

SUPPORTING STATEMENT

A. JUSTIFICATION

1. Circumstances of Information Collection

The Office of the Secretary (OS) at the U.S. Department of Health and Human Services (HHS), on behalf of the other former Public Health Service (PHS) agencies, is requesting the transfer of the PHS 5161-1 form from the Center for Disease Control (CDC) to HHS. The data collection is currently being collected under CDC OMB Number 0920-0428. Once clearance is granted the PHS-5161-1 will be renamed the HHS-5161-1 form. HHS is requesting a 3-year extension under a new OMB number.

HHS is requesting clearance for the Checklist and Program Narrative & the Public Health System Impact Statement (PHSIS), used by several former PHS agencies within HHS; CDC 0.1113 supplemental forms used exclusively by CDC; a supplement form used exclusively by Substance Abuse Mental Health Services Administration (SAMHSA), and the Single Source Agency (SSA) notification form. The Project Abstract form is being added as a component to the HHS 5161-1 package. In addition, HHS will continue to include the use of the 5161-1 form for several emergency acts and funding that were the result of the September 11th attack on the World Trade Center. Specifically, the Public Health Preparedness for Response to Bioterrorism (Emergency Supplement) (CDC), the Bioterrorism Hospital Preparedness Program cooperative agreement (HRSA), and 2 emergency response grants from (SAMHSA).

Other than the transfer of the clearance from CDC to HHS and the addition of the Project Abstract forms to the HHS 5161-1, two other changes will occur since the last clearance. CDC is requesting to discontinue the use of the CDC 0.1246(E) form which was used exclusively by CDC and the Office of Public Health and Science (OPHS) is requesting to discontinue use of the OPHS-1 form which was exclusively used by OPHS. In the case of both forms, the forms were not used in addition to the PHS 5161-1 form but in place of the PHS 5161-1 form. CDC and OPHS will no longer use their separate forms and will use the HHS 5161-1 form for **all** applicants.

We are requesting continued use of the Checklist and Program Narrative sections (and a new request for the use of the Project Abstract Form) and the Public Health System Impact Statement (PHSIS), third party notification, as part of the standard application for State and local governments and for private non-profit and for-profit organizations when applying for health services projects. SAMHSA is requesting to use the SSA notification for its programs when the applicant is not the SSA. CDC requests continued use of the CDC 0.1113 form, which is an assurance to CDC that the grantee will comply with the guidelines and specifications related to the contents of AIDS-related written materials, pictorials, audiovisuals, questionnaires, survey-instruments, and educational sessions in CDC funded programs.

The Checklist and Program Narrative assists applicants to ensure that they have included all

required information necessary to process the application as well as the name, title, and phone number of the business official and project officer responsible for carrying out the project. Checklist information concerning the type of application is also needed since new, competing continuation, noncompeting continuation, and supplemental applications are separated and reviewed differently. The checklist data helps to reduce the time required to process and review grant applications, expediting the issuance of grant awards. A copy of the document is included in **Attachment A**.

The Project Abstract form is a new HHS form that many agencies use for applicants that submit through Grants.gov and it is utilized in internal HHS grants management systems. The Project Abstract form is also utilized by many agencies to post summaries of funded grant projects on their websites so that the public is better informed of how taxpayer dollars are being spent to provide services in their community. It is incorporated into the HHS 5161-1 form. This form will not affect the current burden because the current burden already takes in account the wide ranges of time it takes each program to complete the application. See **Attachment A**.

With the addition of the Project Abstract Form, reference to the core HHS 5161-1 form will include will include the Check List, Program Narrative, **and** the Project Abstract Form. The PHSIS, SAMHSA SSA, and CDC.01113 forms are supplemental forms based on a predetermined need determined by the specific HHS Agency requesting the form.

The Public Health System Impact Statement (PHSIS), Third Party Notification, informs State and local health agencies of community-based proposals submitted by non-governmental applicants for Federal funding. The statement includes a description of the population to be served and that portion of the population whose needs would be met under the proposal, a summary of the services to be provided and the level of such services, and the nature of any coordination planned with the appropriate State or local health agencies.

The PHSIS is one page or less and is included as the first page of the application program narrative. The notification procedure consists of sending a copy of the PHSIS and a copy of the application face page SF424 (both of which are developed as part of the application) to relevant local and state health agencies. A copy of the document is included in **Attachment B**.

SAMHSA has a statutory mandate in section 501(d)(13)(B) of the Public Health Service Act to **A**ssure that...all grants that are awarded to entities other than States are awarded only after the State in which the entity intends to provide services...is afforded an opportunity to comment on the merits of the application[®]. Because of the importance of coordination with the SSA to help ensure communication, reduce duplication and facilitate continuity, SAMHSA has developed a third party notification requirement for SSA Coordination which is comparable to the Public Health System Impact Statement. The SSA Coordination requirement directs applicants who are not the SSA to include with the application a copy of a letter sent to the SSA transmitting the face page of Standard Form 424 and a copy of the project abstract, and informing the SSA that comments on the proposal should be sent to SAMHSA not later than 60 days after the deadline date for receipt of applications. A copy of the Single State Agency Coordination statement is

provided in **Attachment C**.

CDC 0.1113 form is used exclusively by CDC for several grantees once funding has been awarded. The form's purpose is to assure CDC that the grantee will comply with the guidelines and specifications related to the contents of AIDS-related written materials, pictorials, audiovisuals, questionnaires, survey-instruments, and educational sessions in CDC assistance programs. When the grantees sign and submit this form they are assuring that they agree to a panel review and approval of all applicable materials prior to their distribution and use in any activities funded in any part with CDC assistance funds. A copy of the form is located in **Attachment D**.

The legal authorities for the programs requesting use of these supplements are listed below.

Public Health Service Act, Section:

- 301: Research and Investigation; Rural Health Services Outreach Program; Rural Telemedicine Grant Program; Rural Health Research Centers; Integrated Community-Based Primary Care and Drug Abuse Treatment Services; Junior National Health Services Corps; Orphan Product Development
- 303: Minority Fellowship Program
- 303(a)(1): Mental Health Care Provider Education in HIV/AIDS
- 319: Disaster Assistance (42 U.S.C. 247d)
- 319B, C, F Public Health Threats and Emergencies Act
- 320(a)(2): Hansen's Disease
- 329: Migrant Health Centers including Infant Mortality
- 329(e): Migrant Health Environmental Program
- 329(f): Capitol Improvements Projects
- 329(g)(1): Technical and Non-Financial Assistance, Migrant Health Centers
- 330: Community Health Centers, Including Infant Mortality; Healthy Start
- 330(e): Capitol Improvements Projects
- 330(f)(1): Technical and Non-Financial Assistance, Community Health Centers
- 333(d): Primary Care Services Resource Coordination and Development Agreements
- 338(I): Nat. Health Service Corps State Loan Repayment Program
- 338(J): Grants to States for Operation of Offices of Rural Health
- 338(K): Native Hawaiian Health Care Scholarships
- 338(L): Demo. Grants to States for Community Scholarship Programs
- 340: Health Services to the Homeless; Healthy Schools, Healthy Communities
- 340(A): Health Services for Residents of Public Housing
- 371: Organ Procurement Organizations
- 374: Grants to Increase Organ Donation
- 379: National Bone Marrow Donor Registry
- 398/398A/398B: Demonstration Grants to States with Respect to Alzheimer's Disease
- 413(b)(6)(B) and 414(b)PHS Act, as amended(42 U.S.C. " 285a -2(b)(6)(B), 285a-3(b): NCI construction grants

421(b)(2)(B) and 422(c)(3)PHS Act, as amended (42 U.S.C. " 285b - 3(b)(2)(B), 285b-4(c)
(3):NHLBI construction

441(a)PHS Act, as amended (42 U.S.C.'285d-6(a)): NIAMS construction

455 PHS Act, as amended (42 U.S.C. '285i): NEI construction

464C(a)PHS Act, as amended (42 U.S.C. '285m-3(a)): NIDCD construction

464P(b) PHS Act, as amended (42 U.S.C. '285o-4(b)(3): NIDA construction

481A(a) PHS Act, as amended (42 U.S.C. '487a-2(a)): NIH Director, acting through NCRR;
construction of biomedical and behavior research facilities.

481B(a) PHS Act, as amended (42 U.S.C. '287a-3(a)): NIH Director, re NCRR activities,
construction of regional primate centers

501(d)(5): Improved Provision of Mental Health and Substance Abuse Treatment, Prevention
and Related Services

507(b)(11), and 511: Demonstration Cooperative Agreements for Development and
Implementation of Criminal Justice-Treatment Networks

508: Services Grant Program for Residential Treatment for Pregnant and Postpartum Women

510 (b)(1): Demonstration Grant Program for Residential Treatment for Women and Their
Children

510(b)(6): Community-Based Comprehensive HIV/STD/TB Outreach Services for High Risk
Substance Abusers Demo. Pgm.

515: Knowledge Dissemination Conference Grants

515(b)(3)and(9): Communications Programs Aimed at Preventing Alcohol and Other Drug
Programs

517: Substance Abuse Prevention Demonstration Grants for High Risk Youth

520(A): Evaluating Innovative Children's Mental Health Services; Community Support Program
- Mental Health Systems Improvement Demonstration Grants for Consumer and Family
Networks; Cooperative Agreements for Employment Intervention Demonstration
Program; National Consumer Technical Assistance Centers

561: Comprehensive Community Mental Health Services for Children with Serious Emotional
Disturbances

901: AHCPR Research Grants Program

1003: Training Grants (Population Research and Voluntary Family Planning)

1252: State Grants for Demonstration Projects Regarding Traumatic Brain Injury

1610(b): Renovation or Construction of Non-Acute Facilities

1707(d)(1): Minority Health

1910: Emergency Medical Services for Children Demonstration

1935(b)(1)(C): Evaluations of Substance Abuse Data Activities

1948(a): Provision of Technical Assistance to States, Public or Nonprofit Private Entities
Receiving Funding Under the Community Mental Health Services and Substance Abuse
Prevention and Treatment Block Grants

2003: Authority for Demonstration Grants (Population Affairs)

2354B(a) PHS Act, as amended (42 U.S.C. '300cc-41(a)(5)(B): Director for Office of AIDS
Research; construction of AIDS research facilities

2601: Ryan White Title I - Emergency Relief for Areas with Substantial Need for Services

2611: Ryan White Title II, Part B, Care Grant Program

2618(a): Ryan White C.A.R.E. Act of 1990; Special Projects of National Significance
2651: Ryan White Title III: Outpatient Early Intervention
Services--Supbart II
2671: Ryan White Title IV - Pediatric AIDS Demo. Projects

Other Authorities:

Title V, Social Security Act, Sec. 502(a): Maternal & Child Health Federal Consolidated Programs (SPRANS)
Title V, Social Security Act, Sec. 502(b)(1)(a): Maternal & Child Health Community Integrated Service Systems Set-Aside Pgm.
Coal Mine Health and Safety Act, Sec. 427(a): Coal Miners Respiratory Impairment Treatment Clinics and Services
Title X Section 1003, 42 U.S.C. 300a-1; Family Planning Services and Population Research Act of 1970, Section 6(c), Public Law 91-572, 84 Stat.1507, as amended.
Title XVII, Section 1707 (d)(I), 42 U.S.C. 300u et seq.: Disadvantaged Minority Health Improvement Act of 1990, Public Law 101-527
Title XXVI HIV Health Care Services Program
Title XX, Section 2003, Public Law 98-512, 42 U.S.C. 300z-2 as amended
P.L. 93-638, Sec. 103: Navajo Grants; Tribal Demonstration (Diabetes & Mental Health): Child Protection and Child Abuse
P.L. 93-638, Sec. 104: Tribal Management
P.L. 93-638, Title III, Sec. 302: Tribal Self-Governance Planning and Negotiation
P.L. 94-437: Tribal Recruitment and Retention - Coop. Agmnts; Preparatory Scholarships; Indian Health Scholarships
P.L. 94-437: Sec. 110: Tribal Recruitment and Retention
Sec. 120: Tribal Matching Scholarships
P.L. 96-537: Indian Health Professions, Pregraduate
P.L. 100-202: State-Based Projects for Disability Prevention
P.L. 100-579: Native Hawaiian Health Centers
P.L. 100-690, Sec. 4231: Urban Alcohol and Substance Abuse
P.L. 100-713, Sec. 208: IHS Research Program
P.L. 101- 527, Sec. 10: Health Services in the Pacific Basin
P.L. 101-616: Grants to Increase Organ Donation
P.L. 101-630: Health Care Services for Urban Indians - Health Promotion and Disease Prevention
Sec. 307: Indian Health Delivery Demonstration
Sec. 505(b): Health Care Services for Urban Indians (Immunization)
Sec. 511: Indian Urban Mental Health
P.L. 102-573, Sec. 112 & 114: Health Professions Recruitment for Indians (INMED, Nursing)
Sec. 216: Indian Adolescent Health Centers
Sec. 122: Health Professions Recruitment & Placement for Indians - Cooperative Agreements
P.L. 103-183: State Trauma; Rural Trauma; Special State Projects
8 USC 1101(a)(42): Health Programs for Refugees

- 29 USC 669(a): Centers for Agricultural Research, Education, and Disease and Injury Prevention; Occupational Respiratory Disease and Musculoskeletal Disorders Evaluation and Rehabilitation
- 29 USC 670(a)(1): Occupational Health and Safety Programs
- 42 USC 201: Public Health Service Act
- 42 USC 290aa: Public Health Service Act
 - Title V Substance Abuse and Mental Health Services Administration
 - Sec. 501 (m)(n)
- 42 USC 241: Grants for Radiation Studies and Research; Public Health Programs Impacted by Hurricane
- 42 USC 290cc-11: Projects for Transition From Homelessness (PATH)
- 42 USC 290bb-31: Protection and Advocacy for Individuals with Mental Illness (PAIMI)
- 42 USC 241(a): EPI Research Studies and Prevention Projects (AIDS and HIV); Sexually Transmitted Disease Control Program; HIV Conference Support; Hemophilia Centers; Emergency Flood Relief; Advancement of Understanding of Health of Racial and Ethnic Populations
- 42 USC 242(n): CDC General Conference Grant Program
- 42 USC 247(b): Minority HIV Demonstration Projects
- 42 USC 247b-1: Childhood Lead Poisoning Prevention Program
- 42 USC 247(b)&(k): State Demonstration Projects: Comprehensive School Health Programs; Capacity Building for Tobacco Prevention and Control Programs
- 42 USC 247(b)(k)(3): Health Promotion and Disease Prevention Research; State-Based Diabetes Control Program; National Laboratory Training Network for State Laboratories
- 42 USC 280(b): Injury Prevention Research Centers; State and Community-Based Injury Control
- 42 USC 287b and 280b-1: Development of Educational Materials for Prevention of Youth Violence
- 42 USC 287a-2: Construction of Vision Research; Construction for Cancer Research; Construction Projects for Extramural Research Facilities
- 42 USC 300aa-zz: Immunization Program
- 42 USC 300(k), 300(n)(3), and 300(n)(5): Breast and Cervical Cancer Control Program
- 42 USC 300u-3: The Public Health Leadership Institute; Enhancement of Capacity of Assess Progress Towards Healthy People 2000 Objectives
- 42 USC 300u-5: Chronic Disease Prevention and Control
- 42 USC 341(a): Tuberculosis and HIV Risk Factor Data and Serostatus Surveillance
- 42 USC 347(b)(1): State-Based Program for Lead Poisoning Prevention
- 42 USC 9604(a)(5), (i)(5), (9) and (15): Respiratory Effects of Waste Incinerators; Great Lakes Research Program
- 42 USC 9604(I)(4), (6), & (15): Surveillance of Hazardous Substance Emergency Events

2. Purpose and Use of Information

Each agency's financial assistance program evaluates the information provided by the applicants to select the ones most likely to meet program objectives and to determine that satisfactory

progress is being made on funded projects.

3. Use of Improved Technology

The information requested in the program narrative is based on model instructions provided in OMB Circular A-102 and 2 CFR Part 215. Although all government-wide funding opportunities and many grant application packages are now available on Grants.gov, there is currently no mandate that all grant application submissions must be made via Grants.gov. Incoming application packages are managed by each awarding agency. As a consequence, there is no consolidated system or portal to handle all incoming grant applications although it is an ongoing goal to streamline the grants submission process. Toward that end, efforts will be made to convert the HHS-5161-1 package into an electronic format for a variety of grant systems, including Grants.gov, the HHS Public Forms Website, and the two grants management systems used by HHS. It is our hope and intention that the conversion of the application package into an electronic format will lessen the burden of forms completion for the applicant. Every effort is made to hold to a minimum the burden imposed on applicants while requesting sufficient information to adequately evaluate and rank the application.

4. Efforts to Identify Duplication

No other application forms are authorized for the covered programs. No other similar information is available.

5. Involvement of Small Entities

The information requested is the minimum amount needed to meet program requirements. It cannot be reduced for small entities.

6. Consequences if Information is Collected Less Frequently

If this information is not collected, the programs will not have adequate data to select appropriate grantees or to evaluate which grants should be continued. Reduced frequency is not possible as the annual frequency of applications and awards coincides with the annual appropriation of funds. Information is collected once as needed. There are no legal obstacles to reduce the burden.

7. Special Circumstances

These supplements fully comply with the guidelines at 5 CFR 1320.6.

8. Consultation Outside of the Agency

A. The 60-Day Federal Register Notice announcing this data collection was published in the *Federal Register* on February 27, 2006 Vol. 71, No. 38, page 9826. There were no public comments.

B. The information requested in the Program Narrative follows that which is set forth in OMB Circulars A-102 and 2 CFR Part 215.

In the past, the Association of State and Territorial Health Officials (ASTHO) has been

consulted regarding the PHSIS, and that organization is very much in favor of continuing the third-party notification requirement for specified projects. In his letter of May 8, 1995, Christopher G. Atchison, President of ASTHO, states, "Health funding consolidations at the federal level, as well as changes in the Medicaid program, make it essential to integrate and coordinate funding streams for most effective use. It is critical that the state health agency have information on federal health funding targeting both the state and local levels. ... As the President of ASTHO and the Director of the Iowa Department of Health, I believe that the Public Health (System) Impact Statement program is an important element of efforts to increase accountability for federal funds. I offer both the support of ASTHO, and its assistance in working with state health department directors to ensure that the program is functioning effectively."

There were several meetings among the HHS agencies to discuss these forms to ensure that the forms will be of benefit to all.

9. Payments to Respondents

There are no payments or gifts to the respondents.

10. Assurance of Confidentiality

No assurance of confidentiality is given.

11. Questions of a Sensitive Nature

No questions of a sensitive nature are asked.

12. Estimates of Annualized Burden Hours and Costs

A. Annualized Burden Hours

A. Program Narrative, Checklist, and Project Abstract: The total response burden for the HHS Supplements to the Application for Federal Assistance is **40,819** hours. The burden was calculated on the basis of the estimated number of applications received for the covered programs. Applications are requested annually. In consultation with the 10 PHS regional offices and the PHS awarding offices, an estimate of 4 - 50 hours was established for the information required to complete the Program Narrative, Checklist, and Project Abstract. The total includes the amount for the CDC and HRSA narratives.

PHSIS: The total response burden for the PHSIS is **1,185** hours. For covered programs, applicants are directed by the Program Announcement to forward the PHSIS and the SF 424 to state proposal. Each applicant sends statements to an average of 2 to 3 local and state health agencies. The burden, estimated at 10 minutes each, is limited to the time required to copy and mail the two pages.

CDC 0.1113: The total response burden for CDC 0.1113 is **500** hours. The response time is 30 minutes.

SSA: The total response burden for SSA is **187** hours. The 10 minutes response time is the same as the PHSIS.

Total: The total response burden for the Program Narrative, Checklist, Project Abstract and Public Health System Impact Statement, SSA, and CDC 0.1113 is **42,691** hours per year.

The programs requiring the use of the HHS Form 5161-1 and the estimated number of applicants per year are listed below.

Programs requiring a PHSIS are indicated by an asterisk *. Public Health Preparedness and Response for Bioterrorism Programs administered by CDC and HRSA reflect a unique number of responses per respondent and/or the response burden as required by the authorizing legislation. Both programs are identified by **.

Only SAMHSA programs will use the SSA forms.

Programs, by Agency

No. Of Applications

SAMHSA

Knowledge Development and Application

1,205

Services Program

45*

Projects for Transition From Homelessness
Protection and Advocacy
Projects for Transition From Homelessness
(PATH)

56
Protection and Advocacy for Individuals
with Mental Illness (PAIMI)

56
Immediate Emergency Response Grants

3
Intermediate Emergency Response Grants 3

1,368

(Subject to SSA: 1,125)
(Subject to PHSIS: 10)

AHCPR
AHCPR Research Grants Program

3

CDC
Conduct Research on The Diagnosis And Pathogenesis of
Lyme Disease in U.S.

27
Conduct Research and Education Programs on Lyme Disease

in the U.S.

		55
Public Health Conference Support Coop. Agreement Program for HIV Prevention		
		54
Public Health Conference Support Grant Program		
		104
HIV Prevention Project		
		113*
School Health Programs to Prevent Serious Health Problems and Improve Education	158	
Mining Occupational Safety and Health Research Grants		15
Chronic Disease Control and Prevention: World Health Organization (WHO)	1	
Grants for Injury Control Research Centers		11
Demonstration Projects to Promote Integrated Public Health Information	39	
Development & Distribution of American Red Cross Aids Educ. Materials	1	
Research Studies Evaluating Projects on Feasibility of STD Treatment	4	
Applied Research in Emerging Infections HCV Infection-sexual Transmission FACE	11	
		8
Grants for Injury Research		

		67
Childhood Agricultural Safety and Health Research	32	
Childhood Agricultural Safety and Health Research		38
Pfiesteria-Related Illness Surveillance and Prevention		6
Dengue Prevention and Mosquito Control Educational Exhibit		1
Fellowship Program in Violence Prevention for Minority Medical Students		
		2
Applied Research for Traumatic Brain Injury Surv.& TBI Follow-up Registry		
		8
HIV, STDS, & TB Related Applied Research Projects		35
Creating Healthy Work Organizations		9
Program for Playground Safety		1
Research Program for Exposure-Dose Reconstruction		1
Development & Testing for Populations at High Risk for Gonorrhea Stage 1	5	
Grants for Violence-related Injury Prevention Research		43
Occupational Radiation and Energy-Related Health Research Grants		
	23	
Establishment of Medical Monitoring Program - The Bunker Hill Superfund Site		
		1
Prevention of Violence Against Women Electronic Networking Program		1
State-based Diabetes Programs: Comprehensive Program Approach		
	22	
Epidemiological Research Studies of AIDS & HIV Infection		14
Violence Against Women Prevention Research Center	9	

Initiatives by Organizations to Strengthen National Tobacco Control Activities			
		9	
Programs to Prevent the Emergence and Spread of Antimicrobial Resistance			
		28	
Waterborne Disease Occurrence Studies			
	5		
National Partnerships for Human Immunodeficiency Virus (HIV) Prevention			
		20*	
Educational Resource Center Training Grants			
		18	
National Partnerships for Human Immunodeficiency Virus (HIV) Prevention			
		1	
Health Promotion and Disease Prevention Research Centers			
	43		
The National Blood Data Resource Center			
	1		
Evaluation of Toxicologic Risk Assessment Models Using Epidemiology Data			5
A Young Worker Community-Based Health Education Project			4
Enhanced State-Based Birth Defect Surveillance and Use of Surveillance Data			36
Deep South Center for Aging Disease and Injury Research, Education and Prevention			3
Programs for the Prevention of Fire-Related Injuries			21
Prevention of Birth Defects Through Surveillance, Training, & Epi Research			1
Mining Occupational Safety and Health			32
National Sexual Violence Resource Center			
		1	
Identify the Incidence of Occupational Asthma			
	6		
HIV/AIDS Prevention Program Development & Technical Assist. Collaboration			1
Plant Delivered Oral Vaccines			

Cooperative Agreement for Asthma Education	1	
Hepatitis B Immunization Program with Focus on Asians and Pacific Islanders	2	
Building State Capacity to Conduct Site-specific Activities	1	6
Study a Healthy Home/healthy Community Intervention		3
Model Hearing Conservation Program for Coal Miners	3	
Suicide Prevention Research Center	2	
Grants for Radiation Studies and Research	11	
Thyroid Disease in Persons Exposed to Radiation Fallout from Atomic Weapons Testing		
1 Evaluation of Violence Prevention Programs for High-Risk Youth		
Demonstration of School-based Violence Prevention		27
The Evaluation of Interventions to Prevent Suicide	123	
Coop Agreement. to Enhance Efforts to Eradicate Polio & Improve Immunization Levels Globally	11	
The Great Lakes Research Program		1
Surveillance, Research, Services, & Evaluation Directed Toward the Prevention of Birth Defects		10
Programs to Prevent the Emergence & Spread. of Antimicrobial Resist/Food Animals		1

State Grants to Support the Evaluation of 5-a-Day Nutrition Programs	2	
North American Association of Central Cancer Registries		10
National Diabetes Prevention Center		1
NMO Strategies for the Prevention and Control of Diabetes (NDE Program)	1	
Oral Disease Prevention in School-Aged Children Using School-Based/Linked State Cardiovascular Health Programs	9	
Young People in Alternative Education Settings: Preventing HIV & Other STDS		6
Translational Research Centers for Diabetes Control Within Managed-Care	17	
Resource Center for Unintentional Injury Prevention among Older Americans		11
Building Environmental Health Response Capacity in Arctic Communities		16
Evaluation of Health-Care Worker Glove Protection During Surgery & Effects		1
Epidemiology of Opportunistic Infection in Bone Marrow Transplant Recipient		11
Measuring the Risk for Transmission and Sequelae from Chlamydial Disease		6
Enhancement of Local Public Health Dept. Participation in Brownfields Dec.		7
Behavioral Intervention Research		10
Technology Translation and Transfer of Effective HIV Prevention Interventions		3
Grants for Minority Health Statistics Dissertation Research		1
Expanded Use of Rapid HIV Testing, & Barriers to HIV Testing		7
		28

National Heart, Lung, & Blood Institute Asthma Surveillance with an Emphasis on Children		13
Cooperative Agreement to Study Consumer Demand for Food Safety		
	10	
Research Program to Study The Dermal Toxicokinetics of Methyl Parathion		
	1	
Coop. Agreement to Expand International Program Regarding Disability & Health Cooperative Agreement for Enhancement of Poison Control Centers		1
	1	
Studies to Evaluation, Epidemiology, and Laboratory Characteristics of HIV Infection among U.S. Blood Donors		1
Public Health Preparedness and Response for Bioterrorism		
	59**	
Total Competing Applications		1,545
Non-Competing Continuation Application for all Programs		495
		<hr/>
		2,040
(Subject to PHSIS: 133)		

FDA

Orphan Product Development

1

NIH

Construction Grants:
National Cancer Institute

1

National Center for Research Resources

70

71

HRSA

Rural Telemedicine Grant Program

70*

Rural Network Development Grant Program

50*

Rural Health Services Outreach Program

500*

Grants to States for Operation of Offices of
Rural Health

50

Emergency Medical Services for Children
Demonstration Grants

89*

Healthy Start

72*

Maternal & Child Health Community Integrated Service
System Set-Aside Program

114*

Maternal & Child Health Block Grant

59

Maternal & Child Health SPRANS

334*

Traumatic Brain Injury Program		21
Abstinence Education Program		
		53
Primary Care Cooperative Agreements		
	65	
Health Care for the Homeless		
	175*	
Health Services for Pacific Islanders		
	15*	
National Health Service Corps State Loan Repayment Program		
		30
Community Health Centers, including Infant Mortality		
		630*
Technical and Non-financial Assistance to Health Centers		
		55*

Migrant Health Centers including Infant Mortality	35*	
Migrant Health Environment Program		
Health Services for Residents of Public Housing	10*	10*
Black Lung Clinics		
		25*
Native Hawaiian Health Care Scholarships	14*	
Health Centers		1*
Demonstration Grants to States for Community Scholarship Programs		8*

Hansens' Disease		15
Demonstration Grants to States for Alzheimer's	20	10*
Junior National Health Service Corps	15*	
Capital Improvements Projects		
HIV Emergency Relief Program (Part A)		35*
HIV Care Grants to States (Part B)		84 51
HIV Early Intervention Services (Part C)	150*	
HIV Pediatrics Grants		
AIDS Special Projects of national Significance	46*	49*
AIDS Education and Training Centers		
Grants to Increase Organ Donation	15	

Renovation or Construction of Non-acute Facilities Disaster Assistance	5	10
Public Health Preparedness and Response for Bioterrorism (Hospital Preparedness)		18*
_____		59**
(Subject to PHSIS: 2,520)		3,057
<u>IHS</u> Navajo Grants		
Tribal Management		21
Tribal Demonstration (Mental Health)		81
Tribal Demonstration (Diabetes)	7	
Health Professions Recruitment for Indians	64	
Indian Child Protection and Child Abuse	14	

Tribal Recruitment and Retention	50	
Adolescent Health Centers	12	
IHS Research Program	25	
Tribal Self-Governance Planning and Negotiation	34	
Tribal Matching Scholarship	28	
Urban Immunization and Health Promotion/Disease Prevention	4	33*
Urban Indian Alcohol & Substance Abuse & Urban Mental Health		
Health Professions Recruitment and Placement for Indians: Cooperative Agreements		33*
Tribal Recruitment and Retention - Coop. Agreements	4	
	10	—
(Subject to PHSIS: 66)		420

Office of Minority Health
 Bilingual/Bicultural Service Demonstration Projects
 in Minority Health

Minority Community Health Coalition Demonstration Pgm.		50*
Family and Community Violence Prevention Pgm.	66*	
Construction Grants		4

Cooperative Agreements to Improve Minority Health		1
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10

(Subject to PHSIS: 116) 131

Office of Population Affairs
 Adolescent Family Life - Demonstration Projects 250

Family Planning - Personnel Training Program

Family Planning Services

16

100

366

Respondents Grand Total: **7,456**

(Total Subject to PHSIS: 2,845)

(Total Subject to SSA: 1,125)

The total estimated burden is **42,691** hours per year.

Forms	No. Of Respondents	Response per Respondent	Avg. Burden Per Response (in hours)	Total Burden (in hours)
Program Narrative, Checklist, & Project Abstract	7,338	1	4	29,373
Program Narrative, Checklist & Project Narrative (CDC)	59	6	24	8,496
Program Narrative, Checklist, & Project Narrative (HRSA)	59	1	50	2,950
CDC Form 0.1113	1,000	1	30/60	500
Public Health Impact Statement (PHSIS)	2,845	2.5	10/60	1,185

SSA (SAMHSA)	1,125	1	10/60	187
Total				42,691

B. Annualized Cost to the Respondent

Program Narrative , Checklist, and Project Abstract:

We estimate that an applicant can complete the required narrative and checklist in an average of 4 hours. Salaries are estimated at \$25/hour plus an additional \$13/hour for fringe benefits and overhead.

Salary/fringe cost of \$38/hr. x 4 hours = \$152 per application. \$152 x 7338 respondents annually = \$1,115,376 per year.

Program Narrative, Checklist, and Project Abstract (CDC):

We estimate that an applicant can complete the required narrative and checklist in an average of 4 hours. Salaries are estimated at \$25/hour plus an additional \$13/hour for fringe benefits and overhead.

Salary/fringe cost of \$38/hr. x 24 hours = \$912 x 6 applications = \$5,472 x 59 respondents annually = \$322,848 per year.

Program Narrative, Checklist, and Project Abstract (HRSA):

We estimate that an applicant can complete the required narrative and checklist in an average of 50 hours. Salaries are estimated at \$25/hour plus an additional \$13/hour for fringe benefits and overhead.

Salary/fringe cost of \$38/hr. x 50 hours = \$1,900 per application. \$1,900 x 59 respondents annually = \$112,100 per year.

CDC Form 0.1113:

We estimate that an applicant can complete the required CDC Form 0.1113 in an average of 30 minutes. Salaries are estimated at \$25/hour plus an additional \$13/hour for fringe benefits and overhead.

Salary/fringe cost of \$38/hr. x 30 minutes = \$19 per application. \$19 x 1,000 respondents annually = \$19,000 per year.

Public Health System Impact Statement:

The direct cost to the applicant is negligible. It is limited to the cost of copying and mailing two pages of the application to relevant state and local health agencies, which is estimated to require 10 minutes. Since the services provided by most community-based organizations focus on specific populations and geographic areas, the number of health agencies affected is few. It is estimated that each affected applicant sends an average of two to three statements to such agencies.

The annualized cost is estimated to be \$17,220, which is calculated on the basis of 2,845 respondents, times an average of 2.5 responses, times 10 minutes, times \$12 per hour, plus \$3,000 estimated cost for postage and copying.

$$2,845 \times 2.5 \times 10 \text{ minutes} = 1,185 \text{ hours}$$
$$1,185 \times \$12 = \$14,220 + \$3,000 = \$17,220$$

SAMHSA Single State Agency Coordination:

SAMHSA Single State Agency Coordination (SSA) - The total response burden for this notification is 187 hours. For covered programs, applicants are directed by the Program Announcement to forward the materials to the SSA. Each applicant sends statements to an average of one SSA. The burden, estimated at 10 minutes, is limited to the time required to copy and mail the two pages and include a copy of the transmittal with the application.

The annualized cost is estimated to be \$5,244 which is calculated on the basis of 1,125 respondents, times 10 minutes, times \$12 per hour, plus \$3,000 estimated cost for postage and copying.

$$1,125 \times 10 \text{ minutes} = 187 \text{ hours}$$
$$187 \times \$12 = \$2,244 + \$3,000 = \$5,244$$

Total Annual Cost to Respondents

\$1,115,376 (Program Narrative, Checklist, and Project Abstract)

	322,848	(CDC Program Narrative, Checklist, and Project Abstract)
	112,100	(HRSA Program Narrative, Checklist, and Project Abstract)
19,000		(CDC Form 0.1113)
	17,220	(PHSIS)
	5,244	(SSA)
	<hr/>	
	\$1,591,788	Total

13. Estimates of Annualized Respondent Capital and Maintenance Costs

There are no capital or maintenance costs.

14. Estimates of Annualized Cost-Government

Copy Preparation	2,500
Printing	50,500
Mailing and Handling	<u>4,000</u>
Total:	\$ 57,000

The third-party notification constitutes no cost to the Government.

15. Changes in Hour Burden

There is no burden change for this request. The burden was just redistributed.

16. Time Schedule, Publication, and Analysis Plans

These are recurring data collections, and collections are done on an as needed basis. Each agency has different time-lines for the receipt and processing of their applications. Data is not collected for statistical use. There are no current plans to publish any information received from this application process.

17. Expiration Date Display Exemption

We are requesting an expiration date display exemption. The enclosed forms are used by many state and local governments, private non-profit organizations, and for-profit organizations for federally funded health services projects. Applicants can download and review or print the 5161 application forms from Grants.gov or the SAMHSA websites. Although having access to the forms over the Internet is convenient for some it is not available for most, the majority continues to use hard copies.

Applicants can contact a Clearinghouse and receive a hard copy ‘application kit’ containing all relevant application information, including the 5161 forms package. The Clearinghouse does maintain a supply of printed forms. Therefore we are requesting to continue to have the ability to print large quantities of the forms without expiration dates, at one time. This would be very cost effective for the agencies and the applicants. Expiration dates require that perfectly useful forms be discarded because the expiration date is not current.

If a significant change were ever made we could easily cite the new date of revision in the grants/cooperative agreement application instructions. That way the organizations could request and receive the revised version as needed.

18. Exceptions to Certification

No exceptions are requested.

B. Collections of Information Employing Statistical Methods

This information will not be used for statistical purposes.

List of Attachments

Attachment A	Supplemental Form HHS 5161-1
Attachment B	Public Health System Impact Statement
Attachment C	Substance Abuse/Mental Health Single State Agency Coordination
Attachment D	CDC Supplemental Form [CDC 0.113]

Attachment A

Supplemental Form HHS 5161-1

Attachment B

Public Health Service Impact Statement

Appendix B

Form Approved

PUBLIC HEALTH SYSTEM IMPACT STATEMENT

Public Health Service (PHS) awarding components that award health services grants to community-based, nongovernmental organizations require applicants under covered programs to send a copy of the application face page (SF 424, Application for Federal Assistance) and a one-page summary of the project, called the Public Health System Impact Statement (PHSIS), to the appropriate State and/or local health agencies, as determined by the applicant.

The PHSIS is to be not more than one page in length and is to address the extent to which a proposed project affects and is related to existing community services. The PHSIS should include the following information, which may be taken from the application's Program Narrative:

- a description of the population to be served whose needs would be met under the proposal;
- a summary of the services to be provided; and
- a description of any coordination planned with the appropriate State or local health agency(ies).

A copy of the PHSIS and SF 424 application face page must be mailed to the head of the appropriate State and local health agencies in the area to be impacted no later than the Federal application receipt due date.

Public reporting burden for gathering, duplicating, and mailing of the Public Health System Impact Statement is estimated to be 10 minutes. 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. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to HHS Reports Clearance Officer, 200 Independence Ave SW, Room 537-H, Washington, DC 20201. ATTN: PRA (0990-XXXX). **Do not send the completed form to this address.**

Attachment C

Substance Abuse/Mental Health Single State Agency (SSA) Coordination Form

Attachment C

Drug Abuse/Mental Health Single State Agency (SSA) Coordination

Coordination with the SSA helps ensure communication, reduce duplication, and facilitate continuity. Therefore, applicants who are not the SSA, must include in an appendix to the application entitled letter to SSA, with a copy of a letter sent to the SSA that (1) transmits a copy of the face page of the application (Standard Form 424) and a copy of the project abstract, and (2) notifies the State that, if it wishes to comment on the proposal, its comments should be sent not later than 60 days after the deadline date for the receipt of applications to:

Director of Grant Review, Office of Program Services
Substance Abuse and Mental Health Services Administration
Room 3-1044, 1 Choke Cherry Road,
Rockville, MD 20857
ATTN: SSA-Funding Announcement No. ____

Note: Applicants should fill in the pertinent RFA number.

Applicants may request that the SSA send them a copy of any State comments.

A listing of SSAs can be found in the grant application kit. If the proposed project falls within the jurisdiction of more than one State, all representative SSAs should be involved.

Public reporting burden for the SSA Notification is estimated to average 10 minutes per response, including the time for copying the face page of the SF 424 and the abstract and preparing the letter for mailing. 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. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to SAMHSA, Reports Clearance Officer, 1 Choke Cherry Road , Rockville, MD 20857. (OMB No. 0990-XXXX) Do not send the completed form to this address.

Attachment D

CDC Supplemental Form 0.1113