice in Child and Adolescent Mental Health Services,” Pennsylvania Office of Mental Health and Substance Abuse Services.
[http://parecovery.org/documents/Child Adolescent Best Practices 2007.pdf](http://parecovery.org/documents/Child_Adolescent_Best_Practices_2007.pdf)*

Includes section on psychotropic medication (pages 109-115), as well as discussion of an array of mental health issues of relevance to clinicians, families, and youth.