

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 (Co payments, 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, co payment 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:

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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.*

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