TAB 9

(4150-04-M)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF THE SECRETARY

45 CFR Part 84

Nondiscrimination on the Basis of Handicap Relating to Health Care for Handicapped Infants

AGENCY: Office of the Secretary, HHS

ACTION: Proposed Rules

SUMMARY: The notice of proposed rulemaking proposes to modify existing regulations to meet the exigent needs that can arise when a handicapped infant is discriminatorily denied food or medically indicated treatment. Several current regulatory provisions are proposed to be modified to allow timely reporting of violations, expeditious investigation, and immediate enforcement action when necessary to protect a handicapped infant whose life is endangered by discrimination in a program or activity receiving federal financial assistance.

Recipients that provide health care to infants would be required to post a conspicuous notice in locations that provide such care. The notice would describe the protections under federal law against discrimination toward the handicapped, and would provide a contact point in the Department of HHS for reporting violations immediately by telephone.

Notice and complaint procedures have been effective instruments for deterrence and enforcement in a variety of civil rights contexts. The Secretary believes that the proposed rule provides the best means to ensure that violations can be reported in time to save the lives of handicapped

infants who are denied food or are otherwise imperiled by discrimination in the provision of health care by federally assisted programs or activities.

In addition to the vigorous federal role in enforcing the protections of Section 504 of the Rehabilitation Act of 1973, HHS intends to rely heavily on the voluntary cooperation of State and local agencies, which are closest to the scene of violations, and which have traditionally played the key role in the investigation of complaints of child abuse and neglect.

In this regard, the proposed rule would also formalize existing responsibilities of child protective services agencies which receive federal financial assistance to carry out in a nondiscriminatory manner their authorities under their respective State laws to prevent instances of neglect of children, including medical neglect. The proposed rule would require these recipient agencies to establish written procedures and methods of administration to assure that handicapped infants subjected to medical neglect receive necessary child protective services.

The Secretary invites comments on all aspects of the proposed rule. Aspects on which comment is particularly invited are set forth in the supplementary information.

DATES: Comments should be submitted by [insert 60 days after date of publication].

ADDRESSES: Comments should be submitted in writing to the Director, Office for Civil Rights, Department of Health and Human Services, 330 Independence Avenue, S. W., Room 5400, Washington, D. C. 20201, or delivered to the above address between 9:00 a.m. and 5:30 p.m. on regular business days. Comments received may be inspected during these same hours by making arrangements with the contact person shown below.

FOR FURTHER INFORMATION CONTACT: Susan Shalhoub at (202) 245-6585, Office for Civil Rights, Department of Health and Human Services, 330 Independence Avenue, S. W., Room 5514, Washington, D. C. 20201 (TTY No. - 202-472-2916).

SUPPLEMENTARY INFORMATION: The President's directive of April 30, 1982, and the HHS Office for Civil Rights "Notice to Health Care Providers" of May 18, 1982, reminded recipients of federal financial assistance of the applicability of Section 504 of the Rehabilitation Act of 1973. Section 504 provides: "No otherwise qualified handicapped individual. . . shall, solely by reason of his handicap, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving federal financial assistance."

The Notice to Health Care providers explained what is already clear from the language of Section 504 and the implementing regulations (45 CFR Part 84): The discriminatory failure of a health care provider to feed a handicapped infant, or to provide medical treatment essential

to correct a life-threatening condition in a program or activity receiving federal financial assistance, constitutes a violation of Section 504.

Section 504 requires that health services be provided to the handicapped "on a basis of equality with those not handicapped," Doe v. Colautti, 592 F. 2d 704, 709 (3d Cir. 1979), in order to assure "the evenhanded treatment of qualified handicapped persons." Southeastern Community College v. Davis, 442 U.S. 397, 410 (1979).

Section 504 is in essence an equal treatment, non-discrimination standard. Congress patterned Section 504 on Title VI of the Civil Rights Act, which prohibits discrimination based on race. Programs or activities receiving federal financial assistance may not deny a benefit or service solely on grounds of a person's handicap, just as they may not deny a benefit or service on grounds of a person's race.

The Rehabilitation Act of 1973 defines a "handicapped individual" as "any person who (i) has a physical or mental impairment which substantially limits one or more of such person's major life activities,. . . or (iii) is regarded as having such an impairment." 29 U.S.C. 706(7)(B). Thus it is clear that a handicapped infant is an "individual" within the protection of the statute and is a "person" within the protection of the regulation. Nothing in the plain language of Section 504 or its legislative history provides a basis for excluding infants from the statutory coverage of "individuals".

The definition of a qualified handicapped person was clarified by the Supreme Court in Southeastern Community College v. Davis, 442 U.S. 397 (1979). In that case the Court addressed the question of whether a nursing school was prohibited by Section 504 from imposing certain physical qualifications for admission to its clinical training program. Noting that Section 504 prohibits discrimination on the basis of handicap against otherwise qualified handicapped individuals, the Court focused on the question of whether the plaintiff was otherwise qualified. It concluded that she was not a qualified handicapped person because she could not benefit from the program without fundamental alteration of the program. Id. at 409-410. As applied in the context of health care to handicapped infants, Section 504 would hold that where an infant would not benefit medically from a particular treatment, the infant would not be "qualified" to receive the treatment; thus, its denial would not violate Section 504.

Section 504 does not compel medical personnel to attempt to perform impossible or futile acts or therapies. Thus, Section 504 does not require the imposition of futile therapies which merely temporarily prolong the process of dying of an infant born terminally ill, such as a child born with anencephaly or intra-cranial bleeding. Such medical decisions, by medical personnel and parents, concerning whether to treat, and if so, what form the treatment should take, are outside

the scope of Section 504. The Department recognizes that reasonable medical judgments can differ when evaluating these difficult, individual cases.

The Department's existing regulations prohibit a recipient in providing any aid, benefit, or service in a program or activity receiving federal financial assistance from denying a qualified handicapped person "the opportunity to participate in or benefit from the aid, benefit, or service." 45 C.F.R. 84.4(b)(1)(i). The regulations also prohibit a recipient from affording a qualified handicapped person "an opportunity to participate in or benefit from the aid, benefit, or service that is not equal to that afforded others." 45 C.F.R. 84.4(b)(1)(ii) (emphasis supplied).

Recognizing that Section 504 protects only those infants who are able to benefit from treatment, the Department's May 18, 1982 Notice to Health Care Providers explained that a violation of Section 504 occurs when the treatment is withheld because of the existence of a handicap and the handicap does not render the treatment medically contraindicated.

Thus, Section 504 simply preserves the decision-making process customarily undertaken by physicians in any treatment decision: will the treatment be medically beneficial to the patient and are those benefits outweighed by any medical risk associated with the treatment? It is only when non-medical considerations, such as subjective judgments that an unrelated handicap makes a person's life not worth living, are interjected in the decision-making process that the Section 504 concerns arise.

Therefore, it is clear that with respect to the vast majority of seriously ill children who require acute medical attention, Section 504 will not be applicable because there will be no issue of decision-making based on subjective judgments outside the bounds of reasonable medical judgment. For example, medical judgments made daily regarding treatment of premature or low birth weight infants would not typically involve any considerations which might give rise to concerns about compliance with Section 504, even though these infants may be seriously ill and require intensive medical care.

The judgment Section 504 requires of a physician is a medical judgment concerning what medical treatment shall be provided an individual. Not all judgments made by a health care provider, however, are medical judgments. For example, a judgment not to treat a black infant because of the infant's race is not a medical judgment. A judgment not to correct an intestinal obstruction or repair the heart of a Down's syndrome infant because the infant suffers the handicap of Down's syndrome is likewise not a medical judgment.

The decision to forego medical treatment of a correctable life-threatening defect because an infant also suffers from a permanent, irremediable handicap that is not life-threatening, such as mental retardation, is a violation of Section 504. In this context, Section 504 provides that usual and customary medical care afforded to non-handicapped infants not be denied

to handicapped infants when they would benefit from such treatment. Similarly, where a course of medical care is usual and customary to correct or ameliorate a life impairing condition among a particular class of patients, for example, such as infants suffering from meningomyelocele (spina bifida), such beneficial care may not be withheld from an individual infant because of a subjective judgment that such infants as a class possess an insufficient quality of life.

While these are often difficult decisions to make, as well as to review, the standard of customary medical care is not one unfamiliar in the medical community and the Department appreciates the standard set forth in the recent Report of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, entitled, "Deciding to Forego Life-Sustaining Treatment."

The Commission concluded that "a very restrictive standard is appropriate" in decisions regarding the treatment of handicapped infants and the Department requests comments on the following statement of the Commission:

> Though inevitably somewhat subjective and imprecise in actual application, the concept of "benefit" excludes honoring idiosyncratic views that might be allowed if a person were deciding about his or her own treatment. . . As in all surrogate decision-making, the surrogate is obligated to try to evaluate benefits and burdens from the infant's own perspective. The Commission believes that the handicaps of Down's syndrome, for example, are not in themselves of this magnitude and do not justify failing to provide medically proven treatment, such as surgical correction of a blocked intestinal tract.
>
> This is a very strict standard in that it excludes consideration of the negative effects of an impaired child's life on other persons, including parents,

> siblings, and society. Although abiding by this standard may be difficult in specific cases, it is all too easy to undervalue the lives of handicapped infants, the Commission finds it imperative to counteract this by treating them no less vigorously than their healthy peers or than older children with similar handicaps would be treated.

Events of the past several years suggest that handicapped infants have died from denial of food in federally assisted programs. The full extent of discriminatory and life-threatening practices toward handicapped infants is not yet known, but the Secretary believes that for even a single infant to die due to lack of an adequate notice and complaint procedure is unacceptable.

There is a great deal of evidence documenting that the "very strict standard" advocated by the President's Commission and the requirements of Section 504 are not being uniformly followed and that medically indicated treatment is sometimes withheld from infants with congenital anomalies on the basis of their handicaps. For example, a 1973 article by Doctors Duff and Campbell of the Yale-New Haven Hospital documented that of 299 consecutive deaths occurring in that special care nursery, 43 (14 percent) were related to withholding treatment. 289 N. Engl. J. Med. 890. The following was among the cases documented:

> An Infant with Down's syndrome and intestinal atresia, like the much publicized one at Johns Hopkins Hospital, was not treated because his parents thought the surgery was wrong for their baby and themselves. He died several days after birth. Id. at 891.

The Johns Hopkins case became the subject of a documentary produced by the Joseph P. Kennedy Foundation, excerpts from which were shown as part of the "Death in the Nursery" documentary series presented by a Boston television station in February 1983. The facts of this particular case cited by Duff and Campbell were also much like the 1982 Bloomington, Indiana case cited by President Reagan in his statement of April 30, 1982, in which an infant with Down's syndrome and a correctable esophageal atresia was allowed to die.

Another specific case investigated by the HHS Office for Civil Rights similar to the Yale-New Haven, Johns Hopkins, and Bloomington cases related to a 1979 death of an infant with Down's syndrome and an intestinal obstruction at the Kapiolani-Children's Medical Center in Honolulu, Hawaii. As a resolution to the complaint, HHS and the hospital, in May of 1980, agreed to an amendment to the hospital's written consent procedures to assure that cases involving a lack of parental consent to medically indicated treatment for handicapped infants be reported to the State child protective services agency in the same manner as similar cases involving nonhandicapped children.

In addition to the four documented cases, Yale-New Haven, Johns Hopkins, Kapiolani, and Bloomington, and the other cases cited by Duff and Campbell, there is persuasive evidence that cases involving discriminatory denial of care are not unique. A 1977 article, "Ethical Issues in Pediatric Surgery,"

60 Pediatrics 588, reported the results of a survey of 400 members of the Surgical Section of the American Academy of Pediatrics and an additional 308 chairpersons of teaching departments of pediatrics and chiefs of divisions of neonatology and genetics in departments of pediatrics. Responses were received from 267 of the former group (66.8%) and 190 of the latter (61.7%). Id. at 588-9. Responses were anonymous. Among the results of the survey were:

-- 76.8% of the pediatric surgeons and 59.5% of the pediatricians said they would "acquiesce in parents' decision to refuse consent for surgery in a newborn with intestinal atresia if the infant also had Down's syndrome." Id. at 590.

-- 23.6% of pediatric surgeons and 13.2% of pediatricians would encourage parents to refuse consent for treatment of a newborn with intestinal atresia and Down's syndrome. Only 3.4% of pediatric surgeons and 15.5% of pediatricians would get a court order directing surgery if the parents refused. Id. at 591-2.

-- 63.3% of the pediatric surgeons and 42.6% of the pediatricians said in cases of infants with duodenal atresia and Down's Syndrome, where they "accept parental withholding of lifesaving surgery," they would also "stop all supportive treatment including intravenous fluids and nasal gastric suction." Id. at 592-3.

-- 62% of all respondents who believe that children with Down's syndrome "are capable of being useful and bringing love and happiness into the home" would nevertheless acquiesce in parents' decisions not to allow surgery for the atresia. Only 7% who so believe indicate that they would go to court to require surgery. Id. at 595.

These data strongly suggest that instances, such as occurred in Bloomington, Indiana in 1982, in which infants are denied life-sustaining, medically indicated treatment solely on the basis of their handicap cannot be dismissed as isolated events.

For purposes of applying Section 504, it is important to note that only 7.9% of Surgical Section members, and only 2.6% of other pediatricians, would acquiesce in parental refusal to treat intestinal atresia in an infant with no other anomaly. Their acquiescence in non-treatment of Down's children is apparently because of the handicap represented by Down's syndrome. A significant number of Surgical Section members indicated that they would do considerably more than "acquiesce" in parental decisions not to treat: 23.6% said that, given parents who are indecisive about treatment of a Down's syndrome infant with intestinal atresia, they would encourage parents not to consent. Only 3.4% of Surgical Section members said they would get a court order if parents refused consent in such situations. Moreover, the underlying rationale of the surgeons' responses appears not to be so much a deference to parental judgment as a personal view that Down's syndrome children are not worth having. A large majority (78.3% of surgeons, 88.4% of others) said they would get a court order directing surgery on a young child with a treatable malignant tumor whose parents refused consent out of belief in faith healing. But when asked, "If you were the parent of a newborn infant with Down's syndrome and intestinal obstruction, would you consent to intestinal surgery?", only 27% of surgeons answered "Yes." Other pediatricians responded 53.7% "Yes."

In addition, other surveys produced similar results. For example, 61% of California pediatricians responding to a 1975 survey said they would not object to a parental decision not to correct a life-threatening intestinal obstruction of an infant with Down's syndrome. Another study found that 51% of Massachusetts pediatricians responding to a survey would not recommend surgery for such infants. Only 18.5% of the total sample of pediatricians would get a court order to treat intestinal atresia in a Down's syndrome infant whose parents refused consent. See, "Treating the Defective Newborn: A Survey of Pediatricians' Attitudes," 6 Hastings Ctr. Rep. 2 (April 1976) and Todres, et al., "Pediatricians Attitudes Affecting Decision-Making in Defective Newborns," 60 Pediatrics 197 (1977).

The Department recognizes that parents retain the fundamental right, coupled with the high duty, to nurture and direct the destiny of their children (Pierce v. Society of Sisters, 268 U.S. 510). Yet, parental rights over their children are not absolute (Prince v. Massachusetts, 321 U.S. 158). The Department has determined that under every state's law, failure of parents to provide necessary, medically indicated care to a child is either explicitly cited as grounds for action by the state to compel treatment or is implicitly covered by the state statute. These state statutes also provide for appropriate administrative and judicial

enforcement authorities to prevent such instances of medical neglect, including requirements that medical personnel report suspected cases to the state child protective services agency, agency access to medical files, immediate investigations and authority to compel treatment.

For example, in Application of Cicero, 421 N.Y.S.2d 965 (1970), the child was born with spina bifida. Without an operation, it was unlikely that the child would live to the age of six months. The parents elected not to have the surgery and the court reversed this decision stating:

> This is not a case where the court is asked to preserve an existence which cannot be a life. What is asked is that a child born with handicaps be given a reasonable opportunity to live, to grow, and hopefully to surmount those handicaps. Id. at 973.

The court further noted the argument that this would interfere with the parents' rights to control the upbringing of their child but found that such parental rights are not absolute "where, as here, a child has a reasonable chance to live a useful, fulfilled life." Id. at 968.

The requirement imposed by state law that health care providers report instances of improper denial of medical care is no less a part of their program than is the provision of care itself. Both arise from the recipient's program of administering to the medical interests of its patients. Section 504 prohibits discrimination on the basis of handicap in the operation of federally-assisted programs and activities.

Thus, a recipient which as a matter of practice or law reports to state authorities the withholding of needed medical treatment from an infant may not deny the same service or benefit to a qualified handicapped infant because the infant is handicapped. 45 C.F.R. 84.4(b)(1), 84.52(a).

Accordingly, while recipients may be restricted in their provision of treatment by the lack of parental consent, it is no less their obligation to operate their program without discrimination. This includes the obligation to report to appropriate officials instances of parental refusal to consent to the provision of necessary, medically indicated treatment and to cooperate with those officials while continuing to provide all care not disallowed by the parents.

For quick and effective response to complaints, the Secretary counts on not only the enforcement resources of the Federal Government, but also on the assistance of state child protective agencies, which can respond quickly and effectively to referrals from the Federal Government, and which are often closest to the scene for speedy investigation of life-threatening child abuse and neglect. The Secretary intends to contact state child protective agencies whenever a complaint is received that falls within the definition of child abuse or neglect, in order to give States an opportunity to make their own investigation and to take appropriate action.

The Secretary expects that States will follow all necessary procedures for investigating allegations of child abuse and neglect that involve an imminent danger to life. State child protective agencies that receive federal financial assistance are under the same obligation as other recipients not to provide a qualified handicapped person with benefits or services that are less effective than those provided to others.

To formalize this obligation, the proposed rule would require each State child protective services agency which receives federal financial assistance to establish and maintain written methods of administration and procedures to assure that the agency utilizes its full authority pursuant to State law to prevent instances of medical neglect of handicapped infants. State child abuse and neglect laws presently prohibit neglect, including medical neglect, of children by their parents or guardians. As discussed above, the essential duty of recipient health care providers under Section 504 is to provide the treatment which is medically indicated. This corresponds with the responsibilities of parents or guardians under State child abuse and neglect laws to provide medically indicated treatment for their children.

Similarly, the enforcement responsibilities and procedures of the HHS Office for Civil Rights in connection with Section 504 compliance by recipient health care providers parallel those of State child protective services agencies pursuant to State child abuse and neglect laws.

To facilitate effective coordination of the parallel compliance activities, the proposed rule requires the establishment by recipient child protective services agencies of written methods of administration and procedures relating their existing authorities and responsibilities pursuant to State law to suspected cases of medical neglect of handicapped infants. The primary provisions of the written methods of administration and procedures correspond to the essential elements of every State child protective services program: (1) a duty on the part of medical professionals to report to the agency suspected cases of child abuse and neglect; (2) a mechanism for the State agency to receive reports on a timely basis; (3) review and investigation of reports; and (4) action through State courts to remedy or prevent a case of child abuse or neglect.

To maximize coordination with the HHS Office for Civil Rights, which will often have received a report of a suspected violation of Section 504 in the same case as the State's report of suspected medical neglect, the proposed rule would also require State child protective services agencies to notify the Office for Civil Rights of the report it received, the action it took, and its disposition of the case.

For those complaints that are expeditiously and effectively investigated and pursued by State agencies, the Secretary anticipates that additional federal efforts will often be unnecessary. The Secretary will closely monitor all

investigation and enforcement activity taken pursuant to complaints. The Department will make available to State agencies any information and assistance that is helpful and appropriate. For those cases where direct federal action appears helpful, the Department will have at its disposal the usual means of federal civil rights enforcement.

In order to conduct immediate investigations and to make immediate referrals to the Department of Justice for such legal action as may be necessary to save the life of a handicapped child who is subjected to discrimination by a recipient, the Department proposes to amend 45 C.F.R. 80.8 as referenced by 45 C.F.R. 84.61 which sets forth procedures for the Secretary to effect compliance with Section 504, including referrals to the Department of Justice for the initiation of appropriate legal proceedings. The existing regulations require a 10-day waiting period from the time the Secretary notifies a recipient of its failure to comply to the time the Secretary makes a referral to the Department of Justice or takes other legal action to effect compliance. When a handicapped infant is being denied food or other necessary medical care, however, more expeditious action is required. The proposed regulation creates a narrow exception to the 10-day waiting period when in the judgment of the responsible Department official, immediate remedial action is necessary to protect the life or health of a handicapped individual.

A program or activity receiving federal financial assistance must not only comply with the requirements established by the federal statute, but must also provide access to information pertinent to ascertain compliance with Section 504.

45 C.F.R. 80.6(c) as incorporated by 45 C.F.R. 84.61, clearly states that, "asserted considerations of . . . confidentiality may not operate to bar" the Department from seeking access to sources of information. Thus, a reading of the existing Section 504 regulations discloses a clear intent that records kept by recipients be subject to disclosure to ascertain compliance. The disclosure of records to ascertain compliance is one of the requirements a recipient must comply with to obtain and then continue to receive federal funding. 45 C.F.R. 80.8(a) as incorporated by 45 C.F.R. 84.61. The Supreme Court has observed:

> Disclosures of private medical information . . . to public health agencies are often an essential part of modern medical practice . . . . Requiring such disclosures to representatives of the State having responsibility for the health of the community does not automatically amount to an impermissible invasion of privacy. (Whalen v. Roe 429 U.S. 589, 602.)

The Department has for over a decade balanced its need to gain access to medical information under the various civil rights statutes it administers, including Section 504, with the need to preserve confidentiality and it continues to be sensitive to such concerns.

> Information of a confidential nature obtained in connection with compliance evaluation or enforcement shall not be disclosed except where necessary in formal enforcement proceedings or where otherwise required by law. (45 C.F.R. 80.6 (c)).

In addition, the confidentiality of medical records obtained in the course of a Section 504 investigation will be protected through nondisclosure under the Freedom of Information Act; the deletion of patients' and parents' names and other identifying information to the extent such deletion does not

impede the Department's ability to ascertain compliance; and a special and separate filing system maintained in locked files.

In regard to access to medical records, the Department proposes only a limited modification of its existing ability to gain access to such records to assure compliance with Section 504.

45 C.F.R. 80.6(c), as referenced by 45 C.F.R. 84.61, requires each recipient to permit access by Department officials to facilities and information pertinent to ascertaining compliance with Section 504, during normal business hours. Allegations of denial of food or other necessary medical care to handicapped infants may require an immediate effort to ascertain compliance. The Department's proposed change provides that access to records and facilities of recipients shall not be limited to normal business hours when, in the judgment of the responsible Departmental official, immediate access is necessary to protect the life or health of a handicapped individual.

The May 4, 1977, regulations of the Department regarding Section 504 incorporate by reference the procedural provisions applicable to Title VI of the Civil Rights Act of 1964. These procedures provide in part:

> Information to beneficiaries and participants. Each recipient shall make available to participants, beneficiaries, and other interested persons such information regarding the provisions of this regulation and its applicability to the program for which the recipient receives Federal financial assistance, and make such information available to them in such manner, as the responsible Department official finds necessary to apprise such persons of the protections against discrimination assured them by the Act and this regulation. (45 C.F.R. 80.6(d)).

45 C.F.R. 80.6(d), as referenced by 45 C.F.R. 84.61, requires recipients to make available such information, in such a manner, as the Department finds necessary to apprise appropriate persons of the protections afforded under Section 504. The proposed regulation specifies the type of information and manner of posting that is necessary to bring the protections of Section 504 for handicapped infants to the attention of those persons within the recipient program or activity who are most likely to have knowledge of possible violations as they occur. The requirement with regard to the posting of notices is a time-honored and reasonable method for providing notice to concerned individuals with respect to civil rights protections now utilized under a variety of programs (Cf., the Contract Compliance Program administered by the Department of Labor pursuant to E. O. 11246; Title VII of the Civil Rights Act of 1964).

In addition, the purpose of the proposed posting requirement is to acquire timely information concerning violations of Section 504 that are directed against handicapped infants, and to save the life of the infant. The Secretary believes that those having knowledge of violations of Section 504 against handicapped infants do not now have adequate opportunity to give immediate notice to federal authorities. A telephone complaint procedure can provide information to federal authorities in time to save the life of a handicapped infant who is being discriminatorily denied nutrition or treatment in a federally assisted program or activity.

Federal enforcement action can also be taken against any recipient that intimidates or retaliates against any person who provides information concerning possible violations of Section 504. 45 C.F.R. 80.7(e), as referenced by 45 C.F.R. 84.61, prohibits intimidatory or retaliatory acts by recipients against individuals who make complaints or assist in investigations concerning possible violations of Section 504. This provision fully protects individuals who make complaints or assist in investigations concerning possible withholding of food or other necessary medical care from handicapped infants.

This proposed regulation does not in any way change the substantive obligations of health care providers previously set forth in the statutory language of Section 504, in the implementing regulations, and in the Notice to Health Care Providers. The proposed regulation sets forth procedural specifications designed (1) to specify a notice and complaint procedure, within the context of the existing regulations, and (2) to modify existing regulations to recognize the exigent circumstances that may exist when a handicapped infant is denied food or other necessary medical care.

Comments solicited. The Secretary seeks public comment on all aspects of the proposed regulation and on the appendix to the proposed regulation, especially on those categories cited in the appendix as clear violations of Section 504 and on additional situations that may represent clear violations of Section 504. Comments will be considered and modifications made, as appropriate, following the comment period.

The Secretary also solicits comments on the following questions:

1. Should recipients providing health care services to infants be required to perform a self-evaluation, pursuant to 45 C.F.R. 84.6(c)(1), with respect to their policies and practices concerning health services to handicapped infants?

2. Should such recipients be required to identify for parents of handicapped children born in their facilities those public and private agencies in the geographical vicinity that provide services to handicapped infants?

3. Should recipients be required to institute internal review boards, such as were suggested by the report of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, to review cases where the parents and/or physician have decided to withhold life-sustaining treatment? If so, should this be an alternative or an addition to the requirements of the proposed rule? If it is proposed to be an alternative, what procedures should the Department follow to meet its responsibilities under existing law and regulations to investigate complaints and effect compliance with Section 504?

4. Should existing procedures requiring prompt investigations of complaints of violations of Section 504 relating to health care for handicapped infants be revised?

If so, how should these investigations be conducted so as to assure timely and effective investigations while minimizing any disruptive impact on the hospital?

5. As indicated above, Section 504 requires that medically beneficial treatment not be withheld on the basis of handicap. Are there further explanations which would assist health care providers and the public in understanding the requirements of Section 504 in connection with health care for handicapped infants?

6. Are there implications concerning cost and the allocation of medical resources in requiring that medically indicated treatment not be withheld from infants solely on the basis of handicap which are different from the implications inherent in all cases of determining the appropriate course of treatment for patients? If so, what are examples of cases where medically indicated treatment would, but for the legal requirements of Section 504, be withheld? In such cases, is cost or resource allocation the reason medically indicated treatment would be withheld?

7. In balancing the interests of parents in deciding matters relating to their children with the interests of the government in protecting the lives of all of its citizens, if the appropriate dividing line is not the deprivation of life-sustaining, medically indicated treatment, what should the dividing line be? Is there disagreement with the Department's position that the fact that a handicapped infant may be unwanted by parents due to perceived economic, emotional and

marital effects does not justify the deprivation of life-sustaining, medically indicated treatment?

8. In addition to the existing safeguards, explained above, regarding the confidentiality of information obtained by HHS in connection with civil rights investigations, are there other safeguards which should be implemented?

9. Are there other alternative means for the Department to meet its responsibilities to implement and enforce Section 504 in connection with health care for handicapped infants?

Regulatory impact analysis. This proposed rule has been reviewed under Executive Order 12291. It is not a major rule and thus does not require a regulatory impact analysis.

Regulatory flexibility analysis. The Regulatory Flexibility Act (Pub.L. 96-354) requires the federal government to anticipate and reduce the impact of rules and paperwork requirements on small businesses and other small entities. This proposed rule has no significant effect on small entities. Therefore, a regulatory flexibility analysis is not required.

Paperwork Reduction Act. Section 84.61(e) of this proposed rule contains information collection requirements. These requirements have been submitted to the Office of Management and Budget (OMB) for review under Section 3504(h) of the Paperwork Reduction Act of 1980. Interested parties should direct their comments on the information collection requirements contained in this proposed rule to the

Office of Information and Regulatory Affairs, OMB, attention: Desk Officer for the Office of the Secretary, HHS, Room 3208, New Executive Office Building, Washington, D. C. 20503.

List of Subjects in 45 CFR Part 84: Civil rights, Education of Handicapped, Handicapped.

Approved:

JUN 20 1983
Date

Margaret M. Heckler
Secretry

For the reasons set forth in the preamble, 45 C.F.R. 84.61 is proposed to be amended by designating the existing provision as paragraph (a) and by adding paragraphs (b),(c), (d) and (e) to read as follows:

§84.61 Procedures.

(a) * * *

(b) Pursuant to 45 C.F.R. 80.6(d), each recipient that provides covered health care services to infants shall post and keep posted in a conspicuous place in each nurses' station with responsibility for each delivery ward, each maternity ward, each pediatric ward, and each nursery, including each intensive care nursery, the following notice, which shall be no smaller than 8-1/2 by 11 inches:

DISCRIMINATORY FAILURE TO FEED AND CARE FOR
HANDICAPPED INFANTS
IN THIS FACILITY IS PROHIBITED BY FEDERAL LAW

Section 504 of the Rehabilitation Act of 1973 states that no otherwise qualified handicapped individual shall, solely by reason of handicap, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving federal financial assistance.

Any person having knowledge that a handicapped infant is being discriminatorily denied food or customary medical care should immediately contact:

Handicapped Infant Hotline

U.S. Department of Health and Human Services

Washington, D. C. 20201

Phone: 800---368-1019 (Available 24 hours a day)

or

Your State Child Protective Agency

Federal law prohibits retaliation or intimidation against any person who provides information about possible violations of the Rehabilitation Act of 1973.

Identity of callers will be held confidential.

Failure to feed and care for infants may also violate the criminal and civil laws of your State.

(1) Recipients shall add to the notice, in type face or handwriting, under the words "Your State Child Protective Agency," the identification of an appropriate State agency, with address and telephone number. No other alterations shall be made to such notice.

(2) Copies of such notice may be obtained on request from the Department of Health and Human Services.

(c) Notwithstanding the provisions of paragraph (a), the requirement of 45 C.F.R. 80.8(d)(3) shall not apply when, in the judgment of the responsible Department official, immediate remedial action is necessary to protect the life or health of a handicapped individual.

(d) Notwithstanding the provisions of paragraph (a), access to pertinent records and facilities of a recipient pursuant to 45 C.F.R. 80.6(c) shall not be limited to normal business hours when, in the judgment of the responsible Department official, immediate access is necessary to protect the life or health of a handicapped individual.

(e) Within 60 days of the effective date of this subsection, each recipient State child protective services agency shall establish and maintain written methods of administration and procedures to assure that the agency utilizes its full authority pursuant to state law to prevent instances of medical neglect of handicapped infants. These methods of administration and procedures shall include:

(1) A requirement that health care providers report immediately to the State agency suspected cases of medical neglect of handicapped infants;

(2) A method by which the agency can receive reports of suspected medical neglect of handicapped infants from health care providers, other individuals, and the Department on a timely basis;

(3) Immediate review of reports of suspected medical neglect of handicapped infants and, where appropriate, on-site investigation of such reports;

(4) Provision of child protective services to medically neglected handicapped infants, including, where appropriate, seeking a timely court order to compel the provision of necessary nourishment and medical treatment; and

(5) Immediate notification to the Department's Office for Civil Rights of each report of suspected medical neglect of a handicapped infant, the steps taken by the agency to investigate such report, and the agency's final dispositon of such report.

APPENDIX

Applicability of Section 504 to the Provision of Health Care to Handicapped Infants

By a notice to Health Care Providers dated May 18, 1982, the Department reminded hospitals that Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. Section 794) applies to the provisions of health care services to handicapped infants in programs or activities which receive federal financial assistance. Regulations in effect since 1977 have applied Section 504 to providers of health services. (45 C.F.R. Sections 84.51-52). The protections of Section 504 apply to all handicapped persons without regard to age.

The following comments are intended to explain the manner in which Section 504 applies to the provision of health care services to handicapped infants.

The Notice to Health Care Providers of May 18, 1982, explained that under Section 504 "it is unlawful for a recipient of federal financial assistance to withhold from a handicapped infant nutritional sustenance or medical or surgical treatment required to correct a life-threatening condition, if:

(1) the withholding is based on the fact that the infant is handicapped; and

(2) the handicap does not render the treatment or nutritional sustenance medically contraindicated."

The Secretary's experience in enforcing this standard, along with comments received by the Department, suggest a need to clarify in what situations Section 504 does and does not apply.

Section 504 is in essence an equal treatment, nondiscrimination standard. Congress patterned Section 504 on Title VI of the Civil Rights Act, which prohibits discrimination based on race. Programs or activities receiving federal financial assistance may not deny a benefit or service solely on grounds of a person's handicap, just as they may not deny a benefit or service on grounds of a person's race.

Regulations governing federally assisted programs or activities of health care providers implement the nondiscrimination approach of Section 504 by stating that "a recipient may not, on the basis of handicap ... (d)eny a qualified handicapped person these benefits or services ...." 45 C.F.R. Section 84.52(a).

Section 504 applies when (1) a handicapped person is qualified to receive benefits or services from a federally assisted program or activity and (2) these benefits or services are denied because of the person's handicap.

In the context of health care services provided to handicapped infants, a handicapped infant is qualified to receive those benefits and services that are (1) generally provided by the

program or activity, and (2) are appropriate, in the exercise of reasonable medical judgment, to the circumstances of the particular handicapped infant.

Section 504 does not intrude upon legitimate medical judgment. A handicapped infant is not "qualified" to receive medical care or treatment that is contrary to reasonable medical judgment -- i.e., "medically contraindicated."

Not all judgments made by a health care provider, however, are medical judgments. For example, a judgment not to treat a black infant because of the infant's race is not a medical judgment. A judgment not to treat a physical complication in a Down's Syndrome infant because the infant suffers the handicap of Down's syndrome is likewise not a medical judgment.

The Secretary does not interpret Section 504 to apply to any case in which care or treatment is withheld on the basis of legitimate medical judgment. If a particular form of treatment is of dubious medical benefit to the patient or if the patient could not long survive even with the treatment, reasonable medical judgment could withhold the treatment, and Section 504 does not require that the treatment be given. Section 504 does not compel medical personnel to attempt to perform impossible or futile acts or therapies. Thus, Section 504 does not require the imposition of futile therapies which merely temporarily prolong the process of dying of an infant born terminally ill.

For example, a child born with anencephaly will inevitably die within a short span of time; therefore, treatment to correct life-threatening complications may be withheld. Such withholding is on the basis of the legitimate medical judgment that the child would die imminently even with the treatment. The decision to withhold treatment is therefore not based on handicap, and is not prohibited by Section 504.

Also, a decision to withhold extraordinary care from an extremely low-birthweight infant does not implicate Section 504 if the decision is based on a reasonable medical judgment concerning improbability of success in a course of treatment, or risks and potential harm in the course of treatment.

At the same time, the basic provision of nourishment, fluids, and routine nursing care is a fundamental matter of human dignity, not an option for medical judgment. Even if a handicapped infant faces imminent and unavoidable death, no health care provider should take upon itself to cause death by starvation or dehydration. Routine nursing care to provide comfort and cleanliness is required to respect the dignity of such an infant. To deny these forms of basic care to handicapped individuals would constitute discrimination contrary to Section 504.

For those handicapped infants, on the other hand, who could live if given treatment for a life-threatening congenital anomaly, any

decision to withhold treatment which is based on the infant's handicap rather than on a medical judgment, constitutes discrimination contrary to Section 504. Section 504 prohibits any denial of benefits or services because of a handicap such as mental retardation, blindness, paralysis, deafness, or lack of limbs. Any judgment that a person is not worthy of treatment due to such handicap is not, of course, a medical judgment, even if made by doctors within a medical facility.

A clear violation of Section 504 occurs if a federally assisted program or activity denies a benefit or service to a handicapped infant that would be provided but for the individual's handicap. The Secretary deems the following to be examples -- not a comprehensive list -- of denials of treatment that constitute a violation of Section 504:

(1) Down's Syndrome with intestinal obstruction, denial of surgery to correct obstruction. Current medical practice in the United States is to correct intestinal atresia in infants with no other congenital anomaly. See 60 Pediatrics 588, 591 (1977). Any decision not to correct intestinal atresia in a Down's Syndrome child, unless an additional complication medically warrants such decision, must be deemed a denial of services based on the handicap of Down's Syndrome. The same reasoning applies to a case of Down's Syndrome with esophogeal atresia, and the denial of

surgery to correct atresia. Any refusal to give treatment to a Down's Syndrome infant for other physical complications, such as operable heart defects, if such complications would be treated for children without Down's Syndrome, similarly constitutes a violation of Section 504.

(2) Denial of care or treatment that would be given to a non-handicapped infant, on grounds that a particular infant is potentially mentally impaired, or blind, or deaf, or paralyzed, or lacking limbs.

(3) Denial of treatment for medically correctable physical anomalies in children born with Spina Bifida, when such denial is based on anticipated mental impairment, paralysis, or incontinence of such child, rather than on reasonable medical judgments that treatment would be futile or too unlikely of success given complications in the particular case.

File
Rt-to-Life

*LETTER PROCESSING INFORMATION

Letter.....: SRH.830621.8
Name.....: Mrs. Grace M. Gaylord
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Signature....: AH
ENV/LBL.....: LBL
Number Pages.: 2
Number Copies: 1
Reviewer.....: SB
Review Date..: 830622
Print Date...: July 8, 1983

Notes:

Re: P. 2 of letter--CC:Morton Blackwell.
Encl: Pro-Life Booklet

-REFG1-
cc1 ..... Referral:

THE WHITE HOUSE

WASHINGTON

July 8, 1983

Dear Mrs. Gaylord:

On behalf of President Reagan, I want to thank you for your message.

The President welcomes the thoughts of all Americans as he seeks to formulate policies in the best interest of our nation. Your suggestions have been carefully noted.

Your comments regarding abortion are particularly appreciated. The President has spoken out forcefully on this issue. Recently, he set forth his views at length in an article he wrote for the spring 1983 issue of The Human Life Review. I am enclosing a copy of this statement which I know you will find of interest.

As you know, a Federal District judge issued a ruling on April 14, 1983 enjoining the regulations published by the Administration to protect the right of handicapped infants to appropriate medical treatment in facilities receiving Federal support. The judge ruled that we must go through additional administrative procedures before these regulations can be put into effect. We are moving expeditiously to publish a new regulation for public comment, at the same time that we appeal the judge's decision.

I can assure you that the Administration is determined to protect the lives of handicapped children and the unborn, and the President will continue to "fight it out" on these issues during his time in office.

Regarding the other matter you mentioned, I have taken the liberty of forwarding your message to the appropriate government officials for their consideration.

With the President's best wishes,

Sincerely,

Anne Higgins
Special Assistant to the President
and Director of Correspondence

Mrs. Grace M. Gaylord
R.D. 2, Box 335
West Winfield, NY 13491

55

April 26, 1983

Dear Mr. President:

Gaylord
SRM.830621.8

Thank you for all you do, and for your support of life at ~~all~~ NOT all stages.

cc: Morton Blackwell
ENCL: Pro-Life Booklet

Please continue life Pro-Life good work,

You try and love America, that is evident.

Please look at the enclosed note. I know you are busy but perhaps you can do something?

Please put pro-life people wherever you can into office. We need to change our world so much.

Sincerely,

Grace M Gaylord (mrs)

4/26/83

Dear President Reagan:

It is difficult to understand <u>why</u> a Pastor is confined to jail for a "crime" (?) of teaching in a Church in Louisville, Nebraska.

Why should this man be given such a sentence? Where is our religious freedom? Why is it wrong to use a church building for such instruction?

Please advise me. Can you please help this Pastor?

Sincerely

Grace M. Gaylord (Mrs.)

PS His name is Everett Sileven.

PS What has happened to "freedom" in the U.S.A.? Is this a true picture of a democracy?

United States Senate
REPUBLICAN POLICY COMMITTEE
SR-347 RUSSELL SENATE OFFICE BUILDING
WASHINGTON, D.C. 20510

File
Right
to Life MB 8/8/83

Morton,

We expect House votes
on Bliley and Hartman on
Tel. a Thursday of this week.
Can you call Jack Fields
on Tuesday, or early Wednesday?

Bill Gribbin

Please call me — at work or at home —
if you need more information.

Bill

United States Senate
REPUBLICAN POLICY COMMITTEE
SR-347 RUSSELL SENATE OFFICE BUILDING
WASHINGTON, D.C. 20510

*who voted for a rape and incest exception in the Immigration bill in the Energy Committee. That is why we fear his vote on R&I in the Unemployed Benefits bill.

Morton,

Thanks for your help with Jack Fields.* This is terribly important to the movement.

The attached sheet has the practical, pragmatic reasons for voting against Waxman's deceptive "rape and incest exception."

Now, the political reasons:

*Waxman knows what he's doing with his shabbily drafted amendment: deliberately creating an abortion-on-demand loophole with the emotional "rape and incest" issue. This is pretty shabby treatment of his House colleagues

*If Waxman succeeds with this, he will try the same thing with the Hyde Amendment on the HHS Appropriation (or, more likely, in the Continuing Resolution). Will Fields then vote to expand abortion coverage by changing the now-venerable "lifeof the mother only" provision of Hyde?

*This is only the first step in Waxman's strategy. If this "R&I" exception succeeds, the Packwoods and Weickers will tell the Senate -- always more liberal on abortion than the House -- that we should put in all the other "hard cases" -- like fetal deformity. Well, if Jack Fields will pay to abort a perfectly normal child conceived by rape, why won't Fields pay to abort a grossly deformed child conceived in wedlock? If Fields will pay to abort a child of incest, why not a child of a financially desperate woman with mental problems. And so on, and so on.

*The pro-aborts do not care about the tiny handful of rape and incest pregnancies (actually, a few incest and virtually no rape pregnancies). This is really the start of their counteroffensive against the pro-life movement. More than ever, it is time to stand firm along the frontier we have already won: the Hyde Amendment, as Bliley will offer it to H.R. 3021.

** By the way, defeating Waxman, and putting the Bliley Amendment into the bill, is the best way of killing the bill altogether: the hard-core pro-aborts will probably vote against this bill, rather than accept Bliley! That's what they did with the Treasury Appropriation.

Bill Gribbin

POINT SHEET IN OPPOSITION TO WAXMAN AMENDMENT
TO H.R. 3021, HEALTH INSURANCE FOR THE UNEMPLOYED

• The Waxman amendment, because it is so badly drafted, would effectively require coverage of elective abortions under the Health Insurance for the Unemployed Act (H.R. 3021).

• Though it purports to cover only abortions for women who become pregnant as a result of rape or incest, it makes no distinction between forcible and statutory rape. Thus, any teenage dependent of an individual covered under the new program who becomes pregnant will have her abortion paid for.

• The Waxman amendment contains no provision that the incident of rape or incest be reported to public health or law enforcement authorities. Any pregnant woman covered under the plan could get her abortion paid for by claiming her pregnancy was due to rape or incest.

• The lack of reporting requirements would make the Waxman amendment unenforceable. State and federal agencies will be unable to determine whether claims filed by abortionists were legitimate.

*In effect, if the Waxman amendment prevails, anyone eligible for this program could have an abortion at the local clinic, simply by claiming rape. The clinic would explain that the abortion would be paid for by the government only if pregnancy results from rape or incest (or to save the mother's life). So were you raped, young lady? Answer: yes. No police report. No evidence. No time factor. Then the clinic need only tell HHS that we want X amount of money for X number of abortions, so many the result of rape, so many the result of incest. That's what the patients said! And HHS will immediately be under court order to pay those bills.