

**SUPPLEMENTARY INFORMATION:** On January 18, 2001, the Department of Health and Human Services (DHHS) published in the **Federal Register** a Final Rule, with an effective date of March 19, 2001 (66 F.R. 4674), intended to amend Subpart D of 42 CFR part 482, Subpart C of 42 CFR part 416, and Subpart F of 42 CFR part 485 of the Code of Federal Regulations.

The Department has determined that there is a need to delay this rule's effective date in order to consider (1) whether a Governor may certify to the Department, after consultation with the State's Boards of Medicine and Nursing, or their equivalents, and consistent with State law, that it is in the best interests of the citizens of the State that licensed Certified Registered Nurse Anesthetists (CRNAs) within the State administer anesthesia services without physician supervision, and (2) whether a prospective study should be undertaken to assess the impact of different state CRNA practices. The Department will, therefore, very shortly issue a proposed rule to afford the public the opportunity to comment on these changes.

The notice and comment requirements of 5 U.S.C. 553 do not apply to this delay of the rule's effective date, which is a rule of procedure. See 5 U.S.C. 553(b)(3)(A). To the extent that section 553 applies in these circumstances, however, the Department finds that the action comes within that provision's good cause exceptions in that obtaining public comment is impracticable, unnecessary, and contrary to the public interest. See 5 U.S.C. 553(b)(3)(B). Given the imminence of the effective date, and the imminence of a new notice of proposed rulemaking, seeking prior public comment on this delay is impracticable, as well as contrary to the public interest in the orderly promulgation and implementation of regulations. Further, comment is unnecessary because no harm is caused by delay of the effective date of the regulations, as the current rules will remain in effect pending any further action by the Department, and any action taken will be subject to notice and comment before final publication.

Dated: May 16, 2001.

**Tommy G. Thompson,**  
*Secretary.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### 45 CFR Part 46

**RIN: 0925-AA14**

#### Protection of Human Research Subjects: Delay of Effective Date

**AGENCY:** Department of Health and Human Services (DHHS).

**ACTION:** Final Rule; Delay of Effective Date.

**SUMMARY:** To give the Department an opportunity to obtain comment on three modifications to the rule entitled Protection of Human Subjects, Additional Protections for Pregnant Women and Human Fetuses Involved in Research, and Pertaining to Human In Vitro Fertilization, the Department is delaying until November 14, 2001 the effective date of the rule, which was published in the **Federal Register** on January 17, 2001, 66 F.R. 3878, pending the Department's action on forthcoming notice of proposed rulemaking. The rule's effective date was previously delayed by 60 days on March 19, 2001, in accordance with the memorandum of January 20, 2001, from the Assistant to the President and Chief of Staff, entitled A Regulatory Review Plan, published in the **Federal Register** on January 24, 2001. See 66 F.R. 15352.

**DATES:** The final rule, Protection of Human Subjects, published in the **Federal Register** on January 17, 2001, at 66 F.R. 3878 and delayed on March 19, 2001 at 66 FR 15352 is further delayed until November 14, 2001.

**FOR FURTHER INFORMATION CONTACT:** Irene Stith-Coleman, Ph.D., Office of Human Research Protections (OHRP) 200 Independence Avenue, S.W., Room 733-E, Washington, D.C., 20201. Telephone 202-260-1587. Email [istithco@osophs.dhhs.gov](mailto:istithco@osophs.dhhs.gov).

**SUPPLEMENTARY INFORMATION:** On January 17, 2001, the Department of Health and Human Services (DHHS) published in the **Federal Register** a Final Rule, with an effective date of March 19, 2001 (66 Fed. Reg. 3878), intended to amend Subpart B of 45 CFR Part 46 of the Code of Federal Regulations. These regulations provide additional protections for pregnant women and human fetuses involved in research.

The Department has determined that there is a need to delay this rule's effective date in order to consider three limited aspects: (1) Whether paternal consent (when the father is readily available) should be obtained for participation in federally funded

research that is directed solely at a fetus; (2) whether the definition of "fetus" should be modified so that it describes only the stage prior to delivery; and (3) whether the rule should be modified to make clear that fetuses of uncertain viability may be subjected to added risk only if the research is intended to enhance the probability of survival of the particular fetus to the point of viability. The Department will, therefore, very shortly issue a proposed rule to afford the public the opportunity to comment on these changes. In the meantime, current Subpart B remains in effect for the special protection of pregnant women and human fetuses involved in research.

The notice and comment requirements of 5 U.S.C. section 553 do not apply to this delay of the rule's effective date, which is a rule of procedure. See 5 U.S.C. 553(b)(3)(A). To the extent that section 553 applies in these circumstances, however, the Department finds that the action comes within that provision's good cause exceptions in that obtaining public comment is impracticable, unnecessary, and contrary to the public interest. See 5 U.S.C. 553(b)(3)(B). Given the imminence of the effective date, and the imminence of a new notice of proposed rulemaking, seeking prior public comment on this delay is impracticable, as well as contrary to the public interest in the orderly promulgation and implementation of regulations. Further, comment is unnecessary because no harm is caused by delay of the effective date of the regulations, as the current rule, 45 CFR part 46, Subpart B, Protection of Human Subjects, Additional Protections for Pregnant Women and Human Fetuses Involved in Research, and Pertaining to Human In Vitro Fertilization, published in the **Federal Register** on August 8, 1975 and amended January 11, 1978 and June 1, 1994, will remain in effect pending any further action by the Department, and any action taken will be subject to notice and comment before final publication.

Dated: May 16, 2001.

**Tommy G. Thompson,**  
*Secretary.*

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