

§ 84.55 Procedures relating to health care for infants with disabilities.

(a) *Infant Care Review Committees.* The Department encourages each recipient health care provider that provides health care services to infants in programs or activities receiving Federal financial assistance to establish an Infant Care Review Committee (ICRC) to assist the provider in delivering health care and related services to infants and in complying with this part. The purpose of the committee is to assist the health care provider in the development of standards, policies and procedures for providing treatment to infants with disabilities and in making decisions concerning medically beneficial treatment in specific cases. While the Department recognizes the value of ICRC's in assuring appropriate medical care to infants, such committees are not required by this section. An ICRC should be composed of individuals representing a broad range of perspectives, and should include a practicing physician, a representative of a disability organization, a practicing nurse, and other individuals. A suggested model ICRC is set forth in paragraph (f) of this section.

(b)-(e) [Reserved]

(f) *Model Infant Care Review Committee.* Recipient health care providers wishing to establish Infant Care Review Committees should consider adoption of the following model. This model is advisory. Recipient health care providers are not required to establish a review committee or, if one is established, to adhere to this model. In seeking to determine compliance with this part, as it relates to health care for infants with disabilities, by health care providers that have an ICRC established and operated substantially in accordance with this model, the Department will, to the extent possible, consult with the ICRC.

(1) *Establishment and purpose.* (i) The hospital establishes an Infant Care Review Committee (ICRC) or joins with one or more other hospitals to create a joint ICRC. The establishing document will state that the ICRC is for the purpose of facilitating the development and implementation of standards, policies and procedures designed to assure that, while respecting reasonable medical judgments, treatment and nourishment not be withheld, solely on the basis of present or anticipated physical or mental impairments, from infants with disabilities who, in spite of such impairments, will benefit medically from the treatment or nourishment.

(ii) The activities of the ICRC will be guided by the following principles:

(A) The interpretative guidelines of the Department relating to the applicability of this part to health care for infants with disabilities.

(B) As stated in the "Principles of Treatment of Disabled Infants" of the coalition of major medical and disability organizations, including the American Academy of Pediatrics, National Association of Children's Hospitals and Related Institutions, Association for Retarded Citizens, Down's Syndrome Congress, Spina Bifida Association, and others:

When medical care is clearly beneficial, it should always be provided. When appropriate medical care is not available, arrangements should be made to transfer the infant to an appropriate medical facility. Consideration such as anticipated or actual limited potential of an individual and present or future lack of available community resources are irrelevant and must not determine the

decisions concerning medical care. The individual's medical condition should be the sole focus of the decision. These are very strict standards.

It is ethically and legally justified to withhold medical or surgical procedures which are clearly futile and will only prolong the act of dying. However, supportive care should be provided, including sustenance as medically indicated and relief of pain and suffering. The needs of the dying person should be respected. The family also should be supported in its grieving.

In cases where it is uncertain whether medical treatment will be beneficial, a person's disability must not be the basis for a decision to withhold treatment. At all times during the process when decisions are being made about the benefit or futility of medical treatment, the person should be cared for in the medically most appropriate ways. When doubt exists at any time about whether to treat, a presumption always should be in favor of treatment.

(C) As stated by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research:

This [standard for providing medically beneficial treatment] is a very strict standard in that it excludes consideration of the negative effects of an impaired child's life on other persons, including parents, siblings, and society. Although abiding by this standard may be difficult in specific cases, it is all too easy to undervalue the lives of infants with disabilities; the Commission finds it imperative to counteract this by treating them no less vigorously than their healthy peers or than older children with similar disabilities would be treated.

(iii) The ICRC will carry out its purposes by:

(A) Recommending institutional policies concerning the withholding or withdrawal of medical or surgical treatments to infants, including guidelines for ICRC action for specific categories of life-threatening conditions affecting infants;

(B) Providing advice in specific cases when decisions are being considered to withhold or withdraw from infant life-sustaining medical or surgical treatment; and

(C) Reviewing retrospectively on a regular basis infant medical records in situations in which life-sustaining medical or surgical treatment has been withheld or withdrawn.

(2) *Organization and staffing.* The ICRC will consist of at least 7 members and include the following:

(i) A practicing physician (e.g., a pediatrician, a neonatologist, or a pediatric surgeon),

(ii) A practicing nurse,

(iii) A hospital administrator,

(iv) A representative of the legal profession,

(v) A representative of a disability group, or a developmental disability expert,

(vi) A lay community member, and

(vii) A member of a facility's organized medical staff, who shall serve as chairperson.

In connection with review of specific cases, one member of the ICRC shall be designated to act as "special advocate" for the infant, as provided in paragraph (f)(3)(ii)(E) of the section. The hospital will provide staff support for the ICRC, including legal counsel. The ICRC will meet on a regular basis, or as required below in connection with review of specific cases. It shall adopt or recommend to the appropriate hospital official or body such administrative policies as terms of office and quorum requirements. The ICRC will recommend procedures to ensure that both hospital personnel and patient families are fully informed of the existence and functions of the ICRC and its availability on a 24-hour basis.

(3) *Operation of ICRC*—(i) *Prospective policy development*. (A) The ICRC will develop and recommend for adoption by the hospital institutional policies concerning the withholding or withdrawal of medical treatment for infants with life-threatening conditions. These will include guidelines for management of specific types of cases or diagnoses, for example, Down's syndrome and spina bifida, and procedures to be followed in such recurring circumstances as, for example, brain death and parental refusal to consent to life-saving treatment. The hospital, upon recommendation of the ICRC, may require attending physicians to notify the ICRC of the presence in the facility of an infant with a diagnosis specified by the ICRC, e.g., Down's syndrome and spina bifida.

(B) In recommending these policies and guidelines, the ICRC will consult with medical and other authorities on issues involving disabled individuals, e.g., neonatologists, pediatric surgeons, county and city agencies which provide services for the disabled, and disability advocacy organizations. It will also consult with appropriate committees of the medical staff, to ensure that the ICRC policies and guidelines build on existing staff by-laws, rules and regulations concerning consultations and staff membership requirements. The ICRC will also inform and educate hospital staff on the policies and guidelines it develops.

(ii) *Review of specific cases*. In addition to regularly scheduled meetings, interim ICRC meetings will take place under specified circumstances to permit review of individual cases. The hospital will, to the extent possible, require in each case that life-sustaining treatment be continued, until the ICRC can review the case and provide advice.

(A) Interim ICRC meetings will be convened within 24 hours (or less if indicated) when there is disagreement between the family of an infant and the infant's physician as to the withholding or withdrawal of treatment, when a preliminary decision to withhold or withdraw life-sustaining treatment has been made in certain categories of cases identified by the ICRC, when there is disagreement between members of the hospital's medical and/or nursing staffs, or when otherwise appropriate.

(B) Such interim ICRC meetings will take place upon the request of any member of the ICRC or hospital staff or parent or guardian of the infant. The ICRC will have procedures to preserve the

confidentiality of the identity of persons making such requests, and such persons shall be protected from reprisal. When appropriate, the ICRC or a designated member will inform the requesting individual of the ICRC's recommendation.

(C) The ICRC may provide for telephone and other forms of review when the timing and nature of the case, as identified in policies developed by the ICRC, make the convening of an interim meeting impracticable.

(D) Interim meetings will be open to the affected parties. The ICRC will ensure that the interests of the parents, the physician, and the child are fully considered; that family members have been fully informed of the patient's condition and prognosis; that they have been provided with a listing which describes the services furnished by parent support groups and public and private agencies in the geographic vicinity to infants with conditions such as that before the ICRC; and that the ICRC will facilitate their access to such services and groups.

(E) To ensure a comprehensive evaluation of all options and factors pertinent to the committee's deliberations, the chairperson will designate one member of the ICRC to act, in connection with that specific case, as special advocate for the infant. The special advocate will seek to ensure that all considerations in favor of the provision of life-sustaining treatment are fully evaluated and considered by the ICRC.

(F) In cases in which there is disagreement on treatment between a physician and an infant's family, and the family wishes to continue life-sustaining treatment, the family's wishes will be carried out, for as long as the family wishes, unless such treatment is medically contraindicated. When there is physician/family disagreement and the family refuses consent to life-sustaining treatment, and the ICRC, after due deliberation, agrees with the family, the ICRC will recommend that the treatment be withheld. When there is physician/family disagreement and the family refuses consent, but the ICRC disagrees with the family, the ICRC will recommend to the hospital board or appropriate official that the case be referred immediately to an appropriate court or child protective agency, and every effort shall be made to continue treatment, preserve the status quo, and prevent worsening of the infant's condition until such time as the court or agency renders a decision or takes other appropriate action. The ICRC will also follow this procedure in cases in which the family and physician agree that life-sustaining treatment should be withheld or withdrawn, but the ICRC disagrees.

(iii) *Retrospective record review.* The ICRC, at its regularly-scheduled meeting, will review all records involving withholding or termination of medical or surgical treatment to infants consistent with hospital policies developed by the ICRC, unless the case was previously before the ICRC pursuant to paragraph (f)(3)(ii) of this section. If the ICRC finds that a deviation was made from the institutional policies in a given case, it shall conduct a review and report the findings to appropriate hospital personnel for appropriate action.

(4) *Records.* The ICRC will maintain records of all of its deliberations and summary descriptions of specific cases considered and the disposition of those cases. Such records will be kept in accordance with institutional policies on confidentiality of medical information. They will be

made available to appropriate government agencies, or upon court order, or as otherwise required by law.

Note:

The mandatory provisions set forth in paragraphs (b)-(e) inclusive of this section are subject to an injunction prohibiting their enforcement. In *Bowen v. American Hospital Association*, _____ U.S. _____, 106 S. Ct. 2101 (1986), the Supreme Court upheld the action of a United States District Court, 585 F. Supp. 541 (S.D.N.Y. 1984), declaring invalid and enjoining enforcement of provisions under this section, promulgated January 12, 1984.

(Information collection requirements contained in paragraph (c) have been approved by the Office of Management and Budget under control number 0990-0114) [49 FR 1651, Jan. 12, 1984, as amended at 52 FR 3012, Jan. 30, 1987; 70 FR 24320, May 9, 2005; 89 FR 40188, May 9, 2024]