CHAPTER XIII--OFFICE OF HUMAN DEVELOPMENT SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 1340--CHILD ABUSE AND NEGLECT PREVENTION AND TREATMENT

[Code of Federal Regulations]

[Title 45, Volume 4]
[Revised as of October 1, 2002]
From the U.S. Government Printing Office via GPO Access
[CITE: 45CFR1340.1]

TITLE 45--PUBLIC WELFARE

CHAPTER XIII--OFFICE OF HUMAN DEVELOPMENT SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 1340--CHILD ABUSE AND NEGLECT PREVENTION AND TREATMENT--Table of Contents

Subpart A--General Provisions

Sec. 1340.1 Purpose and scope.

(a) This part implements the Child Abuse Prevention and Treatment Act (``Act''). As authorized by the Act, the National Center on Child Abuse and Neglect seeks to assist agencies and organizations at the national, State and community levels in their efforts to improve and expand child abuse and neglect prevention and treatment activities.

(b) The National Center on Child Abuse and Neglect seeks to meet these goals through:

(1) Conducting activities directly (by the Center);

(2) Making grants to States to improve and expand their child abuse and neglect prevention and treatment programs;

(3) Making grants to and entering into contracts for: Research, demonstration and service improvement programs and projects, and training, technical assistance and informational activities; and

(4) Coordinating Federal activities related to child abuse and neglect. This part establishes the standards and procedures for conducting the grant funded activities and contract and coordination activities.

(c) Requirements related to child abuse and neglect applicable to programs assisted under title IV-B of the Social Security Act are implemented by regulation at 45 CFR parts 1355 and 1357.

(d) Federal financial assistance is not available under the Act for the construction of facilities.

[48 FR 3702, Jan. 26, 1983, as amended at 52 FR 3994, Feb. 6, 1987; 55

FR 27639, July 5, 1990]

PART 1340--CHILD ABUSE AND NEGLECT PREVENTION AND TREATMENT--Table of Contents

Subpart A--General Provisions

Sec. 1340.2 Definitions.

For the purposes of this part:

(a) A properly constituted authority is an agency with the legal power and responsibility to perform an investigation and take necessary steps to prevent and treat child abuse and neglect. A properly constituted authority may include a legally mandated, public or private child protective agency, or the police, the juvenile court or any agency thereof.

(b) Act means the Child Abuse Prevention and Treatment Act, 42 U.S.C. 5101, et seq.

(c) Center means the National Center on Child Abuse and Neglect established by the Secretary under the Act to administer this program.

(d) Child abuse and neglect means the physical or mental injury, sexual abuse or exploitation, negligent treatment, or maltreatment of a child under the age of eighteen, or the age specified by the child protection law of the State, by a person including any employee of a residential facility or any staff person providing out of home care who is responsible for the child's welfare under circumstances indicating harm or threatened harm to the child's health or welfare. The term encompasses both acts and omissions on the part of a responsible person.

(1) The term sexual abuse includes the following activities under circumstances which indicate that the child's health or welfare is harmed or threatened with harm: The employment, use, persuasion, inducement, enticement, or coercion of any child to engage in, or having a child assist any other person to engage in, any sexually explicit conduct (or any simulation of such conduct) for the purpose of producing any visual depiction of such conduct; or the rape, molestation, prostitution, or other form of sexual exploitation of children, or incest with children. With respect to the definition of sexual abuse, the term ``child'' or ``children'' means any individual who has not attained the age of eighteen.

(2)(i) ``Negligent treatment or maltreatment'' includes failure to provide adequate food, clothing, shelter, or medical care.

(ii) Nothing in this part should be construed as requiring or prohibiting a finding of negligent treatment or maltreatment when a parent practicing his or her religious beliefs does not, for that reason alone, provide medical treatment for a child; provided, however, that if such a finding is

prohibited, the prohibition shall not limit the administrative or judicial authority of the State to ensure that medical services are provided to the child when his health requires it.

(3) Threatened harm to a child's health or welfare means a substantial risk of harm to the child's health or welfare.

(4) A person responsible for a child's welfare includes the child's parent, guardian, foster parent, an employee of a public or private residential home or facility or other person legally responsible under State law for the child's welfare in a residential setting, or any staff person providing out of home care. For purposes of this definition, out-of-home care means child day care, i.e., family day care, group day care, and center-based day care; and, at State option, any other settings in which children are provided care.

(e) Commissioner means the Commissioner of the Administration for Children, Youth and Families of the Department of Health and Human Services.

(f) Grants includes grants and cooperative agreements.

(g) Secretary means the Secretary of Health and Human Services, or other HHS official or employee to whom the Secretary has delegated the authority specified in this part.

(h) State means each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and the Trust Territory of the Pacific Islands.

[48 FR 3702, Jan. 26, 1983, as amended at 52 FR 3994, Feb. 6, 1987; 55 FR 27639, July 5, 1990]

Sec. 1340.3 Applicability of Department-wide regulations.

(a) The following HHS regulations are applicable to all grants made under this part:

45 CFR Part 16--Procedures of the Departmental Grant Appeals Board.
45 CFR Part 46--Protection of human subjects
45 CFR Part 74--Administration of grants
45 CFR Part 75--Informal grant appeals procedures
45 CFR Part 80--Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services--effectuation of title VI of the Civil Rights Act of 1964
45 CFR Part 81--Practice and procedure for hearings under part 80
45 CFR Part 84--Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance.

(b) The following regulations are applicable to all contracts awarded under this part:

48 CFR Chapter 1--Federal Acquisition Regulations.
48 CFR Chapter 3--Federal Acquisition Regulations--Department of Health and Human Services.

[48 FR 3702, Jan. 26, 1983, as amended at 52 FR 3995, Feb. 6, 1987]

Sec. 1340.4 Coordination requirements.

All Federal agencies responsible for programs related to child abuse and neglect shall provide information as required by the Commissioner to insure effective coordination of efforts.

Sec. 1340.10 Purpose of this subpart.

This subpart sets forth the requirements and procedures States must meet in order to receive grants to develop, strengthen, and carry out State child abuse and neglect prevention and treatment programs under section 107 of the Act.
[55 FR 27639, July 5, 1990]

Sec. 1340.11 Allocation of funds available.

(a) The Commissioner shall allocate the funds available for grants to States for each fiscal year among the States on the basis of the following formula:

(1) An amount of $25,000 or such other amount as the Commissioner may determine; plus

(2) An additional amount bearing the same ratio to the total amount made available for this purpose (reduced by the minimum amounts allocated to the States under paragraph (a)(1) of this section) as the number of children under the age of eighteen in each State bears to the total number of children under eighteen in all the States. Annual estimates of the number of children under the age of eighteen, provided by the Bureau of the Census of the Department of Commerce, are used in making this determination.

(b) If a State has not qualified for assistance under the Act and this subpart prior to a date designated by the Commissioner in each fiscal year, the amount previously allocated to the State shall be allocated among the eligible States.

Sec. 1340.12 Application process.

(a) The Governor of the State may submit an application or designate the State office, agency, or organization which may apply for assistance under this subpart. The State office, agency, or organization need not be limited in its mandate or activities to child abuse and neglect.

(b) Grant applications must include a description of the activities presently conducted by the State and its political subdivisions in preventing and treating child abuse and neglect, the activities to be assisted under the grant, a statement of how the proposed activities are expected to improve or expand child abuse prevention and treatment programs in the State, and other information required by the Commissioner in compliance with the paperwork reduction requirements of 44 U.S.C. chapter 35 and any applicable directives issued by the Office of Management and Budget.

(c) States shall provide with the grant application a statement signed by the Governor that the State meets the requirements of the Act and of this subpart. This statement shall be in the form and include the documentation required by the Commissioner.

Sec. 1340.13 Approval of applications.

(a) The Commissioner shall approve an application for an award for funds under this subpart if he or she finds that:

(1) The State is qualified and has met all requirements of the Act and Sec. 1340.14 of this part, except for the definitional requirement of Sec. 1340.14(a) with regard to the definition of ``sexual abuse'' (see Sec. 1340.2(d)(1)) and the definitional requirement of negligent treatment as it relates to the failure to provide adequate medical care (see Sec. 1340.2(d)(2)). The State must include these two definitional requirements in its definition of child abuse and neglect either by statute or regulation having the force and effect of law no later than the close of the second general legislative session of the State legislature following February 25, 1983;

(2) Either by statute or regulation having the force and effect of law, the State modifies its definition of ``child abuse and neglect'' to provide that the phrase ``person responsible for a child's welfare'' includes an employee of a residential facility or a staff person providing out-of-home care no later than the close of the first general legislative session of the State legislature which convenes following February 6, 1987;

(3) The funds are to be used to improve and expand child abuse or neglect prevention or treatment programs; and

(4) The State is otherwise in compliance with these regulations.

(b) At the time of an award under this subpart, the amount of funds not obligated from an award made eighteen or more months previously shall be subtracted from the amount of funds under the award, unless the Secretary determines that extraordinary reasons justify the failure to

so obligate.

[48 FR 3702, Jan. 26, 1983, as amended at 52 FR 3995, Feb. 6, 1987; 55 FR 27639, July 5, 1990]

Sec. 1340.14 Eligibility requirements.

In order for a State to qualify for an award under this subpart, the State must meet the requirements of Sec. 1340.15 and satisfy each of the following requirements:

(a) State must satisfy each of the requirements in section 107(b) of the Act.

(b) Definition of Child Abuse and Neglect. Wherever the requirements below use the term ``Child Abuse and Neglect'' the State must define that term in accordance with Sec. 1340.2. However, it is not necessary to adopt language identical to that used in Sec. 1340.2, as long as the definition used in the State is the same in substance.

(c) Reporting. The State must provide by statute that specified persons must report and by statute or administrative procedure that all other persons are permitted to report known and suspected instances of child abuse and neglect to a child protective agency or other properly constituted authority.

(d) Investigations. The State must provide for the prompt initiation of an appropriate investigation by a child protective agency or other properly constituted authority to substantiate the accuracy of all reports of known or suspected child abuse or neglect. This investigation may include the use of reporting hotlines, contact with central registers, field investigations and interviews, home visits, consultation with other agencies, medical examinations, psychological and social evaluations, and reviews by multidisciplinary teams. (e) Institutional child abuse and neglect. The State must have a statute or administrative procedure requiring that when a report of known or suspected child abuse or neglect involves the acts or omissions of the agency, institution, or facility to which the report would ordinarily be made, a different properly constituted authority must receive and investigate the report and take appropriate protective and corrective action.

(f) Emergency services. If an investigation of a report reveals that the reported child or any other child under the same care is in need of immediate protection, the State must provide emergency services to protect the child's health and welfare. These services may include emergency caretaker or homemaker services; emergency shelter care or medical services; review by a multidisciplinary team; and, if appropriate, criminal or civil court action to protect the child, to help the parents or guardians in their responsibilities and, if necessary, to remove the child from a dangerous situation.

(g) Guardian ad litem. In every case involving an abused or neglected child which results in a judicial proceeding, the State must insure the appointment of a guardian ad litem or other individual whom the State recognizes as fulfilling the same functions as a guardian ad litem, to represent and protect the rights and best interests of the child. This requirement may be satisfied: (1) By a statute mandating the appointments; (2) by a statute permitting the appointments, accompanied by a statement from the Governor that the appointments are made in every case; (3) in the absence of a specific statute, by a formal opinion of the Attorney General that the appointments are permitted, accompanied by a Governor's statement that the appointments are made in every case; or (4) by the State's Uniform Court Rule mandating appointments in every case. However, the guardian ad litem shall not be the attorney responsible for presenting the evidence alleging child abuse or neglect.

(h) Prevention and treatment services. The State must demonstrate that it has throughout the State procedures and services deal with child abuse and neglect cases. These procedures and services include the determination of social service and medical needs and the provision of needed social and medical services.

(i) Confidentiality. (1) The State must provide by statute that all records concerning reports and reports of child abuse and neglect are confidential and that their unauthorized disclosure is a criminal offense.

(2) If a State chooses to, it may authorize by statute disclosure to any or all of the following persons and agencies, under limitations and procedures the State determines:

(i) The agency (agencies) or organizations (including its designated multidisciplinary case consultation team) legally mandated by any Federal or State law to receive and investigate reports of known and suspected child abuse and neglect;

(ii) A court, under terms identified in State statute;

(iii) A grand jury;

(iv) A properly constituted authority (including its designated multidisciplinary case consultation team) investigating a report of known or suspected child abuse or neglect or providing services to a child or family which is the subject of a report;

(v) A physician who has before him or her a child whom the physician reasonably suspects may be abused or neglected;

(vi) A person legally authorized to place a child in protective custody when the person has before him or her a child whom he or she reasonably suspects may be abused or neglected and the person requires the information in the report or record in order to determine whether to place the child in protective custody;

(vii) An agency authorized by a properly constituted authority to diagnose, care for, treat, or supervise a child who is the subject of a report or record of child abuse or neglect;

(viii) A person about whom a report has been made, with protection for the identity of any person reporting known or suspected child abuse or neglect and any other person where the person or agency making the information available finds that disclosure of the information would be likely to endanger the life or safety of such person;

(ix) A child named in the report or record alleged to have been abused or neglected or (as his/her representative) his/her guardian or guardian ad litem;

(x) An appropriate State or local official responsible for administration of the child protective service or for oversight of the enabling or appropriating legislation, carrying out his or her official functions; and

(xi) A person, agency, or organization engaged in a bonafide research or evaluation project, but without information identifying individuals named in a report or record, unless having that information open for review is essential to the research or evaluation, the appropriate State official gives prior written approval, and the child, through his/her representative as cited in paragraph (i) of this section, gives permission to release the information.

(3) If a State chooses, it may authorize by statute disclosure to additional persons and agencies, as determined by the State, for the purpose of carrying out background and/or employment-related screening of individuals who are or may be engaged in specified categories of child related activities or employment. Any information disclosed for this purpose is subject to the confidentiality requirements in paragraph (i)(1) and may be subject to additional safeguards as determined by the State.

(4) Nothing in this section shall be interpreted to prevent the properly constituted authority from summarizing the outcome of an investigation to the person or official who reported the known or suspected instances of child abuse or neglect or to affect a State's laws or procedures concerning the confidentiality of its criminal court or its criminal justice system.

(5) HHS and the Comptroller General of the United States or any of their representatives shall have access to records, as required under 45 CFR 74.24.

[48 FR 3702, Jan. 26, 1983, as amended at 50 FR 14887, April 15, 1985;
52 FR 3995, Feb. 6, 1987; 55 FR 27639, July 5, 1990]

Sec. 1340.15 Services and treatment for disabled infants.

(a) Purpose. The regulations in this section implement certain provisions of the Act, including section 107(b)(10) governing the protection and care of disabled infants with life-threatening conditions.

(b) Definitions. (1) The term ``medical neglect'' means the failure to provide adequate medical care in the context of the definitions of ``child abuse and neglect'' in section 113 of the Act and

Sec. 1340.2(d) of this part. The term ``medical neglect'' includes, but is not limited to, the withholding of medically indicated treatment from a disabled infant with a life-threatening condition.

(2) The term ``withholding of medically indicated treatment'' means the failure to respond to the infant's life-threatening conditions by providing treatment (including appropriate nutrition, hydration, and medication) which, in the treating physician's (or physicians') reasonable medical judgment, will be most likely to be effective in ameliorating or correcting all such conditions, except that the term does not include the failure to provide treatment (other than appropriate nutrition, hydration, or medication) to an infant when, in the treating physician's (or physicians') reasonable medical judgment any of the following circumstances apply:

(i) The infant is chronically and irreversibly comatose:

(ii) The provision of such treatment would merely prolong dying, not be effective in ameliorating or correcting all of the infant's life-threatening conditions, or otherwise be futile in terms of the survival of the infant; or

(iii) The provision of such treatment would be virtually futile in terms of the survival of the infant and the treatment itself under such circumstances would be inhumane.

(3) Following are definitions of terms used in paragraph (b)(2) of this section:

(i) The term ``infant'' means an infant less than one year of age. The reference to less than one year of age shall not be construed to imply that treatment should be changed or discontinued when an infant reaches one year of age, or to affect or limit any existing protections available under State laws regarding medical neglect of children over one year of age. In addition to their applicability to infants less than one year of age, the standards set forth in paragraph (b)(2) of this section should be consulted thoroughly in the evaluation of any issue of medical neglect involving an infant older than one year of age who has been continuously hospitalized since birth, who was born extremely prematurely, or who has a long-term disability.

(ii) The term ``reasonable medical judgment'' means a medical judgment that would be made by a reasonably prudent physician, knowledgeable about the case and the treatment possibilities with respect to the medical conditions involved.

(c) Eligibility requirements. (1) In addition to the other eligibility requirements set forth in this part, to qualify for a basic State grant under section 107(b) of the Act, a State must have programs, procedures, or both, in place within the State's child protective service system for the purpose of responding to the reporting of medical neglect, including instances of withholding of medically indicated treatment from disabled infants with life-threatening conditions.

(2) These programs and/or procedures must provide for:

(i) Coordination and consultation with individuals designated by and within appropriate health care facilities;

(ii) Prompt notification by individuals designated by and within appropriate health care facilities of cases of suspected medical neglect (including instances of the withholding of medically indicated treatment from disabled infants with life-threatening conditions); and

(iii) The authority, under State law, for the State child protective service system to pursue any legal remedies, including the authority to initiate legal proceedings in a court of competent jurisdiction, as may be necessary to prevent the withholding of medically indicated treatment from disabled infants with life-threatening conditions.

(3) The programs and/or procedures must specify that the child protective services system will prompty contact each health care facility to obtain the name, title, and telephone number of the individual(s) designated by such facility for the purpose of the coordination, consultation, and notification activities identified in paragraph (c)(2) of this section, and will at least annually recontact each health care facility to obtain any changes in the designations.

(4) These programs and/or procedures must be in writing and must conform with the requirements of section 107(b) of the Act and Sec. 1340.14 of this part. In connection with the requirement of conformity with the requirements of section 107(b) of the Act and Sec. 1340.14 of this part, the programs and/or procedures must specify the procedures the child protective services system will follow to obtain, in a manner consistent with State law:

(i) Access to medical records and/or other pertinent information when such access is necessary to assure an appropriate investigation of a report of medical neglect (including instances of withholding of medically indicated treatment from disabled infants with life threatening conditions); and

(ii) A court order for an independent medical examination of the infant, or otherwise effect such an examination in accordance with processes established under State law, when necessary to assure an appropriate resolution of a report of medical neglect (including instances of withholding of medically indicated treatment from disabled infants with life threatening conditions).

(5) The eligibility requirements contained in this section shall be effective October 9, 1985.

(d) Documenting eligibility. (1) In addition to the information and documentation required by and pursuant to Sec. 1340.12 (b) and (c), each State must submit with its application for a basic State grant sufficient information and documentation to permit the Commissioner to find that the State is in compliance with the eligibility requirements set forth in paragraph (c) of this section.

(2) This information and documentation shall include:

(i) A copy of the written programs and/or procedures established by, and followed within, the State for the purpose of responding to the reporting of medical neglect, including instances of withholding of medically indicated treatment from disabled infants with life-threatening conditions:

(ii) Documentation that the State has authority, under State law, for the State child protective service system to pursue any legal remedies, including the authority to inititate legal proceedings in a court of competent jurisdiction, as may be necessary to prevent the withholding of medically

indicated treatment from disabled infants with life-threatening conditions. This documentation shall consist of:

(A) A copy of the applicable provisions of State statute(s); or

(B) A copy of the applicable provisions of State rules or regulations, along with a copy of the State statutory provisions that provide the authority for such rules or regulations; or

(C) A copy of an official, numbered opinion of the Attorney General of the State that so provides, along with a copy of the applicable provisions of the State statute that provides a basis for the opinion, and a certification that the official opinion has been distributed to interested parties within the State, at least including all hospitals; and

(iii) Such other information and documentation as the Commissioner may require.

(e) Regulatory construction. (1) No provision of this section or part shall be construed to affect any right, protection, procedures, or requirement under 45 CFR Part 84, Nondiscrimination in the Basis of Handicap in Programs and Activities Receiving or Benefiting from Federal Financial Assistance.

(2) No provision of this section or part may be so construed as to authorize the Secretary or any other governmental entity to establish standards prescribing specific medical treatments for specific conditions, except to the extent that such standards are authorized by other laws or regulations.

(Approved by the Office of Management and Budget under control number 0980-0165)

[50 FR 14887, April 15, 1985, as amended at 52 FR 3995, Feb. 6, 1987; 55 FR 27639, July 5, 1990]

Sec. 1340.20 Confidentiality.

All projects and programs supported under the Act must hold all information related to personal facts or circumstances about individuals involved in those projects or programs confidential and shall not disclose any of the information in other than summary, statistical, or other form which does not identify specific individuals, except in accordance with Sec. 1340.14(i).

Appendix to Part 1340--Interpretative Guidelines Regarding 45 CFR 1340.15--Services and Treatment for Disabled Infants

Explanatory Note: The interpretative guidelines which follow were based on the proposed rule (49 FR 48160, December 10, 1984) and were published with the final rule on April 15, 1985 (50

FR 14878). References to the ``proposed rule'' and ``final rule'' in these guidelines refer to these actions.

Since that time, the Child Abuse Prevention and Treatment Act was revised, reorganized, and reauthorized by Public Law 100-294 (April 25, 1988) and renumbered by Pub. L. 101-126 (October 25, 1989). Accordingly, the definitions formerly in section 3 of the Act are now found in section 113; the State eligibility requirements formerly in section 4 of the Act are now found in section 107; and references to the ``final rule'' mean references to Sec. 1340.15 of this part.

This appendix sets forth the Department's interpretative guidelines regarding several terms that appear in the definition of the term ``withholding of medically indicated treatment'' in section 3(3) of the Child Abuse Prevention and Treatment Act, as amended by section 121(3) of the Child Abuse Amendments of 1984. This statutory definition is repeated in Sec. 1340.15(b)(2) of the final rule.

The Department's proposed rule to implement those provisions of the Child Abuse Amendments of 1984 relating to services and treatment for disabled infants included a number of proposed clarifying definitions of several terms used in the statutory definition. The preamble to the proposed rule explained these proposed clarifying definitions, and in some cases used examples of specific diagnoses to elaborate on meaning.

During the comment period on the proposed rule, many commenters urged deletion of these clarifying definitions and avoidance of examples of specific diagnoses. Many commenters also objected to the specific wording of some of the proposed clarifying definitions, particularly in connection with the proposed use of the word ``imminent'' to describe the proximity in time at which death is anticipated regardless of treatment in relation to circumstances under which treatment (other than appropriate nutrition, hydration and medication) need not be provided. A letter from the six principal sponsors of the ``compromise amendment'' which became the pertinent provisions of the Child Abuse Amendments of 1984 urged deletion of ``imminent'' and careful consideration of the other concerns expressed.

After consideration of these recommendations, the Department decided not to adopt these several proposed clarifying definitions as part of the final rule. It was also decided that effective implementation of the program established by the Child Abuse Amendments would be advanced by the Department stating its interpretations of several key terms in the statutory definition. This is the purpose of this appendix.

The interpretative guidelines that follow have carefully considered comments submitted during the comment period on the proposed rule. These guidelines are set forth and explained without the use of specific diagnostic exmples to elaborate on meaning.

Finally, by way of introduction, the Department does not seek to establish these interpretative guidelines as binding rules of law, nor to prejudge the exercise of reasonable medical judgment in responding to specific circumstances. Rather, this guidance is intended to assist in interpreting

the statutory definition so that it may be rationally and thoughtfully applied in specific contexts in a manner fully consistent with the legislative intent.

1. In general: The statutory definition of ``withholding of medically indicated treatment."

Section 1340.15(b)(2) of the final rule defines the term ``withholding of medically indicated treatment" with a definition identical to that which appears in section 3(3) of the Act (as amended by section 121(3) of the Child Abuse Amendments of 1984).

This definition has several main features. First, it establishes the basic principle that all disabled infants with life-threatening
conditions must be given medically indicated treatment, defined in terms of action to respond to the infant's life-threatening conditions by providing treatment (including appropriate nutrition, hydration or medication) which, in the treating physician's (or physicians') reasonable medical judgment, will be most likely to be effective in ameliorating or correcting all such conditions.

Second, the statutory definition spells out three circumstances under which treatment is not considered ``medically indicated." These are when, in the treating physician's (or physicians') reasonable medical judgment:

--The infant is chronically and irreversibly comatose:

--The provision of such treatment would merely prolong dying, not be effective in ameliorating or correcting all of the infant's life-threatening conditions, or otherwise be futile in terms of survival of the infant; or

--The provision of such treatment would be virtually futile in terms of survival of the infant and the treatment itself under such circumstances would be inhumane.

The third key feature of the statutory definition is that even when one of these three circumstances is present, and thus the failure to provide treatment is not a ``withholding of medically indicated treatment," the infant must nonetheless be provided with appropriate nutrition, hydration, and medication.

Fourth, the definition's focus on the potential effectiveness of treatment in ameliorating or correcting life-threatening conditions makes clear that it does not sanction decisions based on subjective opinions about the future ``quality of life" of a retarded or disabled person.

The fifth main feature of the statutory definition is that its operation turns substantially on the ``reasonable medical judgment" of the treating physician or physicians. The term ``reasonable medical judgment" is defined in Sec. 1340.15(b)(3)(ii) of the final rule, as it was in the Conference Committee Report on the Act, as a medical judgment that would be made by a reasonably prudent physician, knowledgeable about the case and the treatment possibilities with respect to the medical conditions involved.

The Department's interpretations of key terms in the statutory definition are fully consistent with these basic principles reflected in the definition. The discussion that follows is organized under headings that generally correspond to the proposed clarifying definitions that appeared in the

proposed rule but were not adopted in the final rule. The discussion also attempts to analyze and respond to significant comments received by the Department.

2. The term ``life-threatening condition".

Clause (b)(3)(ii) of the proposed rule proposed a definition of the term ``life-threatening condition." This term is used in the statutory definition in the following context:

[T]he term ``withholding of medically indicated treatment" means the failure to respond to the infant's life-threatening conditions by providing treatment (including appropriate nutrition, hydration, and medication) which, in the treating physician's or physicians' reasonable medical judgment, will be most likely to be effective in ameliorating or correcting all such conditions [, except that] * * *. [Emphasis supplied].

It appears to the Department that the applicability of the statutory definition might be uncertain to some people in cases where a condition may not, strictly speaking, by itself be life-threatening, but where the condition significantly increases the risk of the onset of complications that may threaten the life of the infant. If medically indicated treatment is available for such a condition, the failure to provide it may result in the onset of complications that, by the time the condition becomes life-threatening in the strictest sense, will eliminate or reduce the potential effectiveness of any treatment. Such a result cannot, in the Department's view, be squared with the Congressional intent.

Thus, the Department interprets the term ``life-threatening condition" to include a condition that, in the treating physician's or physicians' reasonable medical judgment, significantly increases the risk of the onset of complications that may threaten the life of the infant.

In response to comments that the proposed rule's definition was potentially overinclusive by covering any condition that one could argue ``may" become life-threatening, the Department notes that the statutory standard of ``the treating physician's or physicians' reasonable medical judgment" is incorporated in the Department's interpretation, and is fully applicable.

Other commenters suggested that this interpretation would bring under the scope of the definition many irreversible conditions for which no corrective treatment is available. This is certainly not the intent. The Department's interpretation implies nothing about whether, or what, treatment should be provided. It simply makes clear that the criteria set forth in the statutory definition for evaluating whether, or what, treatment should be provided are applicable. That is just the start, not the end, of the analysis. The analysis then takes fully into account the reasonable medical judgment regarding potential effectiveness of possible treatments, and the like.

Other comments were that it is unnecessary to state any interpretation because reasonable medical judgment commonly deems the conditions described as life-threatening and responds accordingly. HHS agrees that this is common practice followed under reasonable medical judgment, just as all the standards incorporated in the statutory definition reflect common practice

followed under reasonable medical judgment. For the reasons stated above, however, the Department believes it is useful to say so in these interpretative guidelines.

3. The term ``treatment'' in the context of adequate evaluation.

Clause (b)(3)(ii) of the proposed rule proposed a definition of the term ``treatment.'' Two separate concepts were dealt with in (A) and (B), respectively, of the proposed rule. Both of these clauses were designed to ensure that the Congressional intent regarding the issues to be considered under the analysis set forth in the statutory definition is fully effectuated. Like the guidance regarding ``life-threatening condition,'' discussed above, the Department's interpretations go to the applicability of the statutory analysis, not its result.

The Department believes that Congress intended that the standard of following reasonable medical judgment regarding the potential effectiveness of possible courses of action should apply to issues regarding adequate medical evaluation, just as it does to issues regarding adequate medical intervention. This is apparent Congressional intent because Congress adopted, in the Conference Report's definition of ``reasonable medical judgment,'' the standard of adequate knowledge about the case and the treatment possibilities with respect to the medical condition involved.

Having adequate knowledge about the case and the treatment possibilities involved is, in effect, step one of the process, because that is the basis on which ``reasonable medical judgment'' will operate to make recommendations regarding medical intervention. Thus, part of the process to determine what treatment, if any, ``will be most likely to be effective in ameliorating or correcting'' all life-threatening conditions is for the treating physician or physicians to make sure they have adequate information about the condition and adequate knowledge about treatment possibilities with respect to the condition involved. The standard for determining the adequacy of the information and knowledge is the same as the basic standard of the statutory definition: reasonable medical judgment. A reasonably prudent physician faced with a particular condition about which he or she needs additional information and knowledge of treatment possibilities would take steps to gain more information and knowledge by, quite simply, seeking further evaluation by, or consultation with, a physician or physicians whose expertise is appropriate to the condition(s) involved or further evaluation at a facility with specialized capabilities regarding the conditions(s) involved.

Thus, the Department interprets the term ``treatment'' to include (but not be limited to) any further evaluation by, or consultation with, a physician or physicians whose expertise is appropriate to the condition(s) involved or further evaluation at a facility with specialized capabilities regarding the condition(s) involved that, in the treating physician's or physicians' reasonable medical judgment, is needed to assure that decisions regarding medical intervention are based on adequate knowledge about the case and the treatment possibilities with respect to the medical conditions involved.

This reflects the Department's interpretation that failure to respond to an infant's life-threatening conditions by obtaining any further evaluations or consultations that, in the treating physician's reasonable medical judgment, are necessary to assure that decisions regarding medical intervention are based on adequate knowledge about the case and the treatment possibilities involved constitutes a ``withholding of medically indicated treatment.'' Thus, if parents refuse to consent to such a recommendation that is based on the treating physician's reasonable medical judgment that, for example, further evaluation by a specialist is necessary to permit reasonable medical judgments to be made regarding medical intervention, this would be a matter for appropriate action by the child protective services system.

In response to comments regarding the related provision in the proposed rule, this interpretative guideline makes quite clear that this interpretation does not deviate from the basic principle of reliance on reasonable medical judgment to determine the extent of the evaluations necessary in the particular case. Commenters expressed concerns that the provision in the proposed rule would intimidate physicians to seek transfer of seriously ill infants to tertiary level facilities much more often than necessary, potentially resulting in diversion of the limited capacities of these facilities away from those with real needs for the specialized care, unnecessary separation of infants from their parents when equally beneficial treatment could have been provided at the community or regional hospital, inappropriate deferral of therapy while time-consuming arrangements can be affected, and other counterproductive ramifications. The Department intended no intimidation, prescription or similar influence on reasonable medical judgment, but rather, intended only to affirm that it is the Department's interpretation that the reasonable medical judgment standard applies to issues of medical evaluation, as well as issues of medical intervention.

4. The term ``treatment'' in the context of multiple treatments. Clause (b)(3)(iii)(B) of the proposed rule was designed to clarify that, in evaluating the potential effectiveness of a particular medical treatment or surgical procedure that can only be reasonably evaluated in the context of a complete potential treatment plan, the ``treatment'' to be evaluated under the standards of the statutory definition includes the multiple medical treatments and/or surgical procedures over a period of time that are designed to ameliorate or correct a life-threatening condition or conditions. Some commenters stated that it could be construed to require the carrying out of a long process of medical treatments or surgical procedures regardless of the lack of success of those done first. No such meaning is intended.

The intent is simply to characterize that which must be evaluated under the standards of the statutory definition, not to imply anything about the results of the evaluation. If parents refuse consent for a particular medical treatment or surgical procedure that by itself may not correct or ameliorate all life-threatening conditions, but is recommended as part of a total plan that involves multiple medical treatments and/or surgical procedures over a period of time that, in the

treating physician's reasonable medical judgment, will be most likely to be effective in ameliorating or correcting all such conditions, that would be a matter for appropriate action by the child protective services system.

On the other hand, if, in the treating physician's reasonable medical judgment, the total plan will, for example, be virtually futile and inhumane, within the meaning of the statutory term, then there is no ``withholding of medically indicated treatment.'' Similarly, if a treatment plan is commenced on the basis of a reasonable medical judgment that there is a good chance that it will be effective, but due to a lack of success, unfavorable complications, or other factors, it becomes the treating physician's reasonable medical judgment that further treatment in accord with the prospective treatment plan, or alternative treatment, would be futile, then the failure to provide that treatment would not constitute a ``withholding of medically indicated treatment.'' This analysis does not divert from the reasonable medical judgment standard of the statutory definition; it simply makes clear the Department's interpretation that the failure to evaluate the potential effectiveness of a treatment plan as a whole would be inconsistent with the legislative intent.

Thus, the Department interprets the term ``treatment'' to include (but not be limited to) multiple medical treatments and/or surgical procedures over a period of time that are designed to ameliorate or correct a life-threatening condition or conditions.

5. The term ``merely prolong dying.'' Clause (b)(3)(v) of the proposed rule proposed a definition of the term ``merely prolong dying,'' which appears in the statutory definition. The proposed rule's provision stated that this term ``refers to situations where death is imminent and treatment will do no more than postpone the act of dying.''

Many commenters argued that the incorporation of the word ``imminent,'' and its connotation of immediacy, appeared to deviate from the Congressional intent, as developed in the course of the lengthy legislative negotiations, that reasonable medical judgments can and do result in nontreatment decisions regarding some conditions for which treatment will do no more than temporarily postpone a death that will occur in the near future, but not necessarily within days. The six principal sponsors of the compromise amendment also strongly urged deletion of the word ``imminent.''

The Department's use of the term ``imminent'' in the proposed rule was not intended to convey a meaning not fully consonant with the statute. Rather, the Department intended that the word ``imminent'' would be applied in the context of the condition involved, and in such a context, it would not be understood to specify a particular number of days. As noted in the preamble to the proposed rule, this clarification was proposed to make clear that the ``merely prolong dying'' clause of the statutory definition would not be applicable to situations where treatment will not totally correct a medical condition but will give a patient many years of life. The Department continues to hold to this view.

To eliminate the type of misunderstanding evidenced in the comments, and to assure consistency with the statutory definition, the word ``imminent'' is not being adopted for purposes of these interpretative guidelines.

The Department interprets the term ``merely prolong dying'' as referring to situations where the prognosis is for death and, in the treating physician's (or physicians') reasonable medical judgment, further or alternative treatment would not alter the prognosis in an extension of time that would not render the treatment futile.

Thus, the Department continues to interpret Congressional intent as not permitting the ``merely prolong dying'' provision to apply where many years of life will result from the provision of treatment, or where the prognosis is not for death in the near future, but rather the more distant future. The Department also wants to make clear it does not intend the connotations many commenters associated with the word ``imminent.'' In addition, contrary to the impression some commenters appeared to have regarding the proposed rule, the Department's interpretation is that reasonable medical judgments will be formed on the basis of knowledge about the condition(s) involved, the degree of inevitability of death, the probable effect of any potential treatments, the projected time period within which death will probably occur, and other pertinent factors.

6. The term ``not be effective in ameliorating or correcting all of the infant's life threatening conditions'' in the context of a future life-threatening condition.

Clause (b)(3)(vi) of the proposed rule proposed a definition of the term ``not be effective in ameliorating or correcting all the infant's life-threatening conditions'' used in the statutory definition of ``withholding of medically indicated treatment.''

The basic point made by the use of this term in the statutory definition was explained in the Conference Committee Report:

Under the definition, if a disabled infant suffers more than one life-threatening condition and, in the treating physician's or physicians' reasonable medical judgment, there is no effective treatment for one of those conditions, then the infant is not covered by the terms of the amendment (except with respect to appropriate nutrition, hydration, and medication) concerning the withholding of medically indicated treatment.

H. Conf. Rep. No. 1038, 98th Cong., 2d Sess. 41 (1984).

This clause of the proposed rule dealt with the application of this concept in two contexts: First, when the nontreatable condition will not become life-threatening in the near future, and second, when humaneness makes palliative treatment medically indicated.

With respect to the context of a future life-threatening condition, it is the Department's interpretation that the term ``not be effective in ameliorating or correcting all of the infant's life-threatening conditions'' does not permit the withholding of treatment on the grounds that one or

more of the infant's life-threatening conditions, although not life-threatening in the near future, will become life-threatening in the more distant future.

This clarification can be restated in the terms of the Conference Committee Report excerpt, quoted just above, with the italicized words indicating the clarification, as follows: Under the definition, if a disabled infant suffers from more than one life-threatening condition and, in the treating physician's or physicians' reasonable medical judgment, there is no effective treatment for one of these conditions that threatens the life of the infant in the near future, then the infant is not covered by the terms of the amendment (except with respect to appropriate nutrition, hyrdation, and medication) concerning the withholding of medically indicated treatment; but if the nontreatable condition will not become life-threatening until the more distant future, the infant is covered by the terms of the amendment.

Thus, this interpretative guideline is simply a corollary to the Department's interpretation of ``merely prolong dying,'' stated above, and is based on the same understanding of Congressional intent, indicated above, that if a condition will not become life-threatening until the more distant future, it should not be the basis for withholding treatment.

Also for the same reasons explained above, the word ``imminent'' that appeared in the proposed definition is not adopted for purposes of this interpretative guideline. The Department makes no effort to draw an exact line to separate ``near future'' from ``more distant future.'' As noted above in connection with the term ``merely prolong dying,'' the statutory definition provides that it is for reasonable medical judgment, applied to the specific condition and circumstances involved, to determine whether the prognosis of death, because of its nearness in time, is such that treatment would not be medically indicated.

7. The term ``not be effective in ameliorating or correcting all life-threatening conditions'' in the context of palliative treatment. Clause (b)(3)(iv)(B) of the proposed rule proposed to define the term ``not be effective in ameliorating or correcting all life-threatening conditions'' in the context where the issue is not life-saving treatment, but rather palliative treatment to make a condition more tolerable. An example of this situation is where an infant has more than one life-threatening condition, at least one of which is not treatable and will cause death in the near future. Palliative treatment is available, however, that will, in the treating physician's reasonable medical judgment, relieve severe pain associated with one of the conditions. If it is the treating physician's reasonable medical judgment that this palliative treatment will ameliorate the infant's overall condition, taking all individual conditions into account, even though it would not ameliorate or correct each condition, then this palliative treatment is medically indicated. Simply put, in the context of ameliorative treatment that will make a condition more tolerable, the term ``not be effective in ameliorating or correcting all life-threatening conditions'' should not be construed as meaning each and every condition, but rather as referring to the infant's overall condition.

HHS believes Congress did not intend to exclude humane treatment of this kind from the scope of ``medically indicated treatment.'' The Conference Committee Report specifically recognized that ``it is appropriate for a physician, in the exercise of reasonable medical judgment, to consider that factor [humaneness] in selecting among effective treatments.'' H. Conf. Rep. No. 1038, 98th Cong., 2d Sess. 41 (1984). In addition, the articulation in the statutory definition of circumstances in which treatment need not be provided specifically states that ``appropriate nutrition, hydration, and medication'' must nonetheless be provided. The inclusion in this proviso of medication, one (but not the only) potential palliative treatment to relieve severe pain, corroborates the Department's interpretation that such palliative treatment that will ameliorate the infant's overall condition, and that in the exercise of reasonable medical judgment is humane and medically indicated, was not intended by Congress to be outside the scope of the statutory definition.

Thus, it is the Department's interpretation that the term ``not be effective in ameliorating or correcting all of the infant's life-threatening conditions'' does not permit the withholding of ameliorative treatment that, in the treating physician's or physicians' reasonable medical judgment, will make a condition more tolerable, such as providing palliative treatment to relieve severe pain, even if the overall prognosis, taking all conditions into account, is that the infant will not survive.

A number of commenters expressed concerns about some of the examples contained in the preamble of the proposed rule that discussed the proposed definition relating to this point, and stated that, depending on medical complications, exact prognosis, relationships to other conditions, and other factors, the treatment suggested in the examples might not necessarily be the treatment that reasonable medical judgment would decide would be most likely to be effective. In response to these comments, specific diagnostic examples have not been included in this discussion, and this interpretative guideline makes clear that the ``reasonable medical judgment'' standard applies on this point as well.

Other commenters argued that an interpretative guideline on this point is unnecessary because reasonable medical judgment would commonly provide ameliorative or palliative treatment in the circumstances described. The Department agrees that such treatment is common in the exercise of resaonable medical judgment, but believes it useful, for the reasons stated, to provide this interpretative guidance.

8. The term ``virtually futile''. Clause (b)(3)(vii) of the proposed rule proposed a definition of the term ``virtually futile'' contained in the statutory definition. The context of this term in the statutory definition is: [T]he term ``withholding of medically indicated treatment'' * * * does not include the failure to provide treatment (other than appropriate nutrition, hydration, or medication) to an infant when, in the treating physician's or physicians' reasonable medical judgment, * * * the provision of such treatment would be virtually futile in terms of the survival of

the infant and the treatment itself under such circumstances would be inhumane. Section 3(3)(C) of the Act [emphasis supplied].

The Department interprets the term ``virtually futile'' to mean that the treatment is highly unlikely to prevent death in the near future. This interpretation is similar to those offered in connection with ``merely prolong dying'' and ``not be effective in ameliorating or correcting all life-threatening conditions'' in the context of a future life-threatening condition, with the addition of a characterization of likelihood that corresponds to the statutory word ``virtually.'' For the reasons explained in the discussion of ``merely prolong dying,'' the word ``imminent'' that was used in the proposed rule has not been adopted for purposes of this interpretative guideline.

Some commenters expressed concern regarding the words ``highly unlikely,'' on the grounds that such certitude is often medically impossible. Other commenters urged that a distinction should be made between generally utilized treatments and experimental treatments. The Department does not believe any special clarifications are needed to respond to these comments. The basic standard of reasonable medical judgment applies to the term ``virtually futile.'' The Department's interpretation does not suggest an impossible or unrealistic standard of certitude for any medical judgment. Rather, the standard adopted in the law is that there be a ``reasonable medical judgment.'' Similarly, reasonable medical judgment is the standard for evaluating potential treatment possibilities on the basis of the actual circumstances of the case. HHS does not believe it would be helpful to try to establish distinctions based on characterizations of the degree of general usage, extent of validated efficacy data, or other similar factors. The factors considered in the exercise of reasonable medical judgment, including any factors relating to human subjects experimentation standards, are not disturbed.

9. The term ``the treatment itself under such circumstances would be inhumane.''

Clause (b)(3)(viii) of the proposed rule proposed a definition of the term ``the treatment itself under such circumstances would be inhumane,'' that appears in the statutory definition. The context of this term in the statutory definition is that it is not a ``withholding of medically indicated treatment'' to withhold treatment (other than appropriate nutrition, hydration, or medication) when, in the treating physician's reasonable medical judgment, ``the provision of such treatment would be virtually futile in terms of the survival of the infant and the treatment itself under such circumstances would be inhumane.'' Sec. 3(3)(C) of the Act.

The Department interprets the term ``the treatment itself under such circumstances would be inhumane'' to mean the treatment itself involves significant medical contraindications and/or significant pain and suffering for the infant that clearly outweigh the very slight potential benefit of the treatment for an infant highly unlikely to survive. (The Department further notes that the use of the term ``inhumane'' in this context is not intended to suggest that consideration of the humaneness of a particular treatment is not legitimate in any other context; rather, it is recognized

that it is appropriate for a physician, in the exercise of reasonable medical judgment, to consider that factor in selecting among effective treatments.)

Other clauses of the statutory definition focus on the expected result of the possible treatment. This provision of the statutory definition adds a consideration relating to the process of possible treatment. It recognizes that in the exercise of reasonable medical judgment, there are situations where, although there is some slight chance that the treatment will be beneficial to the patient (the potential treatment is considered virtually futile, rather than futile), the potential benefit is so outweighed by negative factors relating to the process of the treatment itself that, under the circumstances, it would be inhumane to subject the patient to the treatment.

The Department's interpretation is designed to suggest the factors that should be taken into account in this difficult balance. A number of commenters argued that the interpretation should permit, as part of the evaluation of whether treatment would be inhumane, consideration of the infant's future ``quality of life."

The Department strongly believes such an interpretation would be inconsistent with the statute. The statute specifies that the provision applies only where the treatment would be ``virtually futile in terms of the survival of the infant," and the ``treatment itself under such circumstances would be inhumane." (Emphasis supplied.) The balance is clearly to be between the very slight chance that treatment will allow the infant to survive and the negative factors relating to the process of the treatment. These are the circumstances under which reasonable medical judgment could decide that the treatment itself would be inhumane.

Some commenters expressed concern about the use of terms such as ``clearly outweight" in the description of this balance on the grounds that such precision is impractical. Other commenters argued that this interpretation could be construed to mandate useless and painful treatment. The Department believes there is no basis for these worries because ``reasonable medical judgment" is the governing standard. The interpretative guideline suggests nothing other than application of this standard. What the guideline does is set forth the Department's interpretation that the statute directs the reasonable medical judgment to considerations relating to the slight chance of survival and the negative factors regarding the process of treatment and to the balance between them that would support a conclusion that the treatment itself would be inhumane.

Other commenters suggested adoption of a statement contained in the Conference Committee Report that makes clear that the use of the term ``inhumane" in the statute was not intended to suggest that consideration of the humaneness of a particular treatment is not legitimate in any other context. The Department has adopted this statement as part of its interpretative guideline.

10. Other terms.

Some comments suggested that the Department clarify other terms used in the statutory definition of ``withholding of medically-`indicated treatment," such as the term ``appropriate

nutrition, hydration or medication" in the context of treatment that may not be withheld, notwithstanding the existence of one of the circumstances under which the failure to provide treatment is not a ``withholding of medically indicated treatment." Some commenters stated, for example, that very potent pharmacologic agents, like other methods of medical intervention, can produce results accurately described as accomplishing no more than to merely prolong dying, or be futile in terms of the survival of the infant, or the like, and that, therefore, the Department should clarify that the proviso regarding ``appropriate nutrition, hydration or medication" should not be construed entirely independently of the circumstances under which other treatment need not be provided.

The Department has not adopted an interpretative guideline on this point because it appears none is necessary. As noted above in the discussion of palliative treatment, the Department recognizes that there is no absolutely clear line between medication and treatment other than medication that would justify excluding the latter from the scope of palliative treatment that reasonable medical judgment would find medically indicated, notwithstanding a very poor prognosis.

Similarly, the Department recognizes that in some circumstances, certain pharmacologic agents, not medically indicated for palliative purposes, might, in the exercise of reasonable medical judgment, also not be indicated for the purpose of correcting or ameliorating any particular condition because they will, for example, merely prolong dying. However, the Department believes the word ``appropriate" in this proviso of the statutory definition is adequate to permit the exercise of reasonable medical judgment in the scenario referred to by these commenters.

At the same time, it should be clearly recognized that the statute is completely unequivocal in requiring that all infants receive ``appropriate nutrition, hydration, and medication," regardless of their condition or prognosis.

[50 FR 14889, Apr. 15, 1985, as amended at 55 FR 27640, July 5, 1990]