

flood Hazard Area identified on October 21, 1980. Any structures built on the property will be located in Zone C.

Pursuant to the provisions of 5 U.S.C. 605(b), the Associate Director, State and Local Programs and Support, to whom authority has been delegated by the Director, Federal Emergency Management Agency, hereby certifies that this rule if promulgated will not have a significant economic impact on a substantial number of small entities. This rule provides routine legal notice of technical amendments made to designated Special Flood Hazard Areas on the basis of updated information and imposes no new requirements or regulations on participating communities.

#### List of Subjects in 44 CFR Part 70

Flood insurance, Flood plains.

(National Flood Insurance Act of 1988 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended; 42 USC 4001-4128; Executive Order 12127, 44 FR 19367; delegation of authority to Associate Director, State and Local Programs and Support)

Issued January 25, 1983.

**Lee M. Thomas,**

*Associate Director, State and Local Programs and Support.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

#### 45 CFR Part 46

#### Exemption of Certain Research and Demonstration Projects From Regulations for Protection of Human Research Subjects

**AGENCY:** Office of the Secretary, Department of Health and Human Services.

**ACTION:** Final rule.

**SUMMARY:** The Department of Health and Human Services (the Department or HHS) is including among the types of research specifically exempt from the application of the regulatory requirements of 45 CFR Part 46 (protection of human research subjects) research and demonstration projects conducted under the Social Security Act and other federal statutory authority and designed to study certain public benefit or service programs, the procedures for obtaining benefits or services under those programs, and possible changes or alternatives to those

programs or procedures, including changes in methods or levels of payment. These demonstration and service projects are already subject to procedures which provide for extensive review by high level officials in various program administration offices. Review by an Institutional Review Board (IRB), as required under Part 46, would be duplicative and burdensome to state and local agencies and to other entities participating in demonstration projects. Removal of this unnecessary layer of review will not only reduce the cost of the projects but help to avoid unnecessary delays in project implementation. However, in order to ensure the continued protection of human subjects participating in such research activity, the Department is adding a specific requirement of written, informed consent in any instance, not reviewed by an IRB, in which the Secretary determines that the research activity presents a danger to the physical, mental or emotional well-being of a participant.

**EFFECTIVE DATE:** These regulations are effective April 4, 1983.

**FOR FURTHER INFORMATION CONTACT:** F. William Dommel, Jr.; (301) 496-7163.

**SUPPLEMENTARY INFORMATION:** In a notice of proposed rulemaking (NPRM), published March 22, 1982, 47 FR 12276, the Department proposed to exempt certain research and demonstration projects from coverage of the Regulations for the Protection of Human Subjects, 45 CFR Part 46. The research activity proposed for exemption from the regulations generally involves public benefit or service programs under the Social Security Act and other similar programs administered by the Department. Such projects typically study proposed or possible changes in levels of benefits or services or in the systems and procedures for delivering such benefits or services to recipients. As indicated in the NPRM, the Department now believes that such research activity is fundamentally different from the experiments and projects otherwise covered by the Part 46 regulations, which typically involve biomedical or behavioral research.

The NPRM noted that the Department had previously proposed to exempt this class of research activity from the Part 46 regulations. 44 FR 47688 (August 14, 1979). However, when the regulations were published in final form, they continued to cover these activities. 46 FR 8366, 8370 (January 26, 1981). As a result, research and demonstration projects carried out under the Social Security Act and other statutes for the purpose of studying possible changes in

benefit levels or in procedures for delivery of benefits have been subject to a requirement of review by an Institutional Review Board (IRB). The Department's experience has been that this additional layer of review for such projects is duplicative and needlessly burdensome in light of the substantial review process to which they are already subjected by state and federal officials. Furthermore, the Department has found such review by an IRB—which generally focuses on ethical questions arising from biomedical and behavioral research—to be unnecessary and inappropriate in the context of adjustments to benefit and service programs.

In view of these considerations, the Department proposed to exempt this class of research activity from the Part 46 regulations. In doing so, we indicated the following statutory authorities for conducting such research activity as among those which would be exempt from the regulations if the proposed exemption were adopted: Sections 426, 445, 1110(a), 1115 and 1875 of the Social Security Act; section 201 (a) and (b) and section 505 of the Social Security Disability Amendments of 1980, Pub. L. 96-265; section 402(a) of the Social Security Amendments of 1967, as amended (codified at 42 U.S.C. 1395b-1); section 222(a) of the Social Security Amendments of 1972 (codified at 42 U.S.C. 1395b-1 note); section 649 of Pub. L. 97-35 (Head Start Act); section 4 of Pub. L. 93-247, as amended (Child Abuse Prevention and Treatment Act); section 145 of Pub. L. 94-103, as amended (Developmental Disabilities Assistance and Bill of Rights Act); section 805 of Pub. L. 93-644, as amended (Native American Program Act of 1974); sections 421-425 of Pub. L. 93-29, as amended (Older Americans Act of 1965). Section 702 of the Social Security Act is another example of a statutory authority for conducting research which would be exempt from the Part 46 regulations under the exemption we proposed.

We have now carefully considered the comments received in response to the NPRM. These comments are analyzed and addressed below. As indicated, nothing in the comments led us to conclude that this class of research activity should, as a matter of policy, be subject to IRB review as provided by the Part 46 regulations. Moreover, in contrast to biomedical and behavioral research sponsored or conducted by the Department under the Public Health Service Act, there is no statutory requirement that such research activities be reviewed by an IRB.

Nevertheless, the Department does have an obligation, pursuant to the conditions imposed upon its continuing appropriations, to ensure that research activity not present a danger to the physical, mental or emotional well-being of participants. See, e.g., section 412, Pub. L. 93-517. In order to make clear that we will continue to fulfill that obligation and also in response to certain of the comments received, we are adding language to Part 46 to clarify that, with respect to research activity involving public benefit programs now to be exempted from IRB review, the Department will include in its review of such proposed research activity consideration of the effects on participants. To the extent that the proposed activity is determined to pose a danger to the participants, informed consent in writing will be required. This clarification will apply only to those projects which were previously subject to IRB review but are now exempt. All other categories of exempt research set forth in § 46.101(b) will continue not to be subject to any requirement of review for purposes of protecting human subjects since these other categories involve little or no possibility of risk to participants. See 46 FR 8367 (January 26, 1981).

In addition, our review of the proposal and the comments has led us to adopt another refinement to the final regulation. In the NPRM, we indicated that we were deleting entirely the provision in § 46.116(c) which permitted waiver of informed consent by IRB's in certain situations involving Federal, state or local benefit or service programs. The proposed deletion of this provision was prompted by the recognition that this waiver authority would not be needed in circumstances covered by the new exemption—*i.e.*, research or demonstration projects involving public benefit or service programs "conducted by or subject to the approval of" this Department. However, the new exemption does not reach similar projects conducted by or subject to the approval of state or local governments. There was no intention to impose additional burdens on such research carried out under the auspices of state or local government. Accordingly, we have determined that it would be appropriate to continue providing the authority under § 46.116(c) for an IRB to waive informed consent in circumstances where a research or demonstration project involves public benefit or service programs and where the project is conducted by or subject to the approval of state or local governments. The language of the new

§ 46.116(c) has been amended slightly to conform to the language of the new exemption.

#### Response to Comments

We received approximately 50 comments in response to the proposed exemption. Most of these comments came from advocacy groups who regularly represent, in court and otherwise, persons whose benefits might be affected by the research projects proposed to be exempted from the part 46 regulations, and most of them opposed the exemption for one reason or another. Favorable comments were received from several States which generally agreed with the analysis in the NPRM that IRB review of such projects was burdensome and duplicative. Below we have summarized, discussed and responded to the major comments, organized by topic, which were submitted in opposition to the proposed exemption.

1. Some commenters objected to the fact that we did not publish in the notice of proposed rulemaking an exhaustive list of every statutory demonstration authority to which the exemption would pertain. According to these commenters, fairness required a complete listing of every statute pursuant to which a demonstration project might be conducted exempt from the regulations. This suggested approach ignores the fact that the regulations themselves are couched in terms of broad categories of research. In listing the statutory authorities subject to the proposed exemption, we provided prominent examples of the types of authority which would be exempt. In view of the large number of statutory authorities, which are frequently augmented by legislation, we believe that an effort to provide an exhaustive list could be misleading since such a list would inevitably be incomplete. Thus, we did not attempt to catalogue all exempt authorities since the clear intent of the proposed exemption is to cover all projects failing within its terms, whether or not they were specifically referenced in the notice of proposed rulemaking.

2. A few commenters asserted that the list of statutory authorities subject to the proposed exemption was in fact inaccurate because section 505 of the Social Security Disability Amendments of 1980, Pub. L. 96-265, requires that projects conducted thereunder be subject to the Department's regulations for the protection of human subjects. Such comments appear to be based on a misunderstanding as to the scope of the demonstration authority enacted by section 505. That statute created a new demonstration authority relating to the

work activity of disabled beneficiaries under the old-age, survivors and disability insurance program. This new authority is not required to be covered by the Department's regulations governing informed consent and the protection of human subjects. However, section 505 also amended section 1110 of the Social Security Act to add a new subsection (b) providing authority to waive requirements of Title XVI (the Supplemental Security Income program) for the purposes of carrying out demonstration projects. The statute expressly provides that projects conducted pursuant to this authority are subject to "the requirements for informed consent established by the Secretary for use in any experimental, pilot, or demonstration project in which human subjects are at risk." Thus, we recognize that demonstration projects carried out under section 1110(b) are required to be covered by the Part 46 regulations, and for that reason they were not included among the authorities to which the proposed exemption would apply.

3. A number of the comments referred to the decision of the court in *Crane v. Mathews*, 417 F. Supp. 532 (ND. Ga. 1976), as contrary to the proposed exemption. In that case, Georgia Medicaid recipients challenged a demonstration project permitting the state to impose copayments for medical services pursuant to a waiver of statutory provisions otherwise barring such copayments. The plaintiffs alleged, among other things, that the Department's then effective regulations for protection of human subjects required that such projects be first reviewed by an IRB. The court agreed and enjoined the project pending IRB review in accordance with the regulations.

In fact, contrary to the suggestion of these comments, the *Crane* court did not hold that demonstration projects under the Social Security Act were required to be subject to the Part 46 regulations. Instead, the court simply found that the regulations as then in effect were intended to cover such demonstration projects, at least as they pertained to imposition of copayments upon Medicaid recipients. Furthermore, the court in no way concluded that the recipients were placed at risk by the demonstration project. Nothing in the *Crane* decision can be read as mandating the retention of Part 46 coverage in the case of the demonstration projects which we are now exempting from the regulations.

4. Several comments took issue with the manner in which the notice of

proposed rulemaking discussed our statutory authority to regulate experiments other than biomedical and behavioral research. We noted that the principal authority for the Part 46 regulations was section 474 of the Public Health Service Act, which requires the Secretary to establish regulations governing "the conduct of biomedical and behavioral research involving human subjects" and specifies that an IRB shall be the vehicle for review of such research. In so noting, we in no way meant to imply that we lacked statutory authority to regulate the sorts of experiments and demonstration projects which we now are exempting from IRB review under the Part 46 regulations. As the court held in *Crane v. Mathews*, it is clearly within the broad rulemaking authority of the Secretary to regulate activity of that nature. However, in exempting it from IRB review, we felt it appropriate to distinguish this activity from biomedical and behavioral research, where we are mandated by statute to impose such review.

Other comments suggested that certain demonstration projects under the Social Security Act which we are now exempting from IRB review in fact feature considerable biomedical or behavioral aspects, thus bringing them within the scope of section 474's mandate. While the phrase "biomedical and behavioral research" is susceptible to broad interpretation, we see no indication that Congress intended the requirements of section 474 to apply to the demonstration projects subject to the proposed exemption. When passing legislation providing waiver or demonstration authority under the Social Security Act, Congress has made explicit those circumstances in which it believes that human subjects should be protected by an additional layer of regulatory review. See, for example, section 1110(b) of the Social Security Act. Thus, we believe that it is totally consistent with the intent of Congress in passing section 474 that we exempt from IRB review projects involving social welfare and benefit programs. The court in *Crane v. Mathews* agreed with our view that section 474 does not require regulation of such projects. See 417 F. Supp. at 545.

5. Some comments objected that the proposed exemption did not give sufficient consideration to the recommendations of the various National and Presidential Commissions that have studied the issue of protection of human subjects. We believe that we have addressed the major concerns of those Commissions and their findings.

The Commissions have focused principally on problems stemming from biomedical and behavioral research involving human subjects. Nevertheless, we have experimented with broader use of IRB review. As we indicated in the notice of proposed rulemaking, our experience with IRB review led us to conclude that it was in fact unnecessary and burdensome in the context of research concerning benefit programs under the Social Security Act and otherwise. Throughout this process, we have continued to consider, evaluate and place great weight upon the comments of these Commissions. In fact, as discussed below, dialogue with the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research has also continued with respect to the proposed exemption.

6. Among the commenters was the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. The Commission noted that review by state and federal officials did not precisely "duplicate" IRB review unless the reviewers included persons independent of program management, including non-government personnel and persons with expertise in "ethical" aspects of research. Recognizing that "informed consent" requirements could easily frustrate social policy experiments of the sort proposed for exemption, the Commission nevertheless suggested that this concern could be addressed by the waiver provisions in the regulations. In the Commission's view, however, such waivers should be issued by an IRB rather than by the decision of either state or federal program officials. The Commission also suggested that research projects covered by the proposed exemption can create medical risks as well as risks of non-physical intrusions into personal or confidential matters and that such risks should be considered by an IRB. The Commission expressed particular concern about research entailing reduction of benefits to certain recipients while others, similarly situated, continue to receive a higher level of benefits; In light of this concern, the Commission proposed an alternative exemption which would not include such research. Thus, under the Commission's alternative, research projects in any way limiting or reducing the benefits to which recipients would otherwise be entitled would continue to be subject to IRB review.

We have considered the Commission's comments with particular care in recognition of its statutory

mandate in the area of ethical problems in research. We have decided, however, not to follow the Commission's suggestion that the exemption be limited to those research projects not entailing reduction of benefits. A review of the research projects covered by the proposed exemption reflects that many, if not most, of them could be construed as reducing benefits in one way or another. Accordingly, adoption of the Commission's alternative would not adequately address the concerns which prompted us to propose the exemption.

We do not agree with the Commission's belief that the "ethical" aspects of research in benefits programs will go unreviewed unless nongovernmental individuals with expertise in the ethics of research participate in consideration of proposed studies. The questions raised by research involving government benefits are significantly different from those raised by biomedical and behavioral research. IRB's are typically constituted to deal with the special ethical and other problems involved in biomedical and behavioral research. In contrast, ethical and other problems raised by research in benefit programs will be addressed by the officials who are familiar with the programs and responsible for their successful operation under state and federal laws. The risks identified by the Commission can be sufficiently evaluated by those program officials.

7. Some comments disagreed with the NPRM's conclusion that IRB review was duplicative and unnecessary in the context of the research projects proposed for exemption. These comments focused on the need for an independent reviewing body to ensure that recipient rights were properly considered and expressed doubt as to the ability of state officials in particular to fulfill that role. In our view, these comments ignore the fundamental difference between such research projects and biomedical and behavioral research. In contrast to the latter, which may result in either significant physical invasions or intrusions upon the privacy of participants, research in public benefit programs typically involves alterations in eligibility criteria, benefit levels or delivery systems. These are matters not falling within the expertise of IRB members but instead within the knowledge and experience of program officials at both the state and federal levels. In the course of promulgating regulations for the various programs at issue, these officials are regularly called upon to make decisions of the same sort, entailing determinations as to which

persons may or may not receive benefits and at what levels. In that sense, the research projects proposed for exemption do not differ substantially from the normal program activity administered by these officials. Furthermore, with the addition of clarifying language to the Part 46 regulations, there will be a well-defined responsibility of federal program officials to take into consideration potential risks to the health and safety of participants in research activity before making decisions whether or not to approve particular projects.

With respect to the adequacy of review by state program officials, we have no basis to question either the competency or sincerity of state personnel. In any event, research proposals by the states receive thorough review by federal officials experienced in the various programs. It is significant to note that the major Medicaid research authority—section 1115 of the Social Security Act—specifically provides that projects thereunder be consistent with the purposes of the program. In reviewing state proposals, federal officials will be mindful, as always, of this injunction.

8. Certain comments suggested that, in proposing to exempt from IRB review research projects involving public benefit programs, we somehow sought to circumvent congressional intent and impose program limits which had been rejected by Congress. More specifically, these comments referred to legislative proposals to permit more extensive use of copayments in the Medicaid program. In fact, any research project involving copayments will not benefit from the exemption since the Secretary has already exercised his discretion to waive application of Part 46 to such projects, pursuant to his authority under 45 CFR 46.101(e). See 47 FR 9208 (March 4, 1982). This provision of the regulations allows the Secretary to waive IRB review for any particular research activity or class of research activity. Thus, the status of co-payments and other similar cost-sharing devices in the Medicaid program will be unaffected by the new exemption. It should also be noted that the recently enacted Tax Equity and Fiscal Responsibility Act includes specific provisions governing demonstration projects involving Medicaid copayments.

9. A few comments asserted that the proposed exemption was contrary to the due process or equal protection clauses of the Constitution because of the possible impact which exempted demonstration projects could have on disadvantaged groups without adequate

opportunity for a hearing. The function of IRB's, however, is not to provide individual claimants with any "due process" right to be heard. At most, IRB's review in a general way broad-based demonstration projects specifically authorized by statute. In our view, an individualized hearing of the sort which typically is associated with "due process" is not appropriate in this context. To the extent that a "hearing" of any sort is called for, the review provided by state and federal program officials is more than adequate to serve that function.

The proposed exemption also raises no issue of equal protection. The only result of the exemption will be that projects involving public benefit programs will not be subject to IRB review while those involving biomedical or behavioral research are. This disparate treatment of different kinds of research activities is, we believe, completely rational and justified in light of the substantially different character of biomedical and behavioral research. Thus, we do not view this different treatment as violative of equal protection.

10. A small number of the comments took issue with the conclusion that Executive Order 12291 was inapplicable to the NPRM. These comments basically argued that the cost to beneficiaries of Medicaid co-payments alone would exceed the Executive Order's threshold figure of \$100 million or more in annual effect on the economy. Even if this assertion were accurate, the proposed exemption has no direct effect on projects involving co-payments because they have, as noted above, already been exempted from Part 46 coverage pursuant to the Secretary's waiver authority. Moreover, it is not the IRB review provided by Part 46 which controls the financial impact on Medicaid beneficiaries or other participants in research activity. Instead, program officials—at both the state and federal levels—make the decisions which influence the level of benefits by proposing and approving demonstration projects involving their programs. Thus, the proposed exemption has no direct bearing on any financial impact which may occur as a result of such projects.

#### Impact Analysis

##### *Economic Impact on Small Entities*

The Secretary certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility

Act, Pub. L. 96-354. Thus, a regulatory flexibility analysis is not required.

#### *Classification of Rule Under E.O. 12291*

The Secretary has determined that this rule is not a "major rule" under Executive Order 12291 and thus a regulatory impact analysis is not required. The Secretary's determination is based on the finding that the proposed rule would not:

- (1) Have an annual effect on the economy of \$100 million or more;
- (2) Impose a major increase in costs or prices for consumers, individual industries, federal, state or local government agencies, or geographic regions; or
- (3) Result in significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

#### List of Subjects in 45 CFR Part 46

Civil rights, Government contracts, Grant programs—health, Prisoners, Research, Safety.

Dated August 26, 1982.

**Edward N. Brandt, Jr.,**

*Assistant Secretary for Health,*

**Richard S. Schweiker,**

*Secretary.*

#### **PART 46—PROTECTION OF HUMAN SUBJECTS.**

For the reasons set out in the preamble, Part 46 of 45 CFR is amended as set forth below.

1. Section 46.101 is amended by adding a new paragraph (b)(6) and a new paragraph (i) to read as follows:

#### **§ 46.101 To what do these regulations apply?**

\* \* \* \* \*

(b) \* \* \*

(6) Unless specifically required by statute (and except to the extent specified in paragraph (i)), research and demonstration projects which are conducted by or subject to the approval of the Department of Health and Human Services, and which are designed to study, evaluate, or otherwise examine: (i) Programs under the Social Security Act, or other public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for

benefits or services under those programs.

\* \* \* \* \*

(i) If, following review of proposed research activities that are exempt from these regulations under paragraph (b)(6), the Secretary determines that a research or demonstration project presents a danger to the physical, mental, or emotional well-being of a participant or subject of the research or demonstration project, then federal funds may not be expended for such a project without the written, informed consent of each participant or subject.

2. Section 46.116(c) is revised to read as follows:

**§ 46.116 General requirements for informed consent.**

\* \* \* \* \*

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) Programs under the Social Security Act, or other public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

[FR Doc. 83-5549 Filed 3-3-83; 8:45 am]

**BILLING CODE 4150-04-M**

**45 CFR Part 96**

**Block Grant Programs**

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Final rule with comment period.

**SUMMARY:** This rule amends current regulation at 45 CFR 96.112(b) to allow continued funding of the Community Services Block Grant (CSBG) in the territories of Guam and American Samoa during Fiscal Year (FY) 1983. This change was made necessary by the limitations imposed on CSBG funding by section 138 of Pub. L. 97-276.

**DATES:** This rule is effective March 4, 1983. To assure consideration,

comments should be submitted by April 4, 1983.

**ADDRESS:** Submit comments to Spencer L. Lott, II, Director, Office of State and Project Assistance, Office of Community Services, 1200 19th Street, NW., Washington, D.C. 20506.

**FOR FURTHER INFORMATION CONTACT:** Spencer L. Lott, II, (202) 254-7030.

**SUPPLEMENTARY INFORMATION:** Section 675(c)(2)(A)(i) of the Omnibus Budget Reconciliation Act of 1981 (Pub. L. 97-35) ("the Act") required each State receiving funds under the CSBG to use at least 90 percent of its FY 1982 funds to make grants to "eligible entities" (as defined in section 673(1) of the Act) or to organizations which serve migrant or seasonal farmworkers. "Eligible entities" are primarily organizations which had been designated during FY 1981 as community action agencies or community action programs under the Economic Opportunity Act of 1964. For FY 1983 and subsequent years, section 675(c)(2)(A)(ii) of the Act afforded States greater flexibility in the use of their funds to make grants to non-profit private community organizations which serve migrant or seasonal farmworkers, or to political subdivisions within the States.

The territories of Guam and American Samoa do not have any organizations within their jurisdictions which meet the definitions of "eligible entities". Thus they were seemingly precluded from using more than 10 percent of their FY 1982 CSBG funds. Therefore, the final block grant regulations published by this Department of July 6, 1982 (47 FR 29472), explained that because Congress had not intended such a result, States or territories with no eligible entities could distribute their FY 1982 allotments using the funding criteria applicable for FY 1983, as specified in section 675(c)(2)(A)(ii).

However, section 138 of Pub. L. 97-276 imposed a new limitation which in effect extends to FY 1982 funding limitations through FY 1983, by requiring that States pass through 90 percent of their allotments to "eligible entities" or to organizations that serve migrant or seasonal farmworkers during FY 1983 as well. Thus under the current regulation these territories are once again arguably prevented from distributing most of their CSBG funds. We do not believe that this result was intended by Congress. Consequently, we are amending 45 CFR 96.112(b) to allow these territories to distribute their allotments according to the original requirements which would have been applicable under section 675(c)(2)(ii) of the Act.

Because of the limited time available in which territories may obligate FY 1983 funds, we believe that it would be impracticable and contrary to the public interest to delay availability of funds to the affected territories during the time necessary to conduct a rulemaking proceeding. Moreover, since this rule merely extends an existing rule to take into account the extension of the underlying statutory provision, we believe it is unnecessary to solicit public comment. Accordingly, we find that good cause exists to waive the requirement for prior opportunity for comment. For the same reason, and because the rule relieves a restriction, we are making the regulation effective immediately, instead of allowing the customary 30-day delayed effective date. Although we are not soliciting public comment prior to publication of the rule, comments may be submitted as stated above, and appropriate changes will be made in the rule based on any comments received.

**Regulatory Impact**

*Executive Order 12291*

E.O. 12291 requires that a regulatory impact analysis be prepared for major rules—defined in the Order as any rule that has an annual effect on the national economy of \$100 million or more, or certain other specified effects. The Department concludes that this regulation which allows Community Services Block Grant funding for the territories of Guam and American Samoa during Fiscal Year 1983 is not a major rule within the meaning of the Executive Order because it does not have an effect on the economy of \$100 million or more or otherwise met the threshold criteria. It merely sets forth the terms and conditions for spending appropriated funds. In this case, the effect of this regulation change is not to determine whether or not money will be spent, but the procedure by which it will be spent, and it is that effect—which is negligible—against which the threshold criterion is applied. Accordingly, a regulatory impact analysis is not required.

*Regulatory Flexibility Act of 1980*

The Regulatory Flexibility Act (5 U.S.C. Ch. 6) requires the Federal government to anticipate and reduce the impact of rules and paperwork requirements on small businesses. The primary impact of this regulation is on the territories of Guam and American Samoa, which are not "small entities" within the meaning of the Act. Because this regulation provides the two