

Dated: June 19, 2003.

Dawn Willingham,

CMS Reports Clearance Officer, Division of Regulations Development and Issuances, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[CMS-R-64, CMS-R-26, CMS-10005, CMS-3427]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (CMS)), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. Type of Information Collection Request: Extension of a currently approved collection.

Title of Information Collection: Indirect Medical Education (IME) and Supporting Regulations in 42 CFR 412.105.

Form No.: CMS-R-64 (OMB# 0938-0456).

Use: This collection of information on interns and residents (IR) is needed to properly calculate Medicare program payments to hospitals that incur indirect costs for medical education. The agency's Intern and Resident Information System uses the information for producing automated reports of duplicate full-time equivalent IRs for IME. The reports provide

contractors with information to ensure that hospitals are properly reimbursed for IME, and help eliminate duplicate reporting of IR counts, which inflate payments. The collection of this information affects 1,350 hospitals which participate in approved medical education programs.

Frequency: Annually.

Affected Public: Not-for-profit institutions, and Business or other for-profit.

Number of Respondents: 1,225.

Total Annual Responses: 1,225.

Total Annual Hours: 2,450.

2. Type of Information Request: Revision of a currently approved collection.

Title of Information Collection: Clinical Laboratory Improvement Amendments (CLIA) and the ICRs contained in the supporting regulations in 42 CFR 493.1-493.2001.

Form Number: CMS-R-26 (OMB approval #: 0938-0612).

Use: The ICRs referenced in 42 CFR part 493 outline the requirements necessary to determine an entity's compliance with CLIA. CLIA requires laboratories that perform testing on human beings to meet performance requirements (quality standards) in order to be certified by HHS.

Frequency: Other: As needed.

Affected Public: Business or other for-profit, Not-for-profit institutions, Federal government, State, local or tribal gov't.

Number of Respondents: 168,688.

Total Annual Responses: 756,241.

Total Annual Hours Requested: 9,379,917.

3. Type of Information Request: Extension of a currently approved collection.

Title of Information Collection: Ticket to Work and Work Incentives: Medicaid Infrastructure Grants.

Form Number: CMS-10005 (OMB approval #: 0938-0811).

Use: Section 203 of the Ticket to Work and Work Incentives Act of 1999 provides for the establishment of a grants program for states that build infrastructures designed to support people with disabilities. State agencies will be applying for these grants.

Frequency: Annually.

Affected Public: State, local or tribal gov't.

Number of Respondents: 56.

Total Annual Responses: 56.

Total Annual Burden Hours: 5,600.

4. Type of Information Collection Request: Extension of a currently approved collection.

Title of Information Collection: End Stage Renal Disease Application and Survey and Certification Report and

Supporting Regulations in 42 CFR 405.2100-405.2184.

Form No.: CMS-3427 (OMB# 0938-0360).

Use: Part I of this form is a facility identification and screening measurement used to initiate the certification and recertification of ESRD facilities. Part II is completed by the Medicare/Medicaid State survey agency to determine facility compliance with ESRD conditions for coverage.

Frequency: Annually.

Affected Public: State, local or tribal government.

Number of Respondents: 4000.

Total Annual Responses: 1,320.

Total Annual Hours: 330.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web site address at <http://cms.hhs.gov/regulations/prd/default.asp>, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attention: Dawn Willingham, Room: C5-14-03, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: June 19, 2003.

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CMS Reports Clearance Officer, Division of Regulations Development and Issuances, Office of Strategic Operations and Strategic Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Community Services

Compassion Capital Fund Demonstration Program

AGENCY: The Office of Community Services (OCS), Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Announcement of the request for competitive applications and the availability of Federal funding to intermediary organizations to provide

technical assistance to faith-based and community organizations.

CFDA Number: The Catalog of Federal Domestic Assistance Number is 93.647.

SUMMARY: This program announcement announces the availability of funds for Compassion Capital Fund (CCF) awards. These awards provide experienced intermediary organizations with funds to deliver technical assistance to small faith-based and community organizations. Intermediaries will assist these small groups, for example, in their efforts to improve program effectiveness and organizational management, access funds from diverse sources and manage those funds, develop and train staff, expand the types and reach of social services programs in their communities and develop promising collaborations among organizations dedicated to social service delivery. In addition, recipients of awards under this announcement must issue sub-awards to a number of qualified faith-based and community organizations for a variety of capacity-building purposes.

To be eligible for CCF awards, intermediaries should have established relationships with grassroots faith-based and community organizations, as well as a proven track record in providing technical assistance to such groups.

The Administration for Children and Families (ACF) is the agency designated to issue awards under the Fund.

However, the work supported through such awards is expected to address a broad array of services and programs and to complement related activities in other parts of HHS and other Federal departments. CCF will help further the President's goals and objectives regarding faith-based and community organizations and will enhance work being supported by multiple Federal agencies. ACF estimates that the funds available under this announcement will support an estimated 4–8 cooperative agreements¹ with intermediary organizations.

The Federal government wishes to partner with applicant organizations that share the same vision, have similar goals, and are able to share in the cost of this important set of activities. Therefore, ACF is seeking applicants who can provide funding for the proposed project equal to 25 percent of the amount of Federal funds requested (*i.e.*, one-fourth of the total budget. For example, an applicant requesting \$500,000 in Federal funds would need to provide \$125,000 to the total project.

The total budget therefore would be \$625,000. An applicant requesting \$250,000 in Federal funds would need to provide \$62,500. The total budget in this circumstance would therefore be \$312,500).

DATES: The closing date for submission of applications is July 28, 2003. Applications received after the closing date will be classified as late. See Part IV of this announcement for more information on submitting applications.

In order to determine the number of expert reviewers that will be necessary, if you plan to submit an application, you are requested, but not required, to mail, fax, or e-mail written notification of your intentions at least 15 calendar days prior to the submission deadline date. Send the notification, with the following information: The name, address, telephone and fax numbers, and e-mail address of the project director and the name of the applicant to: OCS Operations Center, 1815 North Fort Myer Drive, Suite 300, Arlington, Virginia 22202 or fax to (703) 248-8765 or e-mail to OCS@lcn.net. Label all submissions as follows: Intent to Apply for Compassion Capital Fund Demonstration Program.

FOR FURTHER INFORMATION CONTACT: All questions should be forwarded to Joseph Grogan, Project Officer for the Compassion Capital Fund at 202-401-4830 (ph) or jgrogan@acf.hhs.gov (email).

SUPPLEMENTARY INFORMATION: This program announcement consists of four parts: Part I: Background and Program Purpose—legislative authority, background, and program purpose and objectives; Part II: Project and Applicant Eligibility—eligible applicants, funding availability and instruments, cost sharing, and roles and responsibilities under the cooperative agreement; Part III: The Review Process—intergovernmental review, initial ACF screening, general instructions for the Uniform Project Description, competitive review and evaluation criteria, and review process; and Part IV: The Application Process—required forms, application limits, checklist for complete application, application submission, and Paperwork Reduction Act.

Part I. Background and Program Purpose

A. Legislative Authority

Funding under this announcement is authorized by section 1110 of the Social Security Act governing Social Services Research and Demonstration activities and the Departments of Labor, Health

and Human Services, and Education, and Related Agencies Appropriations Act, 2003, Pub. L. 108-7.

B. Background

Faith-based and community organizations have a long history of providing an array of important services to people and communities in need of charitable services in the United States. These groups are part of their communities and possess unique strengths that the government cannot duplicate. They hold the trust of their neighbors and leaders and have a keen understanding of the particular needs of the community and its systems. As a result, they are well positioned to assist individuals and families with the most pressing needs, such as the homeless, prisoners reentering the community, children of prisoners, at-risk youth, addicts, elders in need, and families moving from welfare to work. Faith-based and community organizations are also equipped to help couples who choose marriage for themselves, develop the skills and knowledge to form and sustain healthy marriages.

In recognition of this history and ability, President Bush believes it is in the public's interest to broaden Federal efforts to work with faith-based and community organizations and has made improving funding opportunities for such organizations a priority. A key part of the effort to enhance and expand the participation of faith-based and community groups serving those in need is CCF. Intermediary organizations awarded funds under this announcement will serve as partners to both the Federal government and to the faith-based and community organizations that they assist. The intermediaries will represent a diverse set of affiliations, and will assist community-level organizations with a range of service goals, target populations, affiliations, and beliefs.

C. Program Purpose and Objectives

The goal of CCF is to assist faith-based and community organizations in increasing their effectiveness, enhancing their ability to provide social services, expanding their organizations, diversifying their funding sources, and creating collaborations to better serve those most in need. This will be accomplished through the funding of established intermediary organizations in well-defined geographic locations with a proven track record of providing technical assistance to smaller organizations in their communities. These intermediary organizations will serve as a bridge between the Federal government and the faith-based and

¹ A cooperative agreement allows substantial Federal involvement in the activities undertaken with Federal financial support.

community organizations that this program is designed to assist. Intermediary organizations will provide two services within their communities: (1) Technical assistance to a diverse range of faith-based and community organizations; and (2) technical assistance and financial support—through sub-awards—to some subset of the faith-based and community organizations in their communities. ACF's expectations for these two activities are described more fully below.

ACF expects to work closely with organizations that receive funding to ensure that CCF monies are used appropriately and in the most effective manner possible. It has also entered into a contract with an organization that serves as the National Resource Center (herein also referred to as the National Center) for these intermediaries. Under this contract, the National Center provides CCF intermediaries with support and assistance. Funded organizations must expect to interact with both ACF and the National Center on an on-going basis and modify their technical assistance and sub-award plans in coordination with ACF.

Technical Assistance. ACF seeks intermediary organizations with demonstrated expertise and a proven track record in working with and providing technical assistance to faith-based and community organizations in a variety of areas. Technical assistance activities funded under the CCF are to be conducted at no cost to interested faith-based and community organizations. Applicants must have demonstrated experience in the delivery of capacity-building assistance to smaller organizations in the following areas:

- Strategic planning;
- Financial management;
- Board development;
- Fund-raising;
- Outcome measurement.

Additionally, there is a range of other needs that may appropriately be provided by the intermediary organizations awarded funds under this announcement. The following list is meant to be illustrative, and not exhaustive.

- Legal assistance in various areas such as the process of incorporation, and obtaining tax-exempt status;
- Needs assessments to identify internal areas needing improvement or areas in which to develop or expand community services to address service gaps;
- Development of internal operating controls and procedures related to all aspects of business management;

- Facilitation of networks, service coordination, and resource sharing among organizations;
- Incorporation of "best practices";
- Expanding outreach and client screening, intake or tracking methods;
- Volunteer management;
- Human resources.

Intermediaries must be established organizations with well-developed connections to and working relationships with faith-based and community organizations in well-defined communities. Typically, these organizations will be located in the same communities as the faith-based and community organizations that they serve. Organizations that provide technical assistance through single or short-term contacts (such as a nationwide series of conferences) are not encouraged to apply.

Sub-Awards. The program goals will be further accomplished through the issuance of sub-awards by the funded intermediary organizations to a diverse set of small faith-based and community organizations that seek to increase program and organizational effectiveness. The total amount of sub-awards proposed in an intermediary's application must represent at least one-quarter or 25 percent of the total Federal share, though applicants are encouraged to exceed this threshold, if possible. Applicants must develop sub-award plans that are consistent with the following principles:

- Participation in the CCF sub-award program must be open to faith-based and community-based organizations;
- Recipients of sub-awards must receive sub-awards through a competitive process and may not be pre-selected;
- The approach must include outreach to both faith-based and community organizations in a fair and open competition;
- Intermediary organizations must provide on-going technical assistance and capacity-building support to the organizations to which they issue sub-awards;
- The criteria for selection of sub-awardees shall not include consideration of the religious nature of a group or the religious nature of the program it offers;
- Intermediaries shall not require sub-award applicants to provide matching funds or give them a preference in the selection process if they offer matching funds in their applications;
- Intermediaries shall not require sub-award applicants to have 501(c)(3) status or to identify a sponsoring organization with 501(c)(3) status;

- As a general rule, organizations that partner with an intermediary to deliver technical assistance or provide cost-sharing funds for the proposed project shall not be eligible for sub-awards;

• Sub-awards should be in amounts that are manageable for a small organization;

• Priority for sub-awards should be given to organizations implementing programs that address priority social service needs, such as the homeless, elders in need, at-risk youth, families and individuals in transition from welfare to work, those in need of intensive rehabilitation such as addicts or prisoners, and organizations that help couples who choose marriage for themselves, to develop the skills and knowledge to form and sustain healthy marriages;

• The sub-award plan should focus on organizations that historically have not received grants from the Federal government;

• Capacity-building activities that further the sustainability of sub-awardees' social service efforts should form the central focus of an intermediary's proposed sub-award concept. Sub-awards should be used to assist organizations in differing stages of development. For example, funds may be provided to fledgling organizations to improve their basic functions, such as attaining 501(c)(3) status or developing sound financial systems. Sub-awards may also be provided to promising organizations to expand the reach of existing programs. Such funding would allow a promising organization to move to a higher level of service, where it is able assist more people on a sustainable basis. Uses for such funding might include employing a key additional staff person; moving to a larger or better-equipped facility; upgrading case management or informational technology capabilities; or supporting a new social service; and

• Sub-awards should not be used for "direct" services. Rather, they should be used to improve the sub-awardees efficiency and capacity. For example, an organization that distributes food to the poor should not receive a sub-award simply to purchase additional food. Nor, for example, should an organization that provides substance abuse treatment services receive additional funds simply to enable it to provide exactly the same services to more people. Although these sub-awards might well enable these organizations to assist additional individuals, they would not serve to improve the organizations' sustainability, efficiency, or capacity. Rather, the organizations would simply use additional funds in the same way

that it used existing funds, without fundamentally changing or improving its services.

Plan for Providing Technical Assistance and Sub-Awards. As part of its application to ACF, each applicant must submit a basic outline of its sub-award approach, describing the kinds of organizations in its community that would benefit and examples of activities that it expects these groups will undertake with sub-award funding. Intermediary organizations that receive CCF awards will be required to develop, with guidance from and in consultation with ACF, a detailed plan for this process within 60 days of receipt of award under this announcement. ACF must review and approve this plan prior to the issuance of any sub-awards using Federal funds awarded under this announcement. Intermediary organizations must report on the use of funds for sub-awards as they do for other types of expenditures of Federal funds received as a result of an award under this announcement and as specified in the Cooperative Agreement. Intermediary organizations will also be required to develop, with guidance from and in consultation with ACF, a plan within six months of receipt of award for working with sub-awardees to develop outcome measures and to evaluate the activities supported by the sub-awards made with Federal funds under this announcement.

Applicants must coherently describe their plan both for providing technical assistance and sub-awards. In providing technical assistance and in making sub-awards, these plans must provide for the establishment of ongoing supportive relationships with those faith-based and community organizations served, rather than single or short-term interactions. Technical assistance conferences and workshops may be parts of an applicant's plan, but they must not be its sole focus of the plan. The plan must also describe how applicants will develop and build upon existing long-term supportive relationships with the faith-based and community organizations within their communities.

Further, approved applicants must be willing to work closely with ACF and any entities funded by ACF to coordinate, assist, or evaluate the activities of the intermediary organizations providing technical assistance and issuing sub-awards. Proposed budgets should include the cost of travel-related expenses for key personnel with responsibility for the CCF award to attend two two-day meetings with Federal officials and others in Washington, DC, shortly after awards are made under this

announcement. This meeting will focus on orientation to Federal objectives for the project, information about related activities supported by HHS and other Federal agencies,² Federal grants management requirements, and coordination between and among the approved intermediary organizations and other entities funded by ACF to be involved in the CCF initiative.

Legal rules that apply to faith-based organizations that receive government funds. CCF monies shall not be used to support inherently religious practices such as religious instruction, worship, or proselytization. Grant or sub-award recipients, therefore, may not and will not be defined by reference to religion. Neutral, non-religious criteria that neither favor nor disfavor religion must be employed in their selection.

Part II. Project and Applicant Eligibility

The Administration for Children and Families (ACF), Department of Health and Human Services (HHS) invites eligible entities to submit applications for the Compassion Capital Fund Demonstration Program.

A. Eligible Applicants

ACF invites applications from a wide variety of organizations or entities with demonstrated knowledge and experience in the provision of the types of technical assistance described herein to a diverse group of faith-based and community organizations. Further, ACF encourages applications from applicants that propose to work with and have experience working with faith-based and community organizations that have not been well served or supported by governmental funds historically. If organizations propose to collaborate to provide Compassion Capital Fund intermediary services, they should have well-developed working relationships and a history of working together prior to announcement of this funding opportunity.

Fiscal Year (FY) 2002 ACF Compassion Capital Fund grantees who received FY 2003 continuation funds are ineligible to apply.

Non-governmental organizations, Tribal governmental organizations, non-profit agencies (including faith-based organizations) public agencies, State and local governments, colleges and universities, and for-profit entities may

² Under the President's Faith-based and Community Initiative program, Federal agencies have begun to provide technical assistance and training services to faith-based and community organizations and address barriers to their participation in Federally sponsored programs. Successful applicants under this announcement must coordinate and not duplicate services.

submit applications under this announcement. It should be noted, however, that no Federal funds received as a result of this announcement can be paid as profit to grantees or sub-grantees, *i.e.*, any amount in excess of allowable direct and indirect costs of the recipient (45 CFR 74.81).

Private, nonprofit organizations are encouraged to submit with their applications the optional survey located under "Grant Manuals & Forms" at <http://www.acf.hhs.gov/programs/ofsf/forms.htm>

B. Project and Budget Periods

This announcement is inviting applications for project periods up to three years (36 months). Awards, on a competitive basis, will be for a 12-month budget period, although project periods may be for three years. Applications for continuation grants funded under these awards beyond the one year budget period but within the 36-month project period will be entertained in subsequent years on a noncompetitive basis, subject to the availability of funds, satisfactory progress on the part of the grantee, and a determination that continued funding would be in the best interest of the Federal Government.

C. Type of Awards

This is a full and open competition for cooperative agreements to implement and operate CCF projects. A cooperative agreement is Federal assistance in which substantial Federal Involvement is anticipated. Responsibilities of Federal Staff and the successful applicants are negotiated prior to an award. The grantees funded under this announcement will work collaboratively with the CCF program office on the development of products and prior to finalization and dissemination will submit products such as sub-award plans and sub-award assessment plans to the CCF program office for review and approval.

D. Funding Availability

ACF will issue Financial Assistance Awards under this announcement as cooperative agreements. ACF expects to award approximately \$4,200,000 in Fiscal Year 2003 for the CCF program and estimates that 4–8 intermediary organizations will receive awards to provide technical assistance and make sub-awards to smaller faith-based and community organizations. Applicants shall specify in their budget documents estimates of the amount of funds to be used for each purpose (technical assistance and sub-awards). The program goals will be further

accomplished through the issuance of sub-awards by the funded intermediary organizations to a diverse set of small faith-based and community organizations that seek to increase program and organizational effectiveness. The total amount of sub-awards proposed in an intermediary's application must represent at least 25 percent of the total Federal share requested.

ACF reserves the right to award less than the funds described, in the absence of worthy applications, or under such other circumstances as may be deemed to be in the best interest of the government.

E. Cost Sharing

Applicants must provide a minimum cost share of twenty-five (25) percent of the total Federal funds requested for each 12-month budget period. The non-Federal share may be met by cash or in-kind contributions, although applicants are encouraged to meet the cost share through cash contributions. For example, an applicant requesting \$500,000 in Federal funds would include a cost share of at least \$125,000. The total budget for the applicant's project would therefore be \$625,000. An applicant requesting \$250,000 in Federal funds would include a cost share of \$62,500. The total budget for the applicant's project in this circumstance would therefore be \$312,500.

F. Roles and Responsibilities Under the Cooperative Agreement

Federal Officials' Minimum Responsibilities

1. Promote collaborative relationships and facilitate the exchange of information (e.g., identified technical assistance and training needs, emerging issues, research findings, available resources and model programs) among intermediary organizations funded under this announcement and between the funded intermediaries and other entities or organizations engaged by ACF for purposes related to the Compassion Capital Fund.

2. Provide consultation to each approved intermediary organization with regard to the development of work plans, special issues and concerns and approaches to address problems that arise, and identification of any special focus areas for technical assistance.

3. Sponsor meetings of all technical assistance providers funded under the Compassion Capital Fund demonstration program to promote coordination, information sharing, and

access to resources, training, and learning opportunities.

4. Work together to address issues or problems identified by the intermediary organization, ACF, or others with regard to the applicant's ability to carry out the full range of activities included in the approved application in the most efficient and effective manner.

Applicant's Minimum Responsibilities

1. Develop and implement work plans that will ensure that the services and activities included in the approved application address the needs of faith-based and community organizations in an efficient, effective, and timely manner.

2. Submit regular reports as requested by ACF, but no less frequently than every six months, on sub-awards made with Federal funds that include, at a minimum, the name and description of the organization receiving the sub-award, summary of the purpose of the award (how the funds are to be used), the amount of the award, and the proposed plan for outcomes measurement and program evaluation of the activities that will be supported with sub-award funds made with Federal funds awarded under this announcement.

3. Work collaboratively with ACF officials, other Federal agency officials conducting similar activities, the other intermediary organizations approved under this announcement, and other entities or organizations engaged by ACF to assist in carrying out the purposes of the Compassion Capital Fund program.

4. Ensure that key staff participate in ACF sponsored workshops and meetings.

5. Develop a reporting system and submit required semi-annual progress and financial reports timely and completely. In addition to information about sub-awards as specified in item 2, above, the regular semi-annual reports shall include, at a minimum, information about the technical assistance provided and unduplicated listings of the organizations receiving assistance during the period. Such listings shall include the organization name, type (e.g., faith-based, community), location, a brief description of the organization, and brief summary of the technical assistance provided.

6. Submit timely sub-award plans for approval by Federal staff.

7. Develop, with guidance from and in consultation with ACF, a plan within six months of receipt of award for working with sub-awardees to develop outcome measures and to evaluate the

activities supported by the sub-awards made with Federal funds under this announcement.

Part III. The Review Process

A. Intergovernmental Review

This program is covered under Executive Order 12372, "Intergovernmental Review of Federal Programs," and 45 CFR part 100, "Intergovernmental Review of Department of Health and Human Services Programs and Activities." Under the Order, states may design their own processes for reviewing and commenting on proposed applications for Federal assistance under covered programs.

As of April 8, 2002, the jurisdictions listed below have elected not to participate in the Executive Order process. Applicants from these jurisdictions or for projects administered by Federally recognized Indian Tribes need take no action in regard to Executive Order 12372. Although the jurisdictions listed below no longer participate in the process, grant applicants are still eligible to apply for a grant even if a state, territory, commonwealth, etc. does not have a Single Point of Contact (SPOC).

Alabama; Alaska; Arizona; Colorado; Connecticut; Kansas; Hawaii; Idaho; Indiana; Louisiana; Massachusetts; Minnesota; Montana; Nebraska; New Jersey; New York; Ohio; Oklahoma; Oregon; Palau; Pennsylvania; South Dakota; Tennessee; Vermont; Virginia; Washington and Wyoming.

All remaining jurisdictions participate in the Executive Order process and have established SPOCs. Applicants from participating jurisdictions should contact their SPOCs as soon as possible to alert them of the prospective applications and receive instructions. The applicant must submit all required materials, if any, to the SPOC and indicate the date of the submittal (or the date of contact if no submittal is required) on the Standard Form 424, item 16a. Under 45 CFR 100.8(a)(2), a SPOC has 60 days from the application deadline to comment on proposed new or competing continuation awards. Applicants must submit any required material to the SPOCs as soon as possible so that the Federal program office can obtain and review SPOC comments as part of the award process. A listing of the SPOC for each participating state and territory with contact and address information is available at: <http://www.whitehouse.gov/omb/grants/spoc.html>.

B. Initial ACF Screening

Each application submitted under this program announcement will undergo a pre-review to determine that (1) the application was received by the closing date and submitted in accordance with the instructions in this announcement and (2) the applicant is eligible for funding.

C. General Instructions for the Uniform Project Description

The Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995, Public Law 104-13 the Department is required to submit to OMB for review and approval any reporting and record keeping requirements in regulations including program announcements. All information collections within this program announcement are approved under the following current valid OMB control numbers 0348-0043, 0348-0044, 034800040, 0348-0046, 0925-0418 and 0970-0139.

Public reporting burden for this collection is estimated to average 25 hours per response, including the time for reviewing instructions, gathering and maintaining the data needed and reviewing the collection of information.

The project description is approved under OMB control # 0970-0139 which expires 12/31/03.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Consistent with the Uniform Program Description format, the specific evaluation criteria applicable to this program follows in section D.

1. Objectives and Need for Assistance: Clearly identify the physical, economic, social, financial, institutional, and/or other problem(s) requiring a solution. The need for assistance must be demonstrated and the principal and subordinate objectives of the project must be clearly stated; supporting documentation, such as letters of support and testimonials from concerned interests other than the applicant, may be included. Any relevant data based on planning studies should be included or referred to in the endnotes/footnotes. Incorporate demographic data and participant/beneficiary information, as needed. In developing the project description, the applicant may volunteer or be requested to provide information on the total range of projects currently being conducted and supported (or to be initiated), some of which may be

outside the scope of the program announcement.

2. Results or Benefits Expected: Identify the results and benefits to be derived. For example, when applying for an award to provide technical assistance to community and faith-based charitable organizations, describe specific goals of the proposed technical assistance strategy; e.g., expansion of program capacity; increase in types of services offered; increased access to funding from different sources and sectors; improvement in staff capabilities; or replication of successful program models ("best practices").

3. Approach: Outline a plan of action which describes the scope and detail of how the proposed work will be accomplished. Account for all functions or activities identified in the application. Cite factors which might accelerate or decelerate the work and state your reason for taking the proposed approach rather than others. Describe any unusual features of the project such as design or technological innovations, reductions in cost or time, or extraordinary social and community involvement. Describe how the faith-based and community organizations with which they would work have been underserved by Federal and other resources in the past and the reasons why the applicant believes its services would benefit the types of faith- and community-based organizations intended to be served through the Compassion Capital Fund. Describe past experience working with faith-based and community organizations to address social needs.

Provide quantitative monthly or quarterly projections of the accomplishments to be achieved for each function or activity in, for example, such terms as the average number of days of technical assistance to be provided, the number of faith and/or community-based organizations to be provided services, or number of sub-awards to be issued to faith- or community-based organizations. When accomplishments cannot be quantified by activity or function, list them in chronological order to show the schedule of accomplishments and their target dates.

If any data is to be collected, maintained, and/or disseminated, clearance may be required from the U.S. Office of Management and Budget (OMB). This clearance pertains to any "collection of information that is conducted or sponsored by HHS." List organizations, cooperating entities, consultants, or other key individuals who will work on the project along with

a short description of the nature of their effort or contribution.

4. Geographic Location: Describe the precise location of the project and boundaries of the area to be served by the proposed project. Maps or other graphic aids may be attached.

5. Staff and Position Data: Provide a biographical sketch for each key person appointed and a job description for each vacant key position. A biographical sketch will also be required for new key staff as appointed.

6. Budget and Budget Justification: The following guidelines are for preparing the budget and budget justification. Both Federal and non-Federal resources shall be detailed and justified in the budget and narrative justification. For purposes of preparing the budget and budget justification, "Federal resources" refers only to the ACF grant for which you are applying. Non-Federal resources are all other Federal and non-Federal resources. It is suggested that budget amounts and computations be presented in a columnar format: First column, object class categories; second column, Federal budget, next column(s), non-Federal budget(s), and last column, total budget. The budget justification should be a narrative.

General

The following guidelines are for preparing the budget and budget justification. Both Federal and non-Federal resources shall be detailed and justified in the budget and narrative justification. For purposes of preparing the budget and budget justification, "Federal resources" should refer only to the HHS grant for which you are applying. For these purposes, "Non-federal resources" are all other resources. If other Federal resources will be used, they should be included under Non-Federal for budget display purposes but other Federal resources may NOT be used to meet the cost sharing provision, as discussed in Part II, section D. It is suggested that budget amounts and computations be presented in a columnar format: First column, object class categories; second column, Federal budget; next column(s), non-Federal budget(s), and last column, total budget. The budget justification should be a narrative.

Personnel

Description: Costs of employee salaries and wages.

Justification: Identify the project director or principal investigator, if known. For each staff person, provide the title, time commitment to the project (in months), time commitment to the

project (as a percentage or full-time equivalent), annual salary, grant salary, wage rates, etc. Do not include the costs of consultants or personnel costs of delegate agencies or of specific project(s) or businesses to be financed by the applicant.

Fringe Benefits

Description: Costs of employee fringe benefits unless treated as part of an approved indirect cost rate.

Justification: Provide a breakdown of the amounts and percentages that comprise fringe benefit costs such as health insurance, FICA, retirement insurance, taxes, etc.

Travel

Description: Costs of project-related travel by employees of the applicant organization (does not include costs of consultant travel).

Justification: For each trip, show the total number of traveler(s), travel destination, duration of trip, per diem, mileage allowances, if privately owned vehicles will be used, and other transportation costs and subsistence allowances. Travel costs for key staff to attend HHS sponsored workshops should be detailed in the budget.

Equipment

Description: "Equipment" means an article of tangible, non-expendable, personal property having a useful life of more than one year and an acquisition cost which equals or exceeds the lesser of (a) the capitalization level established by the organization for the financial statement purposes, or (b) \$5,000. (**Note:** Acquisition cost means the net invoice unit price of an item of equipment, including the cost of any modifications, attachments, accessories, or auxiliary apparatus necessary to make it usable for the purpose for which it is acquired. Ancillary charges, such as taxes, duty, protective in-transit insurance, freight, and installation shall be included in or excluded from acquisition cost in accordance with the organization's regular written accounting practices.)

Justification: For each type of equipment requested, provide a description of the equipment, the cost per unit, the number of units, the total cost, and a plan for use on the project, as well as use or disposal of the equipment after the project ends. An applicant organization that uses its own definition for equipment should provide a copy of its policy or section of its policy which includes the equipment definition.

Supplies

Description: Costs of all tangible personal property other than that included under the equipment category.

Justification: Specify general categories of supplies and their costs. Show computations and provide other information which supports the amount requested.

Contractual

Description: Costs of all contracts for services and goods except for those which belong under other categories such as equipment, supplies, construction, etc. Third-party evaluation contracts (if applicable) and contracts with secondary recipient organizations, including delegate agencies and specific project(s) or businesses to be financed by the applicant, should be included under this category.

Justification: All procurement transactions shall be conducted in a manner to provide, to the maximum extent practical, open and free competition. Recipients and sub-recipients, other than States that are required to use Part 92 procedures, must justify any anticipated procurement action that is expected to be awarded without competition and exceed the simplified acquisition threshold fixed at 41 U.S.C. 403(11) (currently set at \$100,000). Recipients might be required to make available to HHS pre-award review and procurement documents, such as request for proposals or invitations for bids, independent cost estimates, etc.

Note: Whenever the applicant intends to delegate part of the project to another agency, the applicant must provide a detailed budget and budget narrative for each delegate agency, by agency title, along with the required supporting information referred to in these instructions.

Construction

N/A.

Other

Enter the total of all other costs. Such costs, where applicable and appropriate, may include but are not limited to insurance, food, medical and dental costs (noncontractual), professional services costs, space and equipment rentals, printing and publication, computer use, training costs, such as tuition and stipends, staff development costs, and administrative costs.

Justification: Provide computations, a narrative description and a justification for each cost under this category.

Indirect Charges

Description: Total amount of indirect costs. This category should be used only

when the applicant currently has an indirect cost rate approved by the Department of Health and Human Services (HHS) or another cognizant Federal agency. Applicants without an approved indirect cost rate may charge related costs as direct costs.

Justification: An applicant that will charge indirect costs to the grant must enclose a copy of the current rate agreement. If the applicant organization is in the process of initially developing or renegotiating a rate, it should immediately upon notification that an award will be made, develop a tentative indirect cost rate proposal based on its most recently completed fiscal year in accordance with the principles set forth in the cognizant agency's guidelines for establishing indirect cost rates, and submit it to the cognizant agency. Applicants awaiting approval of their indirect cost proposals may also request indirect costs. It should be noted that when an indirect cost rate is requested, those costs included in the indirect cost pool should not also be charged as direct costs to the grant. Also, if the applicant is requesting a rate which is less than what is allowed under the program, the authorized representative of the applicant organization must submit a signed acknowledgment that the applicant is accepting a lower rate than allowed.

Program Income

Description: The estimated amount of income, if any, expected to be generated from this project.

Justification: Describe the nature, source and anticipated use of program income in the budget or refer to the pages in the application which contain this information.

Non-Federal Resources

Description: Amounts of non-Federal resources that will be used to support the project as identified in Block 15 of the SF424.

Justification: The firm commitment of these resources must be documented and submitted with the application in order to be given credit in the review process. A detailed budget must be prepared for each funding source.

Note: In the SF424A, Section B, Budget Categories, list in column 2 non-federal resources separately from federal resources, which must be listed in column 1.

D. Competitive Review and Evaluation Criteria

Applications that have been determined to be eligible for funding through the initial ACF pre-review screening will be evaluated and rated by independent review panels on the basis

of specific evaluation criteria. The evaluation criteria are designed to assess the quality of the proposed project and to determine the likelihood of its success. The evaluation criteria are closely related and are considered as a whole in judging the overall quality of an application. Points are awarded only to applications that are responsive to the evaluation criteria within the context of this program announcement.

There is a 25-page limit for the application narrative. Pages submitted beyond the first 25 in the application narrative section will be removed prior to panel review. Applicants should strive to be concise and provide only the information requested and needed. The budget portion of the application is not subject to this limitation. There is no formal page limit for the budget portion of the application, including the letters detailing the cost-share commitment, though applicants should take care to ensure that budgets are clear and easy to understand. Applicants should limit any supporting documentation to 5 pages. Supporting documentation, including letters of support, in excess of five pages will be removed prior to review.

Supplemental information (e.g., brochures, reports) not required in this announcement will not be reviewed. More information about application submission is provided under Part IV, below.

Proposed projects will be reviewed using the following evaluation criteria:

1. Approach: (45 Points)

Technical Assistance Strategy (15 points). The application should describe how the intermediary's assistance to faith-based and community groups will achieve the broad CCF goals of helping these organizations improve efficiency and broaden their funding base. Applications should describe a plan for delivering capacity-building assistance to smaller organizations in the following areas:

- Strategic planning;
- Financial management;
- Board development;
- Fund-raising;
- Outcome measurement.

Applications should also describe any additional activities that will serve to meet other needs of smaller organizations. Additional activities may include (but are not limited to) the following:

- Legal assistance in various areas such as the process of incorporation, and obtaining tax-exempt status;
- Needs assessments to identify internal areas needing improvement or areas in which to develop or expand

community services to address service gaps;

- Development of internal operating controls and procedures related to all aspects of business management;

- Facilitation of networks, service coordination, and resource sharing among organizations;

- Incorporation of "best practices";
- Expanding outreach and client screening, intake, or tracking methods;
- Volunteer management;
- Human resources development.

Applications should reflect the following additional considerations:

- An applicant's strategy should not focus on any single technical-assistance activity, such as grants writing. The applicant should instead describe how it will offer a range of technical assistance services. Ideal approaches will be multi-tiered and focus on as many areas of need as is logical and achievable.

- Technical assistance should be provided on a long-term, on-going basis to smaller organizations, rather than through single or short-term contacts (such as a nationwide series of seminars or conferences).

- The application should describe the approach the intermediary will employ to reach out to a diverse range of faith-based and community organizations needing assistance.

- Particular attention should be given to including groups that address priority social service needs, such as the homeless, prisoners reentering the community, children of prisoners, at-risk youth, addicts, elders in need, families moving from welfare to work, and groups that help couples who choose marriage for themselves, to develop the skills and knowledge to form and sustain healthy marriages.

- The application should provide a proposed schedule for accomplishing the activities planned.

- The application should discuss factors that may negatively affect the project and how those factors will be addressed.

- Technical assistance activities funded under the CCF are to be conducted at no cost to interested faith-based and community organizations.

Sub-award Strategy (15 points). The application should describe a plan for making sub-awards to smaller faith-based and community organizations. This plan should estimate the types and number of organizations expected to receive funding and the purposes to which sub-awards may be put. It should also describe the procedures the applicant will employ to identify and select organizations to receive sub-awards.

• Intermediary organizations that receive CCF awards will develop, with guidance from and in consultation with ACF, a final plan for making sub-awards within 30 days of receipt of award under this announcement. This final plan will be based upon the proposal in the grantee's application, although it may not contain all proposed elements. ACF must approve the plan prior to the issuance of any sub-awards using Federal funds awarded under this announcement. *Sub-Award Plans.* The following principles underlying the CCF sub-award component must be evident in the applicant's approach. The total amount of sub-award funds proposed must represent at least one-quarter the amount of the total Federal funds requested, though applicants are encouraged to exceed this 25 percent threshold, if possible. For example, an applicant seeking \$500,000 in Federal funds must propose to distribute at least \$125,000 in sub-awards and an applicant seeking \$250,000 in Federal funds must propose to distribute at least \$62,500 in sub-awards.

- Participation in the CCF sub-award program must be open to faith-based and community-based organizations;

- Recipients of sub-awards must receive sub-awards through a competitive process and may not be pre-selected;

- The approach must include outreach to both faith-based and community organizations in a fair and open competition.

- Intermediary organizations must provide on-going technical assistance and capacity-building support to the organizations to which they issue sub-awards;

- The criteria for selection of sub-awardees shall not include consideration of the religious nature of a group or the religious nature of the program it offers;

- Intermediaries shall not require sub-award applicants to provide matching funds or give them a preference in the selection process if they offer matching funds in their applications;

- Intermediaries shall not require sub-award applicants to have 501(c)(3) status or to identify a sponsoring organization with 501(c)(3) status;

- As a general rule, organizations that partner with an intermediary to deliver technical assistance or provide cost-sharing funds for the proposed project shall not be eligible for sub-awards;

- Sub-awards should be in amounts that are manageable for a small organization;

- Priority for sub-awards should be given to organizations implementing

programs that address homelessness, elders in need, at-risk youth, families and individuals in transition from welfare to work, those in need of intensive rehabilitation such as addicts or prisoners, and organizations that help couples, who choose marriage for themselves, develop the skills and knowledge to form and sustain healthy marriages.

- The sub-award plan should focus on organizations that historically have not received grants from the federal government;

- Capacity-building activities that further the sustainability of sub-awardees' social service efforts should form the central focus of an intermediary's proposed sub-award concept. Sub-awards should be used to assist organizations in differing stages of development. For example, funds may be provided to *fledgling* organizations to improve their basic functions, such as attaining 501(c)(3) status or developing sound financial systems. Sub-awards may also be provided to *promising* organizations to expand the reach of existing programs. Such funding would allow a promising organization to move to a higher level of service, where it is able assist more people on a sustainable basis. Uses for such funding might include employing a key additional staff person; moving to a larger or better-equipped facility; upgrading case management or informational technology capabilities; or supporting a new social service; and

- Sub-awards should not be used for "direct" services. Rather, they should be used to improve the sub-awardee's efficiency and capacity. For example, an organization that distributes food to the poor should not receive a sub-award simply to purchase additional food. Nor, for example, should an organization that provides substance abuse treatment services receive additional funds simply to enable it to provide exactly the same services to more people. Although these sub-awards might well enable these organizations to assist additional individuals, they would not serve to improve the organizations' sustainability, efficiency, or capacity. Rather, the organizations would simply use additional funds in the same way they used existing funds, without fundamentally changing or improving their services.

Past Experience Working with Faith-Based and Community Organizations to Address Social Needs (15 Points). CCF intermediary organizations are expected to be established organizations with well-developed connections to and working relationships with faith-based and community organizations in well-

defined communities. They should also have demonstrated experience and a proven track record in providing technical assistance to smaller organizations in their communities. The applicant should list recent examples of technical assistance it has provided to faith-based and community organizations, citing dates, names of groups assisted, and the kind of technical assistance provided. Closely related experience as a partner in a successful collaborative effort should be similarly detailed.

2. Budget and Budget Justification: (20 Points)

CCF Project Budget (10 points). The application should include a budget that is clear, easy to understand, and that provides a detailed justification for the amount requested. (Applicants should refer to the budget information presented in the Standard Forms 424 and 424A and to the budget justification instructions in section C. General Instructions for the Uniform Project Description. Since non-Federal reviewers will be used in the review of applications, applicants may omit from the copies of the application submitted (not from the original), the specific salary rates or amounts for individuals in the application budget and instead provide only summary information.)

Cost share (5 points). The basis for an applicant's meeting its cost sharing commitments must be firm, and cannot be speculative. Cash commitments to meet the cost sharing requirement are preferable to in-kind commitments. If the applicant is submitting letters documenting costs-share commitments from collaborating partners, state, or local governments or philanthropic organizations, the cost-share letters must clearly state that these organizations are committed to providing the funds to the organizations should the applicant be awarded a grant. Commitments in excess of the 25 percent threshold will not receive extra points, though applicants should note that applicants will be held accountable for all cost-share included. Failure to provide the full amount committed in the grant award may result in disallowance of Federal match.

Recent Operating Budgets (5 points). The application should describe, in general, the recent operating budgets of the applicant. A detailed listing is not required, but the recent size of the applicant's operating budget should be proportional to the amount requested under the funding announcement. For example, it would be inappropriate for an organization that operated with \$100,000 in 2001 and \$110,000 in 2002

to request \$1 million in Federal funds. Additionally, the applicant should briefly describe why the amount requested is logical, given the organization's recent operating budgets.

3. Objectives and Need for Assistance: (10 Points)

Need of faith-based and community organizations to be served (5 points). The application should describe how the project addresses vital needs of the faith-based and community organizations that will be provided sub-awards and technical assistance.

Need of communities served (5 points). The application should describe how the faith-based and community organizations that will receive technical assistance and sub-awards serve vital needs in their communities.

4. Geographic Location: (10 Points)

ACF envisions that most CCF-funded intermediary organizations will be located in the same communities as the faith-based and community organizations that they serve.

Organizations that provide technical assistance through single or short-term contacts (such as a nationwide series of conferences) are not encouraged to apply, and proposals for nationwide projects are not recommended. The application should include:

- A description of the precise region to be served, including the boundaries of the area, and the rationale for proposing the geographic area. Maps or other graphic aids may be included.

- Information about the experience and capability of the applicant to address the needs of faith-based and community organizations in the proposed region.

- A detailed description of the population served by faith-based and community organizations in the proposed area. The narrative should display an intimate knowledge of the population in the target area, including statistics and facts that convey an understanding of the unique needs of the population in the area.

5. Staff and Position Data: (10 Points)

The application should include a listing of key positions required to carry out the project, the individuals proposed to fill the positions, and a detailed description of the kind of work they will perform. The staff should have not only good technical skills, but also a record of working with faith-based and community organizations. The application should provide evidence of the staff's skill, knowledge and experience in carrying out the sort of activities to be assigned to them and

include their relevant experience. Similar information should be provided with regard to consultants or staff from other organizations proposed to work on the project.

6. Results or Benefits Expected (5 Points)

The application will be judged on the extent to which the benefits proposed by the applicant are reasonable and likely, will support the stated goals under this announcement, and can be expected to have a positive impact on faith-based and community organizations, particularly very small organizations or those which have not traditionally been served by Federal and other resources. The application will also be judged on the extent to which the results are likely to be beneficial to a wide range of clearly identifiable parties.

E. The Review Process

Applications received by the due date will be reviewed and scored competitively. Experts in the field, generally persons from outside the Federal Government, will use the evaluation criteria listed in Part III of this announcement to review and score the applications. The results of this review will be a primary factor in making funding decisions. ACF may also solicit comments from Regional Office staff and other Federal agencies. In order to ensure that the interests of the Federal Government are met in making the final selections, in addition to the review criteria identified above, ACF may consider a variety of factors including geographic diversity/coverage and types of applicant organizations. Further, ACF may limit the number of awards made to the same or affiliated organizations although they would serve different geographic areas. In this way, ACF may increase opportunities for learning about different ways to provide technical assistance and support to faith-based and community organizations.

Please note that applicants that do not comply with the requirements in the section on "Eligible Applicants" will not be included in the review process.

Part IV. The Application Process

A. Required Forms

Eligible applicants interested in applying for funds must submit a complete application including the required forms listed under the "Checklist for complete application" in Part IV of this announcement. All necessary forms are available at:

<http://www.acf.dhhs.gov/programs/ofs/forms.htm>.

In order to be considered for a grant under this announcement, an application must be submitted on the Standard Form 424 approved by the Office of Management and Budget under Control Number 0348-0043. Each application must be signed by an individual authorized to act for the applicant and to assume responsibility for the obligations imposed by the terms and conditions of the grant award. Applicants requesting financial assistance for non-construction projects must file the Standard Form 424B, "Assurances: Non-Construction Programs" (approved by the Office of Management and Budget under control number 0348-0040). Applicants must sign and return the Standard Form 424B with their application.

Applicants must provide a certification regarding lobbying when applying for an award in excess of \$100,000 (approved by the Office of Management and Budget under control number 0348-0046). Applicants must sign and return the certification with their application.

Applicants must make the appropriate certification of their compliance with the Drug-Free Workplace Act of 1988. By signing and submitting the application, applicants are providing the certification and need not mail back the certification with the application.

Applicants must make the appropriate certification that they are not presently debarred, suspended or otherwise ineligible for award. By signing and submitting the application, applicants are providing the certification and need not mail back the certification with the application.

B. Application Limits

Each application should include one signed original and two additional copies of the following:

The application should be double-spaced and single-sided on 8½ x 11 plain white paper, with 1" margins on all sides. Use only a standard size font no smaller than 12 pitch throughout the application. All pages of the application (including appendices, resumes, charts, references/footnotes, tables, maps and exhibits) must be sequentially numbered, beginning on the first page after the budget justification, the principal investigator contact information and the Table of Contents. There is a 25-page limit for the application narrative. Pages submitted beyond the first 25 in the application narrative section will be removed prior to panel review. The budget and the cost-share letters are not included in

this limitation, yet applicants are urged to be concise. There is a 5-page limit to any additional supporting documentation, including letters of support. Applicants are requested not to send pamphlets, brochures, or other printed material along with their applications as these pose copying difficulties. These materials, if submitted, will not be included in the review process. In addition, applicants must not submit any additional letters of endorsement beyond any that may be required. Applicants are encouraged to submit curriculum vitae in a biographical format.

C. Checklist for a Complete Application

Due to the overwhelming volume of applications received, applications that are not prepared properly may not be reviewed. Please ensure that your application is prepared properly.

The checklist below is for your use to ensure that the application package has been properly prepared.

A. One original, signed and dated application plus two copies.

- Attachments/Appendices, when included, should be used only to provide supporting documentation such as resumes, and letters of agreement/support.

(1) Application for Federal Assistance (SF-424, Rev. 7-97)

(2) Budget information-non-construction programs (SF424A&B)

(3) Budget Justification, including subcontract agency budgets

(4) Application Narrative and Appendices

(5) Assurances Non-Construction Program

(6) Certification Regarding Lobbying

(7) If appropriate, a completed SPOC certification with the date of SPOC contact entered in line 16, page 1 of the SF-424, Rev. 7-97

D. Application Submission

Deadline

The closing (deadline) time and date for receipt of applications is 4:30 p.m. (Eastern Time Zone) July 28, 2003. Applications received after 4:30 p.m. will be classified as late.

Deadline: Mailed applications shall be considered as meeting an announced deadline if they are received on or before the deadline time and date at the: OCS Operations Center, 1815 North Fort Myer Drive, Suite 300, Arlington, Virginia 22202 and labeled:

Application for Compassion Capital Fund Demonstration Program.

Applicants are responsible for mailing applications well in advance, when using all mail services, to ensure that

the applications are received on or before the deadline time and date.

Applications hand-carried by applicants, applicant couriers, or other representatives of the applicant or by overnight/express mail couriers shall be considered as meeting an announced deadline if they are received on or before the deadline date, between the hours of 8 a.m. and 4:30 p.m. at: OCS Operations Center, 1815 North Fort Myer Drive, Suite 300, Arlington, Virginia 22202 and labeled: Application for Compassion Capital Fund Demonstration Program. Applicants are cautioned that express/overnight mail services may not always deliver as agreed.

ACF cannot accommodate transmission of applications by fax or through other electronic media. Therefore, applications transmitted to ACF electronically will not be accepted regardless of date or time of submission and time of receipt.

Late applications. Applications that do not meet the criteria above are considered late applications. ACF shall notify each late applicant that its application will not be considered in the current competition.

Extension of deadlines. ACF may extend an application deadline for applicants affected by acts of God such as floods and hurricanes, when there is widespread disruption of the mail service, or for other disruptions of services, such as a prolonged blackout, that affect the public at large. An unfortunate occurrence that affects an applicant is not considered adequate justification for an extension. A determination to waive or extend deadline requirements rest with ACF's Chief Grants Management Officer.

Dated: June 20, 2003.

Curtis L. Coy,

Deputy Assistant Secretary for Administration.

[FR Doc. 03-16076 Filed 6-25-03; 8:45 am]

BILLING CODE 4184-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0085]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Environmental Impact Considerations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 28, 2003.

ADDRESSES: The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Environmental Impact Considerations—Part 25 (21 CFR Part 25) (OMB Control Number 0910-0322)—Extension

FDA is requesting OMB approval for the reporting requirements contained in the FDA regulation entitled "Environmental Impact Considerations."

The National Environmental Policy Act (NEPA), 42 U.S.C. 4321-4347, states national environmental objectives and imposes upon each Federal agency the duty to consider the environmental effects of its actions. Section 102(2)(C) of NEPA requires the preparation of an environmental impact statement (EIS) for every major Federal action that will significantly affect the quality of the human environment.

The FDA NEPA regulations are at part 25. All applications or petitions requesting agency action require the submission of a claim for a categorical exclusion or an environmental assessment (EA). A categorical exclusion applies to certain classes of FDA-regulated actions that usually have little or no potential to cause significant environmental effects and are excluded from the requirements to prepare an EA or EIS. Section 25.15(a) and (d) specifies the procedures for submitting to FDA a

claim for a categorical exclusion. Extraordinary circumstances (§ 25.21), which may result in significant environmental impacts, may exist for some actions that are usually categorically excluded. An EA provides information that is used to determine whether an FDA action could result in a significant environmental impact. Section 25.40(a) and (c) specifies the content requirements for EAs for nonexcluded actions.

This collection of information is used by FDA to assess the environmental impact of agency actions and to ensure that the public is informed of environmental analyses. Firms wishing to manufacture and market substances regulated under statutes for which FDA is responsible must, in most instances, submit applications requesting approval. Environmental information must be included in such applications for the purpose of determining whether the proposed action may have a significant impact on the environment. Where significant adverse effects cannot be avoided, the agency uses the submitted information as the basis for preparing and circulating to the public an EIS, made available through a **Federal Register** document also filed for comment at the Environmental Protection Agency (EPA). The final EIS, including the comments received, is reviewed by the agency to weigh environmental costs and benefits in determining whether to pursue the proposed action or some alternative that would reduce expected environmental impact. Any final EIS would contain additional information gathered by the agency after the publication of the draft EIS, a copy of or a summary of the comments received on the draft EIS, and the agency's responses to the comments, including any revisions resulting from the comments or other information. When the agency finds that no significant environmental effects are expected, the agency prepares a finding of no significant impact.

Estimated Annual Reporting Burden for Human Drugs

Under 21 CFR 312.23(a)(7)(iv)(e), 314.50(d)(1)(iii), and 314.94(a)(9)(i), each investigational new drug application (IND), new drug application (NDA), and abbreviated new drug application (ANDA) must contain a claim for categorical exclusion under § 25.30 or § 25.31 or an EA under § 25.40. In 2002, FDA received 2,374 INDs from 1,809 sponsors, 109 NDAs from 79 applicants, 2,575 supplements to NDAs from 276 applicants, 392 ANDAs from 107 applicants, and 3,343 supplements to ANDAs from 222