

Practice Protocol

Informed Consent for Psychotropic Medication Treatment



**Developed by the
Arizona Department of Health Services
Division of Behavioral Health Services**

**Effective May 1, 2006
Last Revised November 20, 2007**

Purpose

To improve the practice of obtaining and documenting informed consent from persons/parents/legal guardians for all prescribed psychotropic medications to facilitate positive clinical outcomes through increased understanding, compliance, and empowerment of the behavioral health recipient.

Targeted Population(s)

All enrolled persons prescribed psychotropic medications as part of their treatment plan.

Introduction

ADHS/DBHS, in conjunction with the workgroup for the *“Informed Consent for Psychotropic Medication Prescription”* Performance Improvement Project, has established these guidelines for obtaining informed consent for all T/RBHA enrolled persons who are prescribed psychotropic medications.

Pursuant to [A.A.C. R9-21-206.01\(A\)](#), a medical practitioner (licensed physician, certified physician assistant, or nurse practitioner) shall obtain informed consent from the person or his/her legal guardian. Pursuant to [A.A.C. R9-21-206.01\(D\), \(E\)](#), a person or, if applicable, the person’s legal guardian shall give the informed consent by signing and dating an acknowledgement that the person/legal guardian has received the information, as set out in [A.A.C. R9-21-206.01\(C\)](#), and gives consent to the proposed treatment. If the person/legal guardian refuses to sign an acknowledgement, verbal informed consent may be obtained. If the person/legal guardian gives verbal informed consent, a medical practitioner shall document in the person’s record that the information is given to the person/legal guardian, the person/legal guardian refuses to sign, and the person/legal guardian gives informed consent (verbally).

Procedures

- Informed consent for medications must be accomplished according to ADHS/DBHS Provider Manual sections:
 - [3.15, Psychotropic Medications: Prescribing and Monitoring](#)
 - [3.11, General and Informed Consent to Treatment](#)
- Medications are only to be prescribed according to the provisions of ADHS/DBHS Provider Manual Sections:
 - [3.16, Medication Formulary](#)
 - [3.14, Securing Services and Prior Authorization](#)
 - [3.15, Psychotropic Medications: Prescribing and Monitoring](#)
- Informed consent shall be obtained from the person/legal guardian for each psychotropic medication prescribed. The individual medical record must contain documentation of the informed consent.

- For T/RBHAs and subcontracted providers, ADHS/DBHS has developed [PM Form 3.15.1 “Informed Consent for Psychotropic Medication Treatment.”](#) T/RBHAs are strongly encouraged to use this form, although its use is not mandatory. T/RBHAs may choose to use alternative forms or allow prescribers to document informed consent in their Progress Notes. However, all essential elements must be captured in the informed consent documentation, wherever it is located.

PM Form 3.15.1 includes the following essential elements of informed consent:

- Signature of person/legal guardian for each psychotropic medication prescribed;
 - Name and signature of medical practitioner;
 - The diagnosis and target symptoms for the medication being prescribed;
 - The benefits/intended outcome of treatment, and the risks and side effects of each medication;
 - Alternatives to the proposed medication treatment;
 - The possible results of not taking the recommended medication;
 - The possibility that medication dosages may need to be adjusted over time in consultation with the medical practitioner;
 - The person's right to actively participate in treatment by discussing medication concerns or questions with the medical practitioner; and
 - The person's right to withdraw voluntary consent for medications at any time (unless the medication(s) in the treatment plan are required in a Court Order or in a Special Treatment Plan).
- Information provided in the process of obtaining informed consent must always be communicated in a manner that the person/legal guardian can understand and comprehend. This should include the person's primary language and literacy. Medical practitioners are encouraged to use open-ended questions to assess whether or not the person understands the issues of informed consent. If necessary, translation services must be obtained.
 - If the person, due to a cognitive deficit, is unable to adequately understand and comprehend the necessary information to complete the informed consent process, the medical practitioner should pursue measures to obtain an appropriate guardian who can provide informed consent.
 - Informed consent for medications should always be documented in a consistent manner and located in the person's medical record in a designated location for easy accessibility.
 - It is recommended that written information be provided to the person and/or legal guardian for each new medication prescribed. Such handouts should generally use simple, understandable language. It is recommended that the information in these materials include:
 - Name of the medication (generic and brand name);
 - Indications for and/or common use of the medication;
 - Risks;
 - Important side effects;
 - Significant drug-drug, food-drug interactions;
 - Dosing and administration information; and

- Any other specific information pertaining to the medication prescribed.
- When the person/legal guardian refuses or is unable to sign the informed consent document, but is agreeable to taking the medication and the practitioner provided the essential elements related to the informed consent process to the person/legal guardian, the practitioner should document on the informed consent form “Refused (or Unable) to sign; Verbal consent given” in the blank for the person’s/legal guardian’s signature.
- When two or more medications are listed on the approved form as being initiated at the same time, the medical practitioner may draw all of these together under one signature/initials and date, but should list each medication on a separate line.
- Informed consent for medication treatment is a process that involves ongoing communications between the prescribing medical practitioner and the person who will be taking the medication or his/her legal guardian. These communications can be best accomplished through the use of both verbal and written processes.
- Ongoing informed consent includes medication education and providing information regarding the appropriate dosing and administration of medications.
- A person who is being prescribed medications and/or the legal guardian should always be encouraged to discuss any questions or concerns that he/she may have with the prescribing medical practitioner and be provided applicable contact information.
- For any person who attains the age of 18, new psychotropic medication informed consent must be obtained from the person as a legally responsible adult, unless the person is maintained under other formal legal guardianship.
- In accordance with [A.R.S. § 8-514.05](#), for any child who has been removed from the home by Child Protective Services (CPS) and who is being prescribed psychotropic medications, the foster parent, group home staff, foster home staff, relative, or other person in whose care the child is currently placed may give consent to treatment of common childhood illness or conditions.

It is recommended that for situations as described above involving children who have been removed from the home by CPS, the person who is providing informed consent should be the person from the home where the child is currently residing, who is most knowledgeable about the child’s condition.

- In situations in which the person is incapable or irresponsible to take his/her own medication, the identified party who is responsible for providing the supervision of medication administration should be given the medication information necessary for them to help assure the safety of the person who is taking prescribed medications.
- If a person has filed a Mental Health Power of Attorney or advance directive in accordance with [A.R.S. § 36-3281](#) for mental health care and treatment, the provisions of the Mental Health Power of Attorney or advance directive regarding the use of medications must be followed. In this case, the agent who the person has designated in the Mental Health Power of Attorney or advance directive may provide

authorization and informed consent for the use of medications according to the wishes of the person when he/she is incapacitated for making mental health care and treatment decisions. A copy of the Mental Health Power of Attorney or advance directive should be obtained and placed into the person's medical record.

- For persons who are under court ordered treatment, an attempt should still be made to provide informed consent for all medication treatment. Most court orders contain a specific statement that the person must comply with mental health treatment including medication treatment. However, if the court's order for involuntary treatment does not contain this specific requirement, and the person refuses to cooperate with medication treatment voluntarily, a specific court order should be obtained to require the person's compliance with medication treatment. Alternatively, pursuant to [A.A.C. R9-21-512](#), a special treatment plan may be developed and implemented that contains a written opinion explaining why the medication must be administered against that person's will. The treatment plan must specify:
 - A description of the circumstances under which the medication may be used, and
 - A description of the objectives that are expected to be achieved by the use of the medication. This description must indicate how the individual's condition would be improved by using the medication and indicate what result would be expected if the medication were not used.
 - Whenever a person refuses to voluntarily cooperate with recommended treatment, an effort should still be made to obtain informed consent and should be documented in the person's medical record.
- If medication treatment is provided as a result of an emergency situation without obtaining the consent of the person, the medical practitioner should provide a written explanation of the emergency situation in the person's medical record, including the rationale for the emergency use of medication treatment. For continued use of a medication that was prescribed as a result of an emergency situation, informed consent must be obtained. If the person continues to refuse to take medication voluntarily, the medical practitioner must again declare that an emergency situation exists. Documentation is required as stated above for repeated emergency medication administration. Alternatively, a special treatment plan that specifically addresses the involuntary administration of medication may be implemented.
- If the person being prescribed medications has discontinued the medications for a significant length of time, the decision of whether or not to obtain a new informed consent for the same medications should be left to the medical practitioner's clinical judgment. This should include consideration of the current capacity of the person to continue to consent and the potential risks to the person by taking medications that were previously agreed to as part of the person's treatment plan.
- If a person is seen at the same agency by a different medical practitioner to prescribe the same medications that the previous medical practitioner prescribed, obtaining a new informed consent for those medications is generally not necessary or required.
- If the person's care is enrolled with a new agency with a new medical practitioner, new informed consent for medication treatment should be obtained. However, the new prescriber can indicate that informed consent had previously been obtained in

the prior setting (by previous prescriber). The new prescriber must; however, verify that the person continues to consent to treatment with the medication(s) and the prescriber has addressed any current questions or concerns. This can be done by indicating “previously” in the “How Discussed” section of Form 3.15.1 if this form is used.

- Generally, informed consent that has been obtained for medication treatment is considered to continue indefinitely unless there is a significant change in the person’s condition such that they are no longer willing or able to provide continued consent.