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Bryan Samuels,

*Commissioner, Administration on Children,
Youth and Families.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Funding Opportunity; Street Outreach Program

Program Office: Administration on
Children, Youth and Families (ACYF),
Family and Youth Services Bureau
(FYSB).

Program Announcement Number:
HHS-2010-ACF-ACYF-YO-0042.

Announcement Title: Street Outreach
Program.

CFDA Number: 93.557.

Due Date for Applications: July 19,
2010.

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Executive Summary: This
announcement governs the proposed
award of discretionary grants under the
Street Outreach Program. It sets forth
the application requirements, the
application process, and other
administrative and fiscal requirements
for grants in Fiscal Year (FY) 2010. The
purpose of the Street Outreach Program
is to conduct outreach services designed
to build relationships between grantee
staff and runaway, homeless and street
youth.

I. Description

Statutory Authority

Grants for Runaway and Homeless
Youth Street Outreach Programs (SOP)
are authorized by the Runaway and
Homeless Youth Act, 42 U.S.C. 5701-
5752, as most recently amended by the
Reconnecting Homeless Youth Act of
2008, Public Law 110-378 on October 8,
2008. Text of this legislation can be
located at: [http://www.acf.hhs.gov/
programs/fysb/content/aboutfysb/
rhycomp08.htm](http://www.acf.hhs.gov/programs/fysb/content/aboutfysb/rhycomp08.htm).

Description

Purpose

Today, in communities across the
country, young people are living on the
streets after running from or being asked
to leave homes characterized by abuse,
neglect, or parental drug and alcohol
abuse. Once on the streets, such youth
are at risk of being sexually exploited or
abused by adults for pleasure or profit.
In addition, such youth may engage in
shoplifting, survival sex, or drug dealing
in order to provide for their basic needs.
Since 1996, SOP has been aiding this
population by funding grantees to
provide street-based services to
runaway, homeless, and street youth
who have been subjected to, or are at
risk of being subjected to, sexual abuse,
prostitution, or sexual exploitation.
These services, which are provided in
areas where street youth congregate, are
designed to assist such youth in making
healthy choices regarding where they
live and how they behave. In Fiscal Year
(FY) 2009, \$16.2 million was allocated
for SOP, which funded 54 new projects
and 118 continuation projects in their
second or third year of operation.

Scope of Services

Street outreach programs must assist
runaway, homeless, and street youth in
making healthy personal choices
regarding where they live and how they
behave. Street outreach staff must build
relationships with and provide services
to these young people in their own
environment using an array of
communication strategies that
encourage trust and willingness to seek
shelter and other services. Street
outreach programs must address the
immediate needs of street youth (food,
clothing, shelter, etc.) through
appropriate referrals or direct
interventions. Programs must also focus
on improving the behavioral and
physical health of street youth,
providing them with employment and
educational supports, and either
reunifying them with family or finding
alternative, safe residential placements.
Outreach services must
comprehensively address the individual
strengths and needs of youth as well as
be gender specific (interventions that
are sensitive to the diverse experiences
of male, female and transgender youth),
language appropriate, culturally
sensitive, and respectful of the complex
identities of youth.

Program Requirements

A. Operations: Grantees must operate
a program that will deliver street-based
services to runaway, homeless, and
street youth, as defined by the Runaway

Homeless Youth Act (RHYA). (RHYA
definitions for "street-based services,"
"runaway youth," "homeless youth," and
"street youth" can be found in Section
I of this announcement.) Operations
must include a process for finding street
youth and a system for tracking where
they congregate, including what times
they gather in certain areas, and how
many youth are contacted on any given
day. Grantees must include in their
operations a plan to store and maintain
confidentiality of records and to
implement the restrictions set forth in
section 384 of the RHYA.

B. Services: Grantees must conduct
outreach services that encourage
runaway, homeless, and street youth to
leave the streets and to make other
healthy personal choices regarding
where they live and how they behave.
These services include, but are not
limited to:

- Street-based outreach and
education;
- Access to emergency shelter;
- Survival aid;
- Individual assessments;
- Treatment and counseling;
- Prevention and education activities;
- Information and referrals;
- Crisis and trauma intervention; and
- Follow-up support.

C. Access to Shelter: Grantees must be
able to guarantee runaway, homeless,
and street youth access to age-
appropriate emergency shelter. Shelter
can be provided through a referral
network, but street outreach staff must
have 24-hour access in order to
maintain interaction with youth while
they are in placement. A description of
the shelter and the terms of the
agreement with the shelter provider
must be included in the application.
The agreement must stipulate that the
applicant's street outreach staff workers
will have guaranteed access to runaway,
homeless, and street youth that are
residing in the shelter. If the applicant's
agency is providing shelter services
through other means, the application
must clearly describe how the shelter
services will be carried out.

D. Training: Grantees must provide
initial and periodic training to staff,
including, but not limited to:

- Effective outreach to runaway and
homeless street youth;
- Providing street-based services to
youth of diverse cultural backgrounds
that reflects gender specificity, language
appropriateness, cultural sensitivity and
respect for the complex identities of
youth (i.e. race, gender, sexual
orientation);
- Ethical considerations when
working with street youth;
- Staying safe on the streets;

- Crisis and trauma intervention for runaway and homeless youth and street youth; and

- Positive Youth Development (Grantees must incorporate the positive youth development goals identified by Congress in the RHYA at 42 U.S.C. 5701(3)).

E. Supervision: Grantees must provide supervision of street-based outreach staff, including, but not limited to:

- Written safety plans to include staff and youth;
- Regular on-street supervision by appropriately trained senior staff; and
- Back-up personnel for on-street staff.

F. Positive Youth Development (PYD): Grantees are required to develop and implement their program using a PYD approach. PYD is predicated on the understanding that all young people need support, guidance, and opportunities during adolescence, a time of rapid growth and change. With this support, they can develop self-assurance and create a healthy, successful life.

Some PYD strategies include:

- Intergenerational mentoring;
- Peer mentoring;
- Youth leadership and decision making;
- Volunteerism and service learning; and
- Job preparation and work shadowing.

Grantees are required to incorporate and describe the strategies they will use to meet the PYD goals identified by Congress in the RHYA at 42 U.S.C. 5701(3). These goals ensure a young person a sense of:

- Safety and structure;
- Belonging and membership;
- Self-worth and social contribution;
- Independence and control over one's life; and
- Closeness in interpersonal relationships.

(F) For more ways to implement PYD, applicants may go to <http://www.ncfy.acf.hhs.gov/pyd/>. A free introductory online course on PYD can be found at <http://www.ncfy-learn.jbsinternational.com/>.

G. Emergency Preparedness and Management Plan: Applicants must submit a plan with their application that outlines the steps the organization will take in case of a local or national situation that poses risk to the health and safety of staff and youth. Emergency preparedness plans must, at a minimum, include prevention, preparedness, response, and recovery efforts, as they apply to street-based outreach programs, as well as addressing how grantees will notify

FYSB immediately when emergency plans are executed. For guidance on creating an emergency preparedness plan, please see FYSB's Ready for Anything: A Disaster Planning Manual for Runaway and Homeless Youth Programs at http://www.ncfy.acf.hhs.gov/publications/ready_for_anything/index.htm.

H. Program Sustainability: Applicants must submit a plan with their application that indicates how the organization will continue to fund and provide street outreach services at the end of the grant funding period. The plan must identify the specific services that will continue at the end of the project period as well as how the organization will fund those services on an ongoing basis. The applicant must also provide an alternative plan for phase-out of services in the event that the goals of the sustainability plan are not attained. The plan may include funding from a range of different sources, including individuals, foundations, State agencies, and Federal agencies other than FYSB, as appropriate. The sustainability plan may also include earned income (for instance, from a business owned by the organization) and endowment income. The plan must include a timeline for sustainability activities that begins immediately upon receipt of the grant.

Additional Program Requirements

I. Record Keeping: Grantees must use the Runaway and Homeless Youth Management Information System (RHYMIS) to keep adequate statistical records for profiling the youth and families serviced under this Federal grant. Applicants must have the proper computer equipment to operate RHYMIS. Applicants may budget for computer equipment in their application, as needed. For more information on the proper equipment, applicants may go to the RHYMIS fact sheet located on the FYSB Web site at: <http://www.acf.hhs.gov/programs/fysb/content/youthdivision/resources/rhymfactsheet.htm> or in Section VI.2 of this program announcement. In accordance with the Paperwork Reduction Act of 1995, the data collection under RHYMIS is approved under OMB control number 0970-0123, which expires September 30, 2010.

J. Technical Assistance: Grantees must agree to receive and participate in technical assistance efforts as recommended by Federal staff.

Measuring Program Success

SOP grantees must use RHYMIS to record the number of contacts with runaway, homeless, and street youth

and the distribution of food, information, first aid items, etc. (No personally identifying information is reported to ACF from any RHYMIS data system.) Because of that restriction and the often multiple contacts between youth workers and the same individual, RHYMIS does not provide an unduplicated SOP population count at the national level. The exception is the number of individual youth contacted who subsequently enter shelters or residential programs. However, as a life-line to youth in acute crises, every SOP contact, even with the same youth, can be a vital step towards safety and positive development. This applies whether the encounter provides first aid, a brief respite from hunger, or referral information. The definitive objective is to inspire an intangible sense of trust and confidence so youth agree to enter secure shelter and more structured services.

Intermediate SOP output measures available directly from RHYMIS include:

- Number of youth contacted through the SOP;
- Number of nutritional or hygiene packages distributed (the count for each); and
- Number of informational or motivational items distributed about referrals to shelter and services.

The following RHYMIS measures reflect the primary outcome that SOP activities are intended to achieve through program effectiveness:

- Number of youth accepting shelter.

Definitions

Aftercare Services—The provision of services to runaway or otherwise homeless youth and their families following the youth's return home or the youth's placement in alternative living arrangements, which assist in alleviating the problems that contributed to his or her running away or being homeless. (45 CFR 1351.1(a)) (Runaway and Homeless Youth Act, 42 U.S.C. 5701-5752).

Area—A specific neighborhood or section of the locality in which the runaway and homeless youth project is or will be located. (45 CFR 1351.1(a)) (Runaway and Homeless Youth Act, 42 U.S.C. 5701-5752).

Budget Period—The intervals of time into which a multi-year period of assistance is divided for budgetary and funding purposes. Budget periods are usually 12-months long but may be shorter or longer, if appropriate. (HHS Grants Policy Statement).

Coordinated Networks of Agencies—An association of two or more private agencies, whose purpose is to develop

or strengthen services for runaway or otherwise homeless youth and their families. (45 CFR 1351.1(a)) (Runaway and Homeless Youth Act, 42 U.S.C. 5701–5752).

Counseling Services—The provision of guidance, support, and advice to runaway or otherwise homeless youth and their families that are designed to alleviate the problems that contributed to the youth's running away or being homeless, resolve intra-family problems, to reunite such youth with their families, whenever appropriate, and to help them decide upon a future course of action. (45 CFR 1351.1(a)) (Runaway and Homeless Youth Act, 42 U.S.C. 5701–5752).

Demonstrably Frequented by or Reachable—Located in an area in which runaway or otherwise homeless youth congregate, or an area accessible to such youth by public transportation, or by the provision of transportation by the runaway and homeless youth project itself. (45 CFR 1351.1(a)) (Runaway and Homeless Youth Act, 42 U.S.C. 5701–5752).

Drug Abuse Education and Prevention Services—Services to runaway and homeless youth to prevent or reduce the illicit use of drugs by such youth; and may include individual, family, group, and peer counseling; drop-in services; assistance to runaway and homeless youth in rural areas (including the development of community support groups); information and training related to the illicit use of drugs by runaway and homeless youth for individuals involved in providing services to such youth; and activities to improve the availability of local drug abuse prevention services to runaway and homeless youth. (Section 387 RHY Act, as amended) (Runaway and Homeless Youth Act, 42 U.S.C. 5701–5752).

Homeless Youth—An individual (A) who is: (i) Less than 21 years of age, or in the case of a youth seeking shelter in a center under Part A of the Runaway and Homeless Youth Act, less than 18 years of age or is less than a higher maximum age if the State where the center is located has an applicable State or local law (including a regulation) that permits such higher maximum age in compliance with licensure requirements for child- and youth-serving facilities; and (ii) for the purposes of Part B, not less than 16 years of age and either (I) less than 22 years of age; or (II) not less than 22 years of age as of the expiration of the maximum period of stay permitted under section 322(a)(2) if such individual commences such stay before reaching 22 years of age; (B) for whom it is not possible to live in a safe

environment with a relative; and (C) who has no other safe alternative living arrangement. (Section 387 RHY Act, as amended) (Runaway and Homeless Youth Act, 42 U.S.C. 5701–5752).

Juvenile Justice System—Agencies such as, but not limited to, juvenile courts, law enforcement, probation, parole, correctional institutions, training schools, and detention facilities. (45 CFR 1351.1(a)) (Runaway and Homeless Youth Act, 42 U.S.C. 5701–5752).

Law Enforcement Structure—Any police activity or agency with legal responsibility for enforcing a criminal code including police departments and sheriffs' offices. (45 CFR 1351.1(a)) (Runaway and Homeless Youth Act, 42 U.S.C. 5701–5752).

Project Period—The total time stated in the Notice of Grant Award (including any amendments) for which Federal support is recommended. The period will consist of one or more budget periods. It does not constitute a commitment by the Federal Government to fund the entire period. (HHS Grants Policy Statement).

Runaway and Homeless Youth Project—A locally controlled human service program facility outside the law enforcement structure and the juvenile justice system that provides temporary shelter, directly or through other facilities, counseling, and aftercare services to runaway or otherwise homeless youth. (45 CFR 1351.1(a)) (Runaway and Homeless Youth Act, 42 U.S.C. 5701–5752).

Runaway Youth—An individual who is less than 18 years of age and who absents himself or herself from home or a place of legal residence without the permission of a parent or legal guardian. (Section 387 RHY Act, as amended) (Runaway and Homeless Youth Act, 42 U.S.C. 5701–5752).

Street-Based Services—Services provided to runaway and homeless youth, and street youth in areas where they congregate. These services are designed to assist such youth in making healthy personal choices regarding where they live and how they behave. This may include identification of and outreach to runaway and homeless and street youth; crisis intervention and counseling; information and referral for housing; information and referral for transitional living and health care services; as well as advocacy, education, and prevention services related to alcohol and drug abuse; sexual exploitation; sexually transmitted diseases, including human immunodeficiency virus (HIV); and physical and sexual assault. (Section 387 RHY Act, as amended) (Runaway

and Homeless Youth Act, 42 U.S.C. 5701–5752.).

Street Youth—An individual who is a runaway youth or indefinitely or intermittently a homeless youth; and spends a significant amount of time on the street or in other areas that increase the risk to such youth for sexual abuse, sexual exploitation, prostitution, or drug abuse. (Section 387 RHY Act, as amended) (Runaway and Homeless Youth Act, 42 U.S.C. 5701–5752).

Technical Assistance—The provision of expertise and/or support for the purpose of strengthening the capabilities of grantee organizations to deliver services. (45 CFR 1351.1) (Runaway and Homeless Youth Act, 42 U.S.C. 5701–5752).

II. Award Information

Funding Instrument Type: Grant.
Estimated Total Funding: \$8,500,000.
Expected Number of Awards: 85.
Award Ceiling: \$200,000 per Budget Period.
Award Floor: \$0 per Budget Period.
Average Projected Award Amount: \$100,000 per Budget Period.
Length of Project Periods: 36-month project with three 12-month budget periods.

Additional Information on Awards

Awards made under this announcement are subject to the availability of Federal funds.

Please see *Section IV.5 Funding Restrictions* for any restrictions on the use of grant funds awarded under this announcement.

III. Eligibility Information

III.1. Eligible Applicants

Public and nonprofit private agencies, such as:

- State governments;
- County governments;
- City or township governments;
- Special district governments;
- Public housing authorities/Indian housing authorities;
- 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;
- Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education.

Individuals, foreign entities, and sole proprietorship organizations are not eligible to compete for, or receive, awards made under this announcement.

Faith-based and community organizations that meet eligibility requirements are eligible to receive

awards under this funding opportunity announcement.

See "Legal Status of Applicant Entity" in *Section IV.2* for documentation required to support eligibility.

III.2. Cost Sharing or Matching

Cost Sharing/Matching Requirement: Yes.

Grantees are required to meet a non-Federal share of the project cost, in accordance with section 383 of the RHY Act. (Runaway and Homeless Youth Act, 42 U.S.C. 5701–5752).

Grantees must provide at least 10% percent of the total approved cost of the project. The total approved cost of the project is the sum of the ACF (Federal) share and the non-Federal share. The non-Federal share may be met by cash or in-kind contributions, although applicants are encouraged to meet their match requirements through cash contributions. For example, in order to meet the match requirements, a project requesting \$200,000.00 in ACF (Federal) funds must provide a non-Federal share of the approved total project cost of at least \$22,222.00, which is 10% percent of total approved project cost of \$222,222.00. Grantees will be held accountable for commitments of non-Federal resources even if they exceed the amount of the required match. Failure to provide the required amount will result in the disallowance of Federal funds. A lack of supporting documentation at the time of application submission will not exclude the application from competitive review.

III.3. Other

Disqualification Factors

Applications with requests that exceed the ceiling on the amount of individual awards as stated in *Section II. Award Information*, will be deemed non-responsive and will not be considered for funding under this announcement.

Applications that fail to satisfy the due date and time deadline requirements stated in *Section IV.3. Submission Dates and Times*, will be deemed non-responsive and will not be considered for funding under this announcement.

See *Section IV.3. Submission Dates and Times* for disqualification information specific to electronically-submitted applications:

- Electronically-submitted applications that do not receive a date/time-stamp e-mail indicating application submission on or before 4:30 p.m. e.t., on the due date, will be disqualified and will not be considered for competition.

- Electronically-submitted applications that fail the checks and validations at <http://www.Grants.gov> because the Authorized Organization Representative (AOR) does not have a current registration at the Central Contractor Registry (CCR) at the time of application submission will be disqualified and will not be considered for competition.

IV.1. Address To Request Application Package

Standard Forms, assurances, and certifications are available at the ACF Forms Web page at http://www.acf.hhs.gov/grants/grants_resources.html. Standard Forms are also available at the Grants.gov Forms Repository Web site at: <http://apply07.grants.gov/apply/FormLinks?family=15>.

FYSB Operations Center, c/o Master Key Consulting, Attn: Street Outreach Funding, 4915 St. Elmo Avenue, Suite 101, Bethesda, MD 20814, Phone: (866) 796–1591, e-mail: fysb@luxcg.com. URL: <http://www.acf.hhs.gov/programs/fysb>.

Federal Relay Service: Hearing-impaired and speech-impaired callers may contact the Federal Relay Service for assistance at 1–800–877–8339 (TTY—Text Telephone or ASCII—American Standard Code For Information Interchange).

Section IV.2. Content and Form of Application Submission

This section provides information on the required format, Standard Forms (SFs) and other forms, certifications, assurances, D–U–N–S requirement, project description, budget and budget justification, and methods of application submission. A checklist of required application elements is available for applicants' use in *Section VIII* of this announcement. Applicants are required to submit one original and two copies of all application materials if applying in hard-copy. Applicants submitting applications electronically via <http://www.grants.gov> need not provide additional copies of their application materials. The original signature of the Authorized Organization Representative (AOR) is required only on the original copy. The AOR is named by the applicant, and is authorized to act for the applicant, to assume the obligations imposed by the Federal laws, regulations, requirements, and conditions that apply to the grant application or awards. A point of contact on matters involving the application must also be identified on the SF–424 at 8f. This point of contact,

known as the Project Director or Principal Investigator, should not be identical to the person identified as the AOR.

Each application package must include the original and two copies. Do not staple the application or any section of the application.

The length of the entire application package must not exceed 90 pages. This includes the required Federal Standard Forms/certifications (SF–424, SF–424A, SF–424B and Certification Regarding Lobbying), table of contents, project summary, project description, budget/budget justification, supplemental documentation, proof of non-profit status, summaries of sub-grants and contracts, and letters of agreement. All pages of the application package must be sequentially numbered beginning with page one. The required Federal forms will be counted towards the total number of pages. All pages of each application will be counted to determine the total length. All pages exceeding the 90-page limit will be removed and will not be considered in the reviewing process. A cover letter is not required. Applicants are reminded that if a cover letter is submitted, it will count towards the 90-page limit.

The project description must be typed and double-spaced on a single-side of 8 1/2 x 11 inch plain white paper with at least 1/2 inch margins on all sides, using black print with 12-point size Times New Roman font. For charts, budget tables, supplemental letters, and support documents, applicants may use a different point size and font, but no less than 10-point size and single-spaced.

The application package should include the following and be in the following order:

a. Required Federal Forms/Certifications—See below for description.

b. Table of Contents—This section should reference the order of the application sections and provide page numbers.

c. One-Page Project Abstract—This section should contain the following information: agency name, city, State; proposed service area (State, County, City, etc.); program applied for (e.g., SOP), amount of Federal funding requested for 12-month period; proposed model of program (e.g. street-based); target population (if applicable); point of contact, name, phone, and e-mail; number of youth to receive services during the 36-month project; two to three paragraph statement on what will be accomplished with the project.

A suggested sample format is provided in *Section VIII, Other Information*.

d. Project Description—This section is a comprehensive description of the proposed project, what it will accomplish and how it will be implemented. The project description should address each of the categories in Section V.1 and be structured in a manner that addresses each of the evaluation criterion in a logical format in the following order: Objectives and Need for Assistance; Results and Benefits; Approach; Organizational Profiles; Staff and Position Data; and Budget and Budget Justification. Applicants must title each section accordingly.

e. Budget and Budget Justification—The budget is a line-item format and must be in a worksheet, table, or spreadsheet that illustrates how calculations were derived. The budget should reflect a 12-month budget

period. Each category heading within the line-item budget should correspond with the budget categories listed in Section B of the SF-424A (e.g., Personnel, Fringe Benefits, Travel, Equipment, Supplies, Contractual, Other, Indirect Charges).

The budget justification is a narrative that provides a rationale for the items requested and how these items relate to the overall success of the project.

f. Proof of Non-Profit Status—If you are claiming non-profit status, see *Section IV.2 Part II* for acceptable documentation that must be submitted by date of award. Public agencies are not required to submit proof of non-profit status.

g. Third-Party Agreements—A summary of a monetary sub-grant and/or contract must be provided as part of the application package. The summary must include a description of the project services that will be completed through the sub-grant or contract using Federal

funds or a non-Federal match, and the process by which the primary applicant will maintain a substantive role with the sub-grant and/or contract assuring compliance with the grant requirements and project performance. If the applicant's agency is providing the shelter services through a different agency or entity based on a non-monetary agreement, documentation of these services must enumerate the project services that will be completed.

Forms, Assurances, and Certifications

Applicants seeking financial assistance under this announcement must submit the listed Standard Forms (SFs), assurances, and certifications. All required Standard Forms, assurances, and certifications are available at "ACF Funding Opportunities Forms" or at the *Grants.gov* Forms Repository unless specified otherwise.

Forms/assurances/certifications	Submission requirement	Notes/description
SF-424—Application for Federal Assistance.	Submission required for all applicants by the application due date.	Required for all applications.
SF-P/PSL—Project/Performance Site Location(s) SF-424A—Budget Information—Non-Construction Programs.	Submission required for all applicants applying for a non-construction project by the application due date.	Required for all applications.
SF-424B—Assurances—Non-Construction Programs Certification Regarding Lobbying	Submission required of all applicants prior to award.	Required for all applications.
SF-LLL—Disclosure of Lobbying Activities, if applicable.	If applicable, submission is required prior to award.	If any funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this commitment providing for the United States to insure or guarantee a loan, the applicant shall complete and submit <i>Standard Form (SF)-LLL, "Disclosure Form to Report Lobbying,"</i> in accordance with its instructions. Applicants must furnish an executed copy of the Certification Regarding Lobbying prior to award.

The Pro-Children Act of 2001, 42 U.S.C. 7181 through 7184, imposes restrictions on smoking in facilities where federally funded children's services are provided. HHS grants are subject to these requirements only if they meet the Act's specified coverage. The Act specifies that smoking is prohibited in any indoor facility (owned, leased, or contracted for) used for the routine or regular provision of kindergarten, elementary, or secondary education or library services to children under the age of 18. In addition, smoking is prohibited in any indoor facility or portion of a facility (owned, leased, or contracted for) used for the routine or regular provision of federally

funded health care, day care, or early childhood development, including Head Start services to children under the age of 18. The statutory prohibition also applies if such facilities are constructed, operated, or maintained with Federal funds. The statute does not apply to children's services provided in private residences, facilities funded solely by Medicare or Medicaid funds, portions of facilities used for inpatient drug or alcohol treatment, or facilities where WIC coupons are redeemed. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to \$1,000 per violation and/or the imposition of an

administrative compliance order on the responsible entity.

By signing and submitting the application, applicants are making the appropriate certification of their compliance with all Federal statutes relating to nondiscrimination. Additional information on certifications and assurances may be found in the HHS Grants Policy Statement at: http://www.acf.hhs.gov/grants/grants_related.html.

Non-Federal Reviewers

Since ACF will be using non-Federal reviewers in the review process, applicants have the option of omitting from the application copies (not the original) specific salary rates or amounts

for individuals specified in the application budget as well as Social Security Numbers, if otherwise required for individuals. The copies may include summary salary information. If applicants are submitting their application electronically, ACF will omit the same specific salary rate information from copies made for use during the review and selection process.

D-U-N-S Requirement

All applicants must have a D&B Data Universal Numbering System (D-U-N-S) number. A D-U-N-S number is required whether an applicant is submitting a paper application or using the Government-wide electronic portal, *Grants.gov*. A D-U-N-S number is 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. A D-U-N-S number may be acquired at no cost online at <http://www.dnb.com>. To acquire a

D-U-N-S number by phone, contact the D&B Government Customer Response Center:

U.S. and U.S. Virgin Islands: 1-866-705-5711

Alaska and Puerto Rico: 1-800-234-3867 (Select Option 2, then Option 1)

Monday-Friday 7 a.m. to 8 p.m. c.s.t.
The process to request a D-U-N-S® Number by telephone takes between 5 and 10 minutes. You will need to provide the following information:

- Legal Name.
- Tradestyle, Doing Business As (DBA), or other name by which your organization is commonly recognized.
- Physical Address, City, State and Zip Code.
- Mailing Address (if separate).
- Telephone Number.
- Contact Name.
- SIC Code (Line of Business).
- Number of Employees at your location.
- Headquarters name and address (if there is a reporting relationship to a parent corporate entity).
- Is this a home-based business?

The Project Description

Part I: The Project Description Overview

The project description provides the majority of information by which an application is evaluated and ranked in competition with other applications for available assistance. The project description should be concise and complete. It 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 the project description, information that is 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.

General Expectations and Instructions

ACF is particularly interested in specific project descriptions that focus on outcomes and convey strategies for achieving intended performance. Project descriptions are evaluated on the basis of substance and measurable outcomes, not length. Extensive exhibits are not required. Cross-referencing should be used rather than repetition. Supporting information concerning activities that will not be directly funded by the grant or information that does not directly pertain to an integral part of the grant-funded activity should be placed in an appendix.

Part II: General Instructions for Preparing a Full Project Description

Introduction

Applicants that are 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 topics listed in this section provide a broad overview of what the project description should include while the Criteria in *Section V.1* identify the measures that will be used to evaluate applications.

Table of Contents

List the contents of the application including corresponding page numbers.

Project Summary/Abstract

Provide a summary of the application's project description. The summary must be clear, accurate, concise, and without reference to other parts of the application. The abstract must include a brief description of the proposed grant project including the needs to be addressed, the proposed services, and the population group(s) to be served.

Please place the following at the top of the abstract:

- Project Title.
- Applicant Name.
- Address.
- Contact Phone Numbers (Voice, Fax).
- E-Mail Address.
- Web Site Address, if applicable.

The project abstract must be single-spaced and limited to one page in length.

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 including the nature and scope of the problem must be demonstrated, and the principal and subordinate objectives of the project must be clearly and concisely 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 or needs assessments 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.

Outcomes Expected

Identify the outcomes to be derived from the project. For example, the project description must cite measurable outcomes that show a sound relationship between program activities and the expected outcomes, including but not limited to the number of youth that successfully leave the streets as a result of services.

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. Data may be organized and presented as project tasks and subtasks with their corresponding timelines during the project period. For example, each project task could be assigned to a row in the first column of

a grid. Then, a unit of time could be assigned to each subsequent column, beginning with the first unit (*i.e.*, week, month, quarter) of the project and ending with the last. Shading, arrows, or other markings could be used across the applicable grid boxes or cells, representing units of time, to indicate the approximate duration and/or frequency of each task and its start and end dates within the project period. When accomplishments cannot be quantified by activity or function, list them in chronological order to show the schedule of accomplishments and their target dates. Provide a list of 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.

Legal Status of Applicant Entity

Applicants must provide the following documentation of their legal status:

Proof of Non-Profit Status

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 IRS's 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 non-profit status and that none of the net earnings 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.

When applying electronically, proof of non-profit status may be submitted as an attachment; however, proof of non-profit status must be submitted prior to award.

Logic Model

Applicants are expected to use a model for designing and managing their project. A logic model is a one-page diagram that presents the conceptual framework for a proposed project and explains the links among program

elements. While there are many versions of logic models, for the purposes of this announcement the logic model should summarize the connections between the:

Goals of the project (*e.g.*, objectives, reasons for proposing the interventions, if applicable);

- Assumptions (*e.g.*, beliefs about how the program will work and its supporting resources. Assumptions should be based on research, best practices, and experience);
- Inputs (*e.g.*, organizational profile, collaborative partners, key staff, budget);
- Activities (*e.g.*, approach, listing key intervention, if applicable);
- Outputs (*i.e.*, the direct products or deliverables of program activities); and
- Outcomes (*i.e.*, the results of a program, typically describing a change in people or systems).

Project Sustainability Plan

Provide a plan for sustainability that details how the proposed project approach will create project self-sufficiency and help to ensure that the impact of the project will continue after Federal assistance has ended. The applicant may include information on plans to secure additional financial resources.

Organizational Capacity

- Organizational charts.
- Provide a biographical sketch or resume for each key person appointed. Resumes should be no more than two pages in length. Job descriptions for each vacant key position should be included as well. As new key staff are appointed, biographical sketches or resumes will also be required.

Third-Party Agreements

Provide written and signed agreements between grantees and subgrantees, or subcontractors, or other cooperating entities. These agreements must detail the scope of work to be performed, work schedules, remuneration, and other terms and conditions that structure or define the relationship.

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 (SF-424A or SF-424C). Detailed calculations must include estimation methods, quantities, unit costs, and other similar quantitative detail sufficient for the calculation to be duplicated. If matching is a requirement, include a breakout by the funding sources identified in Block 18 of the SF-424.

Provide a narrative budget justification for the first year of the proposed project. The narrative budget justification should describe how the categorical costs are derived. Discuss the necessity, reasonableness, and allocation of the proposed costs.

General

Use the following guidelines for preparing the budget and budget justification. Both Federal and non-Federal resources (when required) shall be detailed and justified in the budget and budget narrative justification. "Federal resources" refers only to the ACF grant funds for which you are applying. "Non-Federal resources" are all other non-ACF 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 in a narrative form.

Personnel

Description: Costs of employee salaries and wages.

Justification: Identify the project director or principal investigator, if known at the time of application. 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, personnel costs of delegate agencies, or of specific project(s) and/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, Federal Insurance Contributions Act (FICA) taxes, retirement insurance, taxes, etc.

Travel

Description: Costs of project-related travel by employees of the applicant organization. (This item 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 to travel out of town; and other transportation costs and subsistence allowances. If appropriate for this project, travel costs for key staff

to attend ACF-sponsored workshops should be detailed in the budget.

Equipment

Description: "Equipment" means an article of nonexpendable, tangible personal property having a useful life of more than one year and an acquisition cost that 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 and/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, that 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 that supports the amount requested.

Contractual

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

Justification: Demonstrate that all procurement transactions will be conducted in a manner to provide, to the maximum extent practical, open and free competition. Recipients and subrecipients, other than States that are required to use 45 CFR part 92 procedures, must justify any anticipated procurement action that is expected to be awarded without competition and exceeds the simplified acquisition

threshold fixed at 41 U.S.C. 403(11), currently set at \$100,000. Recipients may be required to make pre-award review and procurement documents, such as requests for proposals or invitations for bids, independent cost estimates, etc. available to ACF.

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 same supporting information referred to in these instructions.

Other

Description: Enter the total of all other costs. Such costs, where applicable and appropriate, may include but are not limited to: Local travel; 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.

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, upon notification that an award will be made, it should immediately develop a tentative indirect cost rate proposal based on its most recently completed fiscal year, in accordance with 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. When an indirect cost rate is requested, those costs included in the indirect cost pool should not be charged as direct costs to the grant. Also, if the applicant is requesting a rate that is less than what is allowed under the program, the authorized representative of the applicant organization must submit a signed acknowledgement that the applicant is accepting a lower rate than allowed.

Commitment of Non-Federal Resources

Description: Amounts of non-Federal resources that will be used to support the project as identified in Block 18 of the SF-424.

Justification: If an applicant is relying on match from a third party, then a firm commitment of these resources (letter or other documentation) is required with the application. Detailed budget information must be provided for every funding source identified in Block 18 of the SF-424.

Paperwork Reduction Disclaimer

As required by the Paperwork Reduction Act of 1995, Public Law 104-13, the public reporting burden for the Project Description is estimated to average 40 hours per response, including the time for reviewing instructions, gathering and maintaining the data needed, and reviewing the collection information. The Project Description information collection is approved under OMB control number 0970-0139, which expires 11/30/2012. 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.

Electronic Submission via <http://www.Grants.gov>

- ACF will not accept applications via facsimile or e-mail.
- The Funding Opportunity Announcement is found on the Grants.gov Web site at <http://www.grants.gov> where the electronic application can be downloaded for completion.
- To apply electronically, applicants must be registered with Grants.gov, Dun and Bradstreet, and the Central Contractor Registry (CCR).
- Electronically submitted applications must be submitted and time/date stamped by the due date and receipt time described in *Section IV.3. Submission Dates and Times*, of this announcement.
- To submit an application through Grants.gov, the applicant must be an Authorized Organization Representative (AOR) for their organization and must have a current registration with the Central Contractor Registry (CCR).
- Central Contractor Registry (CCR) registration must be updated annually. Electronically submitted applications will not pass the validation check at Grants.gov if the AOR does not have a current CCR registration and electronic signature credentials.
- Applications rejected by Grants.gov for an unregistered AOR will be

disqualified and will not be considered for competition.

- Additional guidance on the submission of electronic applications can be found at http://www.acf.hhs.gov/grants/registration_checklist.html.

- If difficulties are encountered in using Grants.gov, applicants must contact the Grants.gov Contact Center at: 1-800-518-4726, or by e-mail at support@grants.gov, to report the problem and obtain assistance.

- Applicants are advised to retain Grants.gov Contact Center service ticket number(s) as they may be needed for future reference.

- Applicants that submit their applications electronically are encouraged to retain a hard copy of their application.

- It is to an applicant's advantage to submit their applications 24 hours in advance of the closing date and time.

Contact with the Grants.gov Contact Center prior to the listed due date and time does not ensure acceptance of your application. If difficulties are encountered, the Grants Management Officer (GMO) will make a determination whether the issues are due to system errors or user error.

Hard Copy Submission

Applicants that are submitting their application in paper format should submit one original and two copies of the complete application with all attachments. The original and each of the two copies must include all required forms, certifications, assurances, and appendices, be signed by the Authorized Organization Representative (AOR), and be unbound. The original copy of the application must have original signature(s). See *Section IV.6* of this announcement for address information for hard copy application submissions.

Applicants may refer to *Section VIII. Other Information* for a checklist of application requirements that may be used in developing and organizing application materials. Details concerning acknowledgment of received applications are available in *Section IV.3. Submission Dates and Times* of this announcement.

IV.3. Submission Dates and Times

Due Date for Applications: 07/19/2010.

Explanation of Due Dates

The due date for receipt of applications is listed in this section. Applications received after 4:30 p.m., e.t., on the due date will be classified as late and will not be considered in the current competition.

Applicants are responsible for ensuring that applications are received by mail, hand-delivery, or submitted electronically well in advance of the application due date and time.

Mailed Applications

Mailed applications must be received no later than 4:30 p.m., e.t., at the address provided in *Section IV.6* of this announcement on the due date listed in this section.

Hand-Delivered Applications

Applications hand-delivered by applicants, applicant couriers, other representatives of the applicant, or by overnight/express mail couriers must be received on, or before, the due date listed in this section, between the hours of 8 a.m. and 4:30 p.m., e.t., Monday through Friday (excluding Federal holidays). Applications should be delivered to the address provided in *Section IV.6* of this announcement.

Electronically-Submitted Applications

ACF cannot accommodate transmission of applications by facsimile or e-mail. Instructions for electronic submission through <http://www.Grants.gov> may be found at http://www.acf.hhs.gov/grants/registration_checklist.html.

After the application is submitted electronically via Grants.gov, the applicant will receive three e-mails.

The following e-mails will be sent to the applicant from Grants.gov: An automatic acknowledgement from Grants.gov of the application's submission that provides a Grants.gov tracking number.

The date/time-stamp in this e-mail serves as the official record of your application submission. The date/time-stamp must reflect a submission time on or before 4:30 p.m., e.t., on the application due date for the application to be considered as meeting the due date and to be considered for competition.

1. An acknowledgement from Grants.gov that the submitted application package has passed or failed a series of checks and validations. Applications that fail the validation check at Grants.gov because the Authorized Organization Representative (AOR) is not currently registered with the Central Contractor Registry (CCR) will be disqualified and will not be considered for competition.

2. An additional e-mail from the Administration on Children and Families (ACF) will be sent to the applicant indicating that the application has been retrieved from Grants.gov and received by ACF.

Late Applications

No appeals will be considered for applications classified as late under the three cited circumstances:

- Hard-copy applications received after 4:30 p.m., eastern time, on the due date will be classified as late and will be disqualified.

- Electronically-submitted applications are considered late and are disqualified when the date/time-stamp received by e-mail from <http://www.Grants.gov> is after 4:30 p.m., e.t., on the due date.

- Electronically-submitted applications submitted by an AOR that does not have a current registration with the Central Contractor Registry (CCR) will be rejected by Grants.gov. Although the applicant may have an acceptable dated and time-stamped e-mail from Grants.gov, these applications are considered late and are disqualified and will not be considered for competition.

Extension/Waiver of Due Date and Receipt Time

ACF may extend an application due date and receipt time when circumstances such as natural disasters occur (floods, hurricanes, etc.); when there are widespread disruptions of mail service; or in other rare cases. The determination to extend or waive due date and receipt time requirements rests with ACF's Chief Grants Management Officer.

Acknowledgement of Received Application

ACF will provide acknowledgement of receipt of hard copy application packages submitted via mail or courier services.

Applicants who submit their application packages electronically via <http://www.Grants.gov> will receive two e-mail acknowledgements from that Web site:

1. Your application has been submitted and provides a Time/Date Stamp. This is considered the official submission time.

2. Your application has been validated and provides a Time/Date Stamp. See the previous section on disqualification for failing validation check because of an unregistered Authorized Organization Representative.

An acknowledgement e-mail from the Administration on Children and Families (ACF) indicating that the application has been retrieved and received by ACF will be sent to applicants that apply via <http://www.Grants.gov>.

IV.4. Intergovernmental Review of Federal Programs

This program is covered under Executive Order (E.O.) 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 Executive Order, States may design their own processes for reviewing and commenting on proposed Federal assistance under covered programs.

Applicants should go to the following URL for the official list of the jurisdictions that have elected to participate in E.O. 12372: http://www.whitehouse.gov/omb/grants_spoc/. Applicants from participating jurisdictions should contact their SPOC, as soon as possible, to alert them of their prospective applications and to receive instructions on their jurisdiction's procedures. Applicants must submit all required application materials to the SPOC and indicate the date of submission on the Standard Form (SF) 424 at item 19.

Under 45 CFR 100.8(a)(2), a SPOC has 60 days from the application due date to comment on proposed new awards.

SPOC comments may be submitted directly to ACF to: 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., 6th Floor East, Washington, DC 20447. Entities that meet the eligibility requirements of this announcement are still eligible to apply for a grant even if a State, Territory or Commonwealth, etc., does not have a SPOC or has chosen not to participate in the process. Applicants from non-participating jurisdictions need take no action with regard to E.O. 12372. Applications from Federally-recognized Indian Tribal governments are not subject to E.O. 12372.

IV.5. Funding Restrictions

Costs of organized fund raising, including financial campaigns, endowment drives, solicitation of gifts and bequests, and similar expenses incurred solely to raise capital or obtain contributions, are considered unallowable costs under grants awarded under this announcement.

Grant awards will not allow reimbursement of pre-award costs.

Construction is not an allowable activity or expenditure under this grant award.

Purchase of real property is not an allowable activity or expenditure under this grant award.

IV.6. Other Submission Requirements

Submit applications to one of the following addresses:

Submission By Mail: FYSB Operations Center, c/o Master Key Consulting, Attn: Street Outreach Funding, 4915 St. Elmo Avenue, Suite 101, Bethesda, MD 20814.

Hand Delivery: FYSB Operations Center, c/o Master Key Consulting, Attn: Street Outreach Funding, 4915 St. Elmo Avenue, Suite 101, Bethesda, MD 20814.

Electronic Submission: See Section IV.2 for application requirements and for guidance when submitting applications electronically via <http://www.Grants.gov>.

For all submissions, see Section IV.3 for information on due dates and times.

V. Application Review Information

V.1. Criteria

Applications competing for financial assistance will be reviewed and evaluated using the criteria described in this section. The corresponding point values indicate the relative importance placed on each review criterion. Points will be allocated based on the extent to which the application proposal addresses each of the criteria listed. Applicants should address these criteria in their application materials, particularly in the project description and budget justification, as they are the basis upon which competing applications will be judged during the objective review. The required elements of the project description and budget justification may be found in Section IV.2 of this announcement.

Objectives and Need for Assistance: Maximum Points: 20

1. Describes clear and appropriate program objectives that will fulfill the program purpose consistent with the authorizing RHY legislation and FYSB program requirements as described in Section I.

2. Describes a clear need for the proposed project through a discussion of the conditions of youth and families in the area to be served.

3. Demonstrates that the services will be provided in areas where targeted youth congregate and/or areas that are easily accessible to the youth through a description of the precise geographic location of program services. Maps or other graphic aids may be included.

4. Provides documentation on the number of runaway, homeless and street youth in the proposed service area. If such data does not exist, the application should state this fact and provide a rationale to estimate the number of

runaway, homeless and street youth in the area. Provides documentation on the proposed number of runaway, homeless and street youth in the area to be served through this project.

Results or Benefits Expected: Maximum Points: 10

1. Identifies quantitative outcomes for the proposed project that will fulfill the program purpose and scope of services as described in the authorizing RHY legislation and Section I.

Note: Outcomes are the expected changes that will reasonably occur among youth, families and communities based on the program activities. Examples of a project outcome are included in Section 1, *Measuring Program Success*.

2. Demonstrates a sound relationship between program services that contribute to the quantitative outcomes.

3. Provides an internal process that includes the frequency of data collection and evaluation activities, the collected data is needed to support periodic program adjustments designed to improve program performance.

Approach: Maximum Points: 30

1. Identifies and describes the services that will be provided, and how the proposed project will operate programmatically to provide the services mandated by the authorizing RHY legislation and FYSB program requirements as described in Section I (A-J).

2. Describes an effective street outreach plan that will attract runaway, homeless, and street youth in areas where they congregate.

3. Describes an effective plan to assist runaway, homeless, and street youth in receiving services (either directly or indirectly) on issues pertaining to sexual abuse, domestic violence, sexual exploitation, and drug abuse.

4. Describes an outreach plan that will attract RHY eligible for services. The extent to which the outreach plan will attract members of all sexual orientation, youth of different ethnic, cultural, and racial minorities and/or persons with limited ability to speak English. If the application proposes to only serve a specific RHY population (e.g., single-sex programs, lesbian, gay, bisexual, transgender and questioning (LGBTQ) youth, a particular ethnic group), then the applicant must describe the unique characteristics of the community that requires the need to address the specific special population. Applications will be evaluated on the extent to which the applicant describes plans for making referrals or otherwise providing for the needs of RHY youth

who are not in the specific population the applicant will serve.

5. Describes coordination or service linkages with local agencies to ensure a continuum of care or referrals that allow runaway, homeless, and street youth to receive services outside the scope of the proposed project, but that are important to meet the needs of the population.

6. Describes a plan to store and maintain confidentiality of records and to implement the restrictions set forth in section 384 of the RHY Act.

7. Describes emergency preparedness and management plan by outlining steps to be taken in case of a local or national situation that poses risk to the health and safety of program staff and youth.

8. Describes effective strategies of how Positive Youth Development will be integrated into the operations of the project.

9. If an optional Drop-In Center model is proposed, describes the services, hours of operation, the expected ratio of staff to youth, and how the staffing plan will be sufficient to ensure adequate supervision and treatment.

10. If proposing to sub-grant or contract a significant portion of the proposed project, the applicant demonstrates that it will hold a substantive role in the administration and/or delivery of services of the proposed project.

Organizational Profiles: Maximum Points: 20

1. Demonstrates the organizational capacity necessary to oversee Federal grants through a description of the organization's fiscal controls and an explanation of the organization's governing oversight.

2. If proposing to sub-grant and/or contract to another organization that will provide direct services to youth and their families through this grant, it demonstrates the maintaining of a substantive role with the sub-grant and/or contract the extent to which will be monitored for grant compliance and project performance.

3. Describes the organization's experience in working with runaway, homeless, and street youth populations and demonstrates a sound relationship between organizational experience and the ability to provide program services as required by and consistent with the authorizing RHY legislation and FYSB program requirements as described in *Section I*. Experience does not have to pertain only to past FYSB-funded program experience.

Note: Experience means that a major activity of the agency has been the provision of temporary shelter, counseling, outreach, and referral services to runaway, street or

otherwise homeless youth and their families. The application must specify the length and time the organization has provided these services.

4. If the agency is a current recipient of funds from ACF for services that support RHY other than those applied for in this application, it shows how the services supported by these funds are, or will be, integrated with the existing services.

Note: Applicants must specifically state the other funds are from ACF, if applicable.

5. Provides a plan for sustainability that indicates how the organization will continue to fund and provide street outreach services at the end of the grant funding period. The plan must identify the specific services that will continue at the end of the project period as well as how the organization will fund those services on an ongoing basis.

6. Provides a timeline for sustainability activities that begins immediately upon receipt of the grant.

7. Provides a phase out or transition plan if the organization is unable to secure ongoing funding.

Staff and Position Data: Maximum Points: 15

1. Includes an organizational chart that demonstrates the relationship between all positions (including consultants, sub-grants and/or contractors) to be funded through this grant. The application must provide the name of the person employed in each position on the organizational chart. If the position is vacant, the applicant must note this on the organizational chart.

2. Includes with the application the person and their position who would serve as the Point of Contact (POC) for this grant. POC information must include the telephone number and e-mail address. If the telephone number or e-mail address is not available, the applicant must state this and describe a plan for providing a telephone number and e-mail address to the Federal Project Officer should the application be approved for funding.

3. Provides a staffing plan that demonstrates a sound relationship between the proposed responsibilities of program staff and the educational and professional experience required for staff positions through a discussion of position descriptions and resumes or biographical sketches of key staff, including consultants, which correspond to the organizational chart.

Note: Key staff is defined as those staff members responsible for direct oversight, management, or implementation of the proposed project and/or direct services to youth being served.

4. Describes a detailed staffing plan showing how the program will be executed. The plan must include hours of operation, services provided to youth and the number of staff to provide those services.

5. Describes the agency's policy for conducting criminal history and child abuse registry checks on staff who come into contact with children and youth served or proposed to be served by the agency. The applicant must confirm that its policy is in compliance with State, local, and other applicable laws.

6. Describes a plan for training project staff in the appropriate topics to safely and effectively serve runaway, homeless, and street youth, to deal appropriately with the issues they will encounter while serving these youth and to deliver services in a culturally competent manner that effectively responds to the ethnicity, age, gender identity, cultural practices, sexual orientation, socioeconomic status, educational background and language of the targeted youth and their families as described in *Section I*.

7. Describes a plan for providing supervision of street-based outreach staff to safely and effectively serve runaway, homeless, and street youth as described in *Section I*.

Budget and Budget Justification: Maximum Points: 5

1. Includes a detailed line-item budget for the Federal and non-Federal share of project costs and demonstrates how cost estimates were derived. Detailed calculations must include estimation of methods, quantities, unit costs, and other similar quantitative detail sufficient for the calculation to be duplicated.

2. Demonstrates how the funds requested are necessary and essential to accomplish the scope of services as required by and consistent with the authorizing RHY legislation and FYSB program requirements as described in *Section I*. The budget clearly delineates any allocation of grant resources to partners; provides narrative budget justification that describes how the categorical costs are derived; and discusses the necessity, reasonableness, and allocation of the proposed costs.

V.2. Review and Selection Process

No grant award will be made under this announcement on the basis of an incomplete application.

Initial ACF Screening

Each application will be screened to determine whether it was received by the closing date and time and whether the requested amount exceeds the award

ceiling. Applications that are designated as late according to *Section IV.3. Submission Dates and Times* or those with requests that exceed the award ceiling, stated in *Section II. Award Information* will be returned to the applicant with a notation that they were deemed non-responsive and will not be reviewed.

Objective Review and Results

Applications competing for financial assistance will be reviewed and evaluated by objective review panels using the criteria described in *Section V.1* of this announcement. Each panel is made up of experts with knowledge and experience in the area under review. Generally, review panels are composed of three reviewers and one chairperson.

Results of the competitive objective review are taken into consideration by ACF in the selection of projects for funding; however, objective review scores and rankings are not binding and are one element of the decisionmaking process.

ACF may elect to not fund applicants with management or financial problems that would indicate an inability to successfully complete the proposed project. Applications may be funded in whole or in part. Successful applicants may be funded at an amount lower than that requested. ACF reserves the right to consider a preference to fund organizations serving emerging, unserved, or under-served populations, including those located in pockets of poverty, and to consider the geographic distribution of Federal funds in its funding decisions.

Applications that pass the initial ACF screening will be evaluated and rated by an independent review panel made up of non-Federal reviewers that are experts in the field. The review panel will use the evaluation criteria listed in *Section V.1* to review and score the applications. The panels will assign a score (maximum 100) to each application and identify the application's strengths and weaknesses.

The results of these reviews will assist the ACYF Commissioner, FYSB Senior Management and program staff in considering competing applications. Reviewers' 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 reviewers. However, highly ranked applications are not guaranteed funding because other factors are taken into consideration. These include, but are not limited to: Geographic distribution, previous program performance of applicants, compliance with grant terms

under previous HHS grants, audit reports, an applicant's progress in resolving any final audit disallowance on previous FYSB or other Federal agency grants.

The evaluation criteria were designed to assess the quality of a 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 an application that is responsive to the evaluation criteria within the context of this program announcement.

FYSB has the authority to pass over ranking order based on geographic area (location) and capacity needs.

As required by the RHY Act, in making grant award decisions, priority for funding shall be given to public and private entities with experience in providing services to runaway, homeless and street youth. Experience means that a major activity of the agency has been the provision of temporary shelter, street outreach, counseling, and referral services to runaway, homeless and street youth.

Please refer to *Section IV.2.* of this announcement for information on non-Federal reviewers in the review process.

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.

V.3. Anticipated Announcement and Award Dates

FYSB expects that awards will be made by September 30, 2010. Unsuccessful applicants will be notified in writing subsequent to negotiations and final determination of awards.

VI.1. Award Notices

Successful applicants will be notified through the issuance of a Financial Assistance Award (FAA) document that 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 (if applicable), and the total project period for which support is contemplated. The FAA will be signed by the Grants Officer and transmitted via postal mail. Following the finalization of funding decisions, organizations whose applications will not be funded will be notified by letter, signed by the Program Office head.

VI.2. Administrative and National Policy Requirements

Awards issued under this announcement are subject to the uniform administrative requirements and cost principles of 45 CFR part 74 (Awards and Subawards to Institutions of Higher Education, Hospitals, Other Nonprofit Organizations, and Commercial Organizations), or 45 CFR Part 92 (Grants And Cooperative Agreements To State, Local, And Tribal Governments). An application funded with the release of Federal funds through a grant award, does not constitute, or imply, compliance with Federal regulations. Funded organizations are responsible for ensuring that their activities comply with all applicable Federal regulations.

Grantees are subject to the limitations set forth in 45 CFR part 74, Subpart E—Special Provisions for Awards to Commercial Organizations (45 CFR 74.81 Prohibition against profit), which states that, “ * * * no HHS funds may be paid as profit to any recipient even if the recipient is a commercial organization. Profit is any amount in excess of allowable direct and indirect costs.” Grantees are also subject to the requirements of 45 CFR Part 87, Equal Treatment for Faith-Based Organizations: “Direct Federal grants, sub-award funds, or contracts under this ACF 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 the HHS Web site at: <http://www.hhs.gov/fbc/waisgate21.pdf>.

A faith-based organization receiving HHS funds retains its independence from Federal, State, and local governments, and may continue to carry out its mission, including the definition, practice, and expression of its religious beliefs. For example, a faith-based organization may use space in its facilities to provide secular programs or services funded with Federal funds without removing religious art, icons, scriptures, or other religious symbols. In addition, a faith-based organization that receives Federal funds retains its authority over its internal governance, and it may retain religious terms in its organization's name, select its board members on a religious basis, and

include religious references in its organization's mission statements and other governing documents in accordance with all program requirements, statutes, and other applicable requirements governing the conduct of HHS funded activities." Additional information on "Understanding the Regulations Related to the Faith-Based and Community Initiative" can be found at: <http://www.hhs.gov/fbci/regulations/index.html>.

The Code of Federal Regulations (CFR) is available at <http://www.gpoaccess.gov/CFR/>.

Award Term and Condition for Trafficking in Persons

Awards issued under this announcement are subject to the requirements of section 106 (g) of the Trafficking Victims Protection Act of 2000, as amended (22 U.S.C. 7104). For the full text of the award term, go to http://www.acf.hhs.gov/grants/award_term.html. If you are unable to access this link, please contact the Grants Management Contact identified in *Section VII. Agency Contacts* of this announcement to obtain a copy of the Term.

HHS Grants Policy Statement

The HHS Grants Policy Statement (HHS GPS) is the Department of Health and Human Services' single policy guide for discretionary grants and cooperative agreements. ACF grant awards are subject to the requirements of the HHS GPS, which covers basic grants processes, standard terms and conditions, and points of contact, as well as important agency-specific requirements. Appendices to the HHS GPS include a glossary of terms and a list of standard abbreviations for ease of reference. The general terms and conditions in the HHS GPS will apply as indicated unless there are statutory, regulatory, or award-specific requirements to the contrary that are specified in the Financial Assistance Award (FAA). The HHS GPS is available at http://www.acf.hhs.gov/grants/grants_related.html.

Other Administrative and National Policy Requirements

Program Administration Requirements

Applicants are advised that regulations that implement certain requirements prescribed by the RHY Act can be found at 45 CFR part 1351 or the Runaway and Homeless Youth Act, 42 U.S.C. sections 5701–5752.

Applicants are advised that no grant funds may be used for any program of distributing sterile needles or syringes

for the hypodermic injection of any illegal drug. Prospective grantees are advised that entities that receive SOP grant funds and that operate a program of distributing sterile needles or syringes for hypodermic injections of illegal drugs must account for all funds used for such programs separately from any expenditure of SOP grant funds (42 U.S.C. 5752). See *Section IV.5, Funding Restrictions*.

Runaway and Homeless Youth Management Information System (RHYMIS)

Grantees must agree to keep adequate statistical records profiling the youth and families served under the Federal grant and to gather and submit program and client data required by FYSB. This information is required by the RHY program legislation and defined in user-friendly RHYMIS. Recipients of a grant administered through FYSB are required and expected to submit the data via RHYMIS or in an approved format that RHYMIS can receive. Grantees have the option of using RHYMIS for internal management improvement or for research and other program needs. A RHYMIS hotline/help desk is available at 888-749-6474 and/or at: rhyomis_help@csc.com.

FYSB will fund computer software for RHY program data collection through RHYMIS. An applicant lacking the computer equipment (hardware) for RHYMIS data collection must include an estimated cost for such equipment in their proposed budget. If the applicant already has such equipment, this fact must be noted. (See *Section V.1, Evaluation Criteria/Budget and Budget Justification*.)

(Note: Existing grantees generally report that their staff has been able to easily train themselves to operate RHYMIS due to its user-friendliness, prompts, help features, and FYSB's technical support service.)

In accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13), the data collection under RHYMIS is approved under OMB control number 0970–0123, which expires September 30, 2010.

Confidentiality

Grantees shall keep adequate statistical records profiling the youth and family members whom it serves (including youth who are not referred to out-of-home shelter services), except that records maintained on individual RHY shall not be disclosed without the consent of the individual youth and parent or legal guardian to anyone other than another agency compiling statistical records or a government agency involved in the disposition of

criminal charges against an individual RHY, and reports or other documents based on such statistical records shall not disclose the identity of individual RHY youth. Moreover, section 384 of the RHY Act requires that records containing the identity of individual youth pursuant to this Act under no circumstances be disclosed or transferred to any individual or to any public or private agency.

Continuation of Project

An initial grant award will be for a 12-month budget period. The award of continuation grants beyond the initial 12-month budget period will be subject to the availability of funds, satisfactory progress on the part of the grantee, and a determination that the continued funding would be in the best interest of the Federal Government.

VI.3. Reporting

Grantees under this announcement will be required to submit performance progress and financial reports periodically throughout the project period. The frequency of required reporting is listed later in this section.

In FY 2009, most ACF grantees began using a standard form for required performance progress reporting (PPR). Use of the new standard form, the ACF–OGM SF–PPR, began for new awards and continuation awards made by ACF in FY 2009. At a minimum, grantees are required to submit the ACF–OGM SF–PPR, which consists of the ACF–OGM SF–PPR Cover Page and the Program Indicators–Attachment B. ACF Programs that utilize reporting forms or formats in addition to, or instead of, the ACF–OGM SF–PPR have listed the reporting requirements later in his section.

Grant award documents will inform grantees of the appropriate performance progress report form or format to use beginning in FY 2009. Grantees should consult their award documents to determine the appropriate performance progress report format required under their award. Grantees will continue to use the Financial Status Report (FSR) SF–269 (long form) for required financial reporting.

Performance progress and financial reports are due 30 days after the end of the reporting period. Final program performance and financial reports are due 90 days after the close of the project period. Final reports may be submitted in hard copy to the Grants Management Office Contact listed in *Section VII. Agency Contacts* of this announcement.

The SF–269 (long form) and the ACF–OGM–SF–PPR may be found at http://www.acf.hhs.gov/grants/grants_resources.html.

Program Progress Reports: Semi-Annually.
 Financial Reports: Semi-Annually.

VII. Agency Contacts

Program Office Contact

Marnay Cameron, Family and Youth Services Bureau, ACYF Operations Center, c/o Master Key Consulting, 4915 St. Elmo Avenue, Suite 101, Bethesda, MD 20814, Phone: (866) 796-1591, E-mail: fysb@luxcg.com.

Office of Grants Management Contact

Lisa Dammar, ACYF Grants Officer, Office of Grants Management, Administration on Children and Families, c/o Master Key Consulting, 4915 St. Elmo Avenue, Suite 101, Bethesda, MD 20814, Phone: (866) 796-1591, E-mail: fysb@luxcg.com.

Federal Relay Service

Hearing-impaired and speech-impaired callers may contact the Federal Relay Service for assistance at 1-800-877-8339 (TTY—Text Telephone or ASCII—American Standard Code For Information Interchange).

VIII. Other Information

Reference Web Sites

U.S. Department of Health and Human Services (HHS) on the Internet <http://www.hhs.gov/>. Administration for Children and Families (ACF) on the Internet <http://www.acf.hhs.gov/>.

Administration for Children and Families—Funding Opportunities homepage <http://www.acf.hhs.gov/grants/>.

Catalog of Federal Domestic Assistance (CFDA) <https://www.cfda.gov/>.

Code of Federal Regulations (CFR) <http://www.gpoaccess.gov/cfr/index.html>.

United States Code (U.S.C) <http://www.gpoaccess.gov/uscode/>.

Sign up to receive notification of ACF Funding Opportunities at <http://www.Grants.gov>; http://www.grants.gov/applicants/email_subscription.jsp.

FYSB is providing a pre-recorded pre-application Webinar for all parties interested in applying for the Street Outreach Program. This recording can be found at: <http://www.rhyttac.ou.edu> or by contacting the RHY Technical Assistance Center at (800) 806-2711 or rhytechnicalassistance@ou.edu.

The recording and transcript of the pre-application Webinar will be posted at: http://www.acf.hhs.gov/grants/grants_fysb.html at least 30 days prior to the application due date. It will be available until the closing date of the announcement.

One-Page Project Abstract (Suggested Sample Format)

This format is only suggested to assist the writers in developing their abstract. Agency Name, City, State. Program (e.g., SOP).

Proposed service area (State, county, city, etc.).

Amount of Federal funding requested for 12-month period.

Proposed model of program.

Target population (if applicable).

POC, name, phone, and e-mail.

Number of youth to receive services during the 36-month project.

Two- to three-paragraph statement on what will be accomplished with the project.

Checklist

All required Standard Forms, assurances, and certifications are available on the ACF Forms page at http://www.acf.hhs.gov/grants/grants_resources.html and on the Grants.gov Forms Repository Web page at <http://apply07.grants.gov/apply/FormLinks?family=15>.

Versions of other Standard Forms (SFs) are available on the Office of Management and Budget (OMB) Grants Management Forms Web site at http://www.whitehouse.gov/omb/grants_forms/.

For information regarding accessibility issues, visit the Grants.gov Accessibility Compliance Page at http://www07.grants.gov/aboutgrants/accessibility_compliance.jsp.

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

What to submit	Where found	When to submit
SF-424—Application for Federal Assistance	Referenced in Section IV.2 and found at http://www.acf.hhs.gov/grants/grants_resources.html and at the Grants.gov Forms Repository at http://www.apply07.grants.gov/apply/FormLinks?family=15 .	Submission due by application due date found in Overview and Section IV.3.
SF-P/PSL—Project/Performance Site Location(s).		
SF-424A—Budget Information—Non-Construction Programs.	Referenced in Section IV.2 and found at http://www.acf.hhs.gov/grants/grants_resources.html .	Submission due by application due date found in Overview and Section IV.3.
SF-424B—Assurances—Non-Construction Programs.		
Table of Contents	Referenced in Section IV.2 of the announcement under “Project Description”.	Submission due by application due date found in Overview and Section IV.3.
Project Summary/Abstract	Referenced in Section IV.2 of the announcement under “Project Description”.	Submission due by application due date found in Overview and Section IV.3.
Project Description	Referenced in Section IV.2 of the announcement.	Submission due by application due date found in Overview and Section IV.3.
Budget and Budget Justification	Referenced in Section IV.2 of the announcement under “Project Description”.	Submission due by application due date found in Overview and Section IV.3.
Third-Party Agreements	Referenced in Section IV.2 of the announcement under “Project Description”.	If available, submission is due by application due date found in Overview and Section IV.3. or by time of award.
Documentation of Commitment of Non-Federal Resources.	Referenced in Section IV.2 of the announcement under “Budget and Budget Justification”.	Submission due by application due date found in Overview and Section IV.3.
Proof of Non-Profit Status	Referenced in Section IV.2 of the announcement under “Legal Status of Applicant Entity” in the “Project Description”.	Submission due by date of award.

What to submit	Where found	When to submit
Project Sustainability Plan	Referenced in Section IV.2 of the announcement under "Project Description".	Required of all applicants for projects of three years (36 months) or more in length. By application due date found in Overview and Section IV.3.
Certification Regarding Lobbying	Referenced in Section IV.2 of the announcement and found at http://www.acf.hhs.gov/grants/grants_resources.html .	Submission due by date of award.
This program is covered under E.O. 12372, "Intergovernmental Review of Federal Programs," and 45 CFR Part 100, "Intergovernmental Review of Department of Health and Human Services Programs and Activities". Applicants must submit all required application materials to the State Single Point of Contact (SPOC) and indicate the date of submission on the Standard Form (SF) 424 at item 19.	Applicants should go to the following URL for the official list of the jurisdictions that have elected to participate in E.O. 12372, http://www.whitehouse.gov/omb/grants_s poc/ as indicated in Section IV.4 of this announcement.	Submission due to State Single Point of Contact by the application due date found in Overview and Section IV.3.
Logic Model	Referenced in Section IV.2 of the announcement under "Project Description".	Submission due by application due date found in Overview and Section IV.3.
SF—LLL—Disclosure of Lobbying Activities, if applicable.	"Disclosure Form To Report Lobbying" is referenced in Section IV.2 and found at http://www.acf.hhs.gov/grants/grants_resources.html . Submission of this form is required if any funds have been paid, or will be paid, to any person for influencing, or attempting to influence, an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this commitment providing for the United States to insure or guarantee a loan.	Submission due by application due date found in Overview and Section IV.3.

Contact for Further Information:
Marnay Cameron, Program Specialist,
Family and Youth Services Bureau, 370
L'Enfant Promenade, SW., Washington,
DC 20447. Telephone: 202-205-8657, e-
mail: Marnay.cameron@acf.hhs.gov.

Dated: June 10, 2010.

Bryan Samuels,

*Commissioner, Administration on Children,
Youth and Families.*

[FR Doc. 2010-14798 Filed 6-21-10; 8:45 am]

BILLING CODE 4182-03-P

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

Food and Drug Administration

[Docket No. FDA-2010-D-0249]

**Guidance for Industry on Lupus
Nephritis Caused By Systemic Lupus
Erythematosus—Developing Medical
Products for Treatment; Availability**

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notice.

SUMMARY: The Food and Drug
Administration (FDA) is announcing the
availability of a guidance for industry
entitled "Lupus Nephritis Caused By
Systemic Lupus Erythematosus—
Developing Medical Products for

Treatment." This guidance provides
recommendations for industry on
developing human drugs, therapeutic
biological products, and medical
devices for the treatment of lupus
nephritis (LN) caused by systemic lupus
erythematosus (SLE). This guidance
finalizes the parts of the draft guidance
entitled "Systemic Lupus
Erythematosus—Developing Drugs for
Treatment" (the draft guidance)
regarding LN. Elsewhere in this issue of
the **Federal Register**, FDA is
announcing the availability of the
guidance entitled "Systemic Lupus
Erythematosus—Developing Medical
Products for Treatment," which finalizes
the draft guidance. Additional organ-
specific guidances will be developed in
the future.

DATES: Submit either electronic or
written comments on agency guidances
at any time.

ADDRESSES: Submit written requests for
single copies of this guidance to the
Division of Drug Information, Center for
Drug Evaluation and Research, Food
and Drug Administration, 10903 New
Hampshire Ave., Bldg. 51, rm. 2201,
Silver Spring, MD 20993-0002; the
Office of Communication, Outreach and
Development (HFM-40), Center for
Biologics Evaluation and Research
(CBER), Food and Drug Administration,
1401 Rockville Pike, suite 200N,

Rockville, MD 20852-1448; or the
Division of Small Manufacturers,
International, and Consumer Assistance
(HFZ-220), Center for Devices and
Radiological Health, Food and Drug
Administration, 1350 Piccard Dr.,
Rockville, MD 20850. The guidance may
also be obtained by mail by calling
CBER at 1-800-835-4709 or 301-827-
1800. Send one self-addressed adhesive
label to assist the offices in processing
your requests. See the **SUPPLEMENTARY
INFORMATION** section for electronic
access to the guidance document.

Submit electronic comments on the
guidance to <http://www.regulations.gov>.
Submit written comments to the
Division of Dockets Management (HFA-
305), Food and Drug Administration,
5630 Fishers Lane, rm. 1061, Rockville,
MD 20852.

FOR FURTHER INFORMATION CONTACT:
Jeffrey Siegel, Center for Drug
Evaluation and Research, Food and
Drug Administration, 10903 New
Hampshire Ave., Bldg. 22, rm. 3154,
Silver Spring, MD 20993-0002, 301-
796-2280; or

Stephen Ripley, Center for Biologics
Evaluation and Research (HFM-17),
Food and Drug Administration, 1401
Rockville Pike, suite 200N, Rockville,
MD 20852, 301-827-6210; or

Sahar M. Dawisha, Office of In Vitro
Diagnostic Devices, Center for Devices