



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the Assistant Secretary

1. Log No. HDS-PR-83-1

2. Issuance Date: 2/22/83

3. Originating Office: Office of Policy
Coordination and Review

4. Key Word: For-Profit
Organizations

5.

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7.

PROGRAM REGULATION

TO: STATE AGENCIES ADMINISTERING HDS PROGRAMS

SUBJECT: Final Rule Applicable to Grants and Subgrants to
For-Profit Organizations.

**LEGAL AND
RELATED
REFERENCES:**

Regarding HDS programs, 45 CFR Part 74 and 45 CFR
Part 1336. Regarding other Departmental programs,
42 CFR Parts 52d, 55a and 86.

ATTACHMENT: Attached is a copy of the final rule published in
the Federal Register Wednesday, November 24, 1982
(47 FR 53007).

DISCUSSION: This rule allows for-profit organizations to be
eligible for grants in all Departmental programs
where this is consistent with statutory require-
ments, legislative intent and program purpose.
It contains the provisions that will apply to all
grants, and also to all subgrants, made to for-
profit organizations.

With respect to HDS programs, this rule applies
to the discretionary grants made under the pro-
grams listed on page 53011 of the preamble.

In addition, these rules apply to all subgrants
made to for-profit organizations by HDS programs
which permit subgranting to for-profit organiza-
tions, i.e., State grant programs for Aging, WIN,
Developmental Disabilities, Child Welfare Services,
Child Abuse and Neglect, and Head Start.

EFFECTIVE DATE: December 27, 1982.

INQUIRIES TO: As appropriate:

Regional Program Director - Aging

Regional Director of the WIN Program

Regional Program Director - Developmental
Disabilities

Regional Program Director - Children,
Youth and Families

Dorcas R. Hardy
Assistant Secretary for
Human Development Services

Attachment

To BOB BRIGGS
From TERRY SMITH

7/27/89

12/11/90

TO: Marvin E. Layne
Acting Regional Administrator, Region VI

THROUGH: Pamela Coughlin /s/
Director, Office of Regional Operations

FROM: William Sexton /s/
Acting Director, Grants and Contracts Management Division

SUBJECT: Awarding of ADD Grant Funds to For-Profit Agencies
(Your memorandum of July 6)

You have asked whether ADD Basic State Grant funds may be used for subgrants to for-profit entities. The answer is yes, since HDS-PR-83-1 (attached) specifically authorizes subgranting to for-profit organizations under several OHDS State grant programs, including ADD. Based on an opinion from the Office of General Counsel, we have been informed that HDS-PR-83-1 is legally supportable. In terms of Kentucky's question concerning the non-Federal share, the fact that a subgrantee is a for-profit agency would not change the allowability of costs or third party in-kind contributions which may constitute the non-Federal share.

Please let us know if you have further questions.

Attachment

Prepared by CGale.tw/7-21-89/DN#0248B (page 8)

Signed W 7/21/89

Dave Marchant
Camp Hiller

"For-profit" organization or institution means a corporation or other legal entity which is organized or operated for the profit or benefit of its shareholders or other owners.

3. Section 74.3 is further amended to remove the definition of "OGP" and to add the following definition after the definition of "OMB":

"OPAL" means the Office of Procurement, Assistance and Logistics, which is an organizational component within the Office of the Secretary, HHS, and reports to the Assistant Secretary for Management and Budget.

4. Section 74.4 is amended to remove the words "for-profit organization" from paragraphs (a) and (b) and to add a new paragraph (d). As revised, § 74.4 reads as follows:

§ 74.4 Applicability of this part.

(a) *General.* Except where inconsistent with Federal statutes, regulations, or other terms of a grant, this part applies to all HHS grants, other than the block grant programs identified in 45 CFR 90.1. However, unless expressly made applicable by the granting agency, this part shall not apply when the grantee is a Federal agency, foreign government or organization, international organization such as the United Nations, or individual.

(b) *Subgrants.* For each substantive provision in this part, either the language of the provision itself or other text in the same subpart will indicate whether the provision affects only grants, only subgrants, or both. Use of the term "recipient" (as defined in § 74.3) in a provision shall be taken as referring equally to grantees and subgrantees. Similarly, use of the term "awarding party" (as defined in § 74.3) shall be taken as referring equally to granting agencies and to grantees awarding subgrants. However, unless expressly made applicable by the granting agency, this part need not be applied by the grantee to a subgrant if the subgrantee is a Federal agency, foreign government or organization, international organization such as the United Nations, or individual.

(c) *Public institutions of higher education and hospitals.* Grants and subgrants to institutions of higher education and hospitals operated by a government shall be subject only to provisions of this subpart that apply to non-governmental entities.

(d) *For-profit organizations.* The attention of for-profit organizations is directed to Subpart AA of this part. The special provisions in that subpart for grants and subgrants to those organizations contain exceptions to other portions of this part.

§ 74.6 (Amended)

3. Section 74.6 is amended to revise the abbreviation "OGP" in paragraphs (c)(2) and (d) to read "OPAL".

§ 74.12 (Amended)

6. Section 74.12 is amended to revise the abbreviation "OGP" in the second sentence to read "OPAL".

§ 74.72 (Amended)

7. Section 74.72 is amended to revise the abbreviation "OGP" in paragraphs (a) and (b) to read "OPAL".

8. Section 74.101 is revised to read as follows:

§ 74.101 Relationship to cost principles.

The cost principles prescribed by Subpart Q of this part contain requirements for prior approval of certain types of costs (see § 74.177). Except when waived, those requirements apply to all grants and subgrants even if §§ 74.103 through 74.106 do not.

9. Section 74.105 is amended by revising paragraph (c) to read as follows:

§ 74.105 Budget revisions—nonconstruction projects.

(c) Except as provided in §§ 74.107 and 74.177, other budget changes under nonconstruction grants do not require approval.

§ 74.121 (Amended)

10. Section 74.121 is amended to revise the abbreviation "OGP" in paragraphs (a) and (c) to read "OPAL".

11. Section 74.130 is amended to revise paragraph (d) to read as follows:

§ 74.130. Scope and applicability of this subpart.

(d) Equipment or supplies acquired by a contractor under its contract are not subject to this subpart if, by the terms of the contract, title to the property vests in the contractor or another third party.

12. Section 74.182 is revised to read as follows:

§ 74.182. Must requests for OMB authorizations go through HHS's Office of Procurement, Assistance and Logistics (OPAL)?

Requests for the Office of Federal Procurement Policy approval.

authorizations referred to in paragraphs 1.b. 1.c. and 14. of the OMB Circular A-102 attachment must be submitted, through appropriate HHS granting agency channels, to OPAL. If OPAL concurs in the request, OPAL sends it to the Office of Federal Procurement Policy of OMB.

§ 74.171 (Amended)

13. Section 74.171 is amended to revise the words "Federal Management Circular 75.4" in paragraph (a) to read "OMB Circular No. A-87".

14. Subpart Q is amended by adding a new § 74.175, by redesignating and revising the current § 74.175 as § 74.176 and by redesignating the current § 74.176 as § 74.177. As added § 74.175 and the newly redesignated and revised § 74.176 reads as follows:

§ 74.175 For-profit organizations other than for-profit hospitals.

(a) The principles to be used in determining the allowable costs of activities conducted by for-profit organizations (other than for-profit hospitals) are contained in the Federal Procurement Regulations at 41 CFR Subpart 1-15.2. *Exception:* Independent research and development costs (including the indirect costs allocable to them) are unallowable. Independent research and development are defined in the Federal Procurement Regulations at 41 CFR 1-15.205-35.

(b) For hospitals, see § 74.173.

§ 74.176 Subgrants and cost-type contracts.

The cost principles applicable to a subgrantee or cost-type contractor under an HHS grant will not necessarily be the same as those applicable to the grantee. For example, where a State government awards a subgrant or cost-type contract to an institution of higher education, OMB Circular No. A-21 will apply to the costs incurred by the institution of higher education even though OMB Circular No. A-87 will apply to the costs incurred by the State.

§ 74.177 (Redesignated from § 74.176)

15. Subparts U through Z are reserved, and a new Subpart AA is added as follows:

Subparts U Through Z—(Reserved)

Subpart AA—Special Provisions for Grants and Subgrants to For-Profit Organizations

Esc.

74.701 Scope of subpart.

74.706 Prohibition against profit.

74.710 Real property, equipment, and supplies.

74.715 General program income.

74.720 Cost sharing under Federal grants.

Subparts U Through Z—[Reserved]

Subpart AA—Special Provisions for Grants and Subgrants to For-Profit Organizations

§ 74.701 Scope of subpart.

(a) This subpart contains provisions that apply to grants and subgrants to for-profit organizations. These provisions are in addition to other applicable portions of this part, or they make exceptions for awards to for-profit organizations from other provisions of this part.

b. This subpart also draws attention to, or discusses, provisions elsewhere in this part that need special emphasis or clarification with respect to awards to for-profit organizations.

§ 74.705 Prohibition against profit.

Attention is directed to § 74.170, which provides, in effect, that no grant funds may be paid as profit to any recipient of a grant or subgrant, even if the recipient is a for-profit organization. Profit is any amount in excess of allowable direct and indirect costs of the recipient.

§ 74.710 Real property, equipment, and supplies.

(a) *Scope.* (1) This section applies to real property, equipment, and supplies which, in accordance with § 74.130, would be subject to Subpart O of this part but is acquired under a grant or subgrant to a for-profit organization.

(2) A grantee that is not a for-profit organization may take title to property acquired under a subgrant to a for-profit organization. If so, the property will be considered as acquired by the grantee under its grant, and this section will not apply to the property.

(b) *Applicable rules.* (1) Property subject to this section is exempt from Subpart O of this part. Instead, the clause entitled "Government Property" in 41 CFR 1-7.203-21(a) is deemed to be in every grant or subgrant to a for-profit organization, and the provisions in that clause that apply to property acquired for the Government apply to property subject to this section. For this purpose, the terms "contract" and its derivatives in that clause are considered to refer to the grant or subgrant under which the property is acquired, "subcontract" and its derivatives to refer to any subaward under that grant or subgrant, and "contracting Officer" to refer to the HHS grants officer.

(2) Records subject to the Government Property clause are exempt from Subpart O of this part.

(c) *Appropriation acquisition.* A

grant or subgrant to acquire property is

subject to this section without the prior approval of the granting agency.

§ 74.715 General program income.

The additional costs alternative described in § 74.42(e) of this part may not be applied to general program income earned by a recipient that is a for-profit organization.

§ 74.720 Cost sharing under research grants.

Under research grants to for-profit organizations, HHS does not enter into institutional cost-sharing agreements that cover all or a number of its research project grants to the grantee in the aggregate. In research grants to these organizations, HHS implements statutory requirements for cost sharing through separate cost-sharing agreements negotiated for each research project.

PART 1336—[AMENDED]

F. 45 CFR Part 1336 is amended as follows:

1. The authority citation for 42 CFR Part 1336 reads as follows:

Authority: 86 Stat. 2324 (42 U.S.C. 2001d).

§ 1336.30 [Amended]

2. Section 1336.30 is amended to delete the word "nonprofit" in the two places that it occurs.

(FR Doc. 83-3328 Filed 11-23-82; 8:45 am)

BILLING CODE 4180-04-M

Office of Child Support Enforcement

45 CFR Part 304

Federal Financial Participation in the Costs of Cooperative Agreements With Courts and Law Enforcement Officials

AGENCY: Office of Child Support Enforcement (OCSE), HHS.

ACTION: Final rule.

SUMMARY: The Child Support Enforcement program in many States relies heavily on the cooperation of courts for the processing of child support cases. Some courts have experienced marked increases in the volume of these cases as a direct result of the Child Support Enforcement program. To compensate courts for this increased activity, title IV-D of the Social Security Act permits Federal matching for IV-D related court costs by means of cooperative agreements between courts and child support agencies. In addition, title IV-D permits child support agencies to enter into similar cooperative

enforcement officials to provide for the prosecution of child support cases.

Section 404 of Pub. L. 96-285, the Social Security Disability Amendments of 1980, amended section 455 of the Social Security Act effective July 1, 1980 by expanding the availability of Federal financial participation (FFP) in court costs. This statute for the first time permits FFP in certain costs incurred by courts in connection with the actual judicial decision-making process. These regulations implement the new statutory provision. In addition, we are making several changes in the language of the existing regulations at 45 CFR 304.21 to provide greater clarity for users of the regulations. No substantive changes are being made with respect to agreements with law enforcement officials.

DATE: November 24, 1982.

FOR FURTHER INFORMATION CONTACT: Michael P. Fitzgerald—(301) 443-8350.

SUPPLEMENTARY INFORMATION:

Background

Federal policy governing the financing of prosecutorial law enforcement officials under agreements with child support agencies has undergone little change since the inception of the IV-D program. However, the policy with respect to courts has been gradually liberalized to permit increased FFP.

Original Federal policy under title IV-D provided FFP only in costs of compensation of certain court employees performing IV-D functions. FFP in all the administrative costs in support of these individuals and all other ordinary administrative costs of the judiciary system was prohibited under this early policy.

An expanded level of FFP in court costs was established by a final rule published by OCSE on July 31, 1978 (43 FR 33249). It was later applied retroactively to July 1, 1975 under an amendment published October 3, 1979 (44 FR 56939). This expanded FFP is provided for in existing regulations at 45 CFR 304.21. These regulations prohibit FFP in "any costs incurred by a court in making judicial determinations," including both personnel and administrative court costs associated with the judicial determination process. Under existing regulations, however, FFP is available in the costs of compensation of non-judicial staff and in certain related administrative costs, such as office space, furnishings, supplies, computers, etc., incurred in providing child support enforcement services under the IV-D program. Costs of compensation of court referees and

considered useful for the purpose for which the tolerance is sought. It is concluded that the establishment of the tolerance will protect the public health and is established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this notice in the Federal Register, file written objections with the Hearing Clerk, at the address given above. Such objections should specify the provisions of the regulation deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing and the grounds for the objections. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought.

The Office of Management and Budget has exempted this rule from the requirements of Section 3 of Executive Order 12291.

(Sec. 400(d)(7), 58 Stat. 812 (21 U.S.C. 340a(d)(2)))

List of Subjects in 45 CFR Part 180

Administrative practice and procedures, Raw agricultural commodities, Pesticides and pests.

Dated: November 10, 1982.

Edwin L. Johnson,
Director, Office of Pesticide Programs.

PART 180—[AMENDED]

Therefore, 40 CFR 180.396 is amended by adding and alphabetically inserting the raw agricultural commodity blueberries to read as follows:

§ 180.396 Hexachlorocyclopentadiene; tolerances for residues.

Commodity	Parts per million
Blueberries	0.2

(7) Doc. 82-3714 Filed 11-23-82 at 4:45 am
BILLING CODE 9990-08-01

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

42 CFR Parts 52 and 52h

Extension of 42 CFR Parts 52 and 52h To Cover Projects for Research on Adolescent Pregnancy and Family Life Correction

In FR Doc. 82-50621, beginning on page 50620 on Friday, November 5, 1982.

on page 50621, in the first column, paragraph 2 in the second line of the authority "300-7" should be "2002-7".
BILLING CODE 9990-08-01

Office of the Secretary

Public Health Service

Health Care Financing Administration

Office of Human Development Services

Social Security Administration

42 CFR Parts 52d, 55a, and 56

45 CFR Parts 74 and 1235

Grants and Subgrants to For-Profit Organizations

AGENCY: Department of Health and Human Services (HHS).

ACTION: Final rules.

SUMMARY: This announces HHS's final decision to make for-profit organizations eligible for grants in all programs in which grants to those organizations are consistent with legislative intent and program purposes. For all such programs which we have identified and which still have regulatory bars to grants to for-profit organizations, this removes the bars.

This also (1) makes HHS's Department-wide grants administration regulations, 45 CFR Part 74, apply to grants and subgrants to for-profit organizations and (2) adds to those regulations additional provisions for grants and subgrants to for-profit organizations.

These actions reflect a reversal of the long standing HHS policy of not making grants to for-profit organizations even in programs where they are not barred by law. The new policy is intended to increase competition. This is likely to help the affected HHS programs achieve their objectives better, because they will be able to select from among a greater number of proposed projects.

EFFECTIVE DATE: December 27, 1982.

FOR FURTHER INFORMATION CONTACT: Matthias Lasker, Director, Office of Procurement and Assistance Policy, Department of Health and Human Services, Room 513D, Hubert H. Humphrey Building, 200 Independence Avenue, S.W., Washington, D.C. 20201, 202-243-7505.

SUPPLEMENTARY INFORMATION:

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- I. Background
- II. Comments and responses
- III. Conclusions

... programs that may award grants to for-profit organizations

V. Programs in above list not previously identified

VI. Differences between proposed and final amendments

VII. Timing of applicability of amendments to 45 CFR Part 74

I. Background

On December 3, 1981, at 46 FR 58706, HHS published a notice of proposed rulemaking explaining that it was reversing its general policy of not awarding grants or cooperative agreements to for-profit organizations. Under the new policy, wherever it would be consistent with legislative intent and program purposes to do so, HHS will make these organizations eligible for grants or cooperative agreements. (From here on these awards will be referred to by the single term "grants.") Since most HHS program statutes bar grants to for-profit organizations, only a limited number of HHS grant programs are affected by the new policy.

As a first step in exploring and adopting the new policy, HHS's Public Health Service (PHS), on March 9, 1979 at 44 FR 13025 and on February 28, 1980 at 45 FR 13200 invited comments on a proposal to begin permitting grants to for-profit organizations under certain PHS research programs. Simultaneously with our December 3 notice, PHS took final action to make for-profit organizations eligible for grants in those programs (46 FR 58674 and 58675).

Our December 3 notice listed all other HHS programs we were able to identify under which grants to for-profit organizations would be consistent with legislative intent and program purposes. The notice proposed that any future invitations for grant applications in those programs not preclude applications from for-profit organizations unless there are exceptional circumstances. The programs are included in the list of affected programs in Section IV below to this preamble. For those programs with regulations barring grants to for-profit organizations, the notice proposed to remove the regulatory bars.

The notice also proposed to make the HHS-wide grants administration regulations in 45 CFR Part 74 apply to HHS grants to for-profit organizations and to add a few provisions to Part 74 dealing specifically with those grants. In addition, the notice proposed to make Part 74, including the additional provisions, also apply to subgrants to for-profit organizations. The provisions:

1. Address for grants and subgrants to for-profit organizations are listed below.

principles that are used for Federal cost-type procurement contracts with those organizations.

2. Emphasize the Part 74 rule that prohibits the payment of grant funds as profit to any grantees or subgrantees.

3. Require that, for real property, equipment, and supplies acquired by a for-profit recipient under a grant, title will vest in the Federal Government rather than the recipient.

4. State that, of the three alternatives in Part 74 for the use of general program income earned from grant supported activities, the "additional costs alternative" will not be used if the income is earned by a for-profit recipient.

5. Provide that where disposition of royalties on inventions or patents arising out of a grant to a for-profit organization is not governed by statute, disposition will be governed by case-by-case determinations made by HHS.

6. Provide that, under research grants to for-profit organizations, HHS will implement statutory requirements for cost sharing through project-by-project cost-sharing agreements only, not through "institutional cost-sharing agreements."

II. Comments and Responses

HHS received seven letters in response to the December 3 notice. Four supported making for-profit organizations eligible for grants, two opposed the action, and one opposed it with respect to one program. Following are summaries of the specific adverse substantive comments in these letters together with our responses:

Legal Propriety or Necessity of Making For-Profits Eligible for Grants

1. *Comment:* An examination of the legislative history of virtually all Federal assistance programs, including those covered in the HHS proposed rules, shows that Congress intended such programs be undertaken by public entities and nonprofit organizations—not for-profit organizations. If Congress intended for-profit organizations to carry out the programs, it would have expressly authorized grants to them.

Response: We have determined that, under each program listed, HHS does have the statutory authority to award grants to for-profit organizations. In statutory statements of eligible parties, we construe terms such as "private organizations," when unqualified, to include for-profit organizations unless the legislative history indicates differently. This is the basis for most of our determinations regarding the programs listed.

2. *Comment:* HHS is not required to exercise discretionary authority it has to make grants to for-profit organizations. HHS has discretion in the matter. In its notice, HHS suggested otherwise and cited as its reasons the Federal Grant and Cooperative Agreement Act (Pub. L. 95-224, 41 U.S.C. 801-809) and guidance for implementing the Act issued by the U.S. Office of Management and Budget (OMB) (at 43 FR 36900, August 18, 1978). However, the OMB guidance is unsupported, legally questionable, and nonbinding.

Response: The decision to open up grant competition to profit making organizations is not based on the requirements of law or OMB guidance on the Federal Grant and Cooperative Agreement Act. The decision was based on our determination that, where legally permissible, for-profit organizations should be eligible to compete for grants and that such organizations would enhance the quality of our grant programs. In addition, the decision is consistent with OMB guidance on the Act and with our own interpretation as well. The OMB guidance on implementing the Act, issued under specific authority in the Act, states that grants may be made to for-profit organizations when deemed by the agency to be consistent with legislative intent and program purposes.

Wisdom of Making For-Profits Eligible for Grants

3. *Comment:* Financial assistance programs have traditionally been carried out by non-profit organizations organized and operated for charitable, educational, and scientific purposes—not for private gain. The profit motive is incompatible with social programs. Therefore, it would be unwise and in derogation of their public purpose for the programs mentioned by HHS to make grants to for-profit organizations.

Response: We see no fundamental incompatibility between the goal of making an overall net profit and serving social needs in individual nonprofit projects. There are countless instances of public spirit shown by American business enterprises.

Where performance of activities rather than institutional support is the goal of a grant program, its public purpose is more likely to be served than harmed by awarding the grants to the best performers (in terms of quality and economy) without regard to their profit status.

4. *Comment:* Scandals and other matters of public record show that for-profit organizations involved in health and social programs, including research,

do need for profit. The HHS proposal does continue the general prohibition against profit and does continue cost-sharing requirements where they exist, but for-profit organizations will find ways to circumvent these provisions.

Response: We do not agree that the evidence shows that for-profit organizations are more likely than others to commit improprieties. In any event, we would not wish to deny all for-profit organizations participation in our programs because of potential questionable behavior of some.

5. *Comment:* For-profit organizations often seek Federal funding, sometimes even for less than cost, in order to gain new or greater expertise in an area and thus gain a competitive advantage in the market place over other for-profit organizations. This is not desirable under Federal programs whose purpose is to fill research or social needs. It is not the purpose of these programs to further the interests of for-profit organizations.

Response: Enhancing the capability of for-profit organizations—or of any recipient—is generally not the purpose of most research and social programs. However, we see no harm done if a Federal award has this secondary effect or if the motive of a for-profit organization in seeking a grant is to acquire expertise or experience in a field. No inequity is created, because all eligible for-profit organizations have the same opportunity to compete for the awards and to acquire the expertise or experience.

6. *Comment:* Cost control will not be successful by opening up Federal assistance awards to commercial organizations.

Response: The Department's experience with for-profit organizations in cost-reimbursement contracts does not support the notion that commercial organizations do not exercise adequate cost control or that costs of commercial organizations are more difficult to contain than costs of non-profit organizations.

7. *Comment:* Funds which are already inadequate will be stretched even further by HHS's proposal. To permit for-profit organizations to receive grants will reduce overall quality and may cause the loss of unique and invaluable skills and organizations which will not survive the competition. For-profit organizations can exercise influence to secure the success of their applications.

Response: In a time of budgetary constraints, it is more important than ever that the public obtain the maximum benefit for each grant dollar. We believe

more. Therefore, a regulatory flexibility analysis is required.

Response: The economic effect criterion for determining whether a rule is to be classified as "major" under the Order is not applied against the size of the programs involved. Rather, the criterion is applied to the changes being made by the rule, the results caused by the rule which would otherwise not exist.

This rulemaking will not change the total dollar amount awarded under any of the programs affected. This rulemaking concerns only what organizations are eligible to receive those funds and on what terms and conditions. For this reason, we do not believe the \$100 million annual effect criterion in the Order is met nor do we believe the other criteria are met. Therefore, we believe a regulatory, impact analysis is not required.

16. **Comment:** HHS should make a regulatory flexibility analysis for this rulemaking, in keeping with the Regulatory Flexibility Act.

Response: The Act referred to (5 U.S.C. Ch. 8) requires that, for each rule with a "significant economic impact on a substantial number of small entities," an analysis be prepared describing the rule's impact on small entities and identifying any significant alternatives to the rule that would minimize the economic impact on small entities. Small entities are defined as small businesses, small organizations, and small governmental jurisdictions.

The Department's decision regarding the eligibility of for-profit organizations for grants affects a number of grant programs. However, by far the largest amount of grant funding affected is that for the Public Health Service research programs for which rulemaking on this issue was completed on December 3, 1981. That rulemaking was originally proposed on March 9, 1979 (at 44 FR 13025) and again on February 28, 1980 (at 45 FR 13200). The Regulatory Flexibility Act applies only to rules proposed on or after January 1, 1981 and therefore does not apply to that rulemaking.

Total annual grant funding for the programs whose eligibility requirements are being changed by this present rulemaking is less than \$100 million. We estimate that only a few percent of these funds and of the grants will be diverted to for-profit organizations, small or large, from recipients that would otherwise receive them. In our view, this relatively small funding change does not constitute a significant economic impact on a substantial number of small entities.

Our estimate is based primarily on our experience with biomedical research grants. In the 1950s and early 1960s for-profit organizations were eligible for those grants but obtained considerably less than 1% of the available funding. Furthermore, although a number of for-profit organizations have expressed interest since they have again become eligible for biomedical research grants, only a very few actually submitted applications for the first award cycle.

The only adverse economic impact of the change in eligibility will be on those non-profit entities, large or small, that may lose funding they would otherwise receive. To minimize this impact on small non-profit entities, the award process would have to give preferences to them over for-profit organizations. Such preferences, however, would benefit one group of small entities at the expense of another (small businesses) and, by undermining the principle of free and open competition, defeat the very purpose of this rulemaking.

For the above reasons, we believe we were correct in our original determination that a regulatory flexibility analysis is not required for this rulemaking. In any event, through this preamble, the Department has in effect performed a final regulatory flexibility analysis.

In brief the Act requires that a regulatory analysis for a final rule contain: (1) A succinct statement of the need for, and the objectives of, the rule; (2) a summary of the issues raised by public comments and the agency's assessment of these issues and (3) a description of each of the significant alternatives to the rule which was considered by the agency. This preamble, taken as a whole, meets these requirements.

III. Conclusions

We have concluded that none of the objections listed in the above comments warrant a change in our decision to make for-profit organizations eligible for grants under programs in which it would be consistent with legislative intent and program purposes to do so. In addition, in our opinion, no cogent objections have been raised against making the regulations in 45 CFR Part 74, augmented by the special provisions set forth in the December 3 notice, apply to grants to for-profit organizations.

Accordingly, with minor technical and editorial changes, we are making the amendments proposed in the December 3 notice for removing regulatory bars to grants to for-profit organizations and for making 45 CFR Part 74 apply to grants to for-profit organizations.

Unless there are exceptional circumstances, we intend not to preclude applications from for-profit organizations in any invitation for grant applications in any program in which grants to those organizations are consistent with statutory intent and program purposes and are not barred, or are no longer barred, by regulations. Below is a list of existing programs that we have identified which meet, or following this rulemaking, will meet these requirements and so are affected by this principle.

IV. Programs That May Award Grants to For-Profit Organizations

Public Health Service Programs.

Research projects under Sections 301 and 356 of the Public Health Service (PHS) Act (42 U.S.C. 241 and 253d, 42 CFR Part 52).

Substances and Living Organisms for Biomedical and Behavioral Research (Sec. 301(a) of the PHS Act, 42 U.S.C. 241(a)) (Grants of property).

Health Statistics Research and Epidemiological Research (Secs. 306(b)(2) and (3) of the PHS Act, 42 U.S.C. 242k(b)(2) and (3)).

Health Care Technologies Research (Sec. 309(b) of the PHS Act, 42 U.S.C. 242n, 42 CFR Part 52).

Primary Care Research and Demonstration Projects (Sec. 340 of the PHS Act, 42 U.S.C. 256).

Biological Products (Sec. 352 (b) of the PHS Act, 42 U.S.C. 263(b)) (Grants of property).

National Basic Resource Grants to Scientific Communication Instrumentalities (Sec. 395 of the PHS Act, 42 U.S.C. 280b-7, 42 CFR Part 59a).

Research under the National Cancer Program (Sec. 404 of the PHS Act, 42 U.S.C. 285).

National Cancer Institute Clinical Cancer Education Program (Secs. 404(a)(4) and 404(b)(7) of the PHS Act, 42 U.S.C. 285 (a)(4) and (b)(7), 42 CFR Part 52d).

Educational Programs in Occupational Safety and Health (Sec. 21(a)(1) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 670, 42 CFR Part 86).

National Cancer Institute Clinical Cancer Education Program (Secs. 404(a)(4) and 404(b)(7) of the PHS Act, 42 U.S.C. 285(a)(4) and (b)(7), 42 CFR Part 52d).

National Cancer Program (the rest of the program besides the research

¹ The policy change to make for-profit organizations eligible for a grant under this program was made by the Public Health Service's Federal Register notice of December 3, 1981, at 46 FR 60735. Those regulations are codified at 42 CFR

There should be no loss of quality since potential quality of performance as well as cost are almost always factors in the competitive selection of grantees. The Department's competitive system, using independent objective reviewers, assures equally for both for-profit and nonprofit organizations that grants are awarded on the basis of published criteria only.

8. Comment: If for-profit organizations are awarded grants, they will seek to have the terms imposed on grants by the Federal Government eased and eventually removed. Nonprofit organizations willingly accept these terms.

Response: The possibility that for-profit organizations may seek to have the terms of their grants modified is only a matter of conjecture and does not, in our view, justify continuing to deny them grants.

9. Comment: HHS's proposed rules will raise confusion, delay, disagreement, litigation and program disruption.

Response: We have no reason to suppose that this rulemaking will have any of the effects listed by the commenter.

10. Comment: The proposal will make for-profit organizations eligible for grants for Research, Demonstration, and Pilot Projects under Headstart. The success of the Headstart program is attributable to the unstinting commitment to the program by thousands of public and nonprofit agencies. It would now be a grave injustice to require these agencies to compete with for-profit organizations for the limited grant funds, and it would endanger the credibility and continuing growth and effectiveness of the program.

Response: We agree that the success of Headstart is due in large part to the dedication of public and nonprofit agencies. However, the proposal regarding for-profit organizations applies only to grants for research, demonstration, and pilot projects and for technical assistance and training. Furthermore, because of the commitment and demonstrated capability of public and nonprofit agencies, those agencies should have little difficulty being competitive under the new circumstances.

We believe that the credibility, growth, and effectiveness of the Head Start program is more likely to be promoted than harmed by the increased competition in the above portions of the program.

For Profit Organizations

11. Comment: For determining allowable costs under grants to for-profit organizations, HHS should consider using the same set of cost principles that are used for grants to private non-profit organizations (OMB Circular A-122) rather than the cost principles that are used for Federal contracts with for-profit organizations.

Response: For each kind of non-profit entity (government, institution of higher education, hospital, other private non-profit organization), there is a separate set of cost principles which is used for both grants and contracts. The rationale is that cost principles and the language used to express them have to vary to a limited extent to reflect differences in the accounting, organization, and purposes typical of different kinds of organizations but that, to avoid confusion, there should be only one set of cost principles for each organization, to be used for all its Federal funding agreements. This rationale applies equally to for-profit organizations.

Furthermore, we believe that the cost principles for nonprofit organizations are ill suited to for-profit organizations. Because, for example, those cost principles have a more structured approach to the development of overhead rates, their adoption would likely cause problems for for-profit organizations and be to their disadvantage.

For these reasons, we believe that, for grants to for-profit organizations, we should use the cost principles that have been specifically designed for for-profit organizations and that must, by Federal policy, be used for contracts with them.

12. Comment: HHS should consider permitting a fee or profit under grants to for-profit organizations.

Response: Allowing a profit under these grants will increase costs to HHS and so consume scarce budgeting resources. We believe such a policy would be unfair to nonprofit organizations and be inconsistent with the assistance relationship established by a grant. In any event, we have long interpreted our statutes as not allowing grants to include profits, fees, or any other remuneration in excess of actual costs.

13. Comment: With respect to the issue of treatment of property acquired under grants to for-profit organizations, HHS should use the same rules that apply to property acquired under grants to nonprofit organizations. HHS's proposal to use contract-like rules could be viewed as inconsistent with the intent

Agreement Act (41 U.S.C. 301-309).

Response: The issue of disposition of property acquired under a Federal funding agreement is an incidental administrative matter that does not affect the fundamental relationship of the two parties involved. Therefore, applying to grants the same policy on this matter as is used in contracts does not, in our view, raise any questions of consistency with the Federal Grant and Cooperative Agreement Act.

We believe that we need actual experience with grants to for-profit organizations before we can determine what the best policy would be for property acquired under those grants. In the meantime, we have proposed to follow a contract policy on this matter because it provides strong safeguards for the Federal Government and, for most of the potential grantees, the policy will be already familiar and not require the establishment of a new property management system. In any event, with respect to major items of equipment (those costing \$1,000 or more), the rules we have proposed for for-profit grantees will have similar substantive effects as the standard grant rules and may be procedurally advantageous to the grantees.

14. Comment: HHS should consider waiving cost-sharing requirements on research grants to for-profit organizations.

Response: The requirement for cost sharing in research grants appears in HHS appropriation acts (see, for example, section 202 of H.R. 4560, as reported by the Senate Appropriations Committee on November 9, 1981, and section 101(a)(3) of Pub. L. 97-92). HHS does not have the authority to waive this statutory requirement.

Regulatory Impact

15. Comment: Executive Order 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. HHS has concluded that the rule is not a major rule within the meaning of the Executive Order. The question is whether this conclusion is correct.

The programs affected by the proposed rule involve spending large sums. The rule enlarges the universe of those eligible to participate in the program. It is at least likely that the expenditures of large amounts involving additional organizations will have an annual effect of at least \$100 million or

subprogram and the Clinical Cancer Education subprogram listed above) (Sec. 404(b)(7) of the PHS Act, 42 U.S.C. 285(b)(7)).

National Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources Program (Sec. 413(c)(3) of the PHS Act, 42 U.S.C. 287(c)(3)).

Physical Fitness Improvement and Research (Sec. 1706 of the PHS Act, 42 U.S.C. 300a-7).

Research and dissemination related to adolescent family life (Sec. 2006 of the PHS Act, 42 U.S.C. 300a-7).

Program grants for black lung clinics (Sec. 427(a) of the Federal Coal Mine Health and Safety Act of 1969, 30 U.S.C. 937(a), 42 CFR Part 55a).

Health research and demonstrations under Sec. 20 of the Occupational Safety and Health Act and Sec. 501 of the Federal Coal Mine Health and Safety Act of 1969 (29 U.S.C. 869, 30 U.S.C. 961, 42 CFR Part 67).

Educational Programs in Occupational Safety and Health (Sec. 21(a)(1) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 870, 42 CFR Part 86).

Health Care Financing Administration Programs

Experiments and Demonstration Projects under Titles XVIII and XIX of the Social Security Act (Medicare and Medicaid) (Sec. 222(a) of Pub. L. 92-603, 42 U.S.C. 1395b-1 (note)).

Grants to "Alternate" Professional Standards Review Organizations (Sec. 1152 of the Social Security Act, 42 U.S.C. 1320a-1).

Office of Human Development Services Programs

National Impact Demonstrations Under Title IV of the Older Americans Act (Sec. 425 of the Act, 42 U.S.C. 3035e).

Projects to Relieve Older Individuals from High Utility and Home Heating Costs (Sec. 426 of the Older Americans Act, 42 U.S.C. 3035f).

Native American Programs—Research, Demonstrations, and Pilot Projects (Sec. 805 of the Native American Programs Act of 1974, 42 U.S.C. 2991d, Subpart B of 45 CFR Part 1330).

Evaluation of Projects Assisted by the Native American Programs Act of 1974 (Sec. 810 of the Act, 42 U.S.C. 2992).

Technical Assistance and Training under Headstart (formerly Sec. 621 of the Economic Opportunity Act, now Sec. 648 of Pub. L. 97-25, the Omnibus Budget Reconciliation Act of 1981, 45 CFR Part 1301).

now Sec. 649 of Pub. L. 97-25, the Omnibus Budget Reconciliation Act of 1981, 45 CFR Part 1301).

Social Security Administration

Assistance for the processing, care, maintenance, security, transportation, and initial reception and placement in the United States of Cuban and Haitian entrants (Sec. 501(c) of the Refugee Education Assistance Act of 1980, 8 U.S.C. 1522 note).

V. Programs in Above List Not Previously Identified

The above list includes the following six programs which, through oversight, were not previously identified in either the PHS final rulemaking on December 3, 1981, or the Department-wide notice of proposed rulemaking on the same date:

1. Research and dissemination related to adolescent family life (Public Health Service).

2. Program grants for black lung clinics (Public Health Service).

3. National Basic Resource Grants to Scientific Communications Instrumentalities (Public Health Service).

4. Physical Fitness Improvement and Research (Public Health Service).

5. Head Start Technical Assistance and Training (Office of Human Development Services).

6. Assistance for the processing, care, maintenance, security, transportation, and initial reception and placement in the United States of Cuban and Haitian entrants (Social Security Administration).

The black lung clinics program and the scientific communications instrumentalities program have regulatory bars to grants to for-profit organizations (in 42 CFR Parts 55a and 89a), but we have included amendments below to remove those bars. The other four programs do not have regulations needing amendment.

As an exception to HHS's prior policy, the Cuban and Haitian entrant program had already been making grants to for-profit organizations prior to the policy change and so is unaffected by the eligibility change being made by this rulemaking or the PHS prior rulemaking. We are listing the program for the sake of completeness only. Under Executive Order 12341, the Attorney General directs and coordinates the Federal assistance to Cuban and Haitian entrants authorized by section 501(c) of the Refugee Assistance Act of 1980, and it is at the Attorney General's direction that HHS awards and administers grants under this program.

VI. Differences Between Proposed and Final Amendments

amendments as proposed and the final amendments below:

1. As explained in V above, we are adding amendments (a) to remove regulatory bars to grants to for-profit organizations from 42 CFR Part 55a, "Program Grants for Coal Miners' Respiratory Clinics," and (b) to remove regulatory bars to grants to for-profit scientific communication instrumentalities in 45 CFR Part 89a, "National Library of Medicine Grants," Subpart A, "Grants for Establishing, Expanding, and Improving Basic Resources."

2. The proposed amendment to 45 CFR Part 74 included a section (45 CFR 74.710) on property acquired by a for-profit organization under a grant or subgrant. The purpose of the section was to have the same rules apply to the property as apply to property acquired by for-profit organizations under HHS cost-type procurement contracts. However, the section included provisions making some grant rules and some special rules apply. To fully achieve our purpose, we have removed those provisions and simply provided that the standard contract clause for property acquired by cost-type for-profit contractors will apply to the property. We have also added a requirement that HHS approval be obtained before the property is acquired. This is a standard requirement under HHS cost-type procurement contracts.

3. The proposed amendments to 45 CFR Part 74 included a section (45 CFR 74.720 in the December 3 notice) providing that an option will not be used by HHS for inventions made, under research grants, by for-profit organizations that are not small business firms. The option provides that HHS may make an agreement with a grantee to permit ownership to inventions to be left for determination by the grantee. In a separate action, HHS is amending the patent regulations, 45 CFR Part 8, among other reasons, to remove the option as regards for-profit organizations that are not small business firms. Accordingly, the amendment to Part 74 will no longer be necessary and has been dropped. (Note. Rights to inventions made by small businesses under grants are governed by 35 U.S.C. 200-206.)

4. On January 15, 1981, the Office of Management and Budget reissued Federal Management Circular 74-4 under the former designation, OMB Circular 74-4 (45 FR 944, January 23, 1981). This circular provides that contractors

2. Section 74.2 is amended to add the following definition after the definition of "Federally recognized Indian tribal government":