information collection. E-mail address: *grjohnson@acf.hhs.gov.*

*OMB Comment:* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Attn: Desk Officer for ACF, E-mail address: *Katherine_T._Astrich@omb.eop.gov.*

Dated: July 8, 2005.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 05–13845 Filed 7–13–05; 8:45 am]

**BILLING CODE 4184–01–M**

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# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Administration for Children and Families

## Office of Community Services; CSBG T&TA Promoting Healthy Marriages

*Announcement Type:* Initial.

*Funding Opportunity Number:* HHS–2005–ACF–OCS–ET–0043.

*CFDA Number:* 93.570.

*Due Date for Applications:* Application is due August 15, 2005.

*Executive Summary:* The Office of Community Services (OCS) within the Administration for Children and Families (ACF) announces that competing applications will be accepted for a new grant pursuant to the Secretary's authority under section 678(A) of the Community Services Block Grant (CSBG) Act, as amended, by the Community Opportunities, Accountability, and Training and Educational Services (COATES) Human Services Reauthorization Act of 1998 (Pub. L. 105–285).

These activities must fund training and technical assistance resources for the Community Services Network to ensure that the needs of eligible entities and programs relating to improving program quality (including quality of financial management practices) are addressed to the maximum extent feasible; and incorporate mechanisms to ensure responsiveness to local needs.

The proposed grants will fund training and technical assistance resources for the Community Services Network focusing on improving the quality of programs carried out under the CSBG act and the delivery of healthy marriage strategies among low income people served by local community action agencies.

Specifically, OCS will offer one-year grants to fund a one year project period for the creation and dissemination of ''best practice'' technical assistance materials from local community organizations, including those that are faith-based, that have demonstrated success in promoting or sustaining healthy marriages among clients as part of an overall strategy to help low-income people achieve family and child development, and/or self-sufficiency goals. Special emphasis is being placed on the development and dissemination of ''best practice'' materials that focus on a wide range of low-income populations, including racial and ethnic minorities.

## I. Funding Opportunity Description

The Office of Community Services (OCS) within the Administration for Children and Families (ACF) announces the availability of competitive grants for training and technical assistance activities that will provide Community Services Network organizations with healthy marriage education models and disseminating findings from these models. These grants are for innovative projects, planned and designed specifically to assist in the development and delivery of successful marriage education programs for low-income couples. Projects should be designed to implement activities over a one-year project and budget period. Project implementation should include two phases: (I) Consumer-based data gathering, planning, and model development; (II) Program design and service delivery.

Technical assistance to organizations in the community services network will focus entirely on the lesson's learned and best practices based on grantee's experiences and early findings and will be disseminated throughout the entire project period. Eligible applicants are state-wide or local organizations with demonstrated expertise in providing training to individuals and organizations on methods of effectively addressing the needs of low-income families and communities within the Community Services Network client base. Awarded projects will be administered through a cooperative agreement. This agreement will require a close working relationship between OCS and the successful applicant.

### Background

The Administration for Children and Families (ACF) has encouraged the formation and maintenance of healthy marriages and families as part of its overall strategy to help low-income people achieve family and child development goals, and greater economic self-sufficiency. Over the past four years, many community organizations, including designated community action agencies, faith-based groups, and public human service agencies, have undertaken special initiatives designed to promote healthy marriages, often with financial support from ACF program offices. Although some progress has been made, more needs to be done to expand the current knowledge base about the kinds of marriage support programs that are most effective and culturally appropriate to meet the needs of diverse, low-income families to improve their marital health and stability. The CSBG Supporting Healthy Marriage T&TA grants will give community organizations a valuable opportunity to develop solid strategies to support healthy marriages and provide the Community Services Network with another effective support service for low-income families. These grants will also help to answer questions about what works and what does not work in supporting healthy marriages in low-income settings and provide the network with a training and technical assistance resource as other organizations attempt to offer similar programs.

Healthy marriages are good for children, families, and society as a whole. Research tells us that on average, men and women in healthy marriages are more likely to build wealth, have better health, experience emotional well-being and live longer. More importantly, children who grow up in healthy, married families do better on a host of outcomes than those who grow up in other family forms. For example, studies have shown that children in healthy married families are at less risk for substance abuse, emotional distress and mental illness, suicide, criminal behavior, educational decline, poverty, child abuse and neglect. Further, children raised in healthy, married families are more likely to develop better relationships with their parents, develop stable marriages and families themselves, experience greater economic security, perform better academically and later in occupational settings, and have better physical health. In addition, communities with high proportions of healthy, married families are safer and experience fewer social problems than those with lower proportions of healthy, married families.

Research also tells us that what separates stable and healthy marriages from unstable and unhealthy ones is not

the frequency of conflict, but how couples manage conflict. Couples that are able to listen to each other with respect and resolve conflict in healthy ways, report higher levels of marital satisfaction and are less likely to divorce than those who are not able to do so. Through marriage education we can teach these skills and increase the odds that couples will form and sustain healthy marriages—to the benefit of their children, themselves and society.

Research has shown that individuals and couples across the economic spectrum are similar in their desire to have stable, healthy marriages and family relationships for themselves and their children. However, those dealing with economic difficulties often face additional challenges to achieving these goals relative to couples who are more economically secure. Research shows that lower-income is associated with higher rates of divorce. We have limited information about the factors that contribute to these differences across economic and racial/ethnic groups. We also have limited information about the factors that contribute to marital quality and stability and child well-being within lower-income groups.

More information on how to effectively implement these programs is needed to fully gage how to successfully achieve greater family and child development and how to inform other eligible organizations of implementation and design strategies that show promise in reducing highly stressed families faced with limited resources. The CSBG Supporting Healthy Marriage T&TA grants are one of OCS' efforts to help community organizations share their experiences developing effective models with the broader network of CSBG entities attempting to provide healthy marriage initiatives in diverse settings.

*Program Purpose*

The purpose of this program is to enhance the Community Service Network's ability to support projects that will develop and deliver healthy marriage services to low-income couples via training and technical assistance to organizations eligible to receive CSBG assistance, with a desire to improve family and child development through similar interventions. OCS seeks to fund projects that have thorough, well designed proposals that include implementation activities for the following: (I) Data Gathering, Planning, and Model Development; (II) Program Intervention and Service Delivery; that lead to training and technical assistance activities for organizations eligible to receive CSBG assistance with the Community Services Network.

I. Data Gathering, Planning and Model Development

OCS envisions funding projects that employ a methodical approach to developing healthy marriage models and services for organizations within the Community Services Network that will ultimately help low-income couples so that findings can be easily shared and lesson's learned easily transferable. Because there is limited research and experience with delivering marriage education services to low income consumers, OCS contends that projects should carefully consider the planning and model development stage. Projects may use focus groups, community surveys or other methods to gather information and data to assist them in the development stage. This data gathering process would give the agency a valuable opportunity to obtain information about assets, issues, and barriers that should be considered when developing a program for low-income couples. Potential barriers or issues might be logistical, cultural, etc. The key here is to gather information and use it effectively to design an intervention that meets the needs of the project's target population. For example, during the data gathering process the agency might discover that delivering marriage education classes during the week would not be feasible because most of the potential consumers have small school-aged children. Other factors like weekend offerings, on-site activities for youth, may be identified as preferences, providing valuable insight for model development.

This phase of the project should be programmed to occur in the first two quarters after the award.

II. Program Intervention and Service Delivery

OCS seeks to fund well-designed program interventions that will aid organizations within the Community Services Network in helping low-income couples build and sustain healthy marriages through the acquisition and application of skill building techniques known to improve marital stability so that these development and implementation lessons can be shared with other organizations. Applicants shall provide a thorough description of how the intervention/service will be implemented including reasonable plans for project marketing and outreach, participant recruitment and retention, the type of marriage education services to be offered, guidelines on the frequency and duration of classes or services, staffing,

training plans and projections of the number of couples to be served. Well-designed approaches will also be tailored to meet the needs of the target population. Proposals should demonstrate how the intervention would be designed to provide the necessary support services often required to meet needs of low-income or diverse populations. For example, transportation to and from healthy marriage activities, childcare, translation services, etc.

OCS intends to fund the creation of healthy marriage intervention models that can be used for training and technical assistance activities for use within the Community Services Network that focus on:

• Successful strategies and service models for helping couples interested in learning skills and approaches that will help them create and sustain a healthy marriage and therefore provide a nurturing family environment for their children;

• Successful strategies and service models for helping married couples sustain and enrich their marriage and family, including on-going opportunities for marriage education and other marital skill-building activities; and

• Ways to measure and report the effectiveness, or results, of the healthy marriage and/or enrichment activities described above.

Based on the experiences and successes of currently funded healthy marriage projects, OCS is interested in supporting program interventions and service models that employ the following concepts:

• Deliver marriage education classes or services that are skill based and reflective of industry standards.

• Voluntary participation in healthy marriage activities. Projects should always stress to consumers that participation is voluntary. Providing services to those consumers that have chosen to learn these skills for themselves.

• Culturally relevant program interventions. Projects should use culturally relevant approaches that respectfully account for racial and ethnic perspectives.

• Responsiveness to domestic violence issues and concerns.

• Use of logic models to document and track the linkages between program resources, activities, outputs, and outcomes.

III. Technical Assistance Activities

This area is intended to support healthy marriage technical assistance and training activities that will enhance

the Community Services Network's ability to improve the quality and delivery of healthy marriage education interventions for low-income people. Successful applicants must be able to take the developed model/service and use their experience with that process to provide technical assistance to other community agencies that will implement healthy marriage interventions.

Applicants should present a detailed, comprehensive plan for sharing their experiences and lessons learned with other agencies within the Community Services Network. Plans should describe how the applicant will provide technical assistance activities. These activities can include, but are not limited to: making presentations at community services conferences for those interested in implementing healthy marriage programs; creating and disseminating technical assistance documents that give tips for the development and implementation of healthy marriage programs; the production of quarterly findings and written annual reports for distribution to other community organizations; and hosting site visits; roundtables or other forums to present healthy marriage lessons learned.

Projects funded under this announcement will be expected to provide for the project director and the evaluator to attend an early kickoff meeting for the grantees funded under this priority area to be held within the first three months of the project (first year only) in Washington DC.

OCS strongly encourages applicants to consult their local domestic violence coalition to learn more about the information and services they provide to the community.

## II. Award Information

*Funding Instrument Type:* Cooperative agreement.

*Federal Substantial Involvement with Cooperative Agreement:* A cooperative agreement is a specific method of awarding Federal assistance in which substantial Federal involvement is anticipated. A cooperative agreement clearly defines the respective responsibilities of the Office of Community Services (OCS) and the grantee prior to the award. OCS anticipates that agency involvement will produce programmatic benefits to the recipient otherwise unavailable to them for carrying out the project. The involvement and collaboration includes OCS review and approval of planning stages of the activities before implementation phases may begin; OCS involvement in the establishment of

policies and procedures that maximize open competition, and rigorous and impartial development, review and funding of grant or sub-grant activities, if applicable; and OCS and recipient joint collaboration in the performance of key programmatic activities (*i.e.,* strategic planning, implementation, information technology enhancements, training and technical assistance, publications or products, and evaluation). It also includes close monitoring by OCS of the requirements stated in this announcement that limit the grantee's discretion with respect to scope of services offered, organizational structure and management processes, coupled with close OCS monitoring during performance, which may, in order to ensure compliance with the intent of this funding, exceed those Federal stewardship responsibilities customary for grant activities.

*Anticipated Total Priority Area Funding:* $400,000.

*Anticipated Number of Awards:* 4–6.
*Ceiling on Amount of Individual Awards:* $100,000.

*Floor on Amount of Individual Awards:* $50,000.

*Average Projected Award Amount:* $50,000.

*Length of Project Periods:* 12 month project period with 12 month budget period. The FY 2006 President's Budget does not include or propose funding for the Community Services Block Grant (CSBG) Program.

## III. Eligibility Information

*1. Eligible Applicants*

State Governments
County Governments
City or Township Governments
Special District Governments
Independent School Districts
State Controlled institutions of higher education
Public Housing authorities/Indian housing authorities
Native American tribal governments (Federally recognized)
Native American tribal organizations (other than Federally recognized tribal governments)
Nonprofits having a 501(c)(3) status with the IRS other than institutions of higher education
Non-profits that do not have a 501(c)(3) status with the IRS other than institutions of higher education
Private institutions of higher education
For-profit organizations other than small businesses
Small businesses

Additional Information on Eligibility

As prescribed by the Community Services Block Grant, as amended (Pub.

L. 105–285, Section 678A(c)(2)) eligible applicants are eligible entities, or statewide or local organizations, or associations with demonstrated expertise in providing training to individuals and organizations on methods of effectively addressing the needs of low-income families and communities. Eligible applicants must meet this criterion to be eligible for CSBG T&TA funding.

Faith-based organizations are eligible to apply.

Community Services Block Grant eligible entities and State Community Action Agencies are eligible to apply.

*2. Cost Sharing/Matching*

None.

*3. Other*

All Applicants must have a Dun & Bradstreet Number. On June 27, 2003 the Office of Management and Budget published in the **Federal Register** a new Federal policy applicable to all Federal grant applicants. The policy requires Federal grant applicants to provide a Dun & Bradstreet Data Universal Numbering System (DUNS) number when applying for Federal grants or cooperative agreements on or after October 1, 2003. The DUNS number will be required whether an applicant is submitting a paper application or using the government-wide electronic portal (*www.Grants.gov*). A DUNS number will be required for every application for a new award or renewal/continuation of an award, including applications or plans under formula entitlement and block grant programs submitted on or after October 1, 2003.

Please ensure that your organization has a DUNS number. You may acquire a DUNS number at no cost by calling the dedicated toll-free DUNS number request line on 1–866–705–5711 or you may request a number on-line at *http://www.dnb.com*.

Non-profit organizations applying for funding are required to submit proof of their non-profit status.

Proof of non-profit status is any one of the following:

• A reference to the applicant organization's listing in the Internal Revenue Service (IRS) most recent list of tax-exempt organizations described in the IRS Code.

• A copy of a currently valid IRS tax exemption certificate.

• A statement from a State taxing body, State attorney general, or other appropriate State official certifying that the applicant organization has a non-profit status and that none of the net earning accrue to any private shareholders or individuals.

• A certified copy of the organization's certificate of incorporation or similar document that clearly establishes non-profit status.

• Any of the items in the subparagraphs immediately above for a State or national parent organization and a statement signed by the parent organization that the applicant organization is a local non-profit affiliate.

Private, non-profit organizations are encouraged to submit with their applications the survey located under "Grant Related Documents and Forms," "Survey for Private, Non-Profit Grant Applicants," titled "Survey on Ensuring Equal Opportunity for Applicants," at: *www.acf.hhs.gov/programs/ofs/ forms.htm.*

Disqualification Factors

Applications that exceed the ceiling amount will be considered non-responsive and will not be considered for funding under this announcement.

Any application received after 4:30 p.m. eastern time on the deadline date will not be considered for competition.

## IV. Application and Submission Information

*1. Address To Request Application Package*

Dr. Margaret Washnitzer, Office of Community Services Operations Center, 1515 Wilson Blvd., Suite 100, Arlington, VA 22209. Phone: 800–281–9519. E-mail: *OCSGRANTS@acf.hhs.gov.*

*2. Content and Form of Application Submission*

Originals, Copies, and Signatures

If submitting your application in paper format, an original and two copies of the complete application are required. The original and each of the two copies must include all required forms, certifications, assurances, and appendices, be signed by an authorized representative, have original signatures, and be submitted unbound.

Each application must contain the following items in the order listed:

*Application for Federal Assistance (Standard Form 424).* Follow the instructions below and those that accompany the form.

In Item 5 of Form 424, put DUNS number in "Organizational DUNS:" box.

In Item 5 of Form 424, include name, phone number, and, if available, email and fax numbers of the contact person.

In Item 8 of Form 424, check "New."

In Item 10 of Form 424, clearly identify the Catalog of Federal Domestic Assistance (CFDA) program title and number for the program for which funds

are being requested as stated in this funding opportunity announcement.

In Item 11 of Form 424, identify the single funding opportunity the application addresses.

In Item 12 of Form 424, identify the specific geographic area to be served.

In Item 14 of Form 424, identify Congressional districts of both the applicant and project.

Budget Information Non-Construction Programs (Form 424A) and Budget Justification.

Follow the instructions provided here and those in Section V. Application Review Information.

If applicable, applicants must include a completed SPOC certification (Single Point of Contact) with the date of the SPOC contact entered in line 16, page 1 of the Form 424.

*Proof of non-profit status* (if applicable). Please see Section III.3 Other Eligibility for ways to demonstrate non-profit status.

*Indirect cost rate agreement.* If claiming indirect costs, provide documentation that applicant currently has an indirect cost rate approved by the Department of Health and Human Services (HHS) or another cognizant Federal agency.

*Letters of agreement and memoranda of understanding.* If applicable, include a letter of commitment or Memorandum of Understanding from each partner and/or sub-contractor describing their role, detailing specific tasks to be performed, and expressing commitment to participate if the proposed project is funded.

General Content and Form Information

The application limit is 75 pages total including all forms and attachments. Pages over this page limit will be removed from the application and will not be reviewed.

To be considered for funding, each application must be submitted with the Standard Federal Forms (provided at the end of this announcement or through the electronic links provided) and following the guidance provided. The application must be signed by an individual authorized to act for the applicant agency and to assume responsibility for the obligations imposed by the terms and conditions of the grant award.

The application must be typed, double spaced, printed on only one side, with at least ½ inch margins on each side and 1 inch at the top and bottom, using standard 12 Point fonts (such as Times New Roman or Courier). Pages must be numbered.

All copies of an application must be submitted in a single package, and a separate package must be submitted for each funding opportunity. The package must be clearly labeled for the specific funding opportunity it is addressing.

Because each application will be duplicated, do not use or include separate covers, binders, clips, tabs, plastic inserts, maps, brochures, or any other items that cannot be processed easily on a photocopy machine with an automatic feed. Do not bind, clip, staple, or fasten in any way separate subsections of the application, including supporting documentation; however, each complete copy must be stapled securely in the upper left corner. Applicants are advised that the copies of the application submitted, not the original, will be reproduced by the Federal government for review.

*Tips for Preparing a Competitive Application.* It is essential that applicants read the entire announcement package carefully before preparing an application and include all of the required application forms and attachments. The application must reflect a thorough understanding of the purpose and objectives of the applicable legislation. Reviewers expect applicants to understand the goals of the legislation and OCS's interest in each topic. A "responsive application" is one that addresses all of the evaluation criteria in ways that demonstrate this understanding. Applications that are considered to be "unresponsive" generally receive very low scores and are rarely funded.

The Office of Community Services Web site *http://www.acf.hhs.gov/ programs/ocs/* provides a wide range of information and links to other relevant web sites. Before you begin preparing an application, we suggest that you learn more about the mission and programs of the Office of Community Services by exploring the website.

*Logic Model.* A logic model is a tool that presents the conceptual framework for a proposed project and explains the linkages among program elements. While there are many versions of the logic model, they generally summarize the logical connections among the needs that are the focus of the project, project goals and objectives, the target population, project inputs (resources), the proposed activities/processes/ outputs directed toward the target population, the expected short- and long-term outcomes the initiative is designed to achieve, and the evaluation plan for measuring the extent to which proposed processes and outcomes actually occur. Information on the development of logic models is

available on the Internet at *http:// www.uwex.edu/ces/pdande/* or *http:// www.extension.iastate.edu/cyfar/ capbuilding/outcome/ outcome_logicmdir.html.*

You may submit your application to us in either electronic or paper format. To submit an application electronically, please use the *http://www.Grants.gov/ Apply* site. If you use Grants.gov, you will be able to download a copy of the application package, complete it off-line, and then upload and submit the application via the Grants.gov site. ACF will not accept grant applications via e-mail or facsimile transmission.

Please note the following if you plan to submit your application electronically via Grants.gov:

• Electronic submission is voluntary, but strongly encouraged.

• When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation. We strongly recommend that you do not wait until the application deadline date to begin the application process through Grants.gov.

• We recommend you visit Grants.gov at least 30 days prior to filing your application to fully understand the process and requirements. We encourage applicants who submit electronically to submit well before the closing date and time so that if difficulties are encountered an applicant can still send in a hard copy overnight. If you encounter difficulties, please contact the Grants.gov Help Desk at 1–800–518–4276 to report the problem and obtain assistance with the system.

• To use Grants.gov, you, as the applicant, must have a DUNS Number and register in the Central Contractor Registry (CCR). You should allow a minimum of five days to complete the CCR registration.

• You will not receive additional point value because you submit a grant application in electronic format, nor will we penalize you if you submit an application in paper format.

• You may submit all documents electronically, including all information typically included on the SF 424 and all necessary assurances and certifications.

• Your application must comply with any page limitation requirements described in this program announcement.

• After you electronically submit your application, you will receive an automatic acknowledgement from Grants.gov that contains a Grants.gov tracking number. The Administration for Children and Families will retrieve your application from Grants.gov.

• We may request that you provide original signatures on forms at a later date.

• You may access the electronic application for this program on www.Grants.gov .

• You must search for the downloadable application package by the CFDA number.

All applications, whether received via mail, hand delivery or electronically, will receive a written confirmation of receipt from the OCS operations center.

Private, non-profit organizations are encouraged to submit with their applications the survey located under ''Grant Related Documents and Forms,'' ''Survey for Private, Non-Profit Grant Applicants,'' titled, ''Survey on Ensuring Equal Opportunity for Applicants,'' at: *http://www.acf.hhs.gov/ programs/ofs/forms.htm.*

Standard Forms and Certifications

The project description should include all the information requirements described in the specific evaluation criteria outlined in the program announcement under Section V Application Review Information. In addition to the project description, the applicant needs to complete all the standard forms required for making applications for awards under this announcement.

Applicants seeking financial assistance under this announcement must file the Standard Form (SF) 424, Application for Federal Assistance; SF–424A, Budget Information—Non-Construction Programs; SF–424B, Assurances—Non-Construction Programs. The forms may be reproduced for use in submitting applications. Applicants must sign and return the standard forms with their application.

Applicants must furnish prior to award an executed copy of the Standard Form LLL, Certification Regarding Lobbying, when applying for an award in excess of $100,000. Applicants who have used non-Federal funds for lobbying activities in connection with receiving assistance under this announcement shall complete a disclosure form, if applicable, with their applications (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 also understand they will be held accountable for the smoking prohibition included within Public Law 103–227, Title XII Environmental Tobacco Smoke (also known as the PRO–KIDS Act of 1994). A copy of the **Federal Register** notice which implements the smoking

prohibition is included with forms. 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 of their compliance with all Federal statutes relating to nondiscrimination. By signing and submitting the applications, applicants are providing the certification and need not mail back the certification form. Complete the standard forms and the associated certifications and assurances based on the instructions on the forms. The forms and certifications may be found at: *http://www.acf.hhs.gov/ programs/ofs/forms.htm.*

Those organizations required to provide proof of non-profit status, please refer to Section III.3.

Please see Section V.1, for instructions on preparing the full project description.

*3. Submission Dates and Times*

Explanation of Due Dates

The closing time and date for receipt of applications is referenced above. Applications received after 4:30 p.m. eastern time on the closing date will be classified as late.

*Deadline:* Applications shall be considered as meeting an announced deadline if they are received on or before the deadline time and date referenced in Section IV.6. Applicants are responsible for ensuring applications are mailed or submitted electronically well in advance of the application due date.

Applications hand carried by applicants, applicant couriers, 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., eastern time, at the address referenced in Section IV.6., between Monday and Friday (excluding Federal holidays).

ACF cannot accommodate transmission of applications by facsimile. Therefore, applications transmitted to ACF by fax 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.

Any application received after 4:30 p.m. eastern time on the deadline date will not be considered for competition.

Applicants using express/overnight mail services should allow two working

days prior to the deadline date for receipt of applications. Applicants are cautioned that express/overnight mail services do not always deliver as agreed.

*Extension of deadlines:* ACF may extend application deadlines when circumstances such as acts of God

(floods, hurricanes, etc.) occur, or when there are widespread disruptions of mail service, or in other rare cases. A determination to extend or waive deadline requirements rests with the Chief Grants Management Officer.

Checklist

You may use the checklist below as a guide when preparing your application package.

| What to submit | Required content | Required form or format | When to submit |
|---|---|---|---|
| Project Abstract | See Sections IV.2 and V | Found in Sections IV.2 and V | By application due date. |
| Project Description | See Sections IV.2 and V | Found in Sections IV.2 and V | By application due date. |
| Budget Narrative/Justification | See Sections IV.2 and V | Found in Sections IV.2 and V | By application due date. |
| SF424 | See Section IV.2 | See *http://www.acf.hhs.gov/programs/ofs/forms.htm.* | By application due date. |
| SF–LLL Certification Regarding Lobbying. | See Section IV.2 | See *http://www.acf.hhs.gov/programs/ofs/forms.htm.* | By date of award. |
| Certification Regarding Environmental Tobacco Smoke. | See Section IV.2 | See *http://www.acf.hhs.gov/programs/ofs/forms.htm.* | By date of award. |
| Assurances | See Section IV.2 | Found in Section IV.2 | By date of award. |
| SF424A | See Section IV.2 | See *http://www.acf.hhs.gov/programs/ofs/forms.htm.* | By application due date. |
| SF424B | See Section IV.2 | See *http://www.acf.hhs.gov/programs/ofs/forms.htm.* | By application due date. |
| Proof of Non-Profit Status if applicable. | See Section III.3 | Found in Section III.3. | By date of award. |
| Indirect Cost rate Agreement, if applicable. | See Section IV | Format described in Section IV | By application due date. |
| Letters of commitment from partner organizations, if applicable. | See Section IV | Format described in Section IV | By time of award. |

Additional Forms

Private, non-profit organizations are encouraged to submit with their

applications the survey located under "Grant Related Documents and Forms," "Survey for Private, Non-Profit Grant Applicants," titled, "Survey on

Ensuring Equal Opportunity for Applicants," at: *www.acf.hhs.gov/programs/ofs/forms.htm.*

| What to submit | Required content | Location | When to submit |
|---|---|---|---|
| Survey for Private, Non-Profit Grant Applicants. | See form | May be found on *http://www.acf.hhs.gov/programs/ofs/forms.htm.* | By application due date. |

*4. Intergovernmental Review*

State Single Point of Contact (SPOC)

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 Federal assistance under covered programs.

As of October 1, 2004, the following jurisdictions have elected to participate in the Executive Order process: Arkansas, California, Delaware, District of Columbia, Florida, Georgia, Illinois, Iowa, Kentucky, Maine, Maryland, Michigan, Mississippi, Missouri, Nevada, New Hampshire, New Mexico, New York, North Dakota, Rhode Island, South Carolina, Texas, Utah, West Virginia, Wisconsin, American Samoa, Guam, North Mariana Islands, Puerto Rico, and Virgin Islands. As these

jurisdictions have elected to participate in the Executive Order process, they have established SPOCs. Applicants from participating jurisdictions should contact their SPOC, as soon as possible, to alert them of prospective applications and receive instructions. Applicants must submit all required materials, if any, to the SPOC and indicate the date of this 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. SPOCs are encouraged to eliminate the submission of routine endorsements as official recommendations. Additionally, SPOCs are requested to clearly differentiate between mere advisory comments and those official State process recommendations which may trigger the "accommodate or explain" rule.

When comments are submitted directly to ACF, they should be addressed to the U.S. Department of Health and Human Services, Administration for Children and Families, Office of Grants Management, Division of Discretionary Grants, 370 L'Enfant Promenade SW., 4th floor, Washington, DC 20447.

Although the remaining jurisdictions have chosen not to participate in the process, entities that meet the eligibility requirements of the program are still eligible to apply for a grant even if a State, Territory, Commonwealth, etc. does not have a SPOC. Therefore, applicants from these jurisdictions, or for projects administered by federally-recognized Indian Tribes, need take no action in regard to E.O. 12372.

The official list, including addresses, of the jurisdictions elected to participate in E.O. 12372 can be found on the following URL: *http://www.whitehouse.gov/omb/grants/spoc.html.*

A list of Single Points of Contact for each State and Territory is included with the application materials for this announcement.

### 5. Funding Restrictions

Sub-Contracting or Delegating Projects

OCS will not fund any project where the role of the applicant is primarily to serve as a conduit for funds to organizations other than the applicant. The applicant must have a substantive role in the implementation of the project for which funding is requested. This prohibition does not bar the making of sub-grants or sub-contracting for specific services or activities needed to conduct the project.

### 6. Other Submission Requirements

*Submission by Mail:* An applicant must provide an original application with all attachments, signed by an authorized representative and two copies. The application must be received at the address below by 4:30 p.m. eastern time on or before the closing date. Applications should be mailed to: U.S. Department of Health and Human Services, Administration for Children and Families, Office of Community Services' Operations Center, 1515 Wilson Blvd., Suite 100, Arlington, VA 22209, Attention: Barbara Ziegler Johnson.

*Hand Delivery:* An applicant must provide an original application with all attachments signed by an authorized representative and two copies. The application must be received at the address below by 4:30 p.m. eastern time on or before the closing date. Applications that are hand delivered will be accepted between the hours of 8 a.m. to 4:30 p.m. eastern time, Monday through Friday. Applications should be delivered to: U.S. Department of Health and Human Services, Administration for Children and Families, Office of Community Services' Operation Center, 1515 Wilson Blvd., Suite 100, Arlington, VA 22209, Attention: Barbara Ziegler Johnson.

*Electronic Submission: www.Grants.gov* Please see section IV. 2 Content and Form of Application Submission, for guidelines and requirements when submitting applications electronically.

### V. Application Review Information

*The Paperwork Reduction Act of 1995 (Pub. L. 104–13)*

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

The project description is approved under OMB control number 0970–0139 which expires 4/30/2007.

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.

1. Criteria

Purpose

The project description provides a major means by which an application is evaluated and ranked to compete with other applications for available assistance. The project description should be concise and complete and should address the activity for which Federal funds are being requested. Supporting documents should be included where they can present information clearly and succinctly. In preparing your project description, information responsive to each of the requested evaluation criteria must be provided. Awarding offices use this and other information in making their funding recommendations. It is important, therefore, that this information be included in the application in a manner that is clear and complete.

Introduction

Applicants required to submit a full project description shall prepare the project description statement in accordance with the following instructions while being aware of the specified evaluation criteria. The text options give a broad overview of what your project description should include while the evaluation criteria identifies the measures that will be used to evaluate applications.

Project Summary/Abstract

Provide a summary of the project description (a page or less) with reference to the funding request.

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.

Results or Benefits Expected

Identify the results and benefits to be derived. For example, describe the population to be served by the program and the number of new jobs that will be targeted to the target population. Explain how the project will reach the targeted population, how it will benefit participants including how it will support individuals to become more economically self-sufficient.

Approach

Outline a plan of action that 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 that 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.

Provide quantitative monthly or quarterly projections of the accomplishments to be achieved for each function or activity in such terms as the number of people to be served and the number of activities accomplished.

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 ACF.''

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.

Evaluation

Provide a narrative addressing how the conduct of the project and the results of the project will be evaluated. In addressing the evaluation of results, state how you will determine the extent to which the project has achieved its stated objectives and the extent to

which the accomplishment of objectives can be attributed to the project. Discuss the criteria to be used to evaluate results, and explain the methodology that will be used to determine if the needs identified and discussed are being met and if the project results and benefits are being achieved. With respect to the conduct of the project, define the procedures to be employed to determine whether the project is being conducted in a manner consistent with the work plan presented and discuss the impact of the project's various activities on the project's effectiveness.

Organizational Profiles

Provide information on the applicant organization(s) and cooperating partners, such as organizational charts, financial statements, audit reports or statements from CPAs/Licensed Public Accountants, Employer Identification Numbers, names of bond carriers, contact persons and telephone numbers, child care licenses and other documentation of professional accreditation, information on compliance with Federal/State/local government standards, documentation of experience in the program area, and other pertinent information. If the applicant is a non-profit organization, submit proof of non-profit status in its application.

The non-profit agency can accomplish this by providing: (a) A reference to the applicant organization's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations described in the IRS Code; (b) a copy of a currently valid IRS tax exemption certificate; (c) a statement from a State taxing body, State attorney general, or other appropriate State official certifying that the applicant organization has a non-profit status and that none of the net earnings accrue to any private shareholders or individuals; (d) a certified copy of the organization's certificate of incorporation or similar document that clearly establishes non-profit status; (e) any of the items immediately above for a State or national parent organization and a statement signed by the parent organization that the applicant organization is a local non-profit affiliate.

Budget and Budget Justification

Provide a budget with line item detail and detailed calculations for each budget object class identified on the Budget Information form. Detailed calculations must include estimation methods, quantities, unit costs, and other similar quantitative detail sufficient for the calculation to be

duplicated. Also include a breakout by the funding sources identified in Block 15 of the SF–424.

Provide a narrative budget justification that describes how the categorical costs are derived. Discuss the necessity, reasonableness, and allocability of the proposed costs.

*Evaluation Criteria*

The following evaluation criteria appear in weighted descending order. The corresponding score values indicate the relative importance that ACF places on each evaluation criterion; however, applicants need not develop their applications precisely according to the order presented. Application components may be organized such that a reviewer will be able to follow a seamless and logical flow of information (*e.g.* from a broad overview of the project to more detailed information about how it will be conducted).

In considering how applicants will carry out the responsibilities addressed under this announcement, competing applications for financial assistance will be reviewed and evaluated against the following criteria:

Approach   35 Points

(1) The extent to which the work program is results-oriented, furthers the purposes of 678(A) of the CSBG Act, and specifically related to the priority area under which funds are being requested. The extent to which the applicant addresses the following: specific outcomes to be achieved; performance targets that the project is committed to achieving, including a discussion of and how the project will verify the achievement of these targets; critical milestones which must be achieved if results are to be gained; organizational support, the level of support from the applicant organization; past performance in similar work; and specific resources contributed to the project that are critical to success.

(2) The extent to which the applicant defines the comprehensive nature of the project and methods that will be used to ensure that the results can be used to address a statewide or nationwide project as defined by the description of the particular priority area.

(3) The extent to which the applicant can effectively demonstrate that they have adequate knowledge of the information and services provided by domestic violence coalitions within their community.

Organizational Profiles   25 Points

(1) The extent to which the applicant demonstrates that it has experience and a successful record of accomplishment

relevant to the specific activities it proposes to accomplish.

(2) If extent to which the applicant proposes to provide training and technical assistance, it details its abilities to provide those services on a nationwide basis. If applicable, the extent to which information provided by the applicant also addresses related achievements and competence of each cooperating or sponsoring organization.

(3) The extent to which the applicant fully describes, for example in a resume, the experience and skills of the proposed project director and primary staff showing specific qualifications and professional experiences relevant to the successful implementation of the proposed project.

(4) The extent to which the applicant describes how it will involve partners in the Community Services Network in its activities. Where appropriate, the extent to which the applicant describes how it will interface with other related organizations.

(5) If subcontracts are proposed, the extent to which the applicant documents the willingness and capacity of the subcontracting organization(s) to participate as described.

Objectives and Need for Assistance   20 Points

(1) The extent to which the applicant documents that the proposed project addresses the vital needs related to the CSBG program purposes and provides statistics and other data and information in support of its contention.

(2) The extent to which the application provides current supporting documentation or other testimonies regarding needs from State CSBG Directors, CAAs and local service providers and/or State and Regional organizations of CAAs and other local service providers.

Results or Benefits Expected   15 Points

(1) The extent to which the applicant describes how the project will assure long-term program and management improvements for State CSBG offices, CAA State and/or regional associations, CAAs and/or other local providers of CSBG services and activities.

(2) The extent to which the applicant indicates the types and amounts of public and/or private resources it will mobilize, how those resources will directly benefit the project, and how the project will ultimately benefit low-income individuals and families.

(3) If the applicant proposes a project with a training and technical assistance focus, the extent to which the applicant indicates the number of organizations

and/or staff that will benefit from those services.

(4) If the applicant proposes a project with data collection focus, the extent to which the applicant describes the mechanism it will use to collect data, how it can assure collections from a significant number of States, and the number of States willing to submit data to the applicant.

(5) If the applicant proposes to develop a symposium series or other policy-related project(s), the extent to which the applicant identifies the number and types of beneficiaries.

(6) The extent to which the applicant describes methods of securing participant feedback and evaluations of activities.

Budget and Budget Justification
5 Points

(1) The extent to which the resources requested are reasonable and adequate to accomplish the project.

(2) The extent to which total costs are reasonable and consistent with anticipated results.

2. Review and Selection Process

Initial OCS Screening

Each application submitted to OCS will be screened to determine whether it was received by the closing date and time and whether the proposed budget does not exceed the ceiling amount specified in Section II. Award Information.

OCS Evaluation of Applications

Applications that pass the initial OCS screening will be reviewed and rated by a panel based on the program elements and review criteria presented in relevant sections of this program announcement. The review criteria are designed to enable the review panel to assess the quality of a proposed project and determine the likelihood of its success. The criteria are closely related to each other and are considered as a whole in judging the overall quality of an application. The review panel awards points only to applications that are responsive to the program elements and relevant review criteria within the context of this program announcement.

The OCS Director and program staff will use the reviewer scores when considering competing applications. Reviewer scores will weigh heavily in funding decisions, but will not be the only factors considered.

Applications generally will be considered in order of the average scores assigned by the review panel. Because other important factors are taken into consideration, highly ranked applications are not guaranteed funding.

These other considerations include, for example: The timely and proper completion by the applicant of projects funded with OCS funds granted in the last five (5) years; comments of reviewers and government officials; staff evaluation and input; amount and duration of the grant requested and the proposed project's consistency and harmony with OCS goals and policy; geographic distribution of applications; previous program performance of applicants; compliance with grant terms under previous HHS grants, including the actual dedication to program of mobilized resources as set forth in project applications; audit reports; investigative reports; and applicant's progress in resolving any final audit disallowance on previous OCS or other Federal agency grants.

Approved But Unfunded Applications

Applications that are approved but unfunded may be held over for funding in the next funding cycle, pending the availability of funds, for a period not to exceed one year.

3. Anticipated Announcement and Award Dates

Applications will be reviewed in the summer of 2005. Grant awards will have a start date no later than September 30, 2005.

**VI. Award Administration Information**

*1. Award Notices*

The successful applicants will be notified through the issuance of a Financial Assistance Award document which sets forth the amount of funds granted, the terms and conditions of the grant, the effective date of the grant, the budget period for which initial support will be given, the non-Federal share to be provided, and the total project period for which support is contemplated. The Financial Assistance Award will be signed by the Grants Officer and transmitted via postal mail.

Organizations whose applications will not be funded will be notified in writing.

*2. Administrative and National Policy Requirements*

Direct Federal grants, sub-award funds, or contracts under this program shall not be used to support inherently religious activities such as religious instruction, worship, or proselytization. Therefore, organizations must take steps to separate, in time or location, their inherently religious activities from the services funded under this Program. Regulations pertaining to the Equal Treatment For Faith-Based Organizations, which includes the

prohibition against Federal funding of inherently religious activities, can be found at either 45 CFR 87.1 or the HHS Web site at *http://www.os.dhhs.gov/fbci/waisgate21.pdf.*

45 CFR part 74; 45 CFR part 92. Grantees are subject to the requirements in 45 CFR part 74 (non-governmental) or 45 CFR part 92 (governmental) as well as 45 CFR part 87.

*3. Reporting Requirements*

All grantees are required to submit semi-annual (quarterly or annual) program reports; grantees are also required to submit semi-annual expenditure reports using the required financial standard form (SF–269) which can be found at the following URL: *http://www.acf.hhs.gov/programs/ofs/forms.htm.*

Final reports are due 90 days after the end of the grant period.

Programmatic Reports: Semi-Annually.

Financial Reports: Semi-Annually.

Grantees will be required to submit program progress reports and financial reports (SF269) throughout the project period. Program progress and financial reports are due 30 days after the reporting period. In addition, final programmatic and financial reports are due 90 days after the close of the project period.

**VII. Agency Contacts**

Program Office Contact: Dr. Margaret Washnitzer, Department of Health and Human Services, Administration for Children and Families, Office of Community Services' Operations Center, 1515 Wilson Blvd., Suite 100, Arlington, VA 22209, Phone: 800–281–9519, E-mail: *OCSGRANTS@acf.hhs.gov.*

Grants Management Office Contact: Barbara Ziegler Johnson, Team Leader, Office of Grants Management, Division of Discretionary Grants, Administration for Children and Families, Office of Community Services' Operations Center, 1515 Wilson Blvd., Suite 100, Arlington, VA 22209, Phone: 800–281–9519, E-mail: *OCSGRANTS@acf.hhs.gov.*

**VIII. Other Information**

*Notice:* Beginning with FY 2006, the Administration for Children and Families (ACF) will no longer publish grant announcements in the **Federal Register**. Beginning October 1, 2005 applicants will be able to find a synopsis of all ACF grant opportunities and apply electronically for opportunities via: *www.Grants.gov.* Applicants will also be able to find the complete text of all ACF grant

announcements on the ACF Web site located at: *http://www.acf.hhs.gov/grants/index.html.*

Additional information about this program and its purpose can be located on the following Web sites: *http://www.acf.hhs.gov/programs/cb/.*

For general questions regarding this announcement please contact: Dr. Margaret Washnitzer, Department of Health and Human Services, Administration for Children and Families, Office of Community Services' Operations Center, 1515 Wilson Blvd., Suite 100, Arlington, VA 22209, Phone: 800–281–9519, E-mail: *OCSGRANTS@acf.hhs.gov.*

Applicants will not be sent acknowledgements of received applications.

Dated: July 8, 2005.

**Josephine Robinson,**
*Director, Office of Community Services.*
[FR Doc. 05–13893 Filed 7–13–05; 8:45 am]
**BILLING CODE 4184–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2005N–0262]

**Submission of Chemistry, Manufacturing, and Controls Information in a New Drug Application Under the New Pharmaceutical Quality Assessment System; Notice of Pilot Program**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is seeking pharmaceutical companies to volunteer to participate in a pilot program involving the submission of chemistry, manufacturing, and controls (CMC) information consistent with the new pharmaceutical quality assessment system. The purpose of the pilot program is twofold. First, the pilot program will provide participating pharmaceutical companies with an opportunity to submit critical CMC information that demonstrates their understanding of quality by design, product knowledge, and process understanding of the drug substance and drug product in a new drug application (NDA). Second, the pilot program will enable the public and regulated industry to provide feedback that will assist FDA in developing a guidance for industry on the new quality assessment system.

**DATES:** Submit written and electronic requests to participate in the pilot program by October 31, 2005. Submit written and electronic comments on this pilot program by December 31, 2006.

**ADDRESSES:** Submit written requests to participate in the pilot program and written comments on the program to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic requests to participate and electronic comments to *http://www.fda.gov/dockets/ecomments.*

**FOR FURTHER INFORMATION CONTACT:** Michael Folkendt, Center for Drug Evaluation and Research (HFD–800), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, e-mail: *folkendtm@cder.fda.gov.*

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The Office of New Drug Chemistry (ONDC) in the Office of Pharmaceutical Science, Center for Drug Evaluation and Research, is establishing a modern, risk-based pharmaceutical quality assessment system, as described in a September 2004 White Paper entitled ''ONDC's New Risk-Based Pharmaceutical Quality Assessment System'' (*http://www.fda.gov/cder/gmp/gmp2004/ondc_reorg.htm*). This White Paper was published as part of the FDA final report on ''Pharmaceutical cGMPs for the 21st Century—A Risk-Based Approach'' (*http://www.fda.gov/cder/gmp/gmp2004/GMP_finalreport2004.htm*).

The new quality assessment system will focus on critical pharmaceutical quality attributes (related to chemistry, formulation, manufacturing process design, and product performance) and their relevance to safety and effectiveness. The principles underlying this new quality assessment system can be found in the February 2005 International Conference on Harmonization (ICH) draft guidance entitled ''Q8 Pharmaceutical Development'' (*http://www.fda.gov/cder/guidance/6672dft.pdf*) and the September 2004 FDA guidance for industry entitled ''PAT—A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance'' (*http://www.fda.gov/cder/guidance/6419fnl.htm*). These principles include the following: (1) Ensuring product quality and performance through the design of effective and efficient manufacturing processes; (2) establishing product and process specifications based on a mechanistic understanding of how formulation and process factors affect product performance; and (3) where applicable, continuous ''real time'' quality assurance.

The new quality assessment system is intended to facilitate innovation and improvement throughout the product lifecycle and to provide regulatory flexibility for specification setting and postapproval changes based on scientific knowledge and understanding of product and process by applying quality-by-design principles. To take full advantage of the new quality assessment system, including appropriate regulatory flexibility, applicants should provide information in the CMC section of an NDA that demonstrates their product knowledge and process understanding at the time of submission. A CMC submission under the new system should contain a more comprehensive Quality Overall Summary (Module 2.3 of the ICH Common Technical Document (CTD) ''M4Q: The CTD—Quality'') and a more expansive Pharmaceutical Development section (Module 3.2.P.2, of the CTD). It should also include more relevant information on critical quality attributes and how they relate to clinical safety and effectiveness. The information provided should do the following: (1) Provide an appropriate level of confidence that quality has been built into the product by demonstrating the extent of product knowledge and process understanding at the time of submission, including information explaining critical steps and in-process controls to facilitate setting scientifically sound specifications and acceptance criteria, and (2) identify possible sources of variability in manufacturing by explaining how associated risks can be mitigated. At the same time, there would be less need for information that could be handled through inspectional oversight of current good manufacturing practices (cGMP) requirements (e.g., executed batch record, redundant chromatographic data, standard operating procedures). The pilot is also intended to provide enhanced clarity by distinguishing between information submitted and used in the pharmaceutical assessment process and information that is a condition of approval (e.g., that cannot be modified without further application/supplement review).

**II. Description of Pilot Program**

The pilot program will provide additional information for ONDC to use in implementing the new quality assessment system. FDA will work with each participant on an individual basis,