Psychoactive Medication Packet for Judges Presiding Over DFPS Conservatorship Cases

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Texas Department of Family and Protective Services (DFPS)
Texas Health and Human Services Commission (HHSC)
Texas Department of State Health Services (DSHS)

From the Desk of Joyce James
Assistant Commissioner for Child Protective Services

Your Honor

It is my pleasure to present to you the new *Psychoactive Medication Packet for Judges Presiding Over DFPS Conservatorship Cases*. This Packet has been developed through a collaborative process between the Department of Family and Protective Services (DFPS), the Health and Human Services Commission (HHSC) and the Department of State Health Services (DSHS) with review and input by members of the Supreme Court Task Force on Foster Care.

The *Psychoactive Medication Packet for Judges Presiding Over DFPS Conservatorship Cases* has been developed to serve as a resource for you. Information about psychoactive medications provided in this packet is based on the *Psychotropic Medication Utilization Parameters for Foster Children* (i.e., best practice guidelines) released in February of 2005 and was updated in 2006. A panel of child and adolescent psychiatrists, psychologists, guideline specialists and other mental health experts developed the best practice guidelines, with input from the Federation of Texas Psychiatry, Texas Pediatric Society, Texas Academy of Family Physicians, Texas Osteopathic Medical Association, and Texas Medical Association. They are based on the most current evidence-based literature available at the time of publication and are updated periodically.

We would also like to take this opportunity to inform you of a report released on the *Use of Psychoactive Medication in Texas Foster Children in State Fiscal Year 2005* and some strategies DFPS, HHSC, and DSHS are implementing to ensure appropriate prescribing.

We hope the P*sychoactive Medication Packet for Judges Presiding Over DFPS Conservatorship Cases* is a beneficial resource. Your feedback is very valuable and will help us in future efforts to update this packet. For questions or comments, you may contact Kathy Teutsch at (512) 438-5257 or kathy.teutsch@dfps.state.tx.us.

Thank you for your time and dedication to protecting children.

Sincerely,

Joyce James
DFPS Assistant Commissioner for Child Protective Services

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Martha Laster
Court Coordinator

Ann Owles
Court Reporter

July 1, 2005

Dear Fellow Judge

As you know, in 2005, the Texas Legislature required Judges hearing CPS cases to review the medical care of children in foster care (§ 266.007, TX FAM CODE). We were given no basis or standard by which to review this care.

If you are like me, with no medical training, you were at a loss as to how to review medical care. I have felt very inept in trying to evaluate the medications prescribed for foster children.

Finally, we have a tool to assist us. The Department of Family and Protective services in conjunction with the Texas Department of State Health Services has prepared a packet on the use of psychotropic medications in foster children. The packet includes best practices for the use of these medications and red flags for reviewers. A part of the packet includes a handy reference of four laminated pages to keep on your bench and use during hearings.

I encourage you to review these materials and begin to use them in judicial reviews of medical care. This tool will enable us, as judges, to effectively review and care for the children under our supervision.

Sincerely,

Robin D. Sage

Acknowledgements

The Psychoactive Medication Packet for Judges Presiding Over DFPS Conservatorship Cases was developed through a collaborative effort by the Department of Family and Protective Services, the Department of State Health Services and the Health and Human Services Commission with input from members of the Supreme Court Task Force on Foster Care. We would like to thank all the individuals who contributed to the development of the packet. Your input has greatly enhanced the packet.

Special thanks to:

- The Supreme Court Taskforce on Foster Care for allowing us to present the packet at a meeting of the Taskforce on May 4, 2007
- Nina Jo Muse, MD, Child and Adolescent Psychiatrist, for developing materials for the packet

The following individuals for reviewing the packet and providing input:

- The Honorable Judge Robin Sage
  307th Family District Court
- David Williams
  San Saba County Attorney
- The Honorable Judge Robert R Hofmann
  Associate Judge, Child Protection Court of Hill Country

Psychotropic Medication Utilization Parameters for Foster Children

Developed by:
Texas Department of State Health Services

with review and input provided by:

Federation of Texas Psychiatry
Texas Pediatric Society
Texas Academy of Family Physicians
Texas Osteopathic Medical Association
Texas Medical Association

Introduction and General Principles

The use of psychotropic medications by children is an issue confronting parents, other caregivers, and health care professionals across the United States. Foster children, in particular, have multiple needs, including those related to emotional or psychological stress. Foster children typically have experienced abusive, neglectful, serial or chaotic care taking environments. Birth family history is often not available. These children often present with a fluidity of different symptoms over time reflective of past traumatic and reactive attachment difficulties that may mimic many overlapping psychiatric disorders. Establishment of rapport is often difficult. These multiple factors serve to complicate diagnosis. Foster children may reside in areas of the state where mental health professionals such as child psychiatrists are not readily available. Similarly, caregivers and health providers may be faced with critical situations that require immediate decisions about the care to be delivered. For these and other reasons, a need exists for treatment guidelines and parameters regarding the appropriate use of psychotropic medications in foster children.

Because of the complex issues involved in the lives of foster children, it is important that a comprehensive evaluation be performed before beginning treatment for a mental or behavioral disorder. Except in the case of an emergency, a child should receive a thorough health history, psychosocial assessment, mental status exam, and physical exam before the prescribing of psychotropic medication. Psychological testing may be particularly useful in clarifying a diagnosis and informing appropriate treatment. The physical assessment should be performed by a physician or another healthcare professional qualified to perform such an assessment. It is recognized that in some situations, it may be in the best interest of the child to prescribe psychotropic medications before a physical exam can actually be performed. In these situations, a thorough health history should be performed to assess for significant medical disorders and past response to medications, and a physical evaluation should be performed as soon as possible. The mental health assessment should be performed by an appropriately qualified mental health professional with experience in providing care to children. The child's symptoms and functioning should be assessed across multiple domains, and the assessment should be developmentally appropriate. It is very important that information about the child's history and current functioning be made available to the treating physician in a timely manner, either through an adult who is well-informed about the child or through a comprehensive medical record.

The role of nonpharmacological interventions should be considered before beginning a psychotropic medication, except in urgent situations such as suicidal ideation, psychosis, self injurious behavior, physical aggression that is acutely dangerous to others, or severe impulsivity endangering the child or others; when there is marked disturbance of psychophysiological functioning (such as profound sleep disturbance), or when the child shows marked anxiety, isolation, or withdrawal. Given the unusual stress and change in environmental circumstances associated with being a foster child, counseling or psychotherapy should generally begin before or concurrent with prescription of a psychotropic medication. Patient and caregiver education about the mental disorder, treatment options (nonpharmacological and pharmacological), treatment expectations, and potential side effects should occur before and during the prescription of psychotropic medications.

It is recognized that many psychotropic medications do not have Food and Drug Administration (FDA) approved labeling for use in children. The FDA has a statutory mandate to determine whether pharmaceutical company sponsored research indicates that a medication is safe and effective for those indications in which it has been studied by the manufacturer. The FDA also assures that information in the approved product labeling is accurate, and limits the manufacturer's marketing to the information contained in the approved labeling. ***The FDA does not regulate physician and other health provider practice. In fact, the FDA has stated that it does "not limit the manner in which a practitioner may prescribe an approved drug." Studies and expert clinical experience often support the use of a medication for an "off-label" use.*** Physicians should utilize the available evidence, expert opinion, their own clinical experience, and exercise their clinical judgment in prescribing what they feel is best for each individual patient.

General principles regarding the use of psychotropic medications in children include:

- A DSM-IV psychiatric diagnosis should be made before the prescribing of psychotropic medications.
- Clearly defined target symptoms and treatment goals for the use of psychotropic medications should be identified and documented in the medical record at the time of or before beginning treatment with a psychotropic medication. These target symptoms and treatment goals should be assessed at each clinic visit with the child and caregiver. Whenever possible, recognized clinical rating scales (clinician, patient, or caregiver assessed, as appropriate) or other measures should be used to quantify the response of the child's target symptoms to treatment and the progress made toward treatment goals.
- In making a decision regarding whether to prescribe a psychotropic medication in a specific child, the clinician should carefully consider potential side effects, including those that are uncommon but potentially severe, and evaluate the overall benefit to risk ratio of pharmacotherapy.
- Except in the case of emergency, informed consent should be obtained from the appropriate party(s) before beginning psychotropic medication. Informed consent to treatment with psychotropic medication entails diagnosis, expected benefits and risks of treatment, including common side effects, discussion of laboratory findings, and uncommon but potentially severe adverse events. Alternative treatments, the risks associated with no treatment, and the overall potential benefit to risk ratio of treatment should be discussed.
- During the prescription of psychotropic medication, the presence or absence of medication side effects should be documented in the child's medical record at each visit.
- Appropriate monitoring of indices such as height, weight, blood pressure, or other laboratory findings should be documented.
- Monotherapy regimens for a given disorder or specific target symptoms should usually be tried before polypharmacy regimens;
- Doses should usually be started low and titrated carefully as needed;
- Only one medication should be changed at a time, unless a clinically

appropriate reason to do otherwise is documented in the medical record. (Note: starting a new medication and beginning the dose taper of a current medication is considered one medication change);

- The frequency of clinician follow-up with the patient should be appropriate for the severity of the child's condition and adequate to monitor response to treatment, including: symptoms, behavior, function, and potential medication side effects.
- In depressed children and adolescents, the potential for emergent suicidality should be carefully evaluated and monitored.
- If the prescribing clinician is not a child psychiatrist, referral to or consultation with a child psychiatrist, or a general psychiatrist with significant experience in treating children, should occur if the child's clinical status has not experienced meaningful improvement within a timeframe that is appropriate for the child's clinical response and the medication regimen being used.
- Before adding additional psychotropic medications to a regimen, the child should be assessed for adequate medication adherence, accuracy of the diagnosis, the occurrence of comorbid disorders (including substance abuse and general medical disorders), and the influence of psychosocial stressors.
- If a medication is being used in a child for a primary target symptom of aggression associated with a DSM-IV nonpsychotic diagnosis (e.g., conduct disorder, oppositional defiant disorder, intermittent explosive disorder), and the behavior disturbance has been in remission for six months, then serious consideration should be given to slow tapering and discontinuation of the medication. If the medication is continued in this situation, the necessity for continued treatment should be evaluated at a minimum of every six months.
- The clinician should clearly document care provided in the child's medical record, including history, mental status assessment, physical findings (when relevant), impressions, adequate laboratory monitoring specific to the drug(s) prescribed at intervals required specific to the prescribed drug and potential known risks, medication response, presence or absence of side effects, treatment plan, and intended use of prescribed medications.

Criteria Indicating Need for Further Review of a Child's Clinical Status

The following situations indicate a need for further review of a patient's case. These parameters do not necessarily indicate that treatment is inappropriate, but they do indicate a need for further review.

For a child being prescribed a psychotropic medication, any of the following suggests the need for additional review of a patient's clinical status:

1. Absence of a thorough assessment of DSM-IV diagnosis in the child's medical record.
2. Five (5) or more psychotropic medications prescribed concomitantly.
3. Prescribing of:
   - (a) Two (2) or more concomitant antidepressants
   - (b) Two (2) or more concomitant antipsychotic medications
   - (c) Two (2) or more concomitant stimulant medications[1]
   - (d) Three (3) or more concomitant mood stabilizer medications

   NOTE: For the purpose of this document, polypharmacy is defined as the use of two or more medications for the same indication (i.e., specific mental disorder).

   [1] The prescription of a long-acting stimulant and an immediate release stimulant of the same chemical entity (e.g., methylphenidate) does not constitute concomitant prescribing.
4. The prescribed psychotropic medication is not consistent with appropriate care for the patient's diagnosed mental disorder or with documented target symptoms usually associated with a therapeutic response to the medication prescribed.
5. Psychotropic polypharmacy for a given mental disorder is prescribed before utilizing psychotropic monotherapy.
6. The psychotropic medication dose exceeds usually recommended doses.
7. Psychotropic medications are prescribed for children of very young age, including children receiving the following medications with an age of:
   - Antidepressants: Less than four (4) years of age
   - Antipsychotics: Less than four (4) years of age
   - Psychostimulants: Less than three (3) years of age
8. Prescribing by a primary care provider for a diagnosis **other** than the following (unless recommended by a psychiatrist consultant):
   - Attention Deficit Hyperactive Disorder (ADHD)
   - Uncomplicated anxiety disorders
   - Uncomplicated depression

Usual Recommended Maximum Doses of Common Psychotropic Medications

These tables are intended to reflect usual maximum doses of commonly used psychotropic medications. The preferred drug list of medications potentially prescribed for foster children is the same as for all other Medicaid recipients.

These doses represent usual daily maximum doses, and are intended to serve as a guide for clinicians. The tables are not intended to serve as a substitute for sound clinical judgment in the care of individual patients, and individual patient circumstances may dictate the need for the use of higher doses in specific patients. In these cases, careful documentation of the rationale for the higher dose should occur, and careful monitoring and documentation of response to treatment should be observed.

Not all medications prescribed by clinicians for psychiatric diagnoses in children and adolescents are included in the table on this page. However, in general, medications not listed do not have adequate efficacy and safety information available to support a usual maximum dose recommendation.

Antidepressants/Anxiolytics	Usual Maximum Dose Per Day(1)	
	Children	***Adolescents***
Citalopram	40 mg	60 mg
Escitalopram	20 mg	20 mg
Fluvoxamine(3)	200 mg	200 mg
Fluoxetine(2, 3)	20 mg	40 mg
Paroxetine(4)	(-)	40 mg
Sertraline(3)	200 mg	200 mg
Venlafaxine	3 mg/kg/d	225 mg

(1) In general, doses should be started low and titrated slowly while monitoring the patient for improvement in depressive symptoms, potential side effects, or emergent suicidality
(2) Has FDA approved labeling for treatment of depression in children.
(3) Has FDA approved labeling for treatment of anxiety disorders in children.
(4) Paroxetine is not recommended for use in preadolescents

Antipsychotics	Usual Maximum Dose Per Day	
	Children	***Adolescents***
Aripiprazole	15 mg	30 mg
Clozapine	300 mg	600 mg
Haloperidol	5 mg	10 mg
Olanzapine	12.5 mg	20 mg
Perphenazine	No data	32 mg
Quetiapine	300 mg	600 mg
Risperidone	4 mg	6 mg
Ziprasidone	No data	180 mg

ADHD Medications	Usual Maximum Dose Per Day	
	Children	***Adolescents***
Amphetamine (Mixed amphetamine salts or dextroamphetamine)	40mg	40 mg
Atomoxetine	1.8 mg/kg/d	100 mg
Bupropion	6 mg/kg/d	450 mg
Clonidine	0.4 mg	0.4 mg
Dexmethylphenidate	20 mg	20 mg
Guanfacine	4 mg	4 mg
Imipramine	5 mg/kg/day	300 mg
Methylphenidate	60 mg (72 mg with Concerta® only)	60 mg
Methylphenidate patch	82.5 mg patch (30 mg dose delivered)	
Nortriptyline	3 mg/kg/day	150 mg

Mood Stabilizers	Usual Maximum Dose Per Day	
	Children	***Adolescents***
Carbamazepine(1)	7 mg/kg/day	(Max Cs: 12 mcg/mL)
Lamotrigine	15mg/kg/d (200 mg)	300 mg
Lithium(1)	30 mg/kg/day	(Max Cs: 1.2 mEq/L)
Valproic acid(1) (Divalproex)	20 mg/kg/day	(Max Cs: 125 mcg/ml)

(1) Maximum daily dose typically determined by drug serum concentration (Cs) and individual patient tolerability.

Members of the Ad Hoc Working Group on Psychotropic Medication Guidelines for Foster Children

M. Lynn Crismon, Pharm.D.: Dr. Crismon is the Behrens Inc. Centennial Professor in Pharmacy and Director of the Psychiatric Pharmacy Program at The University of Texas at Austin. He is a diplomat of the American Board of Clinical Pharmacology, and he is a board certified psychiatric pharmacist. He served as project director for the Children Medication Algorithm Project and as a co-director for the Texas Medication Algorithm Project.

Peter Jensen, M.D.: Dr. Jensen is Professor and Director of the Center for Advancement of Children's Mental Health, Columbia University, NYC, NY. He is a renowned researcher and clinician in the care of children with mental disorders.

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Document Review and Input by the clinical committees of:

- The Federation of Texas Psychiatry
- The Texas Pediatric Society
- The Texas Academy of Family Physicians
- The Texas Osteopathic Medical Association
- The Texas Medical Association

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Psychotropic Medication Question and Answer

How Were the Psychotropic Medication Utilization Parameters for Foster Children developed?

A panel of child and adolescent psychiatrists, psychologists, guideline specialists and other mental health experts developed the *Psychotropic Medication Utilization Parameters for Foster Children* (i.e., best practice guidelines), with input from the Federation of Texas Psychiatry, Texas Pediatric Society, Texas Academy of Family Physicians, Texas Osteopathic Medical Association and Texas Medical Association. They are based on the most current evidence-based literature available at the time of publication and are updated periodically.

Have these best practice guidelines been effective in reducing the number of psychoactive medications prescribed to children in DFPS conservatorship?

In June 2006, DFPS, HHSC and DSHS released a report on the Use of Psychoactive Medication in Texas Foster Children in FY '05. This report is based on an analysis of Medicaid claim and medical prescription data and is available at: http://www.hhs.state.tx.us/news/release/Analysis_062306.pdf. The report examined the use of psychoactive medications among children in foster care in the five months before the release of the best practice guidelines, *Psychotropic Medication Utilization Parameters for Foster Children*, and in the five months after the guidelines were distributed to health-care providers in February 2005. The findings showed that during the five months after release of the best practice guidelines:

- The Percentage of children taking two or more psychoactive medications decreased by 28.7%
- Prescribing 5 or more medications at the same time decreased by 30.9%
- Prescribing to children without a mental health diagnosis entered on a claim form decreased by 21.8%

What are the expectations of DFPS concerning the Psychotropic Medication Utilization Parameters for Foster Children?

DFPS has implemented the *Psychotropic Medication Utilization Parameters for Foster Children* in policy and contract standards for residential childcare providers. Residential childcare providers must require physicians who treat children in DPFS conservatorship to follow the principles of the best practice guidelines and to document their rationale in the child's medical record in an exceptional situation, when a child's prescribed psychotropic medication regimen meets the "Criteria Indicating the Need for Further Review of a Child's Clinical Status" on Page 8 (i.e., falls outside of the best practice guidelines).

What is the intent of "Criteria Indicating the Need for Further Review of a Child's Clinical Status" in the best practice guidelines?

These criteria are intended as "audit flags." Meeting these criteria does not necessarily mean the treatment is inappropriate, but indicates the need for further review. Review of the child's medical record or questioning the prescribing physician should provide the rationale for the child's prescribed psychoactive medication regimen. If sound rationale is not provided, then the regimen may be inappropriate.

What does it mean when psychoactive medications do not have Food and Drug Administration (FDA) approval? How do the best practice guidelines address the "off-label" use of psychoactive medications?

The FDA has a statutory mandate to determine whether pharmaceutical company sponsored research indicates that a medication is safe and effective for those indications in which it has been studied by the manufacturer. The FDA also assures that information in the approved product labeling accurately reflects those studies, and limits the manufacturer's marketing to the information contained in the approved labeling. With this in mind, it is recognized that many psychoactive medications do not have FDA approved labeling for use in children. However, the FDA does not regulate physician and other health provider practice, so these drugs may be prescribed for children. In fact, the FDA has stated that it does "not limit the manner in which a practitioner may prescribe an approved drug."

Studies performed by entities other than the manufacturers and expert clinical experience often support the use of a medication for an "off-label" use. Physicians use the available evidence, expert opinion, their own clinical experience, and exercise their clinical judgment in prescribing what they feel is best for each individual patient. Therefore the prescribing of medication for a child that is not FDA approved for use in children may reflect the standard of care and even best practice depending upon the clinical situation.

Why might a child be taking a higher dosage than recommended?

When a lower dose is partially effective, the physician may attempt a higher

dose if the child experiences no significant side affects or adverse reactions. Each person is individual and metabolizes medications differently. Some people are "rapid-metabolizers" meaning that even though the dose is higher, the blood levels may not be. In addition, dosages are often determined by weight. An adult-sized adolescent may be prescribed an adult dosage.

What is the difference between a side effect and an adverse reaction?

Side effects are common, expected, frequently go away with time, usually do not require intervention or may be managed with lifestyle or environmental changes. On the other hand, adverse reactions are unexpected, uncommon, may be life threatening and may require immediate intervention.

How will the new healthcare delivery model for children in DFPS conservatorship address the use of psychotropic medications?

Senate Bill 6 directed HHSC to develop a statewide healthcare delivery model for children in DFPS conservatorship. The expected implementation date of this model is April 2008. The healthcare delivery model vendor will be required to implement and follow the *Psychotropic Medication Utilization Parameters for Foster Children* through prior authorization and retrospective review functions.

What actions is the state taking to ensure appropriate prescribing of psychoactive medications to children in foster care until the new healthcare delivery model is in place?

DFPS, DSHS and HHSC have coordinated to implement some interim strategies targeting physicians who prescribe psychoactive medications to children in DFPS conservatorship, which will include:

- Identifying other treatment alternatives that might assist physicians in decreasing the number of psychoactive medications prescribed
- Distributing newsletters to physicians
- Developing future reports on psychoactive medication use by children in foster care
- Working with physicians to lower the percentage of children whose psychoactive medication regimens fall outside the best practice guidelines
- Holding focus groups with top physician prescribers
- Holding a conference for healthcare providers on mental health care for children in DFPS conservatorship

What is the role of the CPS regional nurse consultants in reviewing psychoactive medications prescribed to children in DFPS conservatorship?

CPS has hired regional nurse consultants in each region of the state. These nurses are all RNs; none are advance practice nurses.

CPS regional nurse consultants may:

- Educate CPS staff about psychoactive medications
- Review and help CPS staff interpret children's medical information and prescribed psychoactive medication regimens
- Identify situations in which children's prescribed psychoactive medication regimens appear to be outside the best practice guidelines
- Help CPS staff talk with doctors and make informed decisions concerning the use of psychoactive medications

CPS nurse consultants may not diagnose, treat or provide an expert opinion as to whether a psychoactive medication regimen is appropriate, because these activities are outside the legal scope of practice for their RN license.

Common Psychotropic Medications Used with Children and Adolescents

June 8, 2007

Dear Legal Professional,

The following table, *Common Psychotropic Medications Used with Children and Adolescents*, is designed to impart some basic information about many of the medications used to treat psychiatric disorders and their attendant behavioral problems in children and adolescents. When using the table please keep in mind the following important points:

1. The field of child psychiatry is evolving rapidly as new studies come out and old studies are re-evaluated; therefore the information in the table reflects the best available at the time it was composed.

2. Lack of FDA approval is not synonymous with inappropriate for children. The FDA does not regulate the practice of medicine. Please see the Q&A in your packet for more information

3. The list does not include all possible medications that may be prescribed; rather it lists those most likely to be prescribed.

4. If a medication is not listed, it may still be appropriate to be prescribed in this population depending upon the circumstances.

5. Many of these medications can be appropriately used for non-psychiatric indications.

6. It can be appropriate to exceed the usual MAX dose in those cases when the child has a partial response to the medication at high dose and is not experiencing any untoward side effects or signs of toxicity. This usually reflects genetic variation in the way the body metabolizes the medications.

7. The table cannot give one all the information necessary to determine whether the medicine prescribed for a child or adolescent is appropriate. It can indicate when it is appropriate to seek further information about the psychiatric care of a child or adolescent.

8. Care that is outside the parameters listed in the *Psychotropic Medication Utlization Parameters for Foster Children* as reflected in this table should have a rationale documented in the medical record that explains the circumstances that necessitate that deviation.

Sincerely,

Nina Jo Muse, MD
Psychiatric Advisor, DFPS

A. ADHD Medications

Class or DRUG Name *generic* - **Brand**	FDA Approval[5]	Usual MAX Daily Dose Child	 Adolescent	Common SIDE EFFECTS	MISC. Information
1. Psychostimulants		**6 to 12 years**	**≥12 years**		
Forms of *amphetamine* **Adderall** **Adderall XR** **Dexadrine**	**≥3 yrs** **(≥6 yrs)**	40 mg[1]	40 mg[1]	Insomnia Anorexia Weight Loss (usually transient) Increased Tics Increased heart rate	Special non-refillable prescription form Very short acting except XR, SR, LA, CD Multiple doses per day are usually needed with immediate release forms
Forms of *dexmethylphenidate:* **Focalin** **Focalin XR**		20 mg[1]	20 mg[1]	Increased blood pressure Muscle twitch Irritability when wears off	May be on more than one dose form to get best coverage
Forms of *methylphenidate:* **Ritalin** **Ritalin SR** **Ritalin LA** **Metadate CD** **Concerta**	**≥6 yrs**	60 mg[1] (except **Concerta**)	60 mg[1] (except **Concerta**)		Abuse potential **Rare adverse reactions:** Psychosis Cardiac problems
Daytrana (skin patch)		72 mg[1] 82.5 mg patch[1] (30 mg delivered internally)	72 mg[1] 82.5 mg patch[1] (30 mg delivered internally)		
II. Non Stimulants					
atomoxetine **Strattera**	**≥6 yrs**	1.8 mg/kg[1]	100 mg[1]	Headache, nausea Fatigue Increased heart rate Increased blood pressure	**Rare adverse reactions:** Liver toxicity
buproprion **Wellbutrin** **Wellbutrin SR** **Wellbutrin XL** **(Zyban)**		6 mg/kg[1]	450 mg[1]	Agitation Insomnia Tremor Vivid dreams	Used for smoking cessation under trade name **Zyban** Lowers seizure threshold
clonidine **Catapres** *guanfacine* **Tenex**		0.4 mg[1] 4 mg[1]	0.4 mg[1] 4 mg[1]	Sedation Dizziness Decrease in heart rate	Both these meds are also used for high blood pressure Careful taper required when discontinuing
imipramine **Tofranil*** *nortriptyline* **Pamelor**	**≥5 yrs**	5 mg/kg[1] 3 mg/kg[1]	300 mg[1] 150 mg[1]	See side effects for tricyclics under depression meds	*Also used to treat enuresis (bed wetting) These are both tricyclic antidepressants

B. Depression Medications

I. (SSRI) Selective Serotonin Reuptake Inhibitors	Usual MAX Daily DOSAGE ~6 to 12 yrs	Usual MAX Daily DOSAGE ≥12 yrs	Common SIDE EFFECTS	MISC. Information
citalopram **Celexa**	40 mg[1]	60 mg[1]	All can cause: Dry mouth Nausea Insomnia Sedation Agitation Jitteriness Sexual dysfunction Weight gain Diarrhea Flu-like symptoms with abrupt discontinuation	Black box warning for suicidal ideation Since introduction suicide rates have actually decreased **Also used for OCD
escitalopram **Lexapro**	20 mg[1]	20 mg[1]		
fluoxetine **Prozac** ≥8 yrs	20 mg[1]	40 mg[1]		
fluvoxamine **Luvox**** ≥8 yrs	200 mg[1]	200 mg[1]		
paroxetine **Paxil** **Paxil CR** **Pexeva**	30 mg[1]	40 mg[1]		
sertraline **Zoloft** ≥7 yrs	200 mg[1]	200 mg[1]		
II. Other newer antidepressants				
venlafaxine **Effexor** **Effexor XR**	3 mg/kg[1]	225 mg[1]	Nausea Dry mouth Headache Increased blood pressure Flu-like symptoms with abrupt discontinuation	Black box warning for suicidal ideation Since introduction suicide rates have actually decreased
duloxetine **Cymbalta**	No data	No data	Nausea Dry mouth Diarrhea Sedation Flu-like symptoms with abrupt discontinuation	Black box warning for suicidal ideation There is no data in the scientific literature to give guidance on appropriate maximum dosages, although expert consensus does list this medication as possibly useful in childhood depression.
mirtazepine **Remeron**	30 mg[3]	45 mg[3]	Sedation Weight gain	Non-addictive sedating property used to treat insomnia caused by SSRIs
trazodone **Desyrel**	200 mg[1]	400 mg[1]	Sedation	Non-addictive sedating property used to treat insomnia caused by SSRIs Rare adverse effect: Priapism (prolonged erection)
III. Tricyclic antidepressants	**Usual MAX Daily DOSAGE ~6 to 12 yrs**	**Usual MAX Daily DOSAGE ≥12 yrs**	**Common SIDE EFFECTS**	**MISC. Information**
amitriptyline **Elavil** ≥12 yrs	150 mg[2]	300 mg[2]	All can cause: Sedation Dry mouth Weight Gain Dizziness Restless Legs Heart rhythm changes	Black box warning for suicidal ideation Tricyclics may sometimes be used in low doses for some types of pain (*amitriptyline*) and enuresis (*imipramine*). They are used to treat depression, panic disorder, other anxiety disorders in adults when other treatments fail. **TCAs are toxic, potentially lethal in the event of an overdose, and have not been demonstrated to be effective for children and adolescents for DEPRESSION and for these reasons are seldom used for in this population for this purpose.** ***Used to treat OCD
imipramine **Tofranil** ≥5 yrs	5 mg/kg[1]	300 mg[1]		
nortriptyline **Pamelor**	3 mg/kg[1]	150 mg[1]		
*clomipramine**** **Anafranil** ≥10 yrs	200 mg[2]	250 mg[2]		

C. Mood Stabilizer Medications (also used for aggression)

I. Lithium Salts	Usual MAX Daily Dose ~6 to 12 yrs	≥12 yrs		
Lithium or LiCO3 **Eskalith** **Lithobid**	30 mg/kg[1]	Max Cs:° 1.2 mEq/L[1]	Dehydration Tremors Diarrhea Agitation Sedation Increased urination Increased thirst Cognitive impairment	°Cs = Serum concentration Need *lithium* level, thyroid, and renal function tests every 6 months **Rare adverse effects:** Kidney toxicity is possible with long-term use.
II. Anticonvulsants				
carbamazepine **Tegretol** **Tegretol CR** *oxcarbazepine* **Trileptal**	7 mg/kg[1] No data	Max Cs:° 12 mcg/ml[1] No data	Dizziness Sedation Weight gain Hyponatremia (low blood sodium) (seen with Trileptal)	Serum *carbamazepine* level generally checked every 6 months May affect level of white blood cells, therefore WBC levels in the blood are generally evaluated when first started and during the period of dose adjustment **One very recent study (2006) has shown that *oxcarbazepine* might not be effective in adolescents in acute mania. It's use should probably be limited to those situations when other appropriate meds are not effective.**
Forms of *valproic acid* **Depakote** **Depakote ER**	20 mg/kg[1]	Max Cs:° 125 mcg/ml[1]	Weight gain Feminization in boys Polycystic ovarian disease in girls Sedation Stomach upset	Serum *valproate* level, generally checked every 6 months May affect level of white blood cells, therefore WBC levels in the blood are generally evaluated when first started and during the period of dose adjustment.
lamotrigine **Lamictal**	15mg/kg[1] (200 mg)[1]	300 mg[1]	Sedation Constipation Dry mouth Rash (indicates need for drug discontinuation	**Rare adverse effects:** Severe rash
topiramate **Topamax**	4.5 mh/kg[2]	4.5 mh/kg[2]	Sedation Weight Loss Impaired cognition	**One very recent (2006) study has shown that *topiramate* might not be effective in adolescents for acute mania. Its use should probably be limited to those situations when other appropriate meds are not effective.**

D. Psychosis and Aggression Medications

I. Atypical (2nd 3rd generation) Antipsychotics	Usual MAX Daily DOSAGE ~6 to 12 yrs	Usual MAX Daily DOSAGE ≥12 yrs	Common SIDE EFFECTS	MISC. Information
clozapine **Clozaril°°** *aripiprazole* **Abilify** *olanzapine* **Zyprexa** **Zyprexa Zydis** *quetiepine* **Seroquel** *risperidone* **Risperdal** *ziprasidone* **Geodon**	300 mg[1] 15 mg[1] 12.5 mg[1] 300mg[1] 4 mg[1] No data[1,2]	600 mg[1] 30 mg[1] 20 mg[1] 600 mg[1] 6 mg[1] 180 mg[1]	All can cause: Sedation Weight gain Extrapyramidal reactions EPS (involuntary muscle movements—dyskinesias) Akathisia (restlessness) Withdrawal dyskinesias See below for treatment of EPS	°°All except *clozapine* are known to be effective to treat acute bipolar disorder. Abilify may be effective, but has not yet been formally studied for this purpose in youth. Pertinent Adverse reactions: °°Severe white cell decrease, therefore get WBC blood level every 2 weeks Diabetes Dyslipidemias Metabolic Syndrome Tardive dyskinesia (risk than in 1st generation agents listed below) Neuroleptic malignant syndrome Seizures
II. Conventional 1st Generation Antipsychotics				
haloperidol **Haldol****** *loxapine* **Loxitane** *fluphenazine* **Prolixin** *trifluoperazine* **Stelazine** *chlorpromazine* **Thorazine** *thiothixene* **Navane** *perphenazine* **Trilafon**	5 mg[1] ?150 mg[2] ?15 mg[2] ?20 mg[2] ?400 mg[2] ?15 mg[2] No data	10 mg[1] 150 mg[2] 10 mg[2] 25 mg[2] 800 mg[2] 25 mg[2] 32 mg[1]	All can cause: Sedation Weight gain Dry mouth Extrapyramidal reactions EPS (involuntary muscle movements—dyskinesias) Akathisia (restlessness) Withdrawal dyskinesias Cognitive impairment See below for treatment of EPS	****Low dose can be used in Tourette's Syndrome Pertinent adverse reactions: Seizures Neuroleptic malignant syndrome (NMS)—rare Tardive dyskinesia—a generally permanent movement disorder ?Max doses for children are given in reference 2 although there is little data to guide use in this population

E. Extrapyramidal (EPS) Medications

DRUG NAME	Usual MAX Daily DOSAGE ~6 to 12 yrs	Usual MAX Daily DOSAGE ≥12 yrs	Common SIDE EFFECTS	MISC. Information
amantadine **Symmetrel**	150 mg[2]	200 mg[2]	Excitement Insomnia Dizziness	Also used to treat influenza
diphenhydramine **Benadryl** *benztropine* **Cogentin** *trihexyphenidyl* **Artane**	100 mg[2] 3 mg[2] 4 mg[2]	150 mg[2] 6 mg[2] 6 mg[2]	Sleepiness Dry mouth Blurred vision Constipation Impaired cognition	Can cause agitation in some users Non-addictive sedating property of diphenhydramine used to treat insomnia

F. Miscellaneous Antianxiety, Sedative Medications

DRUG NAME	Usual MAX Daily DOSAGE ~6 to 12 yrs	Usual MAX Daily DOSAGE ≥12 yrs	Common SIDE EFFECTS	MISC. Information
buspirone **Buspar**	60 mg[3]	60 mg[3]	Dizziness	Used for OCD, PTSD, and anxiety although data to support use in youth is minimal. May be effective for aggression in youth with retardation
propranolol **Inderal**	1 mg/kg[2]	1 mg/kg[2]	Dizziness Decreased heart rate Decreased blood pressure	Used for akathisia (restlessness), aggression, and anxiety Should be tapered when discontinuing
clonazepam **Klonopin** *lorazepam* **Ativan**	0.004 mg/kg[2] 0.09 mg/kg[2]	0.004 mg/kg[2] 0.09 mg/kg[2]	Sedation	Abuse potential Used for anxiety and insomnia **Ativan** used for agitation and aggression *May cause paradoxical excitation and agitation*

References:

[1] *Psychotropic Medication Utilization Parameters for Foster Children,* DSHS, 2006

[2] *Psychotropic Medication for Children and Adolescents*, Los Angeles County Dept. of Mental Health, March 15, 2006

[3] Texas Children's Medication Algorithm Project: Report of the Texas Consensus Conference Panel on medication treatment of childhood major depressive disorder. *Journal of the American Academy of Child and Adolescent Psychiatry,* 38:1442-1454, 1999.See also information on the DSHS CMAP Depression website: http://www.dshs.state.tx.us/mhprograms/mddpage.shtm

[4] *Physicians Desk Reference 2006*

Please see accompanying letter dated June 8, 2007 for important caveats on the use of this table.

The Use of Psychoactive Medication in Texas Foster Children in State Fiscal Year 2005

Executive Summary

Since late 2004, the Health and Human Services Commission (HHSC), the Department of State Health Services (DSHS), and the Department of Family and Protective Services (DFPS) have taken steps to encourage the appropriate use of psychoactive medication in foster children.

In February 2005, DSHS released best practice guidelines to Medicaid healthcare providers entitled *Psychotropic Medication Utilization Parameters for Foster Children*.

Since then, State staff has worked with individual providers whose patients' medication regimens appear to fall outside the guidelines, including getting a second medical opinion when necessary.

In 2006, HHSC, DSHS and DFPS analyzed Medicaid claims data for state fiscal year 2005 to assess compliance with the guidelines. The analysis shows that over 26 percent of foster children received a psychoactive medication beyond a trial period, which reflects the fact that many of them have complex behavioral health conditions and also may be dealing with the trauma of difficult family situations and being removed from their families. Adolescents and older children receive psychoactive medications much more often than younger children, although there is some prescribing to all age groups.

Staff also analyzed how many children and doctors fall outside certain parameters, including prescribing to young children, concurrent use of five or more medications, concurrent use of two or more medications from the same drug class (class polypharmacy), and prescribing without a mental health diagnosis. The claims data show that some foster children fall outside all of these guidelines, and also that there is a relatively small group of physicians who do much of the prescribing to Texas foster children.

Prescribing trends for Medicaid foster children decreased in the five months following the release of the guidelines. In particular, polypharmacy within a drug class decreased by 28.7 percent, prescribing five or more medications at the same time decreased by 30.9 percent, and prescribing to children without a mental health diagnosis decreased by 21.8 percent. Multiple factors, including increased attention by the State and the media, likely contributed to these declines.

The Texas health and human services agencies are developing a comprehensive healthcare program for foster children that will be operational on or after July 2007. In the meantime, we will continue to work with providers, and especially the top 10 percent of prescribers, to better understand the specific problems they treat in foster children and to discuss possible alternative solutions.

Introduction

Concerns were raised regarding the use of psychotropic medications in foster children after the release of an Office of Inspector General (OIG) report in September of 2004. The Texas Health and Human Services Commission (HHSC) along with other health and human services agencies (Department of Family and Protective Services and the Department of State Health Services) implemented a number of strategies to get a more detailed assessment of the problem and to assist providers in utilizing psychoactive medication appropriately. This summary outlines the additional analysis that has been done of the use of psychoactive medication in Texas foster children and outlines steps that we have put in place to assist providers in their appropriate use.

Analysis of the Use of Psychoactive Medication in Texas Foster Children

Since psychoactive medication use is higher on average among foster children than other Medicaid children, HHSC, DSHS and DFPS conducted additional analysis on prescribing to Texas foster children for state fiscal year 2005 (September 1, 2004 through August 31, 2005). This analysis is more targeted than the OIG's 2004 report entitled *Texas Pediatric/Adolescents Drug Review,* which looked at claims for all Medicaid children during the two-month period of July and August 2004.

Both analyses were based on Medicaid prescription and medical claims data. There are, however, several key differences between the two analyses. First, whereas the OIG's report looked only at three of the largest psychoactive drug classes (stimulants, antidepressants and antipsychotics), the recent analysis of foster children included these three drug classes along with all other drug classes considered psychotropic medications in the 2006 DSHS Formulary (e.g. mood stabilizers, sedatives/hypnotics).

Also, the OIG report reflected all children whose claims history showed they had received any prescription for a drug in one of the three classes. Psycho-active medications initially are given on a trial basis to determine if the drug will be effective and well tolerated. Since Medicaid doctors typically write prescriptions for 30 days, one can't tell from a single claim whether a child actually took the drug for 30 days or for just a few days. For this reason, the new analysis on foster children focuses on children who received psychoactive medication for 60 or more days to indicate the child was likely on the medication beyond the trial period.

Finally, the OIG report looked at medical claims history to assess whether a child had a proper diagnosis warranting the use of a drug. The new analysis of foster children checked to see whether a child had a recent mental health diagnosis based on Medicaid claims history, but did not assess whether it was a proper diagnosis for the specific drug(s) prescribed.

The SFY 2005 analysis of foster children reviewed data in the context of DSHS's *Psychotropic Medication Utilization Parameters for Foster Children*, which were released in February 2005. These guidelines use the following criteria (along with some others) to indicate the need for further review of a patient's case.

- Psychotropic medications prescribed for very young children, including any psychotropic medications for children under age 3, and certain types of medications (antidepressants and antipsychotics) for children under age 4
- Five (5) or more psychotropic medications prescribed at the same time
- The use of two (2) or more drugs at the same time from a certain class of drugs (e.g. antidepressants, antipsychotics) to treat the same indication
- Lack of a mental health diagnosis

Data Analysis — Foster Children

Of 37,052 foster children who were eligible for Texas Medicaid at some point during state fiscal year (SFY) 2005, 12,842 (34.7 percent) received a psychoactive medication, and 9,740 (26.3 percent) received a psychoactive medication for at least 60 consecutive days. In comparison, the OIG report found that out of all Medicaid children, 63,118 (less than 4 percent) received at least one stimulant, antidepressant or antipsychotic in either July or August 2004. The higher use of psychoactive medications among foster children reflects the fact that many of them have complex behavioral health conditions and they also may be dealing with the trauma of difficult family situations and being removed from their families.

The use of psychoactive medications in foster children increases with age. As reflected in the table below, utilization of psychoactive medication ranged from less than 1 percent of foster children under age 3 to 51.8 percent of foster children ages 13-17.

Age Group	# Foster Children	# Prescribed Psych Meds 60+ Days	% Prescribed Psych Meds 60+ Days
0-2	11,261	86	0.8%
3	2,196	200	9.1%
4-5	3,955	794	20.1%
6-12	10,648	4,519	42.4%
13-17	8,992	4,662	51.8%
Total	**37,052**	**9,740**	**26.3%**

Prescribing to Young Children

- Of the 86 children under age 3 who received psychoactive medication, the most common medications prescribed were clonidine and diphenhydramine (Benadryl), both of which are probably prescribed to treat a child who is not sleeping or whose behavior is uncontrollable.
- The treatment of 3 year olds with stimulants is well accepted. Of the 200 children age 3 who received psychoactive medication, 174 received a medication other than a stimulant. The most common medications prescribed were clonidine and risperidone. The risperidone likely is for aggression, and the clonidine is probably being used to calm or help the child sleep.

Five or More Medications At the Same Time

- 396 foster children (1.1 percent) received five or more medications at the same time.
- Of the 396 children, 217 were ages 13-17, 174 were ages 6-12, and 6 were ages 4-5. No children under age 4 received five or more medications at the same time.
- Older children more commonly suffer from Bipolar Disorder and Schizophrenia. A scenario that may lead to the prescription of this many medications would be a child diagnosed with Attention Deficit Hyperactive Disorder (ADHD) and Bipolar Disorder who is receiving a stimulant for the ADHD, lithium and another mood stabilizer for mania, an antidepressant for depression, and an antipsychotic for mania, aggression and psychosis.

Two or More Medications from the Same Drug Class at the Same Time

- 1,481 foster children (4 percent) received two or more medications from the same drug class at the same time, termed "class polypharmacy."
- Class polypharmacy is most common in the older age groups. Of the 1,481 children, 883 were ages 13-17, 569 were ages 6-12, 39 were ages 4-5, 3 were age 3, and 1 was under 3.
- The most commonly prescribed polypharmacy was for antidepressants (833 children), which may reflect the common practice whereby the antidepressants trazodone and mirtazepine are used as sleeping agents to deal with the insomnia caused by Selective Serotonin Reuptake Inhibitor (SSRI) antidepressants.
- The second most commonly prescribed polypharmacy was for antipsychotics (380 children). Although prescribing more than one antipsychotic is increasingly common, it is not generally accepted by the experts or validated by the data that exists.

Lack of Mental Health Diagnosis

- Of the foster children who received psychoactive medication for 60 or more days, 134 (1.4 percent) did not have a mental health diagnosis in their SFY 2005 Medicaid claims history.
- This may be due to the perception by some providers that if they list a mental health diagnosis on the claim, they either will not be paid or will be paid a lower rate. Also, some providers may see Medicaid patients, but not bill for the services due to the program's payment rates and administrative requirements.

Data Analysis — Doctors

- 2,651 doctors prescribed psychoactive medication to Medicaid foster children in SFY 2005. Of these:
  - 2,110 prescribed for 60 days or longer.
  - 264 prescribed for children who received five or more medications at the same time.
  - 677 prescribed for children who received two or more medications from the same drug class at the same time.
- 26 doctors (about 1 percent of those prescribing psychoactive medications) had 10 or more patients on five or more psychoactive medications at the same time. All of these doctors had psychiatric certification and/or training, and likely are taking care of foster children with the most complex behavioral health needs.

Trends in Prescribing Practices Since the Release of the Psychotropic Medication Utilization Parameters for Foster Children

DSHS released the *Psychotropic Medication Utilization Parameters for Foster Children* on February 15, 2006, almost halfway through state fiscal year 2005. In order to assess whether there were changes to prescribing patterns after the guidelines were issued, staff compared claims data five months before the release of the guidelines (September 2004 through January 2005) with five months after (April 2005 through August 2005). February and March were excluded, as these were transition months during which doctors would be adjusting their practices and clients would need time to make appointments to see their doctors after the guidelines were issued.

As the table below shows, psychoactive medication prescribing trends for Medicaid foster children decreased in the five months following the release of the guidelines. In particular, polypharmacy within a drug class decreased by 28.7 percent, prescribing five or more medications at the same time decreased by 30.9 percent, and prescribing to children without a mental health diagnosis decreased by 21.8 percent.

	5 Months Prior to the Guidelines 9/1/04 to 1/31/05		5 Months After the Guidelines 4/1/05 to 8/31/05		Percent Change
	Ages 0-17	Percent	Ages 0-17	Percent	
Total children in foster care	27,391*		30,491*		+11.3%
Got a psychoactive medication	9,894	36.12%	10,257	33.64%	-6.9%
Got a psych med for 60 or more days	7,005	25.57%	7,127	23.37%	-8.6%
2+ drugs in same class at same time	862	3.15%	684	2.24%	-28.7%
5 or more meds at same time	204	0.74%	157	0.51%	-30.9%
No MH diagnosis those w/ a psych med for 60 or more days	171	2.44%	136	1.91%	-21.8%

*Of these children, 20,995 were in foster care both before and after the guidelines were issued.

A number of factors may have contributed to the decreased trend in prescribing, including the release of the DSHS guidelines, heightened questioning of prescribing by caseworkers and judges, general media attention to the issue, and the fact that less psychiatric treatment is sought in the summer.

Next Steps

The Texas health and human services agencies will continue to work to encourage doctors to follow the prescribing guidelines for Medicaid foster children.

- The State plans to provide a summary of the above data analysis to doctors who care for Texas foster children and request that they review their practices based on the analysis and the guidelines.
- The State also will focus on one or more of the criteria, such as the concurrent prescribing of five or more medications to a child. We will develop strategies to work with prescribers who meet this criterion, and especially the top 10 percent of prescribers, to better understand the specific problems they are trying to solve with so many medications and discuss possible alternative solutions.

Psychotropic Medication Utilization Parameters for Foster Children

In February 2005, the Department of State Health Services (DSHS) released best practice guidelines for healthcare providers entitled *Psychotropic Medication Utilization Parameters for Foster Children*.

- The guidelines were developed for use in the treatment of foster children who receive services through Texas Medicaid.
- The guidelines were developed by a panel of child and adolescent psychiatrists, psychologists, guideline development specialists, and other mental health experts.
- The guidelines are posted on the DSHS website at: http://www.dshs.state.tx.us/mhprograms/psychotropicMedicationFosterChildren.shtm

Comprehensive Healthcare Program for Foster Care

HHSC, DFPS, DSHS and the other Texas health and human services agencies have been working together to develop a comprehensive healthcare program for foster children.

- Currently, Medicaid foster children are served through the traditional Medicaid fee-for-service model, in which they do not have a primary care physician or coordination of their physical and behavioral health care needs.
- HHSC will contract with a vendor to manage the new comprehensive healthcare program for foster children, and plans to release the request for proposals (RFP) in late May 2006.
- The comprehensive program will be operational on or after July 1, 2007.
- Once the program is in place, one of the vendor's responsibilities will be to work with providers to encourage appropriate prescribing of psychoactive medication for foster children.