INFORMED CONSENT FOR PSYCHOTROPIC MEDICATION

Richard LaVallo
Attorney at Law
Disability Rights Texas

Why Does Informed Consent Matter?

- Under the common law, a physician has a duty to make a reasonable disclosure to a patient of risks that are incident to medical diagnosis or treatment.
- This common law duty is based on patient’s right to information adequate for the patient to exercise an informed consent to or refusal of a treatment.
- In *Barclay v. Campbell*, 704 S.W.2d 8 (Tex. 1986), the Texas Supreme Court held that a psychiatrist was required to obtain informed consent from a patient before administering psychotropic medications.
- A patient does not lose the constitutional right to make medical decisions because of mental illness.

Consent to Medical Care for Foster Children

- Chapter 266 of Family Code governs consent to medical care for foster children.
- Medical care encompasses the administration of psychotropic medications.
- Informed consent was not originally defined in Chapter 266 of the Family Code.
Informed Consent Under HB 915

Amends Chapter 266 of the Family Code by adding:

1) A definition of psychotropic medication. Tex. Fam. Code § 266.001(6); and

HB 915 adopts the standard definition of psychotropic medication and the accepted process for obtaining informed consent.

HB 915 does not impose any new informed consent requirements.

HB 915's Informed Consent Provision

Consent to the administration of a psychotropic medication is valid only if:

1) The consent is given voluntarily and without undue influence; and
2) The person authorized by law to consent for the foster child receives verbally or in writing information that describes:
   A. The specific condition to be treated;
   B. The beneficial effects on that condition expected from the medication;
HB 915’s Informed Consent Provision (cont.)

C. The probable health and mental health consequences of not consenting to the medication;  
D. The probable clinically significant side effects and risks associated with the medication; and  
E. The generally accepted alternative medications and non-pharmacological interventions to the medication, if any, and the reasons for the proposed course of treatment.  
Tex. Fam. Code § 266.0042

HB 915’s Informed Consent Provision

According to DFPS policy, proof of informed consent must be documented by the completion of a form prescribed by DFPS that is signed by the medical consenter and the physician administering psychotropic medication or his or her designee.

DFPS’ Psychotropic Medication Treatment Consent Form

The consent form essentially tracks the informed consent language in Section 266.0042 of the Family Code without providing specific information regarding the benefits, risks or side effects of the psychotropic medication being prescribed to the child.
The DFPS consent form adds that the medical consenter has:
1) the right to ask questions;
2) the right to refuse to consent to the initiation of a new medication; and
3) the right to withdraw or revoke consent for treatment at anytime.

If a consenter refuses to consent to medication, consenter must notify case worker within 24 hours.

Unlike the informed consent form used by DSHS, the DFPS consent form does not provide that the following explanations were given:
1) A description of the proposed course of treatment with the psychotropic medication;
2) The fact that side effects of varying degrees of severity are a risk of all medications;
3) The relevant side effects of the medication may include:
   a) Any side effects which are known to frequently occur in most individuals;
   b) Any side effects to which the individual may be predisposed; and
   c) The nature and possible occurrence of the potentially irreversible symptoms of tardive dyskinesia in some individuals taking neuroleptic medication in large dosages and/or for long periods of time;
4) The need to advise the physician immediately if any of these side effects occur.
5) Provision of a complete explanation of the psychotropic medication by means of oral explanation, video presentation, printed materials or other means.
Even though the DFPS informed consent form does not require the medical consenter being provided the information in the DSHS form, there is no reason why a medical consenter cannot request this information from the physician before consenting to psychotropic medication.

Psychotropic Medication Utilization Parameters for Children & Youth in Foster Care (September 2013)

• Medical consenters and advocates must read and be informed about the new guidelines which are available at:
  • http://www.dfps.state.tx.us/ChildProtection/MedicalServices/guide-psychotropic.asp.

Checklist for Psychotropic Medications Based on Utilization Parameters

1. Did the child receive a comprehensive evaluation before being treated with psychotropic medication?
   • This includes a thorough health history, psychosocial assessment, mental status exam, and physical exam.
   • Information about child’s history of trauma must be made available to physician.
2. Were non-pharmacological interventions such as trauma-informed, evidence-based psychotherapy attempted before being treated with psychotropic drugs?

3. Was the child’s height, weight, blood pressure or other appropriate laboratory findings documented?
   - If so, were there any changes?

4. Was the child prescribed psychotropic medication by a primary care physician, not a psychiatrist, for a diagnosis other than ADHD and uncomplicated anxiety disorders and depression?

5. Was the child given a DSM-5 psychiatric diagnosis before being prescribed psychotropic medications?

6. Are there clearly defined target symptoms and treatment goals documented in the child’s medical record before beginning treatment with psychotropic medications?

7. Is the presence or absence of medication side effects documented in child’s medical record at each visit?

8. Was a single psychotropic medication used to treat a DSM-5 diagnosis attempted before the prescribing additional psychotropic medication to treat the same condition?

9. Were more than one medication changed at a time?

10. Is the child given psychotropic medications on “PRN” or as needed basis?

11. Is the child being seen by the physician prescribing the psychotropic medication once every 90 days?

12. Is a child who is depressed, has history of suicidal behavior, self-harm or anxiety or substance abuse disorders being monitored for suicide?
Checklist for Psychotropic Medications Based on Utilization Parameters (cont.)

13. If the prescribing physician is not a child psychiatrist and the child has not made clinical improvement, has the child been referred to a child psychiatrist?

14. Before adding additional psychotropic medications, was the child assessed for adequate medication adherence, accuracy of diagnosis, the occurrence of other disorders such as substance abuse or general medical disorders, or influence of psychosocial stressors?

15. Before a preschool age child is prescribed psychotropic medication, was the child treated with non-psychopharmacological interventions for up to 12 weeks?

Checklist for Psychotropic Medications Based on Utilization Parameters (cont.)

16. When a preschool age child is being considered for psychotropic medication, were the child’s parents/foster parents functioning and mental health needs assessed?

17. Before a preschool age child is prescribed psychotropic medication, were the parents/foster parents trained in evidence-based behavior management?

18. If the child is being treated with psychotropic drugs to target aggression associated with conduct disorder, oppositional defiant disorder or intermittent explosive disorder and the aggressive behavior has not occurred for six months, was the psychotropic medication discontinued?

Checklist for Psychotropic Medications Based on Utilization Parameters (cont.)

19. Is the dosage of psychotropic medication consistent with amounts listed in the medication tables found in Utilization Guidelines?

20. Is there a Black Box warning for the medication in the FDA Medication Guides?
   - Medication Guides can be found at: http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm
Criteria for Medication Reviews Under the Utilization Parameters

1. Absence of a comprehensive evaluation of the child’s DSM-5 diagnosis(es) in the child’s medical record.
2. 4 or more psychotropic medications prescribed at once.
3. Prescribing 2 or more stimulants, 2 or more alpha agonists, 2 or more antidepressants, 2 or more antipsychotics or 3 or more mood stabilizers.
4. Prescribed medication is not consistent with child’s diagnosis or target symptoms.
5. 2 or more medications for a given mental disorder are prescribed before using one medication.
6. Dose exceeds usual FDA recommended dose.

Criteria for Medication Reviews Under the Utilization Parameters (cont.)

7. Psychotropic medication prescribed for very young child:
   • Stimulants under 3
   • Alpha agonists, antidepressants, antipsychotics and mood stabilizers under 4
8. Prescribing by physician who is not a child psychiatrist for a diagnosis other than ADHD or uncomplicated anxiety disorders and depression.
9. Antipsychotic medication prescribed continuously without monitoring glucose and lipids at least every 6 months.

Psychotropic Medication Utilization Review (PMUR)

- A medication review may be triggered by:
  1) External request by CPS nurse consultant, other CPS staff, CASAs, child’s caregiver, attorneys or other interested parties; or
  2) Court request by Judge have jurisdiction over CPS case to answer questions about a child’s medications.
How to Request PMUR?

- Requests can be directed to a Cenpatico service manager based on the child’s placement region.
  - **DFPS Regions 1, 2, 3, 4, 7, 9, 10**
    Cenpatico Contact
    Michelle Perez-Vega LCSW, Behavioral Health Service Manager
    1-866-534-5946 x42709
    mvega@cenpatico.com
  - **DFPS Regions 5, 6, 8, 11**
    Cenpatico Contact
    Bob Dryden, M.Ed., LPC, Behavioral Health Service Manager
    1-866-534-5946 x42659
    rdryden@cenpatico.com

NOT ALL Requests Result in Formal PMUR

- Cenpatico will only answer questions about medication or refer requestor to prescribing physician:
  1. If the CPS staff, medical consenter, caregiver or other individual has questions about why a specific medication was prescribed by the physician.
  2. If the medication regimen and dosages of medications prescribed are clearly within the DFPS Psychotropic Medication Utilization Parameters.
  3. If the CPS staff, medical consenter, caregiver or other individual has questions about medication side effects, wants to stop a particular medication, or does not think the medication is needed.

NOT ALL Requests Result in Formal PMUR (cont.)

4. If there are questions about giving consent for new medications or changes in medication doses recommended by the child’s treating physician.
5. Requests made because the medication does not appear in the DFPS Psychotropic Medication Utilization Parameters for Foster Children (September 2013).
6. Concerns about giving consent for new medications or changes in medication doses while foster children are in treatment at a psychiatric hospital.
**How Long Does It Take to Complete PMUR**

- PMUR process takes 2–3 weeks to complete.

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**Obtaining a Copy of PMUR Report**

- Cenpatico will attempt to complete PMURs requested by caseworkers for status, permanency and placement hearings.
- If the medication review is “court ordered,” the Cenpatico Service Manager will ask for a copy of the court documents to ensure the court’s concerns are addressed in the report, and will submit to the court a copy of the final PMUR report.
- Upon request, the Cenpatico Service Manager has 3 business days to gather needed information to submit the PMUR request for review. The Cenpatico Medical Director will review the information and forward to the consultant child psychiatrist.

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**Obtaining a Copy of PMUR Report (cont.)**

- If there is not enough information, the process could be delayed.
- The consultant has 10 business days to attempt peer–peer contact with the treating physician, and complete the PMUR report.
- All of the parties are entitled to a copy of the PMUR Report.
Special Circumstances Related to PMUR

1) If the court order is requesting a “second opinion,” the request will be transferred to Cenpatico Care Coordinator for a referral to an in–network psychiatrist.

2) If the court order is requesting a “second opinion,” or medication review outside of the STAR Health network, outside evaluations are not covered by STAR Health even with a court order and are the responsibility of DFPS.

PMUR Determinations

- The PMUR report will contain a formal determination about the child’s medications:
  1) Medication regimen within Parameters.
  2) Medication regimen outside Parameters but within the standard of care – medications fall outside the Utilization Parameters but are within current accepted treatments.
  3) Medication regimen outside Parameters with opportunities to reduce polypharmacy – since quickly changing or stopping medication could cause severe consequences, Cenpatico will work with physician to gradually reduce medications.
  4) Medication regimen is outside Parameters with risk of significant side effects – DFPS Medical Director is contacted so that specific actions can be planned and a new treating physician is found.

Protection to Ensure the Provision of Informed Consent

1) The medical consenter must complete a training on informed consent, the appropriate use of psychosocial therapies, behavior strategies and other non–pharmacological interventions that should be considered before or concurrently with psychotropic medication. Tex. Fam. Code § 266.004 (h–1) & (h–2).

2) The medical consenter shall participate in the doctor’s appointments when the child is being prescribed psychotropic medications or the child’s progress on the medications is being reviewed. Tex. Fam. Code § 266.004(i) & PSA 06–072 (March 21, 2006).
Protection to Ensure the Provision of Informed Consent (cont.)

3) The medical consenter must ensure that the child has an office visit with the physician at least every 90 days to allow the physician to monitor side effects and determine whether medication is helping the child achieve the treatment goals and continued use of the medication is appropriate. Tex. Fam. Code § 266.011

4) The child’s guardian ad litem and attorney ad litem shall review a child’s medical care including psychotropic medication and seek child’s opinion on medical care in developmentally appropriate manner.

Protection to Ensure the Provision of Informed Consent (cont.)

5) The child’s attorney ad litem shall also advise the child 16 years or older of their right to request the court to allow them to consent to their own medical care including psychotropic medications.

6) At each permanency and placement review hearing, as part of its review of the child’s medical care, the court should review:
   a. All mental health treatment and child’s progress with the treatment.
   b. Any medications prescribed for the condition, diagnosis and symptoms for which the medication was prescribed and child’s progress with the medication.

Protection to Ensure the Provision of Informed Consent (cont.)

c. Any adverse side effects of the medication.
d. Any activity that child should avoid that might affect effectiveness of medication, including physical activity, other medication or diet.
e. Any psychosocial therapies, behavior strategies or other non-pharmacological interventions that have been provided in conjunction with psychotropic medication.
f. The dates of any office visits the child had with the prescribing physician to monitor the side effects and benefits of the psychotropic medication.

Tex. Fam. Code § 263.306(a), 263.503(a) & 266.007(a)
Protection to Ensure the Provision of Informed Consent (cont.)

7) At each hearing, the child shall be provided with an opportunity to talk to the judge about being treated with psychotropic medications. Tex. Fam. Code § 266.007(c)

8) DFPS shall notify the child’s parents when the child is initially prescribed psychotropic medication and whenever the dosage is changed. Tex. Fam. Code § 266.005(b–1)

9) If there are any concerns regarding the child’s treatment with psychotropic medications, DFPS, the medical consenter, the parent, the guardian ad litem or attorney ad litem may petition the court for an order related to the administration of psychotropic medication. Tex. Fam. Code § 266.004(e)–(g)

Protection to Ensure the Provision of Informed Consent (cont.)

10) The Department is required to ensure that a youth’s transition plan includes a provision to assist them in managing the use of psychotropic medications, resources to assist in managing psychotropic medications and providing informed consent after aging out of foster care. Tex. Fam. Code § 264.121(g)

11) When a youth reaches the age of 16, the Court must determine if the youth has the capacity to consent to psychotropic medication. Tex. Fam. Code § 266.010(a)(c)

12) Whenever a medical consenter consents to psychotropic medication, the child must be involved in the decision about psychotropic medication in accordance with their developmental level. The medical consenter should attempt to seek the assent of the child to the use of psychotropic medications. Psychotropic Medication Utilization Parameters, p.4 (September 2013)

FIVE EASY STEPS TO ENSURE THE APPROPRIATE USE OF PSYCHOTROPIC MEDICATION

1) ...
1. Be Informed

- Determine whether the medical consenter has given informed consent for the psychotropic medication. Did the person participate in the medical appointment where the medication was prescribed? If the medical consenter did not participate in medical appointments, ask the court to appoint another person.

- Find out whether the child is informed about why he or she is taking medication and what are the benefits, risks and side effects of the medication.

1. Be Informed (cont.)

- Learn about the child’s diagnosis and why was the child given this diagnosis. Don’t be afraid to ask the child’s treating physician.

- Does the child have a history of trauma? Was a trauma assessment done? Did the child receive trauma-informed evidence based psychotherapy or other trauma-focused treatment before being medicated.

- Become familiar with the Psychotropic Medication Utilization Parameters and use them when you are reviewing the psychotropic medications being administered to the child.

1. Be Informed (cont.)

- Be aware of the child’s mental health history. This includes the medications and other forms of mental health treatment that he or she received in the past. Has the child ever had a “drug holiday”?

- For each psychotropic medication prescribed for the child, know what diagnosis and symptoms are being treated by the medication.

- Obtain as much information about the benefits, risks and side effects of the psychotropic medication. Ask the physician for the written documentation provided as part of the informed consent process when the medication was prescribed. Review the FDA Medication Guides, including any Black Box Warnings, for the psychotropic medication being prescribed.
1. Be Informed (cont.)
   - Make sure the lab work and any other follow-up required for the medication is being done.
   - Look for physical signs such as changes in weight, sleepiness, oversedation, overstimulation, slurred speech, confusion, disorientation, increased agitation, irritability and restlessness that may be indicators of the child's adverse reaction to the medication.
   - Talk to the child about how he or she feels about the medication. Take any concerns expressed by the child seriously.

2. Have Courage
   - Don’t be afraid to question physicians and other mental health professionals. Prepare in writing the questions that you want answered.
   - If the child is being treated by a physician who is not a child psychiatrist and is not improving, request that he or she be seen by a child psychiatrist.

3. Request a Medication Review
   - If the child’s medications fall outside of the review criteria for the Psychotropic Medication Utilization Parameters for Foster Children, request a PMUR.
   - If the medical review team conducts a review, obtain a copy of the PMUR.
   - If the review does not satisfy your concerns, ask the court to order a "second opinion" from an independent expert.
4. Use the Procedures in Chapter 266

- Document your concerns about medications in your reports to the court.
- Raise your concerns in court.
- Make sure that at all review hearings, the child has an opportunity to express his or her concerns about psychotropic medications to the court.
- If you have concerns about the psychotropic medications being prescribed to the child which are not being addressed by the physician or DFPS, file a petition for an order related to medical care with the court.

5. Don’t be Complacent

- Remember psychotropic medications are not the panacea for fixing all of the child’s problems.
- The child might be a victim of trauma. Request trauma sensitive programming.
- Advocate that the child be placed in the least restrictive (most family like) setting.
- If the child has not responded to treatment, find an expert to review the child’s case to get new ideas.