

SENATE BILL 1398

By Swann

AN ACT to amend Tennessee Code Annotated, Title 68,
relative to rare diseases afflicting children.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 68, Chapter 1, is amended by adding the following as a new part:

68-1-2601. This part is known and may be cited as the "Access to Pediatric Rare Disease Treatment Information Act."

68-1-2602. As used in this part:

(1) "Essential treatment information" means all treatment information pertaining to patients who are under eighteen (18) years of age at the time they are diagnosed with any form of cancer, including, but not limited to, leukemia (all types), glioma, lymphoma, medulloblastoma, neuroblastoma, osteosarcoma, sarcoma, and Wilms tumor;

(2) "Participating institution" means an institution, within or without this state, that elects to maintain essential treatment information, and issues a statement of participation;

(3) "Participating state" means a state in the United States that has a law that is substantially similar to this part;

(4) "Participation obligation" means the obligation assumed by a participating institution under this part;

(5) "Provide" means to deliver in writing by United States mail, common carrier, or by email or other electronic means;

(6) "Statement of participation" means a statement to the commissioner of health whereby a hospital or other institution declares its intention and ability to be a participating institution. The statement of participation must include the words: "[name of institution] is prepared to maintain essential treatment information in compliance with Tennessee Code Annotated, Title 68, Chapter 1, Part 26, and accordingly declares that it is a participating institution as that term is defined by the Access to Pediatric Rare Disease Treatment Information Act"; and

(7) "Treatment information" means the following items of information, with respect to a given patient:

- (A) All prior zip codes where the patient has resided from birth and the period that the patient resided at each zip code;
- (B) Date of diagnosis;
- (C) Date of recurrence of cancer, if applicable;
- (D) Diagnosis;
- (E) Drug therapies administered;
- (F) Entry into clinical trials;
- (G) Images taken, whether by X-ray, MRI, CAT scan or other means;
- (H) Outcome of treatment;
- (I) Radiation administered; and
- (J) Zip code where the patient resided at the time of diagnosis.

68-1-2603. An institution that desires to be a participating institution and can meet its participation obligation shall issue a written statement of participation. The statement of participation must be delivered to the commissioner of health and must either be posted by the institution on a website accessible by the public or be forwarded by the institution in writing to

every hospital in this state that has in excess of one hundred (100) beds and provides inpatient care to patients under eighteen (18) years of age.

68-1-2604. A participating institution shall maintain all essential treatment information with respect to patients admitted for care after January 1, 2022, or following issuance of a statement of participation, whichever is earlier. Upon receipt of a written request by another participating institution, a participating institution shall provide all requested essential treatment information to the requesting participating institution within ten (10) days.

68-1-2605.

(a) A participating institution that, upon receipt of a participation request from another participating institution, cannot timely fulfill the participation request, shall provide the requesting institution, within ten (10) days from the date of the original request, either a statement of variance or a statement of incapacity.

(b) A statement of variance must state the date on which the participating institution can fulfill the participation request, not to exceed sixty (60) days, and state the reason that the participating institution requires more than ten (10) days to fulfill the participation request.

68-1-2606. A statement of incapacity must state that the participating institution cannot fulfill the participation request in whole or in part. At its sole discretion, a participating institution may include in its statement of incapacity the reason that the participating institution cannot fulfill the request; the actions being taken by the participating institution, if any, to develop the capacity to fulfill such information requests in the future; the expected date that the participating institution will have developed such capacity; and any other information that the participating institution deems informative.

68-1-2607. A participating institution may satisfy a participation request by providing a requesting participating institution access to a database containing the essential treatment

information requested by that participating institution. The database may be on the internet, on a proprietary network, or in another configuration that permits access by participating institutions at the discretion of the participating institution using the database to satisfy participation requests.

68-1-2608. Statements of incapacity and the participation requests to which the statements of incapacity are directed, as well as minutes of the advisory board, with any appendices, are public records as defined in § 10-7-301. A copy of any statement of incapacity, along with a copy of the participation request to which the statement of incapacity is directed, must be provided, within a reasonable time not to exceed sixty (60) days from the date the statement of incapacity was sent to the participating institution making the participation request, to the commissioner of health and the division of records management of the department of state.

68-1-2609. An advisory board shall provide nonbinding guidance with respect to implementation of this part. The appointees are to be selected as follows: two (2) members selected by St. Jude Children's Research Hospital, if it is a participating institution; two (2) members selected by the Monroe Carell, Jr. Children's Hospital at Vanderbilt, if it is a participating institution; one (1) board member selected by each additional participating institution located in this state; and two (2) members selected by the governor to represent patients and other interested members of the public, as determined by the governor at the governor's discretion. The commissioner of health and each of Tennessee's appointees to the National Conference of Commissioners on Uniform State Laws are nonvoting members of the advisory board. The advisory board must have a chair, vice chair, and secretary, to be elected by the members of the advisory board.

68-1-2610. The advisory board shall meet once per year and at such other times as the advisory board deems useful, to be determined at the discretion of the advisory board. The time

and location of any meeting must be determined by the advisory board. A member of the advisory board may participate in its meetings via telephone or other electronic means; however, advisory board members shall make their best effort to attend meetings in person.

68-1-2611. At the required annual meeting, the advisory board shall elect its chair, vice chair, and secretary. The advisory board shall, at its discretion, discuss ways and means whereby participating institutions can expeditiously maintain treatment information, fulfill participation requests, and otherwise contribute to increasing the seamless flow of vital information among participating institutions. In addition, at the request of any member of the advisory board, the advisory board shall address any statement of incapacity issued during the two-year period prior to the annual meeting and, at the discretion of the advisory board, issue a statement regarding the cause for the participating institution's issuance of the statement of incapacity and plans to alleviate that cause and provide for the timely fulfillment of similar participation requests in the future. The advisory board may also address any other subject at its discretion. The secretary of the advisory board shall summarize its proceedings in minutes, which must be provided to all members of the advisory board, voting and nonvoting, within sixty (60) days following the conclusion of the required annual meeting of the advisory board. Any member of the advisory board may distribute a comment to the minutes to all members of the advisory board within ten (10) days of receiving the minutes from the secretary, which comments will be deemed an appendix to the minutes of the advisory board.

68-1-2612. The members of the advisory board shall not be compensated by the state or any subdivision thereof for their participation on the advisory board or for expenses incurred in connection with that participation.

68-1-2613. The requirements of this part are in addition to any imposed by federal law or the law of this state. This part does not slow, inhibit, or restrict transfers of information among participating institutions, between participating institutions and other entities, or between

participating institutions and the public. This part does not require or authorize the violation of any applicable federal or state law concerning the privacy or confidentiality of patient information.

SECTION 2. This act takes effect upon becoming a law, the public welfare requiring it.