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EXECUTIVE OFFICE

The Honorable Margaret M. Heckler  
Secretary, Department of Health and  
Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Madam Secretary:

The American College of Physicians, a professional medical society representing over 57,000 internists -- doctors trained in internal medicine -- takes this opportunity to comment on the Department's proposed rule "Nondiscrimination on the Basis of Handicap Relating to Health Care for Handicapped Infants" (48 Federal Register 30846 - 30852, July 5, 1983).

Summary of the Proposed Rule

The notice of proposed rulemaking would provide procedures for the reporting and investigation of allegations of discrimination against handicapped infants in the provision to them of nutritional and medical care. The proposed procedures are directed primarily toward institutional recipients of federal funds that provide certain health care services to infants, although the proposal would also require certain steps to be taken by state child health protective services agencies. The proposed rule would:

- (1) require the posting in the nurses' stations of delivery, maternity, and pediatrics wards, and nurseries of a notice stating

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

the notice would further explicitly state that anyone "having knowledge that a handicapped infant is being discriminatorily denied food or customary medical care should immediately contact" a toll-free federal "Handicapped Infant Hotline" or a state child protective agency;

- (2) waive the existing 10-day waiting period from the time the Secretary notifies a recipient of federal funds of its failure to comply with regulations under the Rehabilitation Act of 1973, to the time the Secretary takes legal action to effect compliance;
- (3) authorize the Department access, not limited to normal business hours, to pertinent records;
- (4) require state child protective services that receive federal funds to establish specific procedures to prevent medical neglect of handicapped infants, including (a) requiring health care providers to report immediately suspected instances of medical neglect, (b) a method to receive and review such reports, (c) provision of child protective services to medically neglected handicapped infants, including seeking a court order to compel the provision of necessary nourishment and medical treatment, and (d) notification to the Department's Office of Civil Rights of each report and the agency's steps in response to it.

In addition, the notice of proposed rulemaking provides an appendix intended to explain the manner in which Section 504 of the Rehabilitation Act of 1973 (the stated statutory basis for the proposed rules) applies to the provision of health care services to handicapped infants, stating that 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." The appendix then lists three examples of denials of treatment that would constitute a violation of Section 504:

- (1) an individual with Down's syndrome denied surgery to correct an intestinal obstruction;
- (2) an infant who is potentially mentally impaired, or blind, or deaf, or paralyzed, or lacking limbs, who is denied treatment that would be given to a non-handicapped infant; and
- (3) an infant with spina bifida, denied treatment on the basis of anticipated mental impairment, paralysis, or incontinence.

Finally, the preface to the proposed rule states that Section 504 "does not compel medical personnel to attempt to perform impossible or futile acts or therapies." The preface invites comments on all aspects of the rule and the appendix, and requests response also to a series of specific questions.

#### Summary of the College's Response

As internists, our patients are commonly adults. Although the proposed regulation specifically addresses infant care, we are compelled to address the general issues raised by the proposal because they are relevant to medical decisionmaking and the patient-physician relationship generally. We will necessarily comment on the proposal itself.

The treatment of all seriously ill patients involves significant medical, ethical, and legal considerations. Even under the best of circumstances -- when the patient is a competent adult and the disease process is one that is responsive to appropriate therapies -- the coming to an acceptable decision can be a difficult process. When the patient is not able or not competent to choose an appropriate medical approach, the process becomes much more complex, and the care with which the decision is made for the patient is necessarily great. When the patient is an infant whose congenital handicap has confounded the new parents' expectant joy with such other profound emotions as fear for the child's life and disappointment for its potentially limited life choices, the treatment decision must be approached in the most considered way. While the legal and moral responsibility for choosing what is best for the welfare of the infant devolves generally, albeit with limitations, upon the parents, health care givers -- physicians, nurses, and others -- are necessarily brought into what is often a deeply personal and emotional process. Often in such circumstances, those health professionals turn to hospital administrators, and on occasion to the courts, for a determination as to what choice is legally most proper.

It is this circumstance that the Department has chosen to address, and to address with apparent disregard for its medical, ethical, legal, and emotional complexity. Parents, in deciding what is best for their children, exercise a moral and legal responsibility. On occasion, that decision-making process may be incompletely informed or may be clouded by the parents' individual interests. In such a case, it is of societal interest to assure that the interests of the child be fully heard. However, instead of addressing this appropriate societal interest, the Department would mandate a simplistic process insensitive to many of the legitimate parties involved, and apparently would place decisionmaking in the hands of unnamed Department or state officials potentially uninformed of many of the issues involved. The process proposed would, on the one hand, not assure that the interests of the infant be represented adequately, and on the other, intrude excessively in the ways in which health professionals and hospitals serve their patients.

What the Department should propose is the least intrusive process necessary to meet a legitimate need. Instead, it has proposed a most intrusive process that is unlikely to meet the need. In so doing, in addition, it has exceeded the statutory authority on which it purports to base its proposal.

A less intrusive alternative exists that is more likely than that proposed by the Department to meet society's interest in assuring appropriate representation of the interests of the handicapped infant. The alternative is that suggested by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research: for hospitals to have explicit policies for the review of cases in which life-sustaining therapy may be foregone.

The following pages expand further the College's position and the alternative suggested.

## The Proposed Rule Does Not Assure Protection of Society's Interest

Government has a clear responsibility to protect the interests of society. The proposed rule, however, does not articulate well the interest sought to be protected, nor does it assure that a legitimate societal interest is protected. Societal interest in the preservation of human life is fundamental. Society also values the autonomy of the individual and of individual decisionmaking, even to the extent that the competent individual can decide, for himself, to forego life-sustaining therapies. When the individual is not able or is not legally competent to choose for himself, the societal interest in the preservation of human life is met by assuring that the interests of the individual are fully and appropriately considered, usually by allowing or appointing a disinterested individual or institution to act in the incompetent's interest. Normally, in the case of an infant, society allows the parent to represent the interests of the child. Where, however, the parent's objectivity may be clouded by his or her own interest, society has a legitimate need to assure appropriate consideration of the child's interest.

The present proposal does not assure that the interests of handicapped infants will be fully and appropriately considered. It does not assure that those interests will be fully considered because the procedure the Department proposes depends solely upon the serendipity of specific, individual complaints, a process that necessarily involves the recognition of a "discriminatory" event, the communication of the event, and the response to the communication. The proposed rule fails to provide sufficient guidance on what constitutes a discriminatory event, and it provides no information on what the appropriate response to a report of discrimination will be. More importantly, however, the proposed procedure provides no protection to those infants on behalf of whom no complaint is made. Although the preface to the proposed rule states that "notice and complaint procedures have been effective instruments for deterrence and enforcement," normally those processes depend on competent individuals complaining in their own behalf. There is no evidence that such a process is appropriate for infants. By failing to suggest a systematic approach by which such infants are identified and their interests considered, the Department fails to assure that the interests of all such infants are fully considered.

Further, the Department's proposal does not assure that the interests of individual infants are appropriately considered. First, the proposal ignores the complexity both of the issues involved and of individual cases. Second, the procedures proposed depend on the actions of "Department officials" and state agencies whose qualifications are neither mentioned nor addressed by the proposed rule and whose remoteness from any actual clinical situation raises further concerns about the appropriateness and efficacy of their intervention. The rule's failure to address this issue of qualifications and proximity is particularly troubling given the fact that under the proposed rule such individuals and agencies will be asked to make judgments that frequently confound the most thoughtful of people.

Thus, the proposal fails to assure protection of society's interest -- that the interests of infants be both fully and appropriately considered. It establishes neither a system by which the interests of all handicapped

infants may be represented, nor a careful mechanism by which the interests of individual infants may be best considered.

### The Proposed Rule is Potentially Disruptive to Patient Care

The Department should seek to protect the societal interest fully in the manner in which is least disruptive. Instead, it has proposed a process that is potentially very disruptive. The proposal itself is almost silent as to the way in which it may be implemented, and state agencies, lacking any such guidance, may propose even more intrusive processes than posted notices and hotlines. The silence of the proposal as to the nature of the mechanism for federal investigation and action makes it difficult to comment on this aspect, but the investigations actually carried out under the interim final rule of March 7, 1983 (48 Federal Register 9630 - 9632), provide some evidence that the Department's activity may be characterized by insensitivity, adversarial posturing, and assumptions of guilt. In addition, a complaint process that ensures confidentiality is subject to potential abuse and false allegations, and complaints may be motivated by considerations other than the interest of infants. The potential burden on health care givers of answering such complaints should be considered.

Notices, complaints, hotlines, and investigations all have potential for governmental abuse. The silence of the proposal on many of these aspects forces the commenter to rely on the goodwill of governmental officials in the rule's implementation, in an area in which government, by its promulgation of the proposal, indicates it is unwilling to assume that physicians, nurses, hospitals, and parents will act in the best interests of an infant.

The approach proposed to a most complex problem is one that is both simplistic and intrusive, and one that ignores more considered approaches.

### The Department Lacks Sufficient Statutory Basis for the Proposal

The statutory basis for the proposal is at best quite weak, and the Department has not made a sufficient case that Section 504 of the Rehabilitation Act of 1973 is applicable to cases involving the medical care of infants.

First, the legislative history of Section 504 is completely devoid of any suggestion that the Section was intended to apply to such cases. No congressional committee, no member of the House or the Senate, no physician group, and no religious group mentioned in the record the potential for applicability. For nine years, from 1973 until April 1982, when President Reagan directed the Department to apply the Act to such cases, there was no Departmental indication that the Act did so apply.

Second, as Judge Gerhard Gesell stated in his opinion declaring the interim final rule invalid (U.S. District Court for the District of Columbia, April 14, 1983), "whether the coverage of the regulation falls within or outside the authority of Section 504 may well depend upon the manner in which Section 504 is actually applied." He further implied that an overbroad rule might well take the Department's proposal outside the umbrella of Section 504.

Third, the Department itself, in the appendix to the proposal (48 Federal Register 30852), states that 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." What the Department does not do is to clarify what "benefits or services" from what "federally assisted program or activity" are denied on the basis of handicap. If a hospital participates in the Medicare program, for example, by receiving reimbursement for services rendered to Medicare-eligible individuals, does the Department thereby assert that all health services rendered in the institution are part of a "federally assisted program or activity"? The Department should clarify the nexus it purports to draw.

### Alternative Proposal

In commenting in opposition to the proposal as published, the American College of Physicians also wishes to respond to certain of the questions posed in the Department's preface to the rule. There are valid alternatives to the proposed rule that will protect the interests of handicapped infants by assuring that appropriate care is given and will also allow for the Department to meet any relevant statutory or societal responsibilities to these children. One alternative has been provided in Deciding to Forego Life-Sustaining Treatment; Ethical, Medical, and Legal Issues in Treatment Decisions of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (March, 1983). The Commission's report provides a discussion of life-sustaining treatment decisions for all patients, particularly for seriously ill infants, specifically those with life-threatening congenital abnormalities. The report focuses on treatment decisionmaking for the group of infants for which the Department has promulgated its proposed rule -- infants who have both a correctable life-threatening defect and a permanent, irremediable handicap that is not life-threatening, such as mental retardation.

The Commission's recommendations were as follows:

...hospitals that care for seriously ill newborns should have explicit policies on decisionmaking procedures in cases involving life-sustaining treatment for these infants; accrediting bodies could appropriately require this. Such policies should provide for internal review whenever parents and the attending physician decide that life-sustaining therapy should be foregone. Other cases, such as when the physician and parents disagree, might well also be reviewed. The policy should allow for different types of review and be flexible enough to deal appropriately with the range of cases that could arise. Some cases may require only a medical consultation to confirm a diagnosis of an inevitably fatal condition, for example. In other cases, when the benefits of therapy are less clear, an "ethics committee" or similar body might be designated to review the decisionmaking process. This approach would ensure that an

individual or group whose function is to promote good decision-making reviews the most difficult cases. Cases included in this category should certainly encompass those in which a decision to forego life-sustaining therapy has been proposed because of a physical or mental handicap, as well as cases where a dispute has arisen among care givers and surrogates over the proper course of treatment.

Such a review could serve several functions and the review mechanism may vary accordingly. First, it can verify that the best information available is being used. Second, it can confirm the propriety of a decision that providers and parents have reached or confirm that the range of discretion accorded to the parents is appropriate. Third, it can resolve disputes among those involved in a decision, by improving communication and understanding among them and, if necessary, by siding with one party or another in a dispute. Finally, it can refer cases to public agencies (child protection services, probate courts, or prosecuting attorneys) when appropriate. Such a review mechanism has the potential both to guarantee a discussion of the issues with a concerned and disinterested "representative of the public" and to insulate these agonizing tragic decisions from the glare of publicity and the distortions of public posturing that commonly attend court proceedings.

Insofar as possible, infants' lives should be sustained long enough to gather the best information and to permit expeditious review. When the parents and physician feel justified in acting without either or both of these conditions, as might happen with a rapidly deteriorating medical status, retrospective review should be undertaken. Unlike turning to the courts for scrutiny of every case involving treatment of a seriously ill newborn, review of this limited category of cases would not seem likely to generate inappropriate social or financial costs.

The Commission also criticized the Department's publication of the interim final rule, the predecessor to the current proposal. In commenting that the interim final rule would add only further uncertainty to an already complex situation, the Commission recommended that

the Federal government would do better to encourage hospitals to improve their procedures for overseeing life and death decisions, especially regarding seriously ill newborns. Using financial sanctions against institutions to punish an "incorrect" decision in particular cases is likely to be ineffective and to lead to excessively detailed regulations that would involve government reimbursement officials in bedside decisionmaking. Furthermore, imposing such sanctions could unjustly penalize the hospital's other patients and professionals.

The College believes the Commission recommendations appropriately recognize the importance of hospital-specific internal review mechanisms to review decisions to forego life-sustaining treatment. Internal review

committees can be effective advocates for the patient unable to make his own informed choice of treatment. Their review processes should be sufficiently complete so as not only to consider all the circumstances of individual cases but also to present the full range of therapeutic and management options to the families and physicians involved. They can provide assurance that decisions are made with regard to the best interests of the patient.

Although the College believes that requiring the existence of internal review mechanisms should be sufficient to represent the interests of handicapped infants and of society in the infant's welfare, the Department has requested guidance on how to meet its perceived responsibilities under Section 504. While the College views Section 504 as an uncertain statutory basis for the proposed rule, potential monitoring mechanisms suggest themselves. First, there could be established a mechanism to assure access by concerned individuals to the review process. Those with complaints could have the opportunity to present information through the internal review process for possible investigation. The confidentiality of those proceedings could be maintained. Appeal of internal review decisions could be afforded, in exceptional cases, with access then to the Department, the state agency, or to the courts. Hospitals could provide information to the public on the existence of the review process, its purpose and accessibility. Finally, for purposes of state agency or Departmental monitoring, the records of the review process could be opened when evidence indicates inappropriate or inadequate sensitivity to the interests of the infant.

The College believes that the establishment of institutional review mechanisms, refined to meet basic access, appeal, and information criteria, will provide the assurances the Department requires. Such mechanisms contemplate a federal role of monitoring, with intervention only in situations where there has been a thorough presentation of the facts and a local decision has been made. This alternative reserves medical judgment to the physician, preserves the appropriate role of parents in treatment decisions, and ultimately should strengthen the confidence of the American public in our health care system.

Finally, the College believes that it is essential that careful consideration be given to the long term implications of policies that seek to assure appropriate medical care for handicapped infants. In considering such long term implications, we agree with the Commission's conclusion that "When the decision is made to give seriously ill newborns life-sustaining treatment, an obligation is created to provide the continuing care that makes a reasonable range of life choices possible." That obligation is translated to appropriate public support for continued care for these children. Along with the Commission, we conclude that public support for voluntary organizations and governmental programs is "the inescapable extension of society's deep interest in sustaining life in neonatal intensive care units." And finally, we concur in the Commission's most telling comments, "to the extent that society fails to ensure that seriously ill newborns have the opportunity for an adequate level of continuing care, its moral authority to intervene on behalf of a newborn whose life is in jeopardy is compromised."



Conclusion

In conclusion, the American College of Physicians believes that the proposed rule as promulgated should be withdrawn and revised to more adequately address the legitimate societal interest in the care of handicapped infants. The College believes that the process mandated under the rule as presently proposed is unduly intrusive and potentially disruptive to patient care while failing to adequately meet its purported purpose of assuring that the interests of handicapped infants are fully and appropriately represented. The College believes that an alternative method exists -- the establishment of hospital-specific internal review mechanisms -- that will more adequately protect the interests of handicapped infants and will do so in a less intrusive fashion.

Sincerely,

*Richard J. Reitemeier, MD*

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President