

designing the study, the Administrator is to consult with organizations nationally recognized for their expertise in ultrasound. A report on the study is to be sent to Congress within two years of the enactment of this statutory research mandate (approximately November 2001).

2. Purpose

AHRQ is holding this meeting to gather pertinent scientific information and professional views that would contribute to the conduct of this study of the effect of credentialing of technologists and sonographers on the quality of ultrasound services, and especially information with respect to such services provided under the Medicare and Medicaid programs, Titles XVIII and XIX of the Social Security Act. AHRQ is interested in receiving information on the availability of relevant published literature, secondary data sources, and/or unpublished data, as well as information about other factors that may affect ultrasound results (for example, other quality assurance and control processes.)

3. Agenda

The meeting will begin at 9:00 a.m. and continue through 12:00 p.m. The Director of AHRQ's Center for Practice and Technology Assessment will chair the meeting. If more requests to make oral statements are received than can be accommodated at this meeting between 9:00 a.m. and 12:00 p.m., the chair will allocate speaking time in a manner that attempts, to the extent possible, to have a range of information, findings and views presented orally. Those who cannot be granted speaking time because of time constraints are assured that their written comments will be considered along with other evidence during the course of the study.

Dated: February 15, 2000.

John M. Eisenberg,

Director, AHRQ.

[FR Doc. 00-4647 Filed 2-25-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of the Assistant Secretary for Planning and Evaluation and the Office of Planning, Research and Evaluation of the Administration for Children and Families; Notice Inviting Abstracts for Policy Research and Studies on Welfare Reform Outcomes for Fiscal Year 2000

AGENCY: Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services; Office of Planning, Research and Evaluation, Administration for Children and Families, Department of Health and Human Services.

ACTION: Announcement of the request for abstracts and the availability of funds for subsequent welfare reform policy research and studies.

SUMMARY: The Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the Office of Planning, Research, and Evaluation of the Administration for Children and Families (ACF) invite abstracts for policy research and studies related to welfare reform.

CLOSING DATE: The closing date for submitting abstracts under this announcement is March 29, 2000. Only abstracts, not full proposals, will be accepted under this announcement.

MAILING ADDRESS: Abstracts should be submitted to: Adrienne Little, Grants Officer, Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, 200 Independence Avenue, SW., Room 405F, Hubert H. Humphrey Building, Washington, DC 20201, Telephone: (202) 690-8794. Administrative questions will be accepted and responded to up to ten working days prior to closing date of receipt of abstracts.

The printed **Federal Register** notice is the only official program announcement. Any corrections to this announcement will be published in the **Federal Register** as well as published on the ASPE and ACF World Wide Web Pages. The web sites are <http://aspe.hhs.gov/funding.htm> and <http://www.acf.dhhs.gov/programs/opre/frpa.htm> respectively. Although reasonable efforts are taken to assure that the files on the ASPE and ACF World Wide Web Pages containing electronic copies of this Program Announcement are accurate and complete, they are provided for

information only. The applicant bears sole responsibility to assure that the copy downloaded and/or printed from any other source is accurate and complete.

FOR FURTHER INFORMATION CONTACT:

Administrative questions should be directed to the Grants Officer at the address or phone number listed above. Technical questions should be directed to Audrey Mirsky-Ashby, DHHS, ASPE, Telephone, 202-401-6640 or e-mail, amirsky@osaspe.dhhs.gov or Nancye Campbell, DHHS, ACF, 202-401-5760 or email, ncampbell@acf.dhhs.gov. Written technical questions may also be faxed to Audrey Mirsky-Ashby at 202-690-6562 or may be addressed to Ms. Audrey Mirsky-Ashby at the following address, Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, 200 Independence Avenue, SW, Room 404E, Hubert H. Humphrey Building, Washington, DC 20201. Please call Ms. Audrey Mirsky-Ashby to confirm receipt. Technical questions will be accepted and responded to up to ten working days prior to the closing date of receipt of abstracts.

Part I. Supplementary Information

Legislative Authority

This announcement is authorized by Section 1110 of the Social Security Act (42 U.S.C. 1310) and awards will be made from funds appropriated under the Department of Health and Human Services Appropriations Act, 2000, as enacted by section 1000(a)(4) of the Consolidated Appropriations Act, 2000 (Public Law 106-113).

Eligible Applicants

Pursuant to section 1110 of the Social Security Act, any public organization, including state and local governments, and private nonprofit organizations, including universities and other institutions of higher education, may apply. Applications may also be submitted by private for-profit organizations. However, no grant funds may be paid as profit to grantees or subgrantees. *i.e.*, any amount in excess of allowable direct and indirect costs of the recipient (45 CFR 74.81).

Available Funds

ASPE and ACF are engaging in a two-part process. The first part of the process will be the submission of six page research abstracts. After the abstracts are reviewed, a subset of the applicants who submitted abstracts will be invited by either ASPE or ACF to submit full applications. These will be reviewed competitively. Financial

awards will be made only in the second part of the process; no awards will be made based on abstracts submitted. An invitation to submit an application is not a guarantee of funding. The following information on fund availability is provided for planning purposes for applicants.

Approximately \$2,250,000 in total is expected to be available from ASPE and ACF in funds appropriated for fiscal year 2000, and approximately \$1 million from ACF in subsequent fiscal years, subject to the availability of funds. Of the fiscal year 2000 total, \$1,000,000 is expected to be available from ASPE and \$1,250,000 is expected to be available from ACF. We estimate that this level of funding will support between 8 and 12 ASPE awards with *total* budgets ranging from \$75,000 to \$150,000 for most short-term policy analyses (to be completed within about 12 months of award) and between 5 and 8 ACF awards with *total* budgets from \$75,000 to \$500,000 for either short-term or longer-term projects. These figures are provided as guidance but do not constitute minimum or maximum limits. We expect that ASPE will fund primarily short-term projects and ACF will fund either type. If additional funding becomes available in fiscal years 2000 or 2001, a greater number of projects may be funded.

No federal funds received as a result of this announcement can be used to purchase computer equipment and no funds may be paid as profit to grantees or subgrantees, *i.e.*, any amount in excess of allowable direct and indirect costs of the recipient (45 CFR 74.81). Our intent is to sponsor research and analytic work and not to fund the provision of services. Grant funds awarded in the full-proposal phase of this initiative may not be used to pay for programs or services.

Grantees must provide at least 5 percent of the total approved cost of the project. The total approved cost of the project is the sum of the 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, a project requesting \$200,000 in Federal funds must include a match of at least \$10,527 (because \$200,000 is 95% of \$210,526).

If a proposed project activity has approved funding support from other funding sources, the amount, duration, purpose, and source of the funds should be indicated in materials submitted under this announcement. If completion of the proposed project activity is contingent upon approval of funding

from other sources, the relationship between the funds being sought elsewhere and from ASPE/ACF should be discussed in the budget information submitted as a part of the abstract. In both cases, the contribution that ASPE/ACF funds will make to the project should be clearly presented.

If data collection is part of the project and if federal funding support is used for the data collection, the researcher will make the data available for use by other researchers. Awards that include support for data collection will likely include requirements for the data to be made available to the public (e.g., public use data files or restricted access files).

Background

The passage of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA) brought about fundamental changes in our nation's income support program for needy families and children. Welfare reform was expected to alter behavior in regard to work, marriage, fertility and program participation under the Temporary Assistance to Needy Families (TANF) block grant program. Under TANF, states were given considerable flexibility to design and implement their support programs for needy families with children. PRWORA authorized TANF through 2002.

Between January 1993 and June 1999, the number of people receiving cash assistance under the prior Aid to Families with Dependent Children (AFDC) program or the new TANF program fell from 14.1 million to under 7 million recipients, a reduction of 51 percent. This decline has occurred partly in response to the strong economy, the Administration's granting of Federal waivers to support welfare reform initiatives in 43 States prior to passage of PRWORA, and the state implementation of provisions of the PRWORA itself. In response to the need for government officials and others to better understand the policy and programmatic changes that have been made, the effects on families and children, and the implications for other organizations and programs, DHHS and others have sponsored and carried out a broad array of welfare reform research and evaluations.

Studies in progress address a broad set of questions and have and will continue to produce valuable information. However, while we are learning a good deal in some areas there is more we need to know. For example, additional research and analyses are needed on children and family poverty status, labor supply decisions, program participation pattern decisions, family

formation and structure, outcomes for children, outcomes for different sub-populations, and the effects of different reform policies and administrative approaches. Further, more information is needed to better understand the interaction of welfare reform with and its implications for other programs such as Medicaid, Food Stamps, child care, child support, foster care, or child welfare, for example, and for other community services (e.g., emergency food, housing, employment, training, education, mental health, substance abuse treatment). While some families are benefiting from the new incentives, requirements and opportunities, others may be left behind. In response, many state and local governments and organizations have begun to design and implement new strategies to work with families with multiple challenges that interfere with obtaining or sustaining employment at levels that can meet family needs. Little is known about the effectiveness of these strategies.

This announcement is one part of the Department of Health and Human Services' strategy to support research that will address critically important questions about welfare reform and related programs serving low-income families and outcomes for mothers, fathers, children, and other family members. Congress explicitly authorized funds to carry out such research in the Health and Human Services Appropriation Act of 2000. Sound research and analyses on an array of important issues and topics will be needed to help inform the debate and deliberations on TANF reauthorization at the national level. Information is needed to provide information and guidance to state and local governing officials as they continue to reform and refine their policies, programs, and approaches. Further research and analyses are needed to inform us about the experiences of families during these times and their prospects for the future and about the experiences of organizations who are working with families to help them succeed and thrive.

Part II. Purpose

The purpose of these studies is to support policy-relevant research, using rigorous analytical methods, to address critical questions about welfare reform related outcomes for families and children, program design, implementation and management choices and effects at various levels. We are particularly interested in welfare outcomes and those issues that are likely to be of concern in TANF reauthorization discussions. We will

support short-term research and data analysis that are designed to be completed within about twelve months as well as some longer-term studies that may require multiple years. Our intent is to sponsor research and analytic work and not to fund the provision of services. Grant funds awarded in the full-proposal phase of this initiative may not be used to pay for programs or services.

ASPE and ACF are interested in analyses that would inform the general issues discussed above and the questions listed below. We are interested in the effect of welfare reform on families and children, the effects of state policies and practices, and other issues related to low-income families with children. Data from a variety of sources can be used (such as state and county administrative records or survey data). We also encourage the use of national surveys (*e.g.*, PSID, NLSY-79, NLSY-97, SIPP, SPD) and comprehensive state level administrative and survey databases which will allow for detailed analytic work on the causes, consequences and processes of welfare reform and the broader policy and economic environment. (*Note:* While there are positive aspects to the use of national surveys, researchers must be prepared to address the limitation that most data will be based on periods that precede passage of the welfare reform legislation or implementation of its major provisions.) We expect that most short-term projects will rely on secondary data analyses. However, primary data collection and analyses may be necessary for some projects.

While the list represents many of the topics that are important to ASPE and ACF, the suggested questions are by no means meant to be exhaustive or restrictive. ASPE and ACF invite researchers to submit abstracts for analytic work in other areas related to welfare outcomes that they deem to be important.

1. *Composition of Caseload.* Is the cash assistance caseload becoming more disadvantaged? In what ways are the families who remain on welfare different than the ones who have left? What are the characteristics of those who are working and still receiving TANF? Are there differences within this group in work patterns, TANF use, or individual or family and child characteristics? What role do policy decisions (*e.g.*, disregards, sanctions, time limits, working with "harder-to-serve" families) play in the variation in caseloads across states? What are the characteristics of those with little or no work experience? What are the

interactions between low-wage work and state policies related to earnings disregards and time limits and what are the implications for families? In addition to increased numbers of child only cases, are there other changes in the composition of the TANF caseload? What are the implications for applicants and recipients of such changes? What are the implications for the TANF program or related programs?

2. *Patterns of use of government programs.* What are the relative roles of entry and exit effects in caseload decline? How are families (working and non-working) utilizing government sponsored programs including cash assistance, Medicaid, food stamps, child care, child support, SSI, EITC, Unemployment Insurance, workforce development programs, and other support service benefits? Are there differences in the patterns of use across programs among low-income working families, including current and former TANF families and non-welfare families? Have patterns changed? What are the major factors contributing to any change in patterns of use? Are there differences in the characteristics of families with different patterns of program utilization? Are the current utilization patterns affecting other safety-net programs (*e.g.*, foster care, child welfare, housing programs, substance abuse treatment)? What factors affect changes seen by other safety net programs (*e.g.*, early identification and referral by TANF agency, increased investments using TANF funds or other sources, families leaving TANF)? What is known about the usage patterns for the non-resident parent? To what extent do alternative state/local policies and practices affect utilization (*e.g.*, "make work pay" policies, levels of subsidy for child care, adjusted hours of operation for working families, outreach or marketing activities for health care, child care, or other benefits, level of training, extent of collaboration)?

3. *Effects on sub-populations.* What are the effects of welfare reform on those in different geographic settings (*e.g.*, urban centers, rural communities, tribal reservations)? What are the effects of welfare reform and related program changes on different groups of individuals or families (*e.g.*, teen parents, immigrants, ethnic or racial groups, families with infants and toddlers, those with mental or physical health problems, those with low basic skill levels or limited English proficiency, Native Americans, or those living in different types of family or household compositions)? What are the effects on the broader population of

low-income families who are not participating in TANF or other needs-based assistance? To what extent do alternative state/local TANF policies and practices affect outcomes for different groups?

4. *Non-working welfare leavers.* What are the characteristics and circumstances of people who leave welfare and are not working? What are the circumstances of their children? What are the reasons that some families do not reenter the welfare system? To what extent does their employment or welfare status change over time? What are their sources of income, income levels and living arrangements? What kinds of support do they receive from the non-resident parent? Do these or other circumstances change over time? What public, family or community resources do they use and over what periods?

5. *Sanctions.* How effective are full-family sanctions versus partial sanctions or alternative conciliation policies and practices in obtaining compliance with work requirements? What is the level of employment among adults in fully sanctioned cases? Do sanctioned cases use other sources of public support more than other families? What are the effects of TANF sanctions on household income and circumstances? What are the reasons for continued noncompliance among sanctioned families? Are sanctioned families more likely to be involved with child welfare or foster care programs? Are there differences among continuously sanctioned cases and others in the extent or presence of problems such as substance abuse, mental health problems, domestic violence, or very low basic skills?

6. *Labor market experiences.* To what extent do TANF recipients and former recipients who work differ from other low-income working families or individuals without children? Specifically, how do they differ from each other with regard to outcomes such as earnings, increases in wage rates, average hours of work per week, types of work, benefits available, length of employment spells, number of jobs, use of TANF/Medicaid/SCHIP/Food Stamps and EITC, child care arrangements, costs and subsidies, asset accumulation, living arrangements, and marriage? To what extent do they differ with regard to individual, family or other characteristics (*e.g.*, education, skill level, family composition, health status, family supports)? Are certain characteristics associated with better outcomes? Are TANF (and related programs') policies, components, or features associated with better outcomes

for families and children? What role do workforce development programs play?

7. *Employment Stability.* What factors (e.g., individual, family, geographic, public policy) contribute to employment stability among low-income workers (families and individuals without children), including current and former TANF recipients? To what extent is employment stability affected by child care arrangements, options, or costs? Does employment stability lead to better circumstances for adults or children (e.g., wage advancement, jobs with better benefits, increased earnings, increased household income, housing stability or quality, types of child care used, stability of family routines, school outcomes for children, regular receipt of child support)?

8. *The potential importance of marriage and family structure with respect to family well-being.* To what extent does marriage improve the economic well-being of low-income families? How do the economic benefits of marriage differ by demographic characteristics including socioeconomic status and ethnicity? Among the low-income population, how does the economic well-being of married families compare to that of families entering other unions such as cohabitation, and what might be the reason for those differences? To what extent do the relative benefits depend on the sequencing of events such as pregnancy, birth, cohabitation, marriage, and union dissolution? In addition to potential economic benefits, does marriage among the low-income population also have positive impacts on adult and child behaviors, as compared to behaviors among single parent or cohabiting families? To what extent are outcomes among married individuals representative of the potential benefits to marriage among nonmarried individuals, and how can these outcomes be modeled in a way that better controls the selective factors affecting people's decisions to marry or not.

9. *TANF flexibility and implications for other programs.* To what extent has TANF flexibility resulted in changes in types of families served (e.g., working-poor families not/never on cash assistance) and the types of programs or services funded? Has the flexibility within TANF affected the extent or manner of interaction (e.g., policy development, funding decisions, staffing, formal/informal collaboration, referrals) with other programs such as child care, child support, Medicaid, SCHIP, food stamps, SSI, or workforce development programs or types of providers (e.g., private, non-profit, faith-

based)? What is the effect of changes in interaction on participants or on agencies involved? Has TANF flexibility or other aspects of welfare reform affected participation in other programs given the availability of similar benefits under TANF and other programs (e.g., foster care)? To what extent have state/local decisions to utilize TANF flexibility affected the number of cases reported in other systems such as foster care?

10. *Use of TANF and Maintenance of Effort (MOE) funds.* How has TANF affected the total level of funding available for programs for low-income families? How are state and local governments utilizing the flexibility provided under TANF in deciding how to allocate and spend welfare funds (TANF and MOE funds)? What role do TANF and MOE funding levels play in state/local decision making with regard to services for low-income families and children? To what extent is there diversity in the types of organizations administering TANF funds or TANF-funded program activities and has this changed over time? What are the implications of this diversity (e.g., for program accountability, public awareness, uses of cash assistance block grant funds)?

11. *Barrier identification and service utilization.* To what extent are individuals who are identified as having barriers to employment (e.g., substance abuse, mental illness or mental health problems, very low basic skills, learning disabilities, physical disabilities, or violent relationships) referred to appropriate services? To what extent are those referred enrolled or engaged in services to address the barrier? To what extent do participants complete or continue to engage in the services or treatment? Does participation in treatment/services affect compliance with TANF requirements, employment and other outcomes for parents and other caregivers? To what extent has TANF funding flexibility and state/local policies and practices affected access to needed services or the ability of "harder-to-employ" individuals to make progress toward employment and reduced use of TANF?

12. *Entry effects and welfare dynamics.* How do entrants to TANF differ from entrants to AFDC, especially in regard to family and child characteristics (e.g., age, number of children)? How can entries into TANF and AFDC be modeled, and what do such modeling efforts tell us about the effect of TANF policies on entries to TANF and diversion from entries? What events are associated with the beginning and ending of TANF spells? How have

they changed over time in response to the economy and policy changes? How do these compare to beginning and ending AFDC spells? How does spell lengths for TANF entrants compare with spell lengths for AFDC entrants? What are the effects of time limits? What are the characteristics of those likely to hit the federal time limits?

Part III. Abstract Application Guidelines and Evaluation Criteria

As noted previously, ASPE and ACF are engaging in a two-part process. Applicants must first submit an abstract as described in the application section below. Please read this section carefully. Abstracts must comply with the application guidelines. Abstracts that do not comply with the application guidelines will not be considered.

Abstracts must be received in the following format:

12 point font size;
Single spaced;
1 inch top, bottom, left, and right margins

The deadline for receipt of abstracts is March 29, 2000. An abstract will be considered as having met the deadline if it is either received at, or hand-delivered to, the mailing address on or before March 29, 2000, or postmarked before midnight three days prior to March 29, 2000 and received in time to be considered during the competitive review process (within two weeks of the deadline).

Hand-delivered applications will be accepted Monday through Friday, excluding Federal holidays, during the working hours of 9:00 a.m. to 4:30 p.m. in the lobby of the Hubert H. Humphrey building, located at 200 Independence Avenue, SW in Washington, DC. When hand-delivering an application, call (202) 690-8794 from the lobby for pick up. A staff person will be available to receive applications.

An original and two copies are required, but applicants are encouraged to send an additional 4 copies to ease processing, but applicants will not be penalized if these extra copies are not included. The original and copies of the abstract must be mailed to: Adrienne Little, Grants Officer, Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, 200 Independence Avenue, SW, Room 405F, Hubert H. Humphrey Building, Washington, DC. 20201, Telephone: (202) 690-8794.

Abstracts must include the material indicated below. The information provided for items 1 through 4 *must not exceed 6 pages.*

1. *Title page.* This page should include a reference to this program

announcement: Policy Research and Studies on Welfare Reform Outcomes; proposed project title; name of researcher(s); organizational affiliation; and the address, telephone number, and e-mail address of the lead investigator. (This will be the mailing address used by ASPE/ACF to request full proposals from selected applicants.) The title page must include an indication, by number, of the research question(s) presented within this announcement that are being addressed or indicate that the research question is not one of those contained in the announcement. The proposed data set must also be included. The title page must include the total number of months needed for completion of the project and the project's proposed start and end date. This should be the only information on page one.

2. *Statement of research question.* The statement should briefly discuss the relevance of the proposed work to the purposes of this announcement. The statement will be reviewed for policy relevance and the importance of the research question. Please indicate, by number, which research question(s) presented within this announcement are being addressed or indicate that the research question is not one of those contained in the announcement.

3. *Statement of proposed methods.* This section should describe the conceptual model, the data source and the analytic methods. This description should explicitly relate data sources and analytic methods to the research issues to be addressed. This section must also contain information regarding the researcher's ability to obtain the data and information on when data will be available, if they are not already. Note that in the final proposal the researcher will have to provide assurances that the data is available.

4. *Experience.* The principal investigator's relevant research experience must be described. Other key staff must be identified with a brief description of their relevant experience and an indication of the tasks or activities for which they will be primarily responsible.

5. *Estimated budget.* This section must include an estimate of staff time and other direct costs. Information about other funding sources and the contribution that the ASPE/ACF funds will make must be discussed. Only a total project budget need be submitted at this time.

Part IV. The Review Process

An independent review panel will review and score all abstracts that are submitted by the deadline date and which meet the screening criteria (all

information and in formats required by this announcement). The panel will review the abstracts using the evaluation criteria listed below to score each abstract. The review results will be the primary elements used by the Assistant Secretary for Planning and Evaluation and the Assistant Secretary for Children and Families in making decisions regarding full application submission. The Department also reserves the option to discuss abstracts with other Federal or State staff, specialists, experts, and the general public. Comments from these sources, along with those of the reviewers, will be kept from inappropriate disclosure and may be considered in determining which applicants will be requested to submit a competitive application for review.

1. *Research Question(s):* The research must address important unanswered questions of local or national policy significance. The proposed research must contribute significantly to understanding the outcomes of welfare reform. Short-term research studies should provide information likely to be relevant to TANF reauthorization discussions. (35 points)

2. *Methodology/Merits of the Research Design:* The research design must identify the study population, indicate data sources and demonstrate the availability and reliability of proposed data sources and the appropriateness and reliability of data collection instruments or observational techniques as well as the validity of analytic methods proposed for addressing the research questions and hypotheses. The conceptual model and the analysis plan must be clearly explained. It is important to explain the time frame for the proposed work and that explanation must be clear and reasonable. (25 points)

3. *Experience.* The abstract must provide information on the principal investigator's relevant research experience and demonstrate capability to use the proposed data and methods. The relevant experience and proposed roles of other key staff must be presented. (30 points)

4. *Budget.* Applicants must provide an estimate of the total proposed budget, including information about other funding sources. The contribution of ASPE/ACF funding must be presented. The budget must be reasonable for the proposed scope of work. (10 points)

Estimate of Schedule

ASPE and ACF anticipate that abstracts will be reviewed and selected applicants notified to submit full proposals approximately 30 days

following the deadline for submission of abstracts. We expect that full proposals will be required to be submitted within 45 days of the date of the notification letter.

The Catalogue of Federal Domestic Assistance Numbers are 93.239 and 93.647 for ASPE and ACF, respectively.

Dated: February 18, 2000.

Margaret A. Hamburg,
Assistant Secretary for Planning and Evaluation.

Dated: February 16, 2000.

Howard Rolsto,
Director, Office of Planning, Research and Evaluation, Administration for Children and Families.

[FR Doc. 00-4613 Filed 2-25-00; 8:45 am]

BILLING CODE 4151-04-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Medical Device Quality Systems Inspection Technique; Notice of Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a workshop on the FDA Quality System Inspection Technique (QSIT). The topics to be discussed include: The development of QSIT, compliance program and warning letter pilot, management controls, corrective and preventative actions, design controls, production and process controls, and industry perspective of QSIT. The purpose of this QSIT workshop is to increase understanding of QSIT in the medical device community. By explaining this new inspection technique, FDA intends to ensure that the medical device industry takes appropriate action to establish effective quality systems and to prevent regulatory problems when inspections occur.

Date and Time: The workshop will be held on March 8, 2000, from 8:30 a.m. to 4:30 p.m.

Location: The workshop will be held at the Condado Plaza Hotel, 999 Ashford Ave., San Juan, PR 00907.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) along with a registration fee of \$125.00 to Jose P. Rodriguez, Director of Special Programs and Seminars, the Puerto Rico Manufacturers Association, P.O. Box 195477, San Juan, PR 00919-