

reviewed. The Department believes that the proposed waiver includes adequate assurances that OHRP will conduct periodic reviews to determine the adequacy of the waiver in meeting its intended need or if adjustments to the waiver are necessary and appropriate. The Department notes that OHRP will receive and review all certifications of research covered by the proposed waiver.

Other

One commenter suggested that the DHHS regulations should permit prisoners to complete a study in which they were enrolled before being incarcerated. The Department finds that this comment is not relevant to the proposed waiver. The Department may consider this issue at a future time.

One commenter recommended that DHHS adopt a new rule or standard for informed consent when a prisoner is participating as a research subject and the consent occurred in the prison milieu. The Department finds that this comment is not directly relevant to the proposed waiver. The Department notes that because prisoner-subjects are afforded all of the protections of the informed consent requirements listed in § 46.116 of 45 CFR part 46, subpart A, the current standards for obtaining informed consent from prisoner-subjects are adequate.

One commenter found the example given of when the proposed waiver could be used to be incongruent with the requirement that the waiver only may apply to minimal risk research. The commenter asserted that a study of HIV is not minimal risk regarding a loss of confidentiality. The Department believes that the example given could entail no more than minimal risk for research involving prisoners as defined under 45 CFR 46.303(d): the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

One commenter stated that a prisoner should not be required to be a "guinea pig" and that a prisoner should be enrolled in research only if the prisoner agrees to participate in writing. The Department notes that the commenter's objections are not specific to the proposed waiver. The Department further notes that under §§ 46.116 and 46.117 of subpart A of the DHHS regulations for the protection of human subjects, no investigator may involve a human being as a subject in research covered by the regulations unless the investigator has obtained and

documented the informed consent of the subject in accordance with, and to the extent required by, the DHHS regulations.

One commenter states that the proposed waiver should not be approved because it represents a retreat from one of the most important values underlying Subpart C: the fair distribution of the burdens and benefits of research. The Department believes that the waiver as proposed supports the fair distribution of burdens and benefits of research permitting subjects, including some who are prisoners, to participate in certain DHHS-supported or conducted research in which the purposes are (1) to describe the prevalence or incidence of disease by identifying all cases; and (2) to study potential risk factors associations for a disease. Such studies would not be permitted without the waiver.

Summary

After considering the comments, DHHS is adopting the waiver as proposed. The waiver is effective June 20, 2003. All initial and ongoing projects reviewed by IRBs under DHHS-approved assurances after the effective date may be reviewed in accordance with this waiver.

Dated: April 28, 2003.

Richard H. Carmona,

Surgeon General and Acting Assistant Secretary for Health.

Approved: June 13, 2003.

Tommy Thompson,

Secretary, Department of Health and Human Services

[FR Doc. 03-15580 Filed 6-19-03; 8:45 am]

BILLING CODE 4150-36-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 0 and 54

[CC Docket No. 02-6; FCC 03-101]

Schools and Libraries Universal Service Support Mechanism

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Commission takes major steps to simplify and streamline the operation of our universal service mechanism for schools and libraries, while improving our oversight over the support mechanism. The Commission adopts a number of rules to streamline program operation, and promote the

Commission's goal of reducing the likelihood of fraud, waste, and abuse.

DATES: Effective July 21, 2003, except for §§ 54.500(k), 54.503, 54.507(g)(1)(i) and (g)(1)(ii), 54.514(a), and 54.517(b) which will become effective July 1, 2004. In addition, § 54.515(b) contains information collection requirements that have not been approved by the Office of Management Budget (OMB). The Commission will publish a document in the **Federal Register** announcing the effective date of that section.

FOR FURTHER INFORMATION CONTACT: Jonathan Secrest and Katherine Tofigh, Attorneys, Telecommunications Access Policy Division, Wireline Competition Bureau, (202) 418-7400.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Second Report and Order in CC Docket No. 02-6, FCC 03-101 released on April 30, 2003. This Second Report and Order was also released with a companion Further Notice of Proposed Rulemaking FNPRM. The full text of this document is available for public inspection during regular business hours in the FCC Reference Center, Room CY-A257, 445 Twelfth Street, SW., Washington, DC 20554.

I. Introduction

1. In this Order, we take major steps to simplify and streamline the operation of our universal service mechanism for schools and libraries, while improving our oversight over the support mechanism. In section 254 of the 1996 Act, Congress directed the Commission to establish explicit universal service support mechanisms to ensure the delivery of affordable telecommunications service to all Americans, including low-income consumers, rural health care providers, and eligible schools and libraries. Pursuant to section 254, eligible schools, libraries, and consortia that include eligible schools and libraries, may receive discounts for eligible telecommunications services, Internet access, and internal connections. The Commission has issued several orders interpreting rules governing the operation of the schools and libraries universal service support mechanism.

2. Since the inception of the schools and libraries support mechanism in 1997, schools and libraries have received over \$9.6 billion in funding commitments. This funding has provided millions of school children and library patrons access to modern telecommunications and information services. The Commission previously sought comment in a Notice of Proposed Rulemaking (*Schools and Libraries*