

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the Secretary
45 CFR Part 46
Waiver of Requirements as Applied to Medicaid Demonstration Projects Involving Cost-Sharing (Copayments, Deductibles, Coinsurance)
AGENCY: Office of the Secretary, HHS.

ACTION: Notice of waiver.

SUMMARY: The Department of Health and Human Services hereby gives notice that, pursuant to 45 CFR 46.101(e), the Secretary has decided to waive the requirements set forth in Part 46, relating to protection of human subjects, as they pertain to demonstration projects, approved under section 1115 of the Social Security Act, which test the use of cost-sharing, such as deductibles, copayment and coinsurance, in the Medicaid program (Title XIX of the Social Security Act). The Secretary believes that waiver of Part 46 requirements is appropriate since it will facilitate the timely efficient operation of demonstration projects which are likely to assist in promoting the objectives of the Medicaid program.

DATE: Effective: March 4, 1982.

FOR FURTHER INFORMATION CONTACT: Steven Pelovitz, (301) 597-3195.

SUPPLEMENTARY INFORMATION:

The rapid escalation of Medicaid costs in recent years makes it imperative for the Department and the States to conduct research which would explore ways to provide optimum medical care while controlling costs that would otherwise make the program unaffordable. Provisions of the Omnibus Budget Reconciliation Act of 1981 (Pub. L. 97-35) which, beginning in Fiscal Year 1982, imposes certain new restrictions on the amount of Federal reimbursement which will be available to States for the Medicaid program, make it critical that this research proceed expeditiously. Cost-sharing demonstration projects are likely to be an important part of this research and, without a waiver of the Part 46 requirements, each otherwise approved project would have to go through the process of review by an Institutional Review Board (IRB) before it could be implemented.

Under Part 46, the primary functions of IRB review are to assure that the human subjects of research are not exposed to risk which is unreasonable in light of the benefit to be gained, and that their appropriate informed consent has been obtained (§ 46.111). However, in the case of research conducted to study Federal or State benefit programs,

such as a copayment or other cost-sharing demonstration projects, where participation of a large number of individuals would make it impractical to proceed if informed consent had to be obtained from each one, the provisions of Part 46 contemplate IRB waiver of the informed consent requirements. Further, in research such as a Medicaid cost-sharing demonstration project, the possibility of any risk arises solely from the modification of benefits or the means of obtaining benefits available through the governmental assistance program. Modifications of this nature are clearly authorized by, and inherent in the concept of demonstration projects conducted under section 1115. Therefore, the Secretary has concluded that the only appropriate standard by which to assess a cost-sharing demonstration project, including its potential effect on Medicaid beneficiaries, is the standard established by section 1115 itself—whether the project is "likely to assist in promoting the objectives" of the Medicaid program. On the basis of that standard, and pursuant to the waiver authority contained in 45 CFR 46.101(e), the Secretary believes that a waiver is appropriate since IRB review would constitute an inappropriate and unnecessary step in the evaluation and approval of section 1115 Medicaid cost-sharing demonstration projects.

Since there are important reasons for expediting the conduct of research on the use of Medicaid cost-sharing, and it is this Department's policy generally to eliminate unnecessary procedures in the administration of its programs, the waiver announced in this notice is effective immediately (March 4, 1982).

Dated: February 25, 1982.

 Richard S. Schweiker,
 Secretary.

[FR Doc. 82-5723 Filed 3-3-82; 8:45 am]

BILLING CODE 4120-03-M

FEDERAL COMMUNICATIONS COMMISSION
47 CFR Part 1
Completion of the Move From Washington, D.C., to Gettysburg, Pa., by the Private Radio Bureau's Applications Processing Section
AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The FCC modifies its rules to specify that applications for stations authorized by the Private Radio Bureau shall be filed with the Commission's

office in Gettysburg, Pennsylvania, since this is where these applications are now processed.

EFFECTIVE DATE: March 9, 1982.

ADDRESS: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Eugene C. Bowler, Private Radio Bureau, (202) 632-6497.

SUPPLEMENTARY INFORMATION:

Adopted: February 19, 1982.

Released: February 23, 1982.

In the matter of amendment of § 1.912 of the Commission's rules and regulations.

1. The Private Radio Bureau has completed moving all of its application processing functions from Washington, D.C. to Gettysburg, Pennsylvania. Section 1.912 of the rules is, therefore, amended to reflect this fact.

2. Since this amendment of the rules relates solely to a rule of Agency procedure and practice, notice and public procedure thereon are not required. See 5 U.S.C. 553(b).

3. Authority for this action is contained in sections 4(i) and 303(r) of the Communications Act of 1934, as amended and § 0.231 of the Commission's rules and regulations. See 47 CFR 0.231.

4. Accordingly, it is ordered, that § 1.912 of the rules is amended as set out in the attached Appendix.

(Secs. 4, 303, 307, 48 Stat., as amended, 1066, 1082, 1083; 47 U.S.C. 154, 303, 307)

Federal Communications Commission.

 Edward J. Minkel,
 Managing Director.

PART 1—PRACTICE AND PROCEDURE

Part 1 Section 1.912(e) is revised to read as follows:

§ 1.912 Where applications are to be filed.

(e) All other applications shall be filed with the Commission's offices in Gettysburg, Pennsylvania and shall be addressed to: Federal Communications Commission, Gettysburg, Pennsylvania 17325.

[FR Doc. 82-5885 Filed 3-3-82; 8:45 am]

BILLING CODE 6712-01-M

47 CFR Part 73

[BC Docket No. 80-397; RM-3506]

FM Broadcast Station in Uvalde, Crystal City, and Pearsall, Texas; Changes in Table of Assignments
AGENCY: Federal Communications Commission.

1. The Table of Sections is amended by deleting the following:

114-26.406-2 Billing code.
114-26.406-4 Administrative control of credit cards.

2. Sections 114-26.406 and 114-26.406-1 are revised to read as follows:

§ 114-26.406 U.S. Government National Credit Card for use in obtaining service station deliveries and services.

§ 114-26.406-1 General.

(a) The use of Standard Form 149 is encouraged, but commercial credit cards issued by Federal Supply Schedule contractors are also authorized for use.

(b) The head of each bureau and office shall determine the extent to which Standard Form 149 shall be used.

(c) Bureau and office billing code numbers are listed in § 114-38.12.

§§ 114-26.406-2, 114-26.406-4 [Removed]

3. Sections 114-26.406-2 and 114-26.406-4 are deleted.

4. Part 114-38 is amended by the addition of new Subpart 114-38.12 as follows:

SUBPART 114-38.12—PREPARATION AND CONTROL OF STANDARD FORM 149, U.S. GOVERNMENT NATIONAL CREDIT CARD

§ 114-38.1201 Billing code.

(a) The first three digits of the national credit card billing code shall always be 000 for any Department of the Interior activity.

(b) The fourth digit's use is at the option of the head of the bureau or office.

(c) The fifth and sixth digits shall be "14", the Department's agency code.

(d) The following blocks of numbers are assigned to bureaus and offices for use as the seventh, eighth, and ninth digits:

Southwestern Power Administration: 000 thru 009.
Bonneville Power Administration: 010 thru 019.
Geological Survey: 020 thru 029; 675 thru 699; 925 thru 964.
Southeastern Power Administration: 030 thru 039.
Fish & Wildlife Service: 040 thru 069; 100 thru 109.
Bureau of Mines: 060 thru 099.
Bureau of Reclamation: 200 thru 459.
Reserved: 460 thru 499.
Alaska Power Administration: 700 thru 704.
Bureau of Indian Affairs: 500 thru 549; 705 to 784; 865 thru 914.
National Park Service: 550 thru 569; 610 thru 674; 965 thru 999.
Bureau of Land Management: 570 thru 599; 800 thru 864.
Office of the Secretary: 600 thru 609.
Office of Aircraft Services: 785 thru 799.
Mining Enforcement and Safety Administration: 915 thru 924.

(e) The tenth digit cannot be used for any purpose other than validation.

§ 114-38.1202 Administrative control of credit cards.

The head of each bureau and office shall establish administrative control procedures in compliance with FPMR 101-38.1202. When a credit card is lost

or stolen, the following additional actions shall be taken to minimize the opportunity for unauthorized use:

(a) Notify the paying office to be on the alert for bills charged to the lost or stolen card; and

(b) Notify local service stations that the lost or stolen card is not to be honored.

[FR Doc.76-18626 Filed 6-25-76;8:45 am]

Title 43—Public Lands: Interior

CHAPTER II—BUREAU OF LAND MANAGEMENT, DEPARTMENT OF THE INTERIOR

APPENDIX—PUBLIC LAND ORDERS

[Public Land Order 5589; CO-22622]

COLORADO

Withdrawal of Lands for Protection of Cultural Resources and Public Recreation Values; Revocation of Reclamation Project Withdrawal

By virtue of the authority vested in the President and the authority contained in section 3 of the Act of June 17, 1902, as amended and supplemented, 43 U.S.C. 416 (1970), and pursuant to Executive Order No. 10355 of May 26, 1952 (17 FR 4831), it is ordered as follows:

1. Subject to valid existing rights, the following described public land is hereby withdrawn from all forms of appropriation under the public land laws, including the mining laws, 30 U.S.C. Ch. 2, and the mineral leasing laws, and from the construction of roads under Revised Statute 2477, 43 U.S.C. 932:

NEW MEXICO PRINCIPAL MERIDIAN

T. 37 N., R. 15 W.,

Sec. 7, a tract of land in NW¼SE¼, commencing at the northwest corner of NW¼SE¼ of said section 7, the point of beginning:

thence N. 89°31'00" E., 653.400 ft.;
thence S. 26°37'30" E., 752.070 ft.;
thence S. 0°52'45" E., 675.180 ft.;
thence S. 89°34'00" W., 977.130 ft.;
thence N. 1°01'00" W., 1350.360 ft.
to the point of beginning.

The area contains 27.80 acres in Montezuma County.

2. The Secretarial order of January 4, 1943, withdrawing lands for the McPhee Reservoir, Dolores Project, Colorado, is hereby revoked so far as it affects the lands described in paragraph 1 of this order.

JOHN KYL,

Assistant Secretary of the Interior.

JUNE 22, 1976.

[FR Doc.76-18622 Filed 6-25-76;8:45 am]

Title 45—Public Welfare

SUBTITLE A—DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, GENERAL ADMINISTRATION

PART 46—PROTECTION OF HUMAN SUBJECTS

Secretary's Interpretation of "Subject at Risk"

Notice is hereby given of the Secretary's interpretation of his regulations at 45 CFR 46.103(b), defining "subject at

risk." The definition is incorporated in 45 CFR Part 46, pertaining to the Protection of Human Subjects involved in grants and contracts of the Department of Health, Education, and Welfare supporting research, development, and related activities.

Section 46.103(b) defines "subject at risk" at "any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those established and accepted methods necessary to meet his needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service."

The types of risk situations against which the regulations were designed to protect are suggested by the areas of concern which were addressed in the legislative hearings held in conjunction with the enactment of section 474 of the Public Health Service Act, 42 U.S.C. 289f-3 (added by Pub. L. No. 93-343), which forms part of the basis for the Departmental regulations at 45 CFR Part 46, and in the preambles to the proposed and final regulations at 45 CFR Part 46. The subjects addressed included the use of FDA-approved drugs for any unapproved purpose; psycho-surgery and other techniques for behavior control currently being developed in research centers across the nation; use of experimental intrauterine devices; biomedical research in prison systems and the effect of that research on the prison social structure; the Tuskegee Syphilis Study; the development of special procedures for the use of incompetents or prisoners in biomedical research; and experimentation with fetuses, pregnant women, and human *in vitro* fertilization. The regulations were intended, and have been uniformly applied by the Department, to protect human subjects against the types of risks inherent in these types of activities.

The regulations were not, and have never been, intended to protect individuals against the effects of research and development activities directed at social or economic changes, even though those changes might have an impact upon the individual. More particularly, they were not designed to protect against possible financial injury, which may result from alteration in the price, availability, or conditions of eligibility for benefits or services offered under a governmental program. Thus, a requirement for research and development purposes that some welfare recipients report more frequently than others their income for purposes of determining their eligibility for, or the amount of, their welfare benefit, or a requirement that some but not all able-bodied welfare recipients work as a condition of eligibility for welfare, or a diminution in the level of welfare benefits (within prescribed boundaries) payable to some but not all similarly situated welfare beneficiaries, or a requirement that some but not all welfare recip-