

statistical contractor will also write a national analysis of the survey results to identify opportunities for QIO program improvement as a whole. In the few instances with insufficient sample size, we use the actual satisfaction rate to evaluate QIO performance. However, we grant QIOs a passing evaluation score when the overall evaluation status (that is, pass vs. fail) is sensitive to this potentially unreliable rate. Usually this rate does not affect a QIO's overall evaluation status on a particular subtask, since its relative weight is small in a subtask's evaluation.

Comment: One commenter stated that, with the development of the Excel spreadsheet to evaluate the qualitative tasks, these tasks are no longer qualitative. They are now being evaluated in a quantitative way.

Response: The Excel tool allows Project Officers to subjectively evaluate QIO performance in the qualitative tasks. It was developed in response to concerns from QIOs about inter-region variation in the 6th SOW. It uses the same evaluation criterion provided in the J-7, and is not intended to make the evaluation quantitative in nature. Rather, it gives some consistency to the subjective review by the Project Officers. We agree that this tool should be provided to QIOs as early as possible in the contract cycle. We will strive to provide this tool to the QIOs as early as possible for the 8th SOW.

Comment: One commenter stated that a great deal of effort was put into the National Voluntary Hospital Reporting Initiative (NVHRI), but this effort was not included in the evaluation criteria.

Response: We appreciate the fact that the NVHRI did require some additional effort on the part of the hospitals.

However, participation could not be included in the evaluation criteria because this was a voluntary program on the part of hospitals. The voluntary nature of the program requires a different approach by the QIO than is required by the other subtasks and deliverables of the contract.

Comment: One commenter stated that for those States with 100 percent participation in hospital public reporting, the Hospital Generated Data (HGD) Survey is redundant. The commenter stated that the same information may be obtained through both sources.

Response: We have been careful to avoid redundant activities for both providers and QIOs. The HGD Survey does not determine if a hospital is a reporting hospital. Instead, it assesses the hospital's ability to collect data. Therefore both the survey and the actual

hospital reporting are necessary and provide different information to us.

Comment: One commenter questioned the evaluation criteria for Task 3b. In the J-7, the term "reliability" is used. The guidance document states that the QIO will be evaluated based on both "reliability" and "validity of review." This commenter also requested clarification as to why Tasks 3a and 3b require reliability while Task 3c does not require validity for evaluation.

Response: The reliability of the review is the primary criterion for evaluating this component of the task. We will ensure consistency in documents released for the 8th SOW. The evaluation criteria were chosen for each subtask in Task 3 based on the appropriateness for the task.

Comment: One commenter expressed concern over using Medicare physician billing as the method to measure the rate of statewide and identified participants' improvement in quality care measures for Task 1d.

Response: We are investigating this method of measuring improvement for the Round 1 evaluations, and have so far found nothing large-scale or systematic that would alter evaluation results for Task 1d. We believe that the evaluation measures are relatively stable and reliable estimates, and that billing issues as a whole do not contribute significant bias to these estimates. We understand the limitations of using billing information to estimate quality improvement, and are working to minimize its impact by identifying these problems and reporting questionable billing issues to the appropriate parties.

We are adopting the provisions of the notice with comment as final.

IV. Executive Order 12866 Statement

In accordance with the provisions of Executive Order 12866, this notice with comment period was not reviewed by the Office of Management and Budget.

Authority: Section 1153 of the Social Security Act (42 U.S.C. 1320c-2).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: March 14, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 05-14505 Filed 7-21-05; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Administration on Children, Youth and Families; Family and Youth Services Bureau; Notice of the Availability of Financial Assistance and Request for Applications To Establish and Operate the National Domestic Violence Hotline

Announcement Type: Grant.

Funding Opportunity Number: HHS-2005-ACF-ACYF-EV-0039.

CFDA Number: 93.592.

Due Date for Applications: August 22, 2005.

Executive Summary: The Administration for Children and Families (ACF), Administration on Children, Youth and Families (ACYF) announces the availability of funds in fiscal year 2005 for the award of one grant on a competitive basis to operate a national, toll-free telephone hotline to provide information and assistance to victims of domestic violence.

I. Funding Opportunity Description

Authorizing Statutes and Regulations: The Family Violence Prevention and Services Act (the Act) was originally enacted in sections 301-316 of Title III of the "Child Abuse Amendments of 1984" (Pub. L. 98-457, 10/9/84). The Act was most recently amended by the "Keeping Children and Families Safe Act of 2003" (Pub. L. 108-36).

Supplementary Information: In accordance with amendments to the Act enacted by Pub. L. 108-36, ACF will award grants to one or more private, non-profit entities to assist in the establishment and operation of a highly secure Internet website to provide information and assistance to victims of domestic violence. A separate announcement regarding these awards will be issued at a future date.

Program and Focus Area: The purpose of the National Domestic Violence Hotline (Hotline) is to provide information and referral services, counseling, and assistance to victims of domestic violence, their children and other family members, and others affected by such violence; and enable them to find safety and protection in crisis situations. The successful applicant will be required to provide telephonic assistance on a 24 hours-per-day, seven days-a-week basis throughout the continental United States, Alaska, Hawaii, the Commonwealth of Puerto Rico, and the U.S. Virgin Islands.

Priority Area

Notice of the availability of financial assistance and request for applications to establish and operate the National Domestic Violence Hotline.

1. Description

Conceptual Framework and Scope of Services: The prevalence of family violence is widespread and its effective prevention and treatment requires coordination and collaboration among a broad range of legal and justice system entities, health and social service providers, and advocates at the Federal, State, and local levels.

To serve the wide range of expected calls effectively, the entity chosen as the Hotline recipient must have expertise about domestic violence and the delivery of services to victims of domestic violence. The staff also must understand the importance of using appropriate linkages with State and local resources to serve callers to the Hotline. The benefits of a highly visible national Hotline to victims and others affected by domestic violence will be directly related to the productive working relationships and coordinated provision of services between and among the Hotline, State and local hotlines, and other services and resources.

Calls to the Hotline may range from urgent and life-threatening to calls for general reference information. The target population to be served by the Hotline is specified in the statute as victims of domestic violence. The Hotline should be prepared to respond to the broad range of violence that occurs in the context of family and intimate relationships, domestic violence, spouse abuse, partner abuse, battering of women, sexual assault, date rape, and acquaintance rape. The Hotline also will serve those less directly affected by such abuse, *i.e.*, relatives, children of victims and other family members, friends, neighbors, perpetrators and batterers, other concerned individuals, and the general public.

In terms of the scope of the services provided by the Hotline, the statute requires the provision of information and assistance and counseling and referral services. Therefore, the applicant's proposed design and plan for operating the Hotline and responding to callers is important. However, the Hotline is not expected to provide extended or long-term counseling or therapy services. A more complete discussion of a problem and the consideration of options for the caller is done most appropriately at the

local level, given the variation in laws and services available among the States and localities.

As domestic violence often contributes to isolation, helplessness, loss of self-esteem, and dependence, a self-help and empowerment model of services is needed. Such a model:

- Protects and assures safety for all victims and other family members;
- Builds on the strengths and resources of individuals and families;
- Offers options and support for independent decision-making based on specific individual and family needs and circumstances; and
- Assists individuals and families to obtain protection and needed services that are respectful of cultural and community characteristics.

Minimum Requirements: The following requirements must be met by the grantee and addressed in the application:

1. All funds received by the grantee pursuant to Section 316 of the Act must be used to establish and operate a national toll-free telephone hotline to provide information and assistance to victims of domestic violence.

2. In establishing the Hotline, the private, nonprofit entity shall:

- Contract with a carrier for the use of a toll-free telephone line;
- Employ, train, and supervise personnel to answer incoming calls and provide counseling and referral services on a 24-hours-a-day basis;
- Assemble and maintain a current database of information relating to services for victims of domestic violence to which callers may be referred throughout the United States, including information on the availability of shelters that serve victims of battering and their children; and
- Publicize the Hotline to potential users throughout the United States, the Commonwealth of Puerto Rico and the U.S. Virgin Islands.

3. To be approved by the Secretary of Health and Human Services (the Secretary), the application must include a complete description of the applicant's plan for the operation of a National Domestic Violence Hotline, including a description of:

- The training program for Hotline personnel;
- The hiring criteria for Hotline personnel;
- The methodology for the creation, maintenance, and updating of a resource database;
- A plan for publicizing the availability of the Hotline;
- A plan for providing service to non-English speaking callers, including Hotline personnel for callers whose primary language is Spanish; and

- A plan for facilitating access to the Hotline by persons with hearing impairments.

4. The applicant must demonstrate that it has:

- Expertise in the operation of a domestic violence hotline and a record of high quality service to victims of domestic violence, and;
- Commitment to diversity and to the provision of services, regardless of gender, to ethnic, racial, and non-English speaking minorities, in addition to older individuals and individuals with disabilities.

5. The applicant must demonstrate knowledge of the field, including the range of services and the resources available for domestic violence victims, their children and family members, perpetrators and batterers, and other concerned individuals. The applicant must also demonstrate knowledge of services and resources relating to substance and mental health problems, State and Indian Tribal domestic violence laws, including the availability of legal protection and the barriers affecting access to such services, resources, and protection.

6. The applicant must demonstrate experience in providing high quality crisis intervention, information and referral, and counseling services and support to battered individuals, their children, their family, and friends, other domestic violence victims, batterers, and the general public through a national toll-free hotline.

7. The applicant must demonstrate an understanding of the relationship of alcohol, drug abuse, and mental health problems to incidents of domestic violence and the ability to make appropriate referrals to callers.

8. The applicant must demonstrate an understanding of the need for a national hotline for domestic violence victims, including a description of the function and limitation of the current network of national and State crisis hotlines, information lines, and State victims referral services.

9. The applicant must provide a plan and demonstrate its ability to build, maintain, and keep current a comprehensive database of resource information that includes the full range of services available in local communities, the types of legal protection and services available in different States and localities, and the capability to access information.

10. The applicant must provide a detailed description of:

- The telecommunications and computer technology that is, or will be, employed to establish and support the Hotline, including all management

functions, referral functions, resource database management functions, monitoring functions, and overall project administration and quality control.

- The design and operation of the telephone system that will be used to provide the service and its capacity and limitations, including information such as the capacity to facilitate the number of incoming calls, call conferencing, automatic call referral to local providers, and service integration with computers.

- The methods that will be used to ensure that the Hotline is providing confidential crisis intervention and the specific provisions that will be in place to safeguard the confidentiality of callers and ensure the proper handling of confidential or sensitive information;

- The personnel recruitment, hiring, and training program (*i.e.*, a description of an initial and ongoing training plan for staff and volunteers should be included) that will ensure the delivery of quality crisis intervention, information and referral assistance, and counseling services to callers representing diverse populations;

- The specific emergency response and crisis protocol to be used, the ability to conference call (or “patch”) a caller to a local domestic violence, legal services, mental health, or substance abuse program when appropriate; and the plans for minimizing such problems as crank or obscene calls and busy signals; and

- The methods the applicant will use to provide for the development, maintenance, and updating of a comprehensive resource database (distributed to the maximum extent appropriate); the technical capacity to link with other State and local databases in order to maintain an extensive and current resource locator or listing; the ability to facilitate communication among service providers to assist in the provision of services; and how the information on best practices gathered through various inventories will be used to assist victims of family violence.

11. The applicant must demonstrate an understanding of the technological requirements of such a project and include a detailed timeline to provide the following services nationally:

- 24-hours/365 days per year access;
- Direct access to English- and Spanish-speaking personnel at all times and the provision of services to other non-English speaking callers and the hearing impaired;

- Personnel (paid staff and volunteers) trained in crisis intervention, information and referral, and counseling skills;

- Comprehensive database of current information;

- The ability to connect callers directly to local programs or services when appropriate;

- Emergency response protocol for callers in immediate danger; and

- Appropriate confidentiality safeguards; and

- Data collection and data management capability sufficient to support program administration, reporting, monitoring, and an ongoing quality assessment of the Hotline service.

12. The applicant must provide a plan to coordinate, work with, and provide Hotline services and data resource and referrals that make maximum use of existing domestic violence programs and resources including, but not limited to, local and statewide domestic violence hotlines, state domestic violence coalitions, state sexual assault coalitions, shelter programs, emergency services, legal services programs, national domestic violence resource centers, other existing national hotlines and other national organizations, resources related to child abuse and youth endangerment, perpetrators and batterers programs, and the various activities of the Centers for Disease Control under its campaign to prevent violence against women. The applicant must provide support to State and local domestic violence hotlines in response to any increased demand generated by a national public awareness campaign.

13. The applicant must provide a description of the quality assurance system it will use to assess regularly the quality of the services being provided by the Hotline and the extent to which the goals and objectives of the service are being met. The quality assurance system also must include actions to address identified problems, such as, unanswered calls, wait time, data corruption, and other past and current technological problems.

14. The applicant must provide a comprehensive plan to publicize the Hotline to a national audience, including efforts to ensure promotion through the national media and through targeted outreach to racially and ethnically diverse communities, older individuals, and individuals with disabilities.

15. The applicant must demonstrate the ability to staff, financially support, and programmatically administer a national project of this scope.

16. The author(s) of the application must be clearly identified together with a description of their current relationship to the applicant

organization and any future project role they may have if the project is funded.

17. The applicant must provide an assurance that any information collected as a part of this grant will become the property of the Federal Government.

18. The applicant must provide an assurance that it will work with the Federal Project Officer to identify the information that will be compiled based on incoming calls; this includes compilation of information on both maternal and child victims of domestic violence and the individual and situational factors characterizing violent and abusive behavior.

19. The applicant must provide an assurance that it will comply with grant administration requirements in 45 CFR Part 74.

II. Award Information

Funding Instrument Type: Grant.

Anticipated Total Priority Area

Funding: \$3,000,000.

Anticipated Number of Awards: 1.

Ceiling on Amount of Individual Awards: \$3,000,000 per budget period.

Floor on Amount of Individual Awards: None.

Average Projected Award Amount: \$3,000,000 per budget period.

Length of Project Periods: 60-month project with five 12-month budget periods.

Non-competitive, continuation grant awards for each of years two through five (FYs 2006–2009) are projected to be \$3,000,000 per fiscal year subject to the availability of funds. As required by the Act, the provision of payments under a grant awarded to establish or operate the National Domestic Violence Hotline is subject to annual approval of the Secretary. Such annual approval may be withheld if a grantee does not comply with pertinent statutory changes enacted during the project period. Moreover, potential grantees are advised that the enactment of significant legislative changes during the project period may prompt a finding that early termination of the project and the holding of a new competition is in the best interest of the Federal Government.

III. Eligibility Information

1. Eligible Applicants

- Non-profits having a 501(c)(3) status with the IRS, other than institutions of higher education.

- Non-profits that do not have a 501(c)(3) status with the IRS, other than institutions of higher education.

Additional Information on Eligibility: Faith-based and community organizations are eligible applicants under this announcement.

Please see Section IV for required documentation supporting eligibility or funding restrictions if any are applicable.

2. Cost Sharing/Matching

None.

3. Other

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

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

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

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

- A reference to the applicant organization's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations described in the IRS Code.
- A copy of a currently valid IRS tax exemption certificate.
- A statement from a State taxing body, State attorney general, or other appropriate State official certifying that the applicant organization has a non-profit status and that none of the net earnings accrues 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 we strongly suggest you attach your proof of non-profit status with your electronic application.

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

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

Any application that fails to satisfy the deadline requirements referenced in Section IV.3 will be considered non-responsive and will not be considered for funding under this announcement.

IV. Application and Submission Information

1. Address To Request Application Package

ACYF Operations Center, c/o Dixon Group, Attn: FV-FYSB Funding for National Domestic Violence Hotline, 118 Q Street, NE., Washington, DC 20002-2132. Phone: 866-769-1591. E-mail: fysb@dixongroup.com.

2. Content and Form of Application Submission

The narrative should be typed and double-spaced on a single-side of an 8½" x 11" plain white paper, with 1" margins on all sides. All pages of the narrative (including charts, references/footnotes, tables, maps, exhibits, etc.) must be sequentially numbered, beginning with "Objectives and Need for the Project" as page number one. Applicants should not submit reproductions of larger size paper, reduced to meet the size requirement.

The length of the application, including the application forms and all attachments, should not exceed 60 pages. A page is a single side of an 8½" x 11" sheet of paper. Applicants are requested not to send pamphlets, maps, brochures, or other printed material along with their application as these pose photocopy difficulties. These materials, if submitted, will not be included in the review process if they exceed the 60-page limit. Each page of the application will be counted to determine the total length.

You may submit your application to us in either electronic or paper format.

To submit an application electronically, please use the <http://www.Grants.gov/Apply> site. If you use

Grants.gov, you will be able to download a copy of the application package, complete it off-line, and then upload and submit the application via the Grants.gov site. ACF will not accept grant applications via e-mail or facsimile transmission.

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

- Electronic submission is voluntary, but strongly encouraged.

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

- We recommend you visit Grants.gov at least 30 days prior to filing your application to fully understand the process and requirements. We encourage applicants who submit electronically to submit well before the closing date and time so that if difficulties are encountered an applicant can still send in a hard copy overnight. If you encounter difficulties, please contact the Grants.gov Help Desk at 1-800-518-4726 to report the problem and obtain assistance with the system.

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

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

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

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

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

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

- You may access the electronic application for this program on <http://www.grants.gov/>.

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

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

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

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

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

Applicants must furnish prior to award an executed copy of the Standard Form LLL, Certification Regarding Lobbying, when applying for an award in excess of \$100,000. Applicants who have used non-Federal funds for lobbying activities in connection with receiving assistance under this announcement shall complete a disclosure form, if applicable, with their applications (approved by the Office of Management and Budget under control

number 0348-0046). Applicants must sign and return the certification with their application.

Applicants must also understand they will be held accountable for the smoking prohibition included within Pub. L. 103-227, Title XII Environmental Tobacco Smoke (also known as the PRO-KIDS Act of 1994). A copy of the **Federal Register** notice which implements the smoking prohibition is included with this form. By signing and submitting the application, applicants are providing the certification and need not mail back the certification with the application.

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

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

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

3. Submission Dates and Times

Due Date for Applications: August 22, 2005.

Explanation of Due Dates

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

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

Applications hand carried by applicants, applicant couriers, other representatives of the applicant, or by overnight/express mail couriers shall be considered as meeting an announced deadline if they are received on or before the deadline date, between the hours of 8 a.m. and 4:30 p.m., eastern time, at the address referenced in Section IV.6., between Monday and Friday (excluding Federal holidays).

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

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

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

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

Extension of deadlines: ACF may extend application deadlines when circumstances such as acts of God (floods, hurricanes, etc.) occur, or when there are widespread disruptions of mail service, or in other rare cases. A determination to extend or waive deadline requirements rests with the Chief Grants Management Officer.

Receipt acknowledgement for application packages will not be provided to applicants who submit their package via mail, courier services, or by hand delivery. Applicants will receive an electronic acknowledgement for applications that are submitted via <http://www.grants.gov/>.

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

What to submit	Required content	Required form or format	When to submit
Project Abstract	See Sections IV.2. and V	Found in Sections IV.2. and V	By application due date.
Project Description	See Sections IV.2. and V	Found in Sections IV.2. and V	By application due date.
Budget Narrative/Justification	See Sections IV.2. and V	Found in Sections IV.2. and V	By application due date.
SF 424	See Section IV.2	See http://www.acf.hhs.gov/programs/ofs/forms.htm .	By application due date.
SF LLL Certification Regarding Lobbying.	See Section IV.2	See http://www.acf.hhs.gov/programs/ofs/forms.htm .	By date of award.
Certification Regarding Environmental Tobacco Smoke.	See Section IV.2	See http://www.acf.hhs.gov/programs/ofs/forms.htm .	By date of award.
Assurances	See Section IV.2	See http://www.acf.hhs.gov/programs/ofs/forms.htm .	By date of award.
SF 424A	See Section IV.2	See http://www.acf.hhs.gov/programs/ofs/forms.htm .	By application due date.

What to submit	Required content	Required form or format	When to submit
Support Letters	See Section V	Found in Section V	By application due date.
Proof of Non-Profit Status	See Section III.3	Found in Section III.3	By date of award.

Additional Forms: Private, non-profit organizations are encouraged to submit with their applications the survey located under "Grant Related

Documents and Forms," "Survey for Private, Non-Profit Grant Applicants," titled, "Survey on Ensuring Equal Opportunity for Applicants," at: [http://](http://www.acf.hhs.gov/programs/ofs/forms.htm)

www.acf.hhs.gov/programs/ofs/forms.htm.

What to submit	Required content	Required form or format	When to submit
Survey for Private, Non-Profit Grant Applicants.	See form	Found in http://www.acf.hhs.gov/programs/ofs/forms.htm .	By application due date.

4. Intergovernmental Review

State Single Point of Contact (SPOC)

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

As of October 1, 2004, the following jurisdictions have elected to participate in the Executive Order process:

Arkansas, California, Delaware, District of Columbia, Florida, Georgia, Illinois, Iowa, Kentucky, Maine, Maryland, Michigan, Mississippi, Missouri, Nevada, New Hampshire, New Mexico, New York, North Dakota, Rhode Island, South Carolina, Texas, Utah, West Virginia, Wisconsin, American Samoa, Guam, North Mariana Islands, Puerto Rico, and Virgin Islands. As these jurisdictions have elected to participate in the Executive Order process, they have established SPOCs. Applicants from participating jurisdictions should contact their SPOC, as soon as possible, to alert them of prospective applications and receive instructions. Applicants must submit all required materials, if any, to the SPOC and indicate the date of this submittal (or the date of contact if no submittal is required) on the Standard Form 424, item 16a.

Under 45 CFR 100.8(a)(2), a SPOC has 60 days from the application deadline to comment on proposed new or competing continuation awards. SPOCs are encouraged to eliminate the submission of routine endorsements as official recommendations. Additionally, SPOCs are requested to clearly differentiate between mere advisory comments and those official State process recommendations, which may trigger the "accommodate or explain" rule.

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

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

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

5. Funding Restrictions

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

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

Construction and the purchase of real property are not allowable activities or expenditures under this grant award.

6. Other Submission Requirements

Submission by Mail: An applicant must provide an original application with all attachments, signed by an authorized representative and two copies. Please see Section IV.3 for an explanation of due dates. Applications

should be mailed to: Operations Center, c/o The Dixon Group, Inc., FV-FYSB Funding for the National Domestic Violence Hotline, 118 Q Street, NE., Washington, DC 20002-2132.

Hand Delivery: An applicant must provide an original application with all attachments signed by an authorized representative and two copies. The application must be received at the address below by 4:30 p.m. eastern time on or before the closing date.

Applications that are hand delivered will be accepted between the hours of 8 a.m. to 4:30 p.m. eastern time, Monday through Friday. Applications should be delivered to: Operations Center, c/o The Dixon Group, FV-FYSB Funding for the National Domestic Violence Hotline, 118 Q Street, NE., Washington, DC 20002-2132.

Electronic Submission: Please see Section IV.2 for guidelines and requirements when submitting applications electronically via <http://www.grants.gov/>.

V. Application Review Information

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

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

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

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

1. Criteria

The following are instructions and guidelines on how to prepare the "project summary/abstract" and "full project description" sections of the

application. Under the evaluation criteria section, note that each criterion is preceded by the generic evaluation requirement under the ACF Uniform Project Description (UPD).

Part I—The Project Description Overview

Purpose

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

Introduction

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

Project Summary/Abstract

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

Objectives and Need for Assistance

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

range of projects currently being conducted and supported (or to be initiated), some of which may be outside the scope of the program announcement.

Results or Benefits Expected

Identify the results and benefits to be derived.

For example, indicate the aggregate number of calls expected to be received and the number of individuals who will be assisted on an annual basis. Provide estimates of the expected volume of calls in service areas, such as, crisis counseling, immediate referrals to shelters, or the number of referrals made in response to non-English speaking callers.

Approach

Outline a plan of action that describes the scope and detail of how the proposed work will be accomplished. Account for all functions or activities identified in the application. Cite factors that might accelerate or decelerate the work and state your reason for taking the proposed approach rather than others. Describe any unusual features of the project such as design or technological innovations, reductions in cost or time, or extraordinary social and community involvement.

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

When accomplishments cannot be quantified by activity or function, list them in chronological order to show the schedule of accomplishments and their target dates.

If any data is to be collected, maintained, and/or disseminated, clearance may be required from the U.S. Office of Management and Budget (OMB). This clearance pertains to any "collection of information that is conducted or sponsored by ACF."

List organizations, cooperating entities, consultants, or other key individuals who will work on the project along with a short description of the nature of their effort or contribution.

Evaluation

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

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

Additional Information

The following are requests for additional information that need to be included in the application:

Staff and Position Data

Provide a biographical sketch and job description for each key person appointed. Job descriptions for each vacant key position should be included as well. As new key staff is appointed, biographical sketches will also be required.

Organizational Profiles

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

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

organization is a local non-profit affiliate.

Letters of Support

Provide statements from community, public and commercial leaders that support the project proposed for funding. All submissions should be included in the application *OR* by application deadline.

Budget and Budget Justification

Provide a budget with line-item detail and detailed calculations for each budget object class identified on the Budget Information form. Detailed calculations must include estimation methods, quantities, unit costs, and other similar quantitative detail sufficient for the calculation to be duplicated. Also include a breakout by the funding sources identified in Block 15 of the SF-424.

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

Personnel

Description: Costs of employee salaries and wages.

Justification: Identify the project director or principal investigator, if known. For each staff person, provide the title, time commitment to the project (in months), time commitment to the project (as a percentage or full-time equivalent), annual salary, grant salary, wage rates, etc. Do not include the costs of consultants or personnel costs of delegate agencies or of specific project(s) or businesses to be financed by the applicant.

Fringe Benefits

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

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

Travel

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

Justification: For each trip, show the total number of traveler(s), travel destination, duration of trip, per diem, mileage allowances, if privately owned vehicles will be used, and other transportation costs and subsistence allowances. Travel costs for key staff to attend 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 which equals or exceeds the lesser of (a) the capitalization level established by the organization for the financial statement purposes, or (b) \$5,000. (Note: Acquisition cost means the net invoice unit price of an item of equipment, including the cost of any modifications, attachments, accessories, or auxiliary apparatus necessary to make it usable for the purpose for which it is acquired. Ancillary charges, such as taxes, duty, protective in-transit insurance, freight, and installation shall be included in or excluded from acquisition cost in accordance with the organization's regular written accounting practices.)

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

Supplies

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

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

Contractual

Description: Costs of all contracts for services and goods except for those 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) 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 Part 92 procedures, must justify any anticipated procurement action that is expected to be awarded without competition and exceed the simplified acquisition threshold fixed at 41 U.S.C. 403(11) (currently set at \$100,000).

Recipients might be required to make available to ACF pre-award review and procurement documents, such as request for proposals or invitations for bids, independent cost estimates, etc.

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

Other

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

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

Indirect Charges

Description: Total amount of indirect costs. This category should be used only when the applicant currently has an indirect cost rate approved by the Department of Health and Human Services (HHS) or another cognizant Federal agency.

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 also be charged as direct costs to the grant. Also, if the applicant is requesting a rate which is less than what is allowed under the program, the authorized representative of the applicant organization must submit a signed acknowledgement that the applicant is accepting a lower rate than allowed.

Evaluation Criteria: The following evaluation criteria appear in weighted descending order. The corresponding score values indicate the relative importance that ACF places on each evaluation criterion; however,

applicants need not develop their applications precisely according to the order presented. Application components may be organized such that a reviewer will be able to follow a seamless and logical flow of information (*i.e.*, from a broad overview of the project to more detailed information about how it will be conducted).

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

Approach—30 Points

The extent to which the application provides a sound workable plan of action (approach), which details: How the proposed work will be accomplished; how each task relates to the project's goals and activities; identifies the key staff member responsible for the specific tasks; provides a chart indicating the timetable for completing each task, the phasing in of the tasks over time, the lead staff person, and the time committed to the task; cites factors that might accelerate or decelerate the work; justifies the approach selected over other approaches; makes maximum use of existing facilities and resources and off-the-shelf technology; describes and supports any unusual features of the project, such as design or technological innovations, reductions in cost or time, or extraordinary social or community involvement; and provides projections of the accomplishments to be achieved and identifies the activities for which Federal technical assistance, advice, or guidance as the project is implemented is anticipated and would be acceptable. The extent to which the application details how possible problems such as unanswered calls, wait time, outdated equipment and technology, and data corruption would be avoided or resolved.

Results or Benefits Expected—20 Points

The extent to which the application identifies, in specific terms, the results and benefits to be derived from the project and relate each result and benefit to a specific objective. The extent to which the application indicates the aggregate number of calls expected to be received and individuals to be assisted on an annual basis, *e.g.*, the expected volume of calls in such service areas as crisis counseling, immediate referrals to shelters, or the number of referrals made in response to non-English speaking callers. The extent to which the application indicates the anticipated impact on and the

subsequent benefit of the national hotline to victims of domestic violence and on the existing network of State and local shelters and services. The extent to which the application identifies the kinds of data to be collected, maintained, and updated, and discuss the criteria to be used to assure the quality of the services provided.

Objectives and Need for Assistance—20 Points

Need for Assistance: The extent to which the application provides a detailed discussion of the need for a national domestic violence hotline of the scope being proposed. The extent to which the application provides a detailed analysis of the available data related to the problem being addressed (both domestic violence in general and the specific lack of a national domestic violence hotline); the strengths and limitations of other national and local crisis intervention and victim services hotline/referral services available, and the "state-of-art" relative to the problem being addressed by the proposal.

Goals and Objectives: The extent to which the application clearly states the project goals and objectives. The extent to which the objectives are stated in concrete, measurable terms that clearly identify the population(s) to be served; the type, quality, and level of service to be provided; the timeline for the establishment and delivery of services; and other project benchmarks. The extent to which the application discusses the anticipated demand for hotline services during the initial start-up period; provides a projection of the demand on an ongoing basis; and provides supporting documentation.

Budget and Budget Justification—6 Points

The extent to which the proposed budget relates to the level of effort required to obtain the project objectives. The extent to which the proposed budget demonstrates that the project's costs are reasonable in view of the anticipated results.

Organizational Profiles—6 Points

The extent to which the application describes the adequacy of the staffing pattern for the proposed project; how the individual responsibilities are linked to project tasks; and the contributions to be made by key staff. The extent to which the application lists each collaborating or cooperative organization, individual consultant, or other key individuals who will work on the project, along with a description of the nature of their effort or contribution.

Letters of Support—12 Points

Collaborative Efforts: The extent to which the application describes the additional anticipated private sector resources that may be available to support or enhance the overall program. The extent to which the application discusses in detail and provides documentation for any proposed collaborative or coordinated efforts with other public and private agencies or organizations. The extent to which the application identifies these agencies or organizations and explains how their participation will enhance the project. The extent to which the application provides letters from these agencies and organizations discussing their interest and/or commitment in supporting this project, the stage of the planning and decision-making, and the expected level of resource commitment.

Staff and Position Data—6 Points

The extent to which the application describes the background and experience of the project director and key project staff, and the history and accomplishments of the organization; the qualifications of the project team, including any experience with similar projects; the variety of skills, relevant educational background, and the ability to effectively manage the project and to coordinate activities with other agencies. (One or two pertinent paragraphs on each key member are preferred to vitae/resumes. However, vitae/resumes may be included.)

2. Review and Selection Process

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

Experts from the domestic violence community as well as experts from social services programs will use the evaluation criteria listed in this announcement to review and score the applications. The results of this review are a primary factor in recommending funding decisions. To the extent possible, efforts will be made to ensure that funding decisions reflect an equitable distribution among states and geographical regions, and rural and urban areas.

Since ACF will be using non-Federal reviewers in the 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 and Social Security Numbers, if otherwise required for individuals. The copies may include summary salary information.

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.

VI. Award Administration Information

1. Award Notices

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

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

2. Administrative and National Policy Requirements

Grantees are subject to the requirements in 45 CFR Part 74 (non-governmental) or 45 CFR Part 92 (governmental).

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 either 45 CFR 87.1 or the HHS Web site at: <http://www.os.dhhs.gov/fbc/waisgate21.pdf>.

3. Reporting Requirements

Grantees will be required to submit program progress and financial reports (SF-269 found at <http://www.acf.hhs.gov/programs/ofs/forms.htm>) throughout the project period. Program progress and financial reports are due 30 days after the reporting period. Final programmatic and financial reports are due 90 days after the close of the project period.

Program Progress Reports: Semi-Annually.

Financial Reports: Semi-Annually.

VII. Agency Contacts

Program Office Contact: William D. Riley, Director, Family Violence

Division, 330 C Street, SW., Switzer Building, Room 2117, Washington, DC 20447. Phone: 202-104-5529. E-mail: wriley@acf.hhs.gov.

Grants Management Office Contact: Peter Thompson, Grants Officer, Administration on Children, Youth and Families, 330 C Street, SW., Switzer Building, SW., Washington, DC 20447. Phone: 202-401-4608. E-mail: pthompson@acf.hhs.gov.

VIII. Other Information

Notice: Beginning with FY 2006, the Administration for Children and Families (ACF) will no longer publish grant announcements in the **Federal Register**. Beginning October 1, 2005, applicants will be able to find a synopsis of all ACF grant opportunities and apply electronically for opportunities via: <http://www.Grants.gov>. Applicants will also be able to find the complete text of all ACF grant announcements on the ACF Web site located at: <http://www.acf.hhs.gov/grants/index.html>.

Please reference Section IV.3 for details about acknowledgement of received applications.

Dated: July 15, 2005.

Joan E. Ohl,

Commissioner, Administration on Children, Youth & Families.

[FR Doc. 05-14459 Filed 7-21-05; 8:45 am]

BILLING CODE 4184-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of the Committee: General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on August 9, 2005, from 8 a.m. to 4 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Scott A. Colburn, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-827-6892, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512520. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will hear a presentation by the Office of Surveillance and Biometrics in the Center for Devices and Radiological Health outlining their responsibility for the review of postmarket study design. The committee will discuss and make recommendations on methods to assess the potential of disease transmission by multiple-use nozzle jet injectors (i.e., jet injectors for which the fluid path for the injection is used more than once). The discussion will include premarket testing recommendations to address this issue.

Background information for the topic, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting, on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by August 3, 2005. Oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of deliberations and for approximately 30 minutes near the end of deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before August 3, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at 240-276-0450, ext. 113, at least 7 days in advance of the meeting.