By: Uresti S.B. No. 450

(In the Senate - Filed February 5, 2007; February 21, 2007, read first time and referred to Committee on Health and Human Services; April 2, 2007, reported adversely, with favorable Committee Substitute by the following vote: Yeas 8, Nays 0; April 2, 2007, sent to printer.)

COMMITTEE SUBSTITUTE FOR S.B. No. 450 By: Uresti

A BILL TO BE ENTITLED
AN ACT

relating to enrollment and participation in certain research programs of certain children in foster care.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Section 266.001, Family Code, as added by Chapter 268, Acts of the 79th Legislature, Regular Session, 2005, is amended by adding Subdivisions (2-a) and (4-a) to read as follows:

(2-a) "Drug research program" means any clinical trial, clinical investigation, drug study, or active medical or clinical research that has been approved by an institutional review board in accordance with the standards provided in the Code of Federal Regulations, 45 C.F.R. Sections 46.404 through 46.407, regarding:

(A) an investigational new drug; or

(B) the efficacy of an approved drug.

(4-a) "Investigational new drug" has the meaning assigned by 21 C.F.R. Section 312.3(b).

SECTION 2. Subchapter A, Chapter 266, Family Code, as added by Chapter 268, Acts of the 79th Legislature, Regular Session, 2005, is amended by adding Section 266.0041 to read as follows:

Sec. 266.0041. ENROLLMENT AND PARTICIPATION IN CERTAIN RESEARCH PROGRAMS. (a) Notwithstanding Section 266.004, a person may not authorize the enrollment of a foster child or consent to the participation of a foster child in a drug research program without a court order as provided by this section.

(b) Before issuing an order authorizing the enrollment or participation of a foster child in a drug research program, the court must:

(1) appoint an independent medical advocate;

(2) review the report filed by the independent medical advocate regarding the advocate's opinion and recommendations concerning the foster child's enrollment and participation in the drug research program;

(3) consider whether the person conducting the drug research program:

(A) informed the foster child in a developmentally appropriate manner of the expected benefits of the drug research program, any potential side effects, and any available alternative treatments and received the foster child's assent to enroll the child to participate in the drug research program as required by the Code of Federal Regulations, 45 C.F.R. Section 46.408; or

(B) received informed consent in accordance with Subsection (h); and

(4) determine whether enrollment and participation in the drug research program is in the foster child's best interest.

(c) An independent medical advocate appointed under Subsection (b) is not a party to the suit but may:

(1) conduct an investigation regarding the foster child's participation in a drug research program to the extent that the advocate considers necessary to determine:

(A) whether the foster child assented to or provided informed consent to the child's enrollment and participation in the drug research program; and

(B) the best interest of the child for whom the advocate is appointed; and

(2) obtain and review copies of the foster child's relevant medical and psychological records and information describing the risks and benefits of the child's enrollment and participation in the drug research program.

(d) An independent medical advocate shall, within a reasonable time after the appointment, interview:

(1) the foster child in a developmentally appropriate manner, if the child is four years of age or older;

(2) the foster child's parent, if the parent is entitled to notification under Section 266.005;

(3) an advocate appointed by an institutional review board in accordance with the Code of Federal Regulations, 45 C.F.R. Section 46.409(b), if an advocate has been appointed;

(4) the medical team treating the foster child as well as the medical team conducting the drug research program; and

(5) each individual who has significant knowledge of the foster child's medical history and condition, including any foster parent of the child.

(e) After reviewing the information collected under Subsections (c) and (d), the independent medical advocate shall:

(1) submit a report to the court presenting the advocate's opinion and recommendation regarding whether:

(A) the foster child assented to or provided informed consent to the child's enrollment and participation in the drug research program; and

(B) the foster child's best interest is served by enrollment and participation in the drug research program; and

(2) at the request of the court, testify regarding the basis for the advocate's opinion and recommendation concerning the foster child's enrollment and participation in a drug research program.

(f) The court may appoint any person eligible to serve as the foster child's guardian ad litem, as defined by Section 107.001, as the independent medical advocate, except that a foster parent, employee of a substitute care provider or child placing agency providing care for the foster child, representative of the department, medical professional affiliated with the drug research program, independent medical advocate appointed by an institutional review board, or any person the court determines has a conflict of interest may not serve as the foster child's independent medical advocate.

(g) A person otherwise authorized to consent to medical care for a foster child may petition the court for an order permitting the enrollment and participation of a foster child in a drug research program under this section.

(h) Before a foster child, who is at least 16 years of age and has been determined to have the capacity to consent to medical care in accordance with Section 266.010, may be enrolled to participate in a drug research program, the person conducting the drug research program must:

(1) inform the foster child in a developmentally appropriate manner of the expected benefits of participation in the drug research program, any potential side effects, and any available alternative treatments; and

(2) receive written informed consent to enroll the foster child for participation in the drug research program.

(i) A court may render an order approving the enrollment or participation of a foster child in a drug research program involving an investigational new drug before appointing an independent medical advocate if:

(1) a physician recommends the foster child's enrollment or participation in the drug research program to provide the foster child with treatment that will prevent the death or serious injury of the child; and

(2) the court determines that the foster child needs the treatment before an independent medical advocate could complete an investigation in accordance with this section.

(j) As soon as practicable after issuing an order under Subsection (i), the court shall appoint an independent medical advocate to complete a full investigation of the foster child's enrollment and participation in the drug research program in accordance with this section.

(k) This section does not apply to:

(1) a drug research study regarding the efficacy of an approved drug that is based only on medical records, claims data, or outcome data, including outcome data gathered through interviews with a child, caregiver of a child, or a child's treating professional;

(2) a retrospective drug research study based only on medical records, claims data, or outcome data; or

(3) the treatment of a foster child with an investigational new drug that does not require the child's enrollment or participation in a drug research program.

(l) The department shall annually submit to the governor, lieutenant governor, speaker of the house of representatives, and the relevant committees in both houses of the legislature, a report regarding:

(1) the number of foster children who enrolled or participated in a drug research program during the previous year;

(2) the purpose of each drug research program in which a foster child was enrolled or participated; and

(3) the number of foster children for whom an order was issued under Subsection (i).

SECTION 3. Subsection (b), Section 266.005, Family Code, as added by Chapter 268, Acts of the 79th Legislature, Regular Session, 2005, is amended to read as follows:

(b) Except as provided by Subsection (c), the department shall make reasonable efforts to notify the child's parents within 24 hours of:

(1) a significant medical condition involving a foster child; and

(2) the enrollment or participation of a foster child in a drug research program under Section 266.0041.

SECTION 4. The change in law made by this Act by the enactment of Section 266.0041, Family Code, applies only to the enrollment and participation of a foster child in a drug research program on or after the effective date of this Act. A foster child enrolled or participating in a drug research program before the effective date of this Act is governed by the law in effect when the foster child was enrolled or began participating in the drug research program, and the former law is continued in effect for that purpose.

SECTION 5. This Act takes effect September 1, 2007.

* * * * *