

POLICY & PROCEDURE



TITLE: Consent for Services				
Scope/Purpose: To ensure appropriate consent is obtained prior to procedures or treatments and that the client is properly informed of the inherent risks and hazards.				
Division/Department: All HealthPOiNT Clinics			Policy/Procedure #:	
Original Date: 10/05/2012			<input type="checkbox"/> New <input checked="" type="checkbox"/> Replacement for:	
Date Reviewed:	Date Revised:	Implementation:	CPIC Approved:	Board Approved:
	November 8, 2013	07/28/2014	07/28/2014	
Responsible Party: Director Compliance/QA; Administrator of Initiatives; Clinical COO				

DEFINITIONS:

Informed Consent

Consent that includes an explanation of the nature of the procedure or treatment; its inherent risks and hazards; its expected benefits; the reasonable alternatives, if any (and their risks, hazards, and benefits); the consequences of not receiving the procedure or treatment; and any other information that is material to the patient’s (or legal representative’s) decision to consent to, or to refuse, the procedure or treatment.

Informed consent is not required for simple and common procedures where the inherent risks, hazards, and side effects and the consequences of not receiving such procedures are commonly understood to be remote (e.g., routine lab tests).

Informed Consent Process

The informed consent process is the informed discussion or dialogue between the patient and provider performing the medical procedure or treatment. The patient must be given the opportunity to have his/her questions answered to his/her satisfaction, and after consideration of the information disclosed, the patient must voluntarily consent to the treatment or procedure prior to its performance

Capacity and Competency

A capable or competent person possesses “the ability, based on reasonable medical judgment, to understand and appreciate the nature and consequences of a treatment decision, including the significant benefits and harms of and reasonable alternatives to a proposed treatment decision.” Patients who are incapacitated or incompetent and unable to exercise their rights of self-determination and informed consent have the right to be represented by their legal representative (as their surrogate decision maker) who will protect their interests.

POLICY:

It is HealthPOiNT policy to obtain a patient's written, informed, voluntary consent to receive services prior to receiving any clinical services.

A General consent must be signed by each client in eligibility prior to seeing a provider. General consent must be signed at the time of requesting services. If a client has not been in our clinic for a period of two years or more during which the client has not received services **a new consent must be signed.**

The center will adhere to the law set forth in the Texas Administrative Code in determining which treatments and procedures require informed consent. (The treatments and procedures requiring full disclosure by a physician or health care provider to a patient or person authorized to consent for the patient are found in §601.2 - Procedures Requiring Full Disclosure of Specific Risks and Hazards—List A).

Consent information must be effectively communicated to every patient in a manner that is understandable by that patient and allows the patient to participate and make sound decisions regarding his/her medical care. The center must comply with Limited English Proficiency (LEP) regulations and address any disabilities that impair communications.

Only the patient may consent except for situations when the patient is legally unable to consent (e.g. a minor or an individual with development disability), a parent, legal guardian or a caregiver must consent.

Consent must never be obtained in a manner that could be perceived as coercive. Participant's acceptance of Family Planning services will not be subjected to coercion to receive service or to use or not to use any particular method of family planning.

PROCEDURE:

I. General Consent and Disclosure

- A. The appropriate staff member determines that the person consenting has the legal authority to consent.
- B. The disclosure and consent form is completed in accordance to the specific risks and hazards of the treatment or procedure. Informed Consent forms are available for most treatments and procedures performed at HealthPOiNT. These are in generated in accordance to Texas Medical Disclosure Panel (Procedures Requiring Full Disclosure of Specific Risks and Hazards—List A).
- C. The healthcare provider who will be performing the procedure or treatment that requires informed consent should inform the patient of the risks of the procedure or treatment as well as the risks of not receiving the procedure or treatment.
 1. The provider discusses alternative procedures and treatments as well as the risks and benefits of the alternatives.

2. The provider should also inform the patient about any circumstances under which the patient's health information must be disclosed or reported (e.g., mandatory disease reporting to the Department of State Health Services).
 3. The healthcare provider documents this education in the patient's medical record.
- D. If the patient (or the patient's legal representative) consents to the procedure or treatment, he or she should sign and date the Disclosure and Consent form.
 - E. The Disclosure and Consent form must also be completed by a witness who can attest to the patient's giving his/her informed consent prior to the treatment or procedure.
 - F. The witness to the informed consent should document in the patient's medical record that the patient's informed consent was obtained prior to the medical treatment or procedure requiring such.
 - G. The original fully completed consent form is entered into the patient's medical record.

II. Consent for Services to Minors

- A. The general rule is that parents must consent for minors (Family Code §151.001). A minor is defined as a person less than 18 years of age who has never been married.
- B. HealthPOINT providers must have proof of a parent's or guardian's consent prior to providing family planning services to a minor client.
 1. Proof of consent must be included in the minor client's medical record as required by Chapter 32 of the Texas Family Code and DSHS regulations effective January 1, 2014.
 2. Parental consent is NOT required for minors to receive pregnancy testing, HIV/STD testing, or treatment for a STD.
- C. Minor patients being treated for conditions that do not require parental consent should be warned that if their parent/guardian demands release of their medical record, the law requires the physician to do so. However, physicians may deny access to the minor's medical record if they believe that release of the information would be harmful to the physical, mental, or emotional health of the patient.
- D. Provisions in the Texas Family Code Section 32.003 allow for a minor to consent to his or her own treatment when the minor:
 1. is on active duty with armed forces of the United States;
 2. is 16 years of age or older; resides separately and apart from his or her parents, managing conservator or guardian; and manages his or her own financial affairs, regardless of the source of income;
 3. Consents to the diagnosis and treatment of any infectious, contagious, or communicable disease that is required to be reported;
 4. is unmarried and pregnant, and consents to hospital, medical or surgical care, other than abortion, related to her pregnancy;
 5. consents to examination and treatment for chemical addiction, chemical dependency, or any other condition directly related to chemical use; and/or
 6. Is unmarried, is the parent of a child, has actual custody of his or her child and consents to the medical, dental, psychological, or surgical care for the child. The minor may consent to his or her own treatment.
 7. Is serving a term of confinement in a facility operated by or under contract with the Texas Department of Criminal Justice.

8. Consents to counseling or counseling in conjunction with treatment by a physician, psychologist, counselor, or social worker if the treatment and/or counseling is for sexual abuse, physical abuse, suicide prevention, chemical addiction, dependency or abuse.

III. Procedure Specific Consents

- A. A procedure specific consent must be obtained for procedures as required by the Texas Medical Disclosure Panel.

<http://www.dshs.state.tx.us/hfp/tmdp.shtm>

<http://www.dshs.state.tx.us/hfp/rules.shtm#tmdp>

IV. Consent for HIV Tests

- A. Texas Health and Safety Code §81.105 and §81.106 is as follows:

§81.105. Informed Consent

1. Except as otherwise provided by law, a person may not perform a test designed to identify HIV or its antigen or antibody without first obtaining the informed consent of the person to be test.
2. Consent need not be written if there is documentation in the medical record that the test has been explained and the consent has been obtained.

§81.106 General Consent

1. A person who has signed a general consent form for the performance of medical tests or procedures is not required to also sign or be presented with a specific consent form relating to medical test or procedures to determine HIV infection, antibodies to HIV, or infection with any other probable causative agent of AIDS that will be performed on the person during the time in which the general consent form is in effect.
- B. Except as otherwise provided by the chapter, the result of a test or procedure to determine HIV infection, antibodies to HIV, or infection with any probable causative agent of AIDS performed under the authorization of a general consent form in accordance with this section may be used only for diagnostic or other purposes directly related to medical treatment.

V. Sterilization Procedures (Sterilization procedures require two consent forms)

- A. Family Planning clients requesting sterilization will be referred to the HealthPOiNT ABC Women's and Children's Clinic. The Clinic Manager will coordinate the procedure and coordinate with the provider. *Refer to Sterilization Services Procedure.*

B. Sterilization Consent Form

1. This consent form is provided in the Texas Medicaid Provider Procedures Manual and is the only acceptable consent form for sterilizations funded by regular Medicaid (Title XIX), the Texas Women's Health Program or DSHS Family Planning funds.
2. The federally mandated consent form necessary for both abdominal and transcervical sterilization procedures in women and vasectomy in men.
3. The individual to be sterilized must:
 - a. Be at least 21 years old at the time the consent is obtained;
 - b. Be mentally competent;
 - c. Voluntarily give his or her informed consent;
 - d. Sign the consent form at least 30 days but not more than 180 days prior to the sterilization procedure*; and
 - e. May choose a witness to be present when the consent is obtained.

*An individual may consent to be sterilized at the time of premature delivery or emergency abdominal surgery, if at least 72 hours have passed after the client gave informed consent to sterilization. In the case of premature delivery, the informed consent must have been given at least 30 days before the expected date of delivery.
4. The consent form must be signed and dated by:
 - a. The individual to be sterilized;
 - b. The interpreter, if one is provided;
(Note: the interpreter must also specify the language under his/her signature)
 - c. The person who obtains the consent; and
 - d. The physician who will perform the sterilization procedure.
5. Informed consent may not be obtained while the individual to be sterilized is:
 - a. In labor or in the process of delivering an infant or infants;
 - b. Seeking to obtain or obtaining an abortion; or
 - c. Under the influence of alcohol or other substances that affect the individual's state of awareness.

C. Texas Medical Disclosure Panel Consent

1. The TMDP Disclosure and Consent Form is required for contractors who directly perform the tubal ligation.
2. This consent is in addition to the Sterilization Consent Form.

RELATED POLICY:

Consent for Disclosure of Health Information & Consent by Proxy for Non-Urgent Care
Fertility Regulation
Male and Female Sterilization
Sterilization Services
Family Planning Sterilization Payment & Billing
Limited English Proficiency

REFERENCES:

<http://www.dshs.state.tx.us/hfp/tmdp.shtm>

<http://www.dshs.state.tx.us/hfp/rules.shtm#tmdp>
Texas Administrative Code; Title 25, Part 7, Chapter 601-, Rule §601.1
DSHS Family Planning Policy FY 2014
Texas Health and Safety Code, §166.002(4),(8) [[Definitions of “Competent” and “Incompetent,” respectively, under the Texas Advance Directives Act](#)]
TACHC

REQUIRED BY:

Texas Civil Practice and Remedies Code, Chapter 74, Medical Liability, Subchapter C, §74.102 (relating to Texas Medical Disclosure Panel).

§601.2 of this title (relating to Procedures Requiring Full Disclosure of Specific Risks and Hazards--List A).

§601.3 of this title (relating to Procedures Requiring No Disclosure of Specific Risks and Hazards--List B).

ATTACHMENTS/ENCLOSURES:

Informed Consent Forms
Addendum for Women over 35 yrs of age
Disclosure and Consent: Medical Procedures – Elective Circumcision
Disclosure and Consent: Medical Procedures – Colposcopy and Cervical Biopsy
Disclosure and Consent: Medical Procedures – Mole Removal/Biopsy
Disclosure and Consent: Medical Procedures – Incision and Drainage
Disclosure and Consent: Medical Procedures – Toenail Removal
Disclosure and Consent: Medical Procedures – Laparoscopic Tubal Ligation
Sterilization Consent Form

POLICY/PROCEDURE TRACKING FORM

TITLE: Consent for Seviles				
Scope/Purpose: To ensure appropriate consent is obtained prior to procedures or treatments and that the client is properly informed of the inherent risks and hazards				
Division/Department: All HealthPOiNT Clinics			Policy/Procedure #:	
Original Date: 10/05/2012			<input type="checkbox"/> New <input checked="" type="checkbox"/> Replacement for: Same	
Date Reviewed:	Date Revised:	Implementation:	CPIC Approved:	Board Approved:
11/08/2013	11/27/2013	07/28/2014	07/28/2014	
Date of Revision	Description of Changes			
11/08/2013	DSHS updates- Minors must get parental permission prior to providing family planning services and to receive a prescription contraceptive			
11/08/2013	Sterilization consent added. Removed Method Specific consent as no longer required with 2014 DSHS Family Planning standards.			
11/27/2013	Must have proof of parental/guardian's consent prior to Family Planning services to minors age 17 & younger (per DSHS memo for Jan 1,2014 revision). Removed Title X information.			