Subpart C—Discretionary Grants and Contracts

§ 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 § 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 § 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 § 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 §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

clause (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.'' §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]