DEPARTMENT OF HEALTH AND HUMAN SERVICES

HHS Annual Performance Plan

FISCAL YEAR 2005

Justification of Estimates for Appropriations Committees

Message from the Acting Assistant Secretary for Budget, Technology and Finance

I am pleased to present the Department of Health and Human Services (HHS) Annual Performance Plan for fiscal year (FY) 2005. Our mission is to enhance the health and well-being of Americans by providing effective health and human services and by fostering strong, sustained advances in the sciences underlying medicine, public health, and social services. The Department executes this mission by managing more than 120 performance program areas with over 600 performance measures. Agency-specific highlights in the *Annual Performance Plan* include:

- The Health Resources and Services Administration Health Center program, a Presidential initiative to increase health care access for those uninsured and underserved Americans who are most in need of access to health care services;

- The National Institutes of Health "HapMap" project, which will identify patterns of human genetic variations and increase understanding of the role of genetic factors contributing to health and disease;

- The Administration for Children and Families Child Support Enforcement program, which seeks to assure that assistance in obtaining support is available to children, and is an integral part of the Department's effort to increase parental responsibility; and

- The Indian Health Service Special Diabetes Program for Indians, that has a mission to develop, document, and sustain a public health effort to prevent and control diabetes in American Indian and Alaskan Native people.

These are just a few examples of the programs in which the Department is working to achieve its strategic and performance goals. Additional detail about particular agencies can be found in the individual Operating Division Annual Performance Plans.

The FY 2005 *HHS Annual Performance Plan* integrates budget and performance information and demonstrates how we are building a permanent capability for ensuring that budget decisions are informed by program results.

Sincerely,

Kerry Weems
February 2, 2004

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Overview

The Department of Health and Human Services FY 2005 *Annual Performance Plan* presents an illustrative group of key programs in which the Department is working to fulfill its mission:

> ***To enhance the health and well-being of Americans by providing for effective health and human services, and by fostering sound, sustained advances in the sciences underlying medicine, public, health, and social services.***

The *Annual Performance Plan* meets the reporting requirements of the Government Performance and Results Act (GPRA) and supports the President's Management Agenda initiative for Budget and Performance Integration. The *Annual Performance Plan*, with its companion documents, the FY 2005 *Budget in Brief*, and the Department *Strategic Plan FY 2004-2009*, presents an integrated picture of the Department's planned efforts in FY 2005 to achieve its long-term strategic and performance goals. The *Strategic Plan* describes the Department's goals for the FY 2004 through FY 2008 period; the *Annual Performance Plan* highlights performance measures and targets specific to FY 2005.

The *Annual Performance Plan* presents 19 key programs covering all 8 Department Strategic Goals. The programs represent the breadth of activities the Department is carrying out, in partnership with States, localities, and the private sector, to meet the health and human service needs of Americans. The *Annual Performance Plan* describes for each program:

- The program's background, context, and purpose;
- Performance planning, including the primary or long-term goal of the program and one or two illustrative performance measures for FY 2005;
- Means and strategies to achieve performance goals; such as research, technical assistance, and the use of performance-based awards to program partners;
- FY 2005 budget and policy priorities which support program performance;
- How information from PART (Program Assessment and Rating Tool) Reviews has been used to justify funding requests, direct program improvements, develop legislative proposals, and guide management actions where appropriate; and
- External factors affecting program performance.

Each HHS illustrative program includes the FY 2005 budget request amount and the FY 2005 full cost request amount. The full cost request reflects the Department’s estimate of the full cost of a program including overhead and other indirect costs, as part of the President’s Management Agenda budget and performance integration initiative.

The illustrative programs and performance goals in the FY 2005 *Annual Performance Plan*, several related FY 2005 budget initiatives, and the Department Strategic Goals they support, include:

Strategic Goal 1 - Reduce the major threats to the health and well-being of Americans:

- The Centers for Disease Control and Prevention (CDC) will continue its efforts to prevent HIV infections through strengthening capacity nationwide to develop and implement effective prevention strategies; and to prevent diseases through increased childhood immunization.

- The Substance Abuse and Mental Health Services Administration will continue the President's commitment to reduce current illicit drug use. Two fundamental components of this initiative are the Substance Abuse Prevention and Treatment Block Grant - accounting for at least 40 percent of all public financing for drug abuse prevention and treatment services - and the new Access to Recovery State Voucher program - that gives individuals the ability to choose effective treatment providers, including those that are faith-based.

Strategic Goal 2 - Enhance the ability of the Nation's health care system to effectively respond to terrorism and other public health challenges:

- CDC will continue its work to ensure that 100 percent of State public health agencies are prepared to use material in the Strategic National Stockpile and to annually exercise plans that demonstrate their capacity to respond to emergencies.

- CDC, through its Terrorism Preparedness and Emergency Response Program, will continue to work with State, local, and territorial public health departments to develop public health infrastructure, capacity and plans to respond to events of terror.

- FDA will build upon its recent increase in the number of field examinations of imported food products, expand the laboratory capacity of State partners, and work to find faster and better detection methods.

- CDC and the Food and Drug Administration also will support the government-wide biosurveillance effort to develop new tools and procedures designed to provide the earliest possible detection of potential disease outbreaks or releases of deadly pathogens into food, water, or the environment.

- The Health Resources and Services Administration (HRSA) will seek to ensure that 100 percent of the Bioterrorism Hospital Preparedness Program awardees, including all 50 States, develop regional plans to address surge (a large and rapid increase in the number of persons requiring care) capacity.

Strategic Goal 3 - Increase the percentage of the Nation's children and adults who have access to health care services, and expand consumer choices:

- The President signed into law, on December 8, 2003, the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), which provides enhanced coverage for the lowest income beneficiaries and an immediate prescription drug discount card for all beneficiaries until the full plan is available nationwide. To begin implementing this ground-breaking new legislation, the Centers for Medicare & Medicaid Services (CMS) will establish program regulations and a major initiative to educate health care providers and consumers.

- CMS, in partnership with the States, will maintain the number of uninsured and underserved children who enroll in Medicaid and the State Children's Health Insurance Program (SCHIP). CMS will assess health care quality for low-income children enrolled in Medicaid and SCHIP against a core set of performance measures developed with the States and establish formal collaborations to make improvements.

- HRSA will continue to expand access to health care services through the President's Health Center Initiative. Through this program, 15 million individuals will receive health care services—40 percent of whom have no insurance coverage. By FY 2006, HRSA will have expanded access to 6.1 million individuals through over 1,200 new and expanded sites.

- The Indian Health Service, through prevention and control activities including direct care and developing and sharing models of diabetes control, will seek to maintain the proportion of Indian, Tribal, and Urban (I/T/U) facilities Native American patients with diagnosed diabetes that have demonstrated improved glycemic control (blood sugar levels). This is an ambitious goal given that the number of diabetics that receive services through the I/T/U network is increasing three to four percent annually.

Strategic Goal 4 - Enhance the capacity and productivity of the Nation's health science research enterprise:

- The National Institutes of Health (NIH) will continue its progress implementing the HapMap Project, which will contribute to research identifying the role of genetic factors contributing to underlying common diseases. In FY 2005, NIH has set the goal of developing a first-pass draft haplotype map, which will pinpoint, for the first time, genetic variations among individuals across all human chromosomes. The long-term benefits of the HapMap are increased understanding of the influence of genetics on health and disease and interven tions that can be made more precise, predictable, and effective.

- NIH will develop two new animal models to use in research on at least one agent of bioterror. This effort will increase the capacity of NIH and the extramural scientific community to evaluate products for biodefense, and aid in the development and testing of the growing number of promising biodefense therapies and vaccines.

Strategic Goal 5 - Improve the quality of health care services:

- FDA will expand the network of facilities in the Medical Product Surveillance System (MedSun), a postmarket reporting system through which FDA receives reports of serious adverse events associated with medical devices. When fully implemented, MedSun will reduce device-related medical errors.

Strategic Goal 6 - Improve the economic and social well-being of individuals, families, and communities, especially those most in need:

- The Administration for Children and Families (ACF) will continue to provide leadership to States, Territories, and Tribes as they move families from welfare to work and self-sufficiency in their Temporary Assistance for Needy Families (TANF) programs. The President's FY 2003 TANF Reauthorization proposal refocuses financial incentives to program partners to provide performance bonuses based on achieving recipient employ ment goal, and supports initiatives that emphasize healthy marriages and child well-being..

- The Administration on Aging is committed to work with its State and local partners to ensure that comprehensive social and supportive services are available to vulnerable elderly residents of rural areas.

Strategic Goal 7 - Improve the stability and healthy development of our Nation's children and youth:

- ACF plans to continue to work with the States to increase the child support collection rate. ACF will provide performance-based incentive funding to States for current support collection, as well as paternity establishment, past-due cases payment, and cost-effectiveness.

- In the area of child welfare, ACF has set an ambitious FY 2005 goal of finalizing 62,000 adoptions toward an overall goal of finalizing 327,000 adoptions between 2003 and 2008. ACF will continue to monitor the overall performance of child welfare programs through Child and Family Services reviews, which focus on outcomes for children and families in the areas of safety, permanency, and child and family well-being. The FY 2004 President's Budget proposes the Child Welfare Program Option, which will provide flexible grants to States as an incentive to create innovative child welfare programs.

Strategic Goal 8 - Achieve excellence in management practices:

- CMS will continue its focus on maintaining program integrity in the Medicare program, to ensure that it pays the right amount to legitimate providers for covered, reasonable and necessary services to eligible beneficiaries. CMS sets ambitious annual program integrity targets, including reducing the percentage of improper payments made under the Medicare fee-for-service program, as well as reducing the contractor error rate and improving the provider compliance error rate.

- The Department's Office of the Inspector General (OIG) fights fraud, waste and abuse, and recommends policies to promote economy, efficiency, and effectiveness in HHS programs. Approximately 80 percent of OIG resources are devoted to Medicare and Medicaid; the remaining 20 percent is dedicated to all other HHS programs. OIG estimates that for FY 2003, it achieved $23 billion in savings resulting from implementation of its recommendations and recoveries or receivables from investigations and audits. This is a return on investment (ROI) of 117 (savings/operating costs). For FY 2005, OIG has set an ambitious target of increasing ROI to more than 150.

For additional information on these and other FY 2005 programs and budget initiatives, see the HHS FY 2005 *Budget in Brief*, and individual Operating Division Congressional Justifications and Annual Performance Plans.

Following are:

- A table which displays the Department's FY 2005 total discretionary budget request, organized by Department Strategic Goal*; i.e., the total Department discretionary budget for program activities that support achievement of that Strategic Goal; and

- A summary table of the 19 representative programs and 22 highlighted performance measures in this report.

Highlighted programs and performance measures may be identified by the following symbols as Presidential priorities, Secretarial priorities, or Healthy People 2010 goals:

Presidential Priority

Secretarial Priority

Healthy People 2010 Goal

* This report includes some programs that are part of the mandatory budget; mandatory program dollars are shown in *italics* and are not included in the totals for each Strategic Goal.

The table below displays the Department's FY 2005 discretionary budget request, organized by Strategic Goal. It was developed by associating HHS programs, projects, and activities with each of the eight HHS Strategic Goals. The total of these goals equals the Department's FY 2005 discretionary budget request.

FY 2005 HHS Budget by Strategic Goals

(Dollars in Millions)

	Strategic Goal	Total Goal Budget
Goal 1	Reduce the major threats to the health and well-being of Americans.	$6,669
Goal 2	Enhance the ability of the Nation's health care system to effectively respond to bioterrorism and other public health challenges.	$3,377
Goal 3	Increase the percentage of the Nation's children and adults who have access to health care services, and expand consumer choices.	$12,726
Goal 4	Enhance the capacity and productivity of the Nation's health science research enterprise.	$28,726
Goal 5	Improve the quality of health care services.	$222
Goal 6	Improve the economic and social well-being of individuals, families, and communities, especially those most in need.	$4,719
Goal 7	Improve the stability and healthy development of our Nation's children and youth.	$10,333
Goal 8	Achieve excellence in management practices.	$787
	Total FY 2005 Discretionary Budget Request*	***$67,558***

* This total reflects the HHS current law budget authority

Highlighted Performance Measures in FY 2005 Annual Performance Plan

Strategic Goal 1: Reduce the major threats to the health and well-being of Americans

Performance Measure and FY 2005 Targets	Agency Program	Most Recent Results	PART Review
Achieve or sustain immunization coverage of at least 90 percent in children ages 19- to 35-months of age for 3 doses DtaP vaccine, 3 doses Hib vaccine, 1 dose MMR vaccine, 3 doses hepatitis B vaccine, 3 doses polio vaccine, 1 dose varicella vaccine, and 4 doses pneumococcal conjugate vaccine.	CDC National Immunization Program	FY 02 target: 90% for all vaccines; FY 02 results: DTap 95%; Hib 93%; MMR 91%; Hepatitis 90%; Polio 90%; Varicella 81%.	2004
Reduce the number of new HIV infections among people less than 25 years of age from 2,100 in 2000 to 1,600 in 2010. FY 2005 target: 1,800. Decrease the number of perinatally acquired AIDS cases from the 1998 baseline of 235 cases.	CDC HIV/AIDS Prevention in the U.S.	FY 02: 2,926 reported cases (from 30 areas); 2000 baseline: 2,100 cases (from 25 areas). CDC will continue to revise baseline and targets when data from more States are available. 1998 baseline: 235 cases; FY 02 target: 141 cases; FY 02 results: 90 cases.	2004
Increase the number of clients served. FY 2005 target: 1.96 million.	SAMHSA Substance Abuse Prevention and Treatment Block Grant	FY 01 target: 1.64 million; FY 01 results: 1.74 million.	2005

Strategic Goal 2: Enhance the ability of the Nation's health care system to effectively respond to bioterrorism and other public health challenges

Performance Measure and FY 2005 Targets	Agency Program	Most Recent Results	PART Review
100 percent of State public health agencies improve their capacity to respond to exposure to chemicals of category A agents by annually exercising scalable plans and implementing corrective action plans to minimize any gaps identified.	CDC Terrorism Preparedness and Emergency Response Program	New measure for FY 2005.	2005
100 percent of State public health agencies are prepared to use material contained in the Strategic National Stockpile as demonstrated by the evaluation of standard functions as determined by CDC.	CDC The Strategic National Stockpile	New measure for FY 2005.	N/A
Increase the percent of awardees that have developed plans to address surge capacity to 100 percent.	HRSA Bioterrorism Hospital Preparedness Program	FY 03 baseline estimate: 59%.	2005
Perform 97,000 physical exams and conduct sample analyses on products with suspect histories.	FDA Foods Program	FY 03 target: 48,000; FY 03 results: 78,000.	2005

Strategic Goal 3: Increase the percentage of the Nation's children and adults who have access to health care services, and expand consumer choices

Performance Measure and FY 2005 Targets	Agency Program	Most Recent Results	PART Review
Improve satisfaction of Medicare beneficiaries with the health care services they receive (Managed Care, Fee-For-Service).	CMS Medicare	Indicators for beneficiary satisfaction: percentage reporting getting needed care; percentage reporting having access to specialist. Managed Care: FY 2002 targets: 93%; 86%. FY 2002 results: targets met. Fee-for-Service: FY 2002 targets: 95%; 85%. FY 2002 results: targets met.	2005
Increase the number of children enrolled in regular Medicaid and SCHIP. FY 2005 target: maintain FY 2004 enrollment levels. Improve health care quality across Medicaid and SCHIP.	CMS Medicaid and State Children's Health Insurance Program	FY 99 baseline: 21.9 million. FY 2002 target: additional 1 million children enrolled over FY 2001; FY 2002 results: 2.75 million more children enrolled.	2004
In FY 2005 broaden access to health care services for the uninsured and underserved by funding 332 new and expanded health center sites and increasing to 14.8 million the number of uninsured and underserved persons served by Health Centers. Continue to assure access to preventive and primary care for racial/ethnic minority individuals by serving 9.6 million racial/ethnic minority persons in 2005 (65 percent of total patients served by Health Centers).	HRSA Health Center Program	FY 03 target: 180 sites; FY 03 results: 188 sites. FY 02 target: 11.7 million; FY 02 results: 11.3 million. FY 02 target: 65% (7.6 million); FY 02 results: 64% (7.2 million).	2004
Maintain the proportion of Indian/Tribal/Urban Native American patients with diagnosed diabetes that have demonstrated improved glycemic control (blood sugar levels).	IHS IHS National Diabetes Program	FY 02 target: Improve from FY 01. FY 01 results: 29%; FY 02 results: 30%.	2004

Strategic Goal 4: Enhance the capacity and productivity of the Nation's health science research enterprise

Performance Measure and FY 2005 Targets	Agency Program	Most Recent Results	PART Review
Develop a first-pass draft haplotype map containing 600,000 SNPs.	NIH Map of Genetic Variation Across All Human Chromosomes	FY 2005-specific project milestone.	N/A

Strategic Goal 5: Improve the quality of health care services

Expand implementation of the MedSun System to a network of 250 facilities.	FDA Medical Devices and Radiological Health	FY 2003 target: 180 facilities; FY 2003 results: 206 facilities.	2004

Strategic Goal 6: Improve the economic and social well-being of individuals, families, and communities, especially those most in need

Increase percentage of those employed in a quarter that are still employed one and two quarters later. FY 2005 target: 67 percent.	ACF Temporary Assistance for Needy Families	FY 2002 target: 65%; FY 2002 results: 59%.	N/A
Increase the percentage of AoA clients who reside in rural areas to 34 percent.	AoA Community Based Services Program	FY 2002 target: 25%; FY 2002 results: 29%.	2004

Strategic Goal 7: Improve the stability and healthy development of our Nation's children and youth

Performance Measure and FY 2005 Targets	Agency Program	Most Recent Results	PART Review
Increase the Title IV-D collection rate (collections on current support/current support owed) to 61 percent.	ACF Child Support Enforcement	FY 2002 target: 55%; FY 2002 results: 58%.	2005
Increase the number of adoptions toward achieving the goal of finalizing 327,000 adoptions between FY 2003 - FY 2008. FY 2005 target: 62,000.	ACF Child Welfare	FY 2002 target: 55,000; FY 2002 results: 51,000.	2004

Strategic Goal 8: Achieve excellence in management practices

Reduce the percentage of improper payments made under the Medicare fee-for-service program.	CMS Medicare Integrity Program	FY 2003 target: 5%; FY 2003 results: 5.8%*	2004
Increase Return on Investment. FY 2005 target: $154.	Office of the Secretary Office of Inspector General	FY 2003 target: $114; FY 2003 results: $117.	2004

Strategic Goal 1: Reduce the Major Threats to the Health and Well-Being of Americans

HHS is taking steps to reduce health threats through the promotion of healthy behaviors as well as through building partnerships with States, communities, and health professionals. Reinforcing healthy behaviors in youth, from abstinence to reducing obesity, is critical. Steps to a Healthier US is a Secretarial initiative that emphasizes coordination across the Department to promote healthy behaviors and choices that will prevent and control disease, focusing in particular on asthma, diabetes, and obesity. Steps advances President Bush's Healthier US Program, which mobilizes the Federal government to alert the American people to the vital health benefits of simple and modest improvements in physical activity, nutrition, and behavioral choices such as eliminating tobacco and illegal drug use.

Prevention is also a hallmark of the HHS approach to fighting HIV/AIDS, sexually transmitted diseases, and tuberculosis. HHS is making considerable progress slowing the transmission of HIV from pregnant women to their children and preventing the spread of tuberculosis. Similarly, the HHS vaccine program protects the population from a wide variety of infectious diseases, including diphtheria, measles, polio, and influenza.

A risk behavior affecting youth and other segments of the U.S. population is substance abuse. Consistent with the Office of National Drug Control Policy's (ONDCP) overall recommendations, the FY 2005 budget request makes a fourth installment on the President's Drug Treatment Initiative, and HHS continues to work with ONDCP to implement an effective drug strategy that will increase the number of clients served.

The FY 2005 Annual Performance Plan highlights performance goals and measures within the Centers for Disease Control and Prevention's (CDC) National Immunization Program, CDC programs to prevent HIV infection, and the Substance Abuse and Mental Health Administration's Substance Abuse Prevention and Treatment Block Program. These representative performance measures demonstrate the Department's continued commitment to reducing the major threats to the health and well-being of Americans.

NATIONAL IMMUNIZATION PROGRAM

Centers for Disease Control and Prevention

FY 2005 Budget Request: $644 million

FY 2005 Full Cost Budget Request: $651 million

(Budget numbers are for the Section 317 Immunization Program and do not include VFC)

Program Background and Context

The Centers for Disease Control and Prevention (CDC) protects the health of children and adults from disability and death associated with vaccine-preventable diseases by developing and implementing immunization programs and monitoring vaccine use. The CDC National Immunization Program (NIP) focuses on several major programmatic areas, including childhood immunization, adult and adolescent immunization, global polio eradication, global measles control, and vaccine safety. NIP provides national leadership in the ongoing effort to protect America's children and adults from vaccine-preventable diseases and to ensure the safety of vaccines. Appropriate administration of safe and effective vaccines remains one of the most successful and cost-effective public health tools for preventing disease, disability, and death as well as reducing economic costs resulting from vaccine-preventable diseases.

Vaccines are responsible for the control of many infectious diseases, including diphtheria, mumps, and pertussis, that were once common in the United States. As childhood immunization coverage continues to increase, the incidence of vaccine-preventable diseases continues to decline. For example, there have been no cases of polio caused by wild polio virus in the Western Hemisphere since 1991; measles is no longer endemic in the United States; only one child was born with congenital rubella syndrome in 2002; and cases of Haemophilus influenzae type b (Hib) have dropped more than 99 percent among children younger than five years since the Hib vaccine was introduced in 1990.

Although vaccine coverage levels for children are at an all-time high, every day in the United States, 11,000 babies are born who will need up to 22 vaccinations before they are two years old to be protected against 12 vaccine-preventable diseases. Even though coverage levels for preschool immunization are high in many States, approximately one million two-year-olds in the United States have not received one or more doses of the recommended vaccines.

The Section 317 immunization grant program helps State and local health departments to ensure that children, adolescents, and adults receive appropriate immunizations by working in partnership with health providers in the public and private sectors. The program supports infrastructure for essential activities such as immunization registries, outreach, disease surveillance, outbreak control, education, and service delivery. A strong immunization infrastructure assures optimal coverage with routinely recommended vaccines. Immunization infrastructure is crucial, especially when public health priorities can shift rapidly in the event of a naturally occurring outbreak of a vaccine-preventable disease, or a bioterrorism event.

NIP works with local, State, national, and international partner organizations to develop an immunization infrastructure that includes increasing awareness of immunization recommendations, fostering the development and implementation of effective immunization programs, and achieving high immunization coverage levels. NIP has effective partnerships with organizations such as the American Academy of Pediatrics, the American Academy of Family Physicians, the Association of State and Territorial Health Officials, and managed care organizations. NIP also partners with the Centers for Medicare & Medicaid Services, the Health Resources and Services Administration, the Administration on Aging, the Agency for Healthcare Research and Quality, and other Federal agencies, as well as State and local organizations. Through these partnerships, NIP has implemented innovative and effective intervention programs and has gained the attention of other key audiences (e.g., corporate and community leaders and the media) to help achieve the mission of eliminating vaccine-preventable diseases.

NIP global immunization efforts are key to sustaining low disease rates domestically. Working with international partners, NIP has helped to reduce the number of measles cases in the Western Hemisphere by more than 99 percent from approximately 250,000 cases in 1990 to 104 cases in 2003 (provisional data). Additionally, NIP works with the World Health Organization, Rotary International, the U.S. Agency for International Development, the Task Force for Child Survival and Development, the United Nation's Children's Fund, and international agencies to bolster polio eradication efforts by providing scientific assistance and financial support. Today more than 200 countries and territories are polio-free, and the disease is now indigenous to only seven countries in South Asia and Africa.

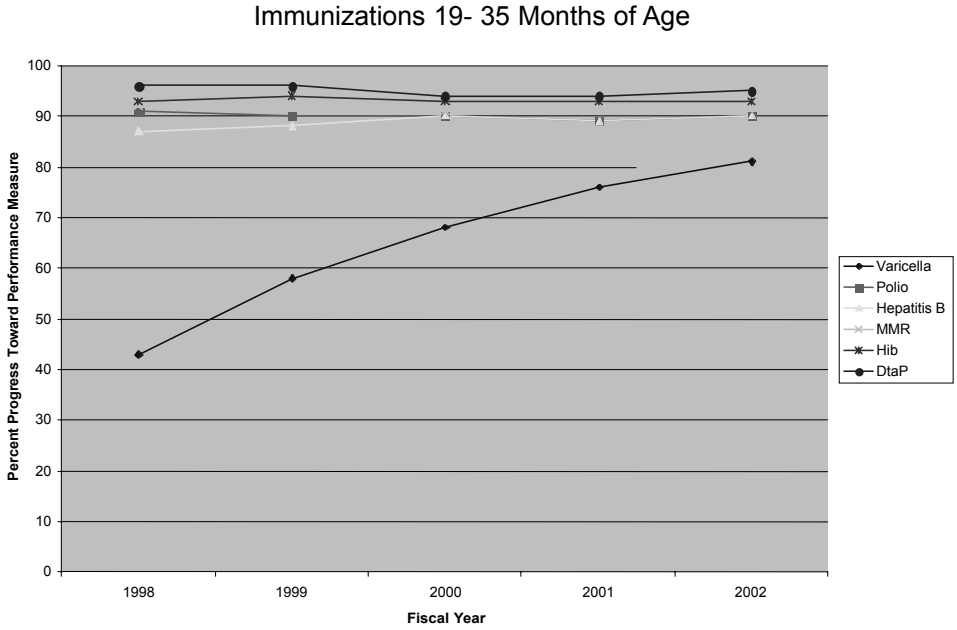
Program Performance Planning

The National Immunization Program has six goals and eleven performance measures in the Centers for Disease Control and Prevention Annual Performance Plan. The performance measures address childhood, adolescent, adult, and global immunizations. For instance, reducing the number of indigenous cases of vaccine preventable diseases is one of these goals. The measures for this goal include reducing or sustaining the number of cases of polio, rubella, measles, and Hib to zero, as well as reducing the number of indigenous cases of mumps and pertussis. Another goal is to increase the proportion of adults who are vaccinated annually against influenza and ever vaccinated against pneumococcal disease. The measures are divided by those 65 years of age and older and those who are high-risk ages (i.e., 18 to 64 years). Global polio eradication and reduction of the cumulative global measles-related mortality are also NIP goals. Because vaccine safety is vital, one NIP goal is to improve vaccine safety surveillance.

The following illustrative NIP performance measure focuses on childhood immunization.

- ✓ ***Achieve or sustain immunization coverage of at least 90 percent in children 19- to 35-months of age for 3 doses DTaP vaccine, 3 doses Hib vaccine, 1 dose MMR vaccine, 3 doses hepatitis B vaccine, 3 doses polio vaccine, 1 dose varicella vaccine, and 4 doses pneumococcal conjugate vaccine***

Vaccination coverage levels of 90 percent are, in general, sufficient to prevent circulation of viruses and bacteria causing vaccine-preventable diseases. Coverage levels are currently the highest ever recorded. However, each new cohort of children born in the United States must be fully vaccinated with all recommended vaccine doses because subgroups or pockets of under-vaccinated persons make the entire population vulnerable to major outbreaks of vaccine-preventable diseases. CDC has made progress toward fulfilling this performance measure, but must continue its work to fully achieve the goal.



Data are collected through the National Immunization Survey

Means and Strategies

NIP will work with State and local public health partners and other providers to achieve the performance measure by using grants, assessments, and technical assistance, and by setting vaccine policies.

- Vaccine Purchase Grants. Since 1963, CDC has provided grant support to assist State and local health departments in purchasing safe and effective vaccines. The Section 317 immunization grant program and the Vaccines for Children (VFC) program were instrumental

during the 2003-2004 influenza season in which an early onset of influenza outbreaks led to increased demand for the vaccine. To address these unusual circumstances, additional doses of federally procured influenza vaccine were delivered to State and local health departments to alleviate some of their reported spot shortages.

- State Operations/Infrastructure Grants. NIP provides grant support to help State and local health departments plan, develop, and conduct childhood immunization programs. These immunization infrastructure investments are crucial to maintain immunization systems and ensure that high immunization levels are not jeopardized. In recent years, efforts have been expanded to include adolescents and adults by implementing proven strategies to raise immunization coverage, and conduct disease surveillance.

Although coverage for preschool immunization is high in almost all States, pockets of need - areas with substantial numbers of under-immunized children - still exist. These areas cause great concern because of the potential for outbreaks of vaccine-preventable diseases to occur within these communities. NIP uses several strategies to improve immunization coverage in these areas. For example, Assessment, Feedback, Incentives, and Exchange (AFIX) is a tool to assess immunization coverage and provide feedback to providers-methods that have resulted in higher coverage rates. Linkages with the U.S. Department of Agriculture's Women, Infants, and Children (WIC) program have increased coverage among low-income preschool children. Reminder and recall systems (manually generated mail or telephone appointment reminders) consistently improve patient compliance for scheduled health visits. NIP also plays a critical role in developing immunization policy by providing technical and scientific support to policy-making advisory groups.

Budget and Policy Priorities

The National Immunization Program is developing several changes and improvements to its program to increase performance and improve vaccination coverage nationwide. These improvements include proposed law changes to increase access and the development of an immunization strategic stockpile to ensure a consistent supply. Legislation is being proposed to improve the VFC program by expanding access to underinsured children seeking immunization services in State and local public health clinics. Increased VFC funds to expand the pediatric vaccine stockpile (provided for 2003-2006) will provide for a six-month supply of all recommended pediatric vaccines. A fully implemented, six-month stockpile can greatly reduce the potential public health consequences associated with supply disruptions. These improvements to the VFC Program will reduce by $110 million the demand for vaccines financed through the 317 immunization program. These proposed law changes are not reflected in the budget numbers cited above; consistent with the treatment of proposed law changes in the appropriations request.

PART Review

The National Immunization Program's Section 317 Immunization grant program underwent a PART review during the FY 2004 budget process and received an "Adequate" rating. As discussed earlier, the 317 grant program gives funds to State and local health departments for vaccine purchase, program management, vaccine management, immunization registries, provider quality assurance, service delivery, consumer information, surveillance, and population assessment. The FY 2004 assessment determined that the program had strong management practices and was successful in improving vaccination coverage levels among children. Program improvements and management initiatives that will significantly advance the 317 grant program's progress toward fully implementing performance-based budgeting principles are underway. Since the initial assessment of the 317 grant program, CDC has made progress implementing the PART recommendations by:

- Undergoing an independent evaluation of program effectiveness;
- Establishing processes and procedures to measure and/or improve program efficiency; and
- Improving mechanisms that link the program's budget for State immunization program and operations activities to program performance.

External Factors

Challenges to meeting the illustrative performance measure include the difficulties of implementing effective strategies in private provider practices; the complicated schedule of vaccinations for children; shortages of vaccines; and the difficulty of acquiring accurate and complete immunization records. Vaccine safety is also a challenge that must be met to attain and sustain high immunization levels. Private providers may face financial and time constraints that limit their ability to implement provider-based strategies such as reminder/recall systems, and the assessment of immunization levels among patients in their practice. As science progresses and more vaccines become available, including combination vaccines with varying antigens, the immunization schedule becomes more complex. Before the age of two years, it is recommended that children receive up to 22 vaccinations for 12 vaccine-preventable diseases.

In the past several years, the United States has experienced shortages of many vaccines in the recommended childhood immunization schedule, as well as a recent shortage of influenza vaccine. Some of these shortages were widespread while others were localized. Reasons for these shortages were multi-factorial and included companies leaving the vaccine market, manufacturing or production problems, insufficient stockpiles, and one manufacturer-specific shortage.

Because children are often seen in multiple provider offices, and parents typically do not have complete immunization records, it can be difficult for providers to assess a child's need for specific immunizations. Also, some children are underinsured and ineligible for vaccine from other sources. Given the number of immunizations and the expense of vaccine, parents may find it difficult to assure these children are immunized at the appropriate ages. For instance, the underinsured are only eligible for the Vaccines for VFC if seen in a federally qualified health

center (FQHC). These centers are located in health professional shortage areas and may be inaccessible geographically to certain underinsured children.

Public confidence in childhood vaccines is critical in obtaining high immunization levels. Because vaccines are given to healthy people, immunizations are subject to a higher standard of safety than other medical interventions. No vaccine is 100 percent safe or effective. NIP has a multifaceted strategy for addressing immunization safety issues to maintain public confidence in immunizations, preserve high coverage levels, prevent a resurgence of vaccine-preventable diseases, and detect adverse events quickly. The National Immunization Program plays a vital role in striving for vaccine safety by monitoring harmful effects; conducting scientific research to evaluate the safety of vaccines; communicating to the public the benefits and risks of vaccines; and supporting development of new vaccine administration devices, combination vaccines, and potential candidate vaccines to prevent additional infectious diseases. Assessments of the risks and benefits of vaccines can also influence vaccine policy and recommendations.

HIV/AIDS PREVENTION IN THE U.S.

Centers for Disease Control and Prevention

FY 2005 Budget Request: $696 million

FY 2005 Full Cost Budget Request: $706 million

(Budget numbers are for the Domestic HIV Programs in the National Center for HIV, STD, and TB Prevention (NCHSTP))

Program Background and Context

Human Immunodeficiency Virus (HIV) remains a deadly infection for which there is no cure. Over 500,000 Americans have died of acquired immunodeficiency syndrome (AIDS) and an estimated 850,000 to 950,000 are currently infected with the virus. The Centers for Disease Control and Prevention (CDC) has been involved in the fight against HIV and AIDS from the earliest days of the epidemic and remains a leader in HIV/AIDS prevention and control. While HIV incidence has decreased substantially, from an estimated 150,000 new infections per year in the late 1980s, new infections remain unacceptably high at an estimated 40,000 per year. CDC is the Federal agency charged with preventing HIV infection. CDC works with an array of partners including other Federal agencies, State and local health and education departments, HIV prevention community-planning groups, academic institutions, community-based and other not-for-profit groups and the private sector. During the past decade, the HIV/AIDS epidemic has expanded into new populations, and CDC has focused its efforts on those populations that are at highest-risk.

Program Performance Planning

The overarching CDC goal in HIV is to reduce by 25 percent the number of new HIV infections in the United States, as measured by a reduction in the number of HIV infections diagnosed each year among people less than 25 years of age, from 2,100 in 2000 to approximately 1,600 in 2010. Under this goal are two measures, the first focusing on HIV infections among people less than 25 years of age and the second focusing on perinatally acquired AIDS.

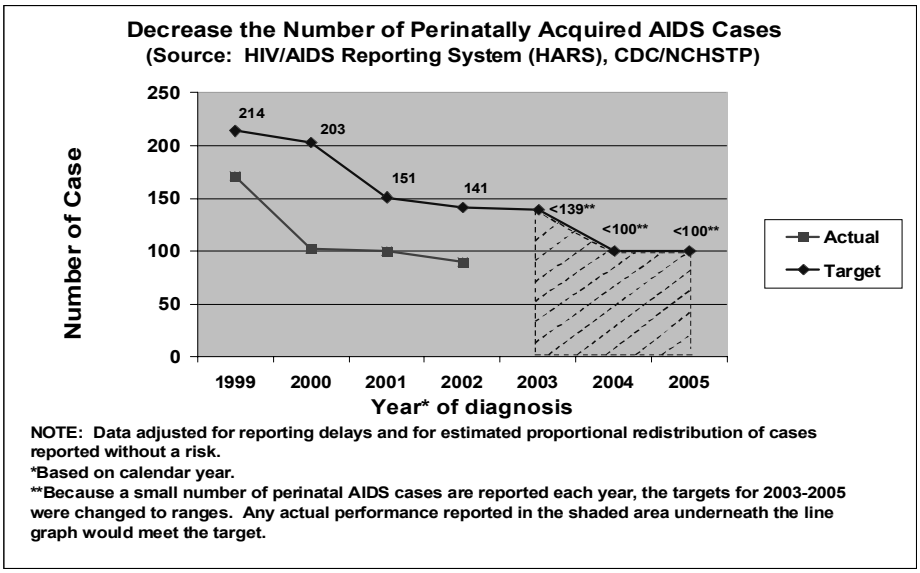
- ✓ ***Reduce the number of new HIV infections among people less than 25 years of age from 2,100 in 2000 to 1,600 in 2010.***

Historically, new AIDS cases (AIDS incidence) was the basis for assessing needs for prevention and treatment programs. However, potent new antiretroviral therapies are delaying or preventing the development of AIDS in many HIV-infected persons, and AIDS data are no longer sufficient to describe the epidemic. Data on HIV are now needed to monitor the effect of the epidemic. CDC is working with States to implement and improve HIV reporting and is studying methods to estimate HIV incidence nationally. The number of HIV infection cases among persons under 25 years of age diagnosed each year is the best data currently available to monitor new HIV infections. HIV infections occurring in those under 25 years of age are likely to have been acquired recently and thus are a relatively accurate proxy measure of HIV incidence.

Performance data regarding reported HIV infections is from 25 States with longstanding HIV reporting. CDC will add States as data become available.

The other illustrative performance measure focuses on HIV transmission from infected pregnant mothers to their infants.

✓ ***Decrease the number of perinatally acquired AIDS cases from the 1998 baseline of 235 cases.***



During the early 1990s, an estimated 1,000 to 2,000 infants were born with HIV infection each year. Surveillance data show sharply declining trends in perinatal AIDS cases, and approximately 101 cases were reported in 2001. These declines reflect the success of widespread implementation of the Public Health Service (PHS) recommendations for routine HIV counseling and voluntary HIV testing of pregnant women; the use of zidovudine (AZT, also called ZDV) by infected women during pregnancy and delivery and for treatment of the infant after birth; and the use of combination antiretroviral therapies for the pregnant woman's own care. Performance data for the perinatal AIDS measure are consistent across all 50 States, the District of Columbia, U.S. dependencies and possessions, and independent nations in free association with the United States. All of these units use a uniform surveillance case definition and case report form for reporting AIDS cases to CDC.

Means and Strategies

CDC uses a number of strategies to prevent HIV focusing on the following sub-goals outlined in its HIV Strategic Plan:

- Decrease the number of persons in the United States at high risk for acquiring or transmitting HIV infection by delivering targeted, sustained and evidence-based HIV prevention interventions.
- Increase from the proportion of HIV-infected people in the United States who know they are infected through voluntary counseling and testing.
- Increase the proportion of HIV-infected people in the United States who are linked to appropriate prevention, care, and treatment services.
- Strengthen the capacity nationwide to monitor the epidemic, develop and implement effective prevention interventions, and evaluate prevention programs.

These goals are supported through a core set of HIV prevention activities including surveillance research, intervention, capacity building, and evaluation. Priority setting for health protection activities is based on information gathered through surveillance and research. CDC funds intervention programs that seek to involve communities in HIV prevention, including community planning, coordinated through health departments, and direct funding of community-based organizations (CBOs). Underpinning these intervention programs are capacity-building efforts conducted directly by CDC and by State, local and non-governmental partners. Finally, CDC works to evaluate its programs so that the agency can monitor progress and refine its efforts. To achieve further reductions in HIV incidence in the United States, CDC announced a new HIV initiative in partnership with other HHS agencies and other government and nongovernmental organizations. The new initiative, launched on April 17, 2003, "Advancing HIV Prevention: New Strategies for a Changing Epidemic (AHP)," involves four principal strategies to further reduce HIV in the United States:

1) Making HIV testing a routine part of medical care;
2) Implementing new models for diagnosing HIV infections outside medical settings;
3) Preventing new infections by working with persons diagnosed with HIV and their partners; and
4) Further decreasing perinatal HIV transmission.

These strategies are designed to use new tools and knowledge to prevent new infections and promote the health of persons with HIV.

Budget and Policy Priorities

The President's FY 2005 budget request for Domestic HIV at the National Center for HIV, STD, and TB Prevention (NCHSTP) is $695.9 million, slightly above the FY 2004 level of $694.9 million. The entire budgeted amount supports Secretarial priorities to address HIV/AIDS as well as the overarching goal of CDC of reducing new HIV infections. Much of the budget is awarded extramurally, supporting cooperative agreements with State and local governments and

non-governmental organizations. For instance, in 2004, CDC will award a new cycle of funding in support of HIV prevention projects for State and local governments. The agency anticipates spending approximately $317 million on this program. In addition, CDC will provide $49 million to support a new, consolidated cooperative agreement program to directly fund community-based organizations and $21 million to support a consolidated program for capacity-building assistance. The agency also supports other ongoing prevention efforts, and surveillance, research and evaluation activities. This budget information only includes Domestic HIV/AIDS Programs at NCHSTP. CDC also conducts HIV/AIDS domestic prevention programs through the National Center for Infectious Disease (NCID) and the National Center for Chronic Disease Prevention and Health Promotion (NCHSTP).

PART Review

The CDC domestic HIV/AIDS program received a PART review during the FY 2004 budget process. The analysis cited deficiencies in the area of performance measurement. The assessment found that (1) the program had long-term health outcome goals, but not specific targets and timeframes that are consistent with the existing budget; (2) the program had developed new annual performance indicators but that baseline data for these measures was unavailable at the time of review; (3) budget and program performance information were not aligned; (4) no measures were in place to improve efficiency; and (5) the program had some weaknesses in the management and oversight of grantees.

Based on these findings, CDC managers implemented various actions for program direction and improvements, such as developing performance indicators with measurable goals and targets consistent with current resources; and strengthening grantee accountability and oversight in HIV prevention efforts.

In its Annual Performance Plan, CDC has revised three of its five domestic HIV/AIDS prevention goals. These goals contain ambitious targets that are measurable; include specific targets and timeframes; and are consistent with CDC current budgetary resources.

To address the PART review, CDC conducted an assessment, based on an internal stratified random sample of CBOs, to ensure that funded grantees follow proper fiscal procedures, have scientifically sound programs, and comply with Content Review Guidelines. Preliminary findings indicate that CDC needs to provide more focused technical assistance and guidance to CBO grantees. CDC is currently providing such technical assistance including issuance of new technical guidance to support the new CBO program.

CDC has also worked to achieve program and administrative efficiencies. For instance, CDC is consolidating six program announcements for the CBOs into one announcement in FY 2004. This move will have several benefits: it will lessen the amount of administrative work, simplify oversight, strengthen protocols, and standardize monitoring.

To collect better performance data from grantees, CDC has strengthened oversight procedures and put new reporting systems in place. Grantees will be held accountable for performance, and action will be taken if grantees fail to perform according to standards. Corrective action can range from providing additional technical assistance to redirecting funding. CDC is also updating its HIV/AIDS Reporting System to make it more compatible with the data surveillance reporting systems maintained at the local and State levels. With upgrades in software and hardware, the Enhanced HIV/AIDS Reporting System will allow State and local agencies to report HIV and AIDS data to the CDC more easily.

External Factors

Factors beyond CDC control may affect whether CDC is able to reach its HIV infection reduction goal and targets. For example, if an infected woman does not seek or receive care, an opportunity to prevent perinatal HIV transmission may be missed. Also, an increased number of HIV positive men and women are living longer, healthier lives because of treatment. Over time, this situation can lead to increased opportunities to transmit HIV. The changing trends in drug use, which are associated with HIV transmission, are another external factor. Those external factors pose challenges to HIV prevention. Scientists have also speculated that those persons at risk may be suffering from "prevention fatigue" and may have difficulty maintaining safer behaviors over the years.

SUBSTANCE ABUSE PREVENTION AND TREATMENT BLOCK GRANT

Substance Abuse and Mental Health Services Administration

FY 2005 Budget Request: $1,832 million

FY 2005 Full Cost Budget Request: $1,844 million

Program Background and Context

The Substance Abuse Prevention and Treatment (SAPT) Block Grant Program is an integral part of the President's Drug Treatment Initiative in providing the cornerstone of State substance abuse programs. Alcohol and drug abuse remain significant public health problems that afflict every American community. The goal of the program is to improve the health and well-being of the Nation by bringing effective alcohol and drug treatment and prevention services to every community through block grants to the States. Program effectiveness continues to be demonstrated as the Substance Abuse and Mental Health Services Administration (SAMHSA) works with the States in transforming the block grants into Performance Partnership Grants in order to maximize outcomes of publicly funded treatment and prevention services, and by exceeding performance targets. Performance Partnership Grants (PPG) will provide improved performance measurement and technical assistance for development of more effective services.

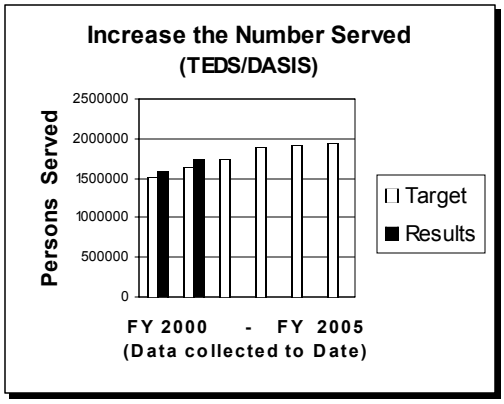
Program Performance Planning

The treatment portion of the block grant program has a total of ten measures in SAMHSA's Annual FY 2005 Performance Plan, and there are additional measures provided through the prevention 20 percent set-aside. Treatment measures include three outcome goals, one efficiency goal, two long-term goals, two process goals and two customer satisfaction goals. These measures are being replaced or merged with SAMHSA's Performance Partnership Grant (PPG) measures determined with the States that are under development. Over the next few years, SAMHSA will continue to improve the availability and use of performance data as measures are finalized and new technologies are implemented to expedite data collection, analysis and application for performance budgeting.

It is anticipated that the number of reported measures will decrease as SAMHSA moves to adopt an aggregated form of reporting. For each program area, SAMHSA is focusing on a few key measures to report and monitor performance. Performance on these key measures is used in making budget and management decisions. One such measure is:

- ✓ ***Increase the number of clients served.***

Estimating the number of clients served reflects the contribution the SAPT Block Grant make towards increasing the availability of services as part of the President's Drug Treatment Initiative.



The proxy data source for the "number of clients served" by the SAPT Block Grant is provided through the Treatment Episode Data Set of the Drug and Alcohol Services Information System (TEDS/DASIS). The data being reported represent treatment admissions data that are reported after a two-year time lag. These data are limited, in that they report admissions and may contain duplicated numbers of unique individuals who may have been admitted more than once for treatment. Also, the TEDS data reports the numbers of persons whose treatment was financed by a variety of different public and private funds, not just SAPT Block Grant resources. However, the SAPT Block Grant constitutes 40 percent of public funds available for treatment, the largest public source available, and the TEDS data provides the best current estimate of the number of persons served.

This measure is important to key SAMHSA stakeholders as it reflects progress in support of the President's Drug Treatment Initiative. Also, tracking the numbers served is a critical component of cost-benefit analysis and full cost accounting needed for performance budget integration. Future targets have been set in consideration of factors such as past performance achievement and currently available data. Analysis of targets shows that they are aggressive from FY 2000 through FY 2003 increasing at an average annual rate of 7.3 percent. The above graph shows that for 2001, the target was exceeded. An estimated 1,740,000 persons received services.

Means and Strategies

SAMHSA plans to accomplish its goals for this program through several means and strategies. These approaches flow from SAMHSA's draft strategic plan, partnership with the States, as well as the needs of the substance abuse prevention and treatment fields as evidenced by data from TEDS, the National Survey for Drug Use and Health and other SAMHSA surveys.

SAMHSA plans to:

- Continue active partnerships with the States to gather and assess performance data on the measures that SAMHSA and the States have identified for Performance Partnership Grants;

- Improve performance measure data collection, analysis and reporting technologies;

- Collaborate with the States to improve the performance of block grant funded programs through staff training in data analysis and technical assistance on evidence based practices to address identified States' needs;

- Implement a new focus on cost efficiency by setting a performance measure to monitor the percentage of States that provide drug treatment services within approved cost bands by the type of treatment provided; and,

- Begin implementing a national evaluation study.

Budget and Policy Priorities

Total funding for the Substance Abuse Prevention and Treatment Block Grant in FY 2005 is $1.83 billion, an increase of $53 million over FY 2004. The FY 2005 budget will support admissions to drug treatment programs to approximately 2 million individuals. The Block Grant is a major part of the President's Drug Treatment Initiative. Total funding in FY 2005 for the drug treatment programs is $2.3 billion.

PART Review

This program received a PART review during the FY 2005 budget process. The PART score was 43; and the rating was Ineffective. The review assessed strengths and identified a number of areas needing improvement. The main area identified as requiring improvement related to performance measures that were not finalized until late in FY 2003 as part of the PPG process. The PART also found that the SAPT Block Grant was the only Federal program supporting statewide drug prevention and treatment services in all States. States are heavily dependent upon the SAPT Block Grant funding for substance abuse services that are urgently needed.

The PART review identified the need for specific management actions. For example, in response to a PART finding, the program is expediting the posting of disaggregated State specific descriptive data on the Internet so that the data are fully accessible and transparent to the public. Also, the assessment found that SAMHSA faces continuing challenges in collecting performance data. SAMHSA proposed Performance Partnerships will address this problem over time by implementing new measures, and improving data collection, analysis and utilization. SAMHSA has developed new performance measures that will be used for making future budget decisions. SAMHSA has made significant progress with the States in determining performance measures for the SAPT Block Grant program, and States will begin reporting data in FY 2005. In addition, SAMHSA has initiated funding for a national evaluation of the Block Grant. Due to these factors, SAMHSA is requesting a 3 percent increase in the Block Grant for FY 2005.

External Factors

There are three major external factors that could have a significant impact on performance: (1) the status of the national economy and related employment figures; (2) the amount of resources States and communities allocate toward treating and preventing substance abuse and the collection of corresponding data; and (3) fluctuations in the supply of illegal drugs such as heroin and cocaine and possibly the availability of new addictive drugs and substances. The improvement or deterioration in these external factors would likely affect performance results.

Strategic Goal 2: Enhance the Ability of the Nation's Health Care System to Effectively Respond to Bioterrorism and Other Public Health Challenges

HHS has a number of initiatives and programs directed at protecting Americans from bioterrorist attacks and other public health challenges. The events of September 11, 2001, and subsequent anthrax attacks have reinforced the HHS role in protecting Americans from attacks on our health and food supply by enhancing preparedness and response capabilities.

The Office of the Assistant Secretary for Public Health Emergency Preparedness (ASPHEP) was established to direct the Department's efforts in preparing for, protecting against, responding to, and recovering from all acts of bioterrorism and other public health emergencies that could affect the civilian population. ASPHEP serves as the focal point within HHS for these activities, directing and coordinating the development and implementation of a comprehensive HHS strategy.

The Centers for Disease Control and Prevention has an integral role in strengthening State and local public health infrastructure to effectively respond to emergencies. The Health Resources and Services Administration works to prepare hospitals and other medical facilities for the health consequences of bioterrorism and other mass casualty events. The Food and Drug Administration works to provide responsive regulatory review of new biodefense medical countermeasures and plays a major role by inspecting high risk domestic food manufacturers and enhancing food import inspections to protect our Nation's food supply and prevent food borne illness.

The measures described in this section are representative of HHS progress towards building the necessary infrastructure to respond to bioterrorist and other public health challenges.

TERRORISM PREPAREDNESS AND EMERGENCY RESPONSE PROGRAM

Centers for Disease Control and Prevention/
Agency for Toxic Substances and Disease Registry
FY 2005 Budget Request: $1,110 million
FY 2005 Full Cost Budget Request: $1,114 million

Program Background and Context

In 1998, the Centers for Disease Control and Prevention/Agency for Toxic Substances and Disease Registry (CDC/ATSDR) began a program to provide technical assistance and funding to 62 State, local, and territorial public health departments to develop public health infrastructure, capacity and plans to respond to events of terror. In 2002, shortly after the September 11th and anthrax attacks, this program, with substantial supplemental funding, grew rapidly into the agency's Division of State and Local Readiness (DSLR). This program was formerly known as the State and Local Preparedness Program (SLPP). Given the national security interest in public health preparedness, the DSLR's Cooperative Agreement with the 62 health departments has grown significantly in importance and reflects the unique role of CDC within the Federal government to prepare public health to address the impact of all potential hazards that might result from natural and intentional releases of chemical, biological, radiological, and nuclear (CBRN) agents, outbreaks of infectious diseases, mass trauma events, and other public health threats and emergencies.

Since its inception, the DSLR and the cooperative agreement partners have made significant improvements in readiness and contributions towards achieving the goals and mission of the CDC Terrorism Preparedness and Emergency Response effort. Recent accomplishments demonstrate the program's success, as well as how the grantees are leveraging the direct and technical assistance coordinated by DSLR Project Officers to develop public health infrastructure, capacity, and plans to respond. One specific example is in the State of New York, where the New York Department of Health created 38 Public Health Response Teams (PHRTs) with staff from the State Health Department, 4 State Regional Offices, and the State's 57 local health departments. Staffing is based on skills and roles/responsibilities, to respond and report on cases of suspect BT agents. The PHRTs will be the primary organizational structures to engage in an epidemiological response to a bioterrorist agent.

Program Performance Planning

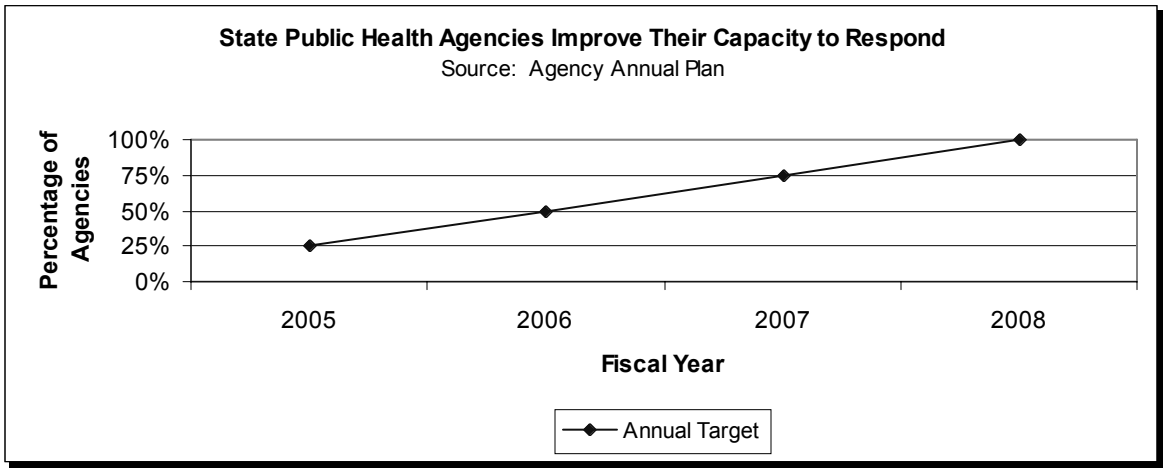
The Terrorism Preparedness and Response effort has nine goals and 12 performance measures in the CDC FY 2005 Annual Performance Plan. Several of these measures were developed during the DSLR recent Program Assessment Rating Tool (PART) review. The new measures are targeted to demonstrate more outcome-oriented results and are based on public health departments' specific abilities to (1) conduct biological laboratory proficiency testing; (2) access chemical laboratories; (3) operate under surveillance standards; (4) conduct comprehensive

response testing and exercises with the proper results; and (5) obtain certification to receive material from the Strategic National Stockpile.

One of the recently developed performance measures, illustrated below, reflects the commitment of the Division of State and Local Readiness to ensuring the cooperative agreement partners have developed complete and scalable plans, that-when exercised-demonstrate their capacity to respond to emergencies.

- ✓ ***100 percent of State public health agencies improve their capacity to respond to exposure to chemicals or category A agents by annually exercising scalable plans and implementing corrective action plans to minimize any gaps identified.***

This measure was selected because it is outcome-oriented and specifically demonstrates a partner's capacity to respond to events of terror or public health emergencies, which is a key indicator of the program's success. This is a new performance measure with ambitious targets established for FY 2005 - FY 2008.



Means and Strategies

The mission of the CDC/ATSDR terrorism preparedness and response effort is to prevent death, disability, disease and injury associated with urgent health threats by improving preparedness of the public health system, the healthcare delivery system and the public through excellence in science and services. In support of this mission, DSLR assists its cooperative agreement partners in the development of capacity across the following seven focus areas:

Preparedness Planning and Readiness Assessment;
Surveillance and Epidemiology Capacity;
Laboratory Capacity - Biologic Agents;
Laboratory Capacity - Chemical Agents;
Health Alert Network/Communications and Information Technology;
Communication of Health Risks and Health Information Dissemination; and
Education and Training.

Within each focus area, HHS has defined both critical capacities needed for baseline levels of preparedness, as well as enhanced capacities that represent more advanced levels of preparedness and response capability. Working with its project officers and subject matter experts across CDC/ATSDR, DSLR is employing several key strategies to help States achieve both the critical and enhanced capacities in each of the defined focus areas. These strategies include:

- Guidance which sets forth the focus areas, capacities, and recipient activities which each public health department should expect to undertake to achieve readiness;
- Technical project officer support to help identify solutions to barriers in preparedness efforts;
- Team and matrix management of subject matter experts from CDC/ATSDR's centers, institutes, and offices to help grantees achieve the levels of performance associated with the new measures finalized from the PART process; and
- Enhanced reporting to identify areas that challenge grantees so that appropriate assistance can be provided and leading practices and lessons learned shared to improve preparedness and planning across all 62 grantees.

Budget and Policy Priorities

In FY 2005, CDC is requesting $1.1 billion in total funding. This funding level is consistent with FY 2004, and includes programs such as State and Local Preparedness, Upgrading CDC Capacity, Anthrax Vaccine Research, and the new biosurveillance initiative, which will be a new advanced approach to infectious disease /human health surveillance. The $130 million investment in biosurveillance is a redirection of funds of $105 million in the State and local capacity budget and of $25 million in CDC capacity and anthrax research. CDC's commitment to State and local preparedness remains strong; between FY 2002 and FY 2004, CDC invested a total of $2.9 billion in this activity. In FY 2005, CDC has budgeted another $829 million. The request for CDC preparedness grants to States reflects an effort to accelerate targeted progress in preparedness. CDC is directing funds to develop surveillance data for States; in the past, States developed information piecemeal and forwarded information sometime later to CDC for national assessment.

With on-going investments in FY 2005, CDC will continue to play a critical role in strengthening the Nation's public health system in preparation for public health emergencies with respect to natural and intentional releases of CBRN agents, outbreaks of infectious diseases, mass trauma events, and other public health threats and emergencies. With FY 2005 funds, CDC will build upon these efforts by:

- Funding and providing technical assistance to States and communities to engage in comprehensive preparedness planning and response exercises;
- Improving CDC, State and local laboratory capacity to detect biological and chemical agents;
- Detecting emerging threats through an information and data collection system that uses existing national and local sources to detect and monitor and emerging infectious diseases; and
- Ensuring health information can reach all clinicians in times of crisis through a comprehensive network of satellite and other communication capacities.

PART Review

In 2003, the Centers for Disease Control Division of State and Local Readiness was selected to undergo the FY 2005 PART review process. This assessment of the program cited deficiencies in the areas of:

- Strategic planning (independent evaluations);
- Program management (accountability-federal/grantee managers-for cost, schedule and performance results; sufficient oversight of grantee activities, and annual performance data made publicly available in a transparent and meaningful way); and
- Program results (efficiency goals).

Following the PART review, DSLR developed long-term goals and measures to emphasize a greater public health impact in the preparedness and response capacity of grantees. The program established baselines and developed ambitious, annual targets, for each of the new measures. CDC awards for State and local preparedness and HRSA awards for hospital preparedness are more performance-focused. Beginning this spring, awardees will be asked to demonstrate how these major investments have led to tangible improvements in preparedness. For instance, States may be evaluated against a benchmark that their local and/or State public health agencies have mechanisms in place to enable submission of emergency reports involving biological agents 24 hours a day, seven days a week.

External Factors

External factors have a great impact on the program's control and ability to meet performance goals, of which the greatest factor is the challenge of preparing for the unknown. Challenges to the achievement of readiness across CDC/ATSDR and with cooperative agreement partners include the following:

- Preparing for the Unknown and Defining Readiness: The most significant challenge is planning to respond to the unknown. Plans developed by grantees must be developed to manage all hazards, including biological, chemical, radiological, nuclear, and mass trauma. The grantee might not have primary responsibility for all hazards, but the management of any hazard should be managed the same way in the State, triaging the activities to the appropriate governmental agency.

- Balancing Terrorism with other Public Health Priorities: Terrorism preparedness and response efforts have necessitated an unprecedented dedication of resources (financial, human, equipment, time). At the same time, CDC/ATSDR must maintain its focus upon the daily public health problems that impact millions of Americans such as obesity, heart disease and asthma.

- Working within Partners' Constraints: The ability of State and local public health departments to spend cooperative agreement funds is always subject to the budgeting regulations of their jurisdictions, overlapping and shortened State fiscal calendars in comparison to the federal fiscal year, complications in contracting, and the lag in receipt of goods and services

from contractors. In some States, such as Kansas, the State legislature must convene and vote upon how grant money will be spent, even after the Federal government has approved budgets and activities. Such regulations may create delays in the grantee's ability to expend funds within the timeframes set by Federal government regulations.

TERRORISM AND EMERGENCY RESPONSE PROGRAM

THE STRATEGIC NATIONAL STOCKPILE

Centers for Disease Control and Prevention/

FY 2005 Budget Request: $400 million

FY 2005 Full Cost Budget Request: $400 million

Program Background and Context

The Strategic National Stockpile (SNS) is a national repository of antibiotics, chemical antidotes, antitoxins, life-support medications, IV administration and airway maintenance supplies, and medical/surgical items. The SNS is designed to provide States the medicines, vaccines, and supplies to treat those affected by a bioterrorism attack, and prevent the further spread of those pathogens.

CDC has always administered the SNS and provided scientific leadership. Since March 1, 2003, the SNS has been owned and financed through the Department of Homeland Security (DHS). The FY 2005 budget reflects the Administration's plan to return the fiduciary management of the Strategic National Stockpile to HHS. Both HHS and DHS will be authorized to order deployment in an emergency. This change will align and parallel the Federal role with the roles of the State and local public health departments, the lead agencies for planning and deployment of the SNS assets. HHS has a long history of strong relationships with State and local public health officials, who rely on the scientific and clinical expertise that exists in HHS. This change will clarify for State and local officials a single Federal focal point for both strategic stockpile operations and public health emergency response.

The SNS is organized for flexible response. The first line of support lies within the immediate-response, 12-hour Push Packages. Each of the dozen 12-hour Push Packages includes pharmaceuticals, antidotes, and medical supplies. The packages are designed to provide rapid delivery of supplies in the early hours of a catastrophic event. They are strategically located in secure warehouses ready for immediate deployment to a designated site within 12 hours of the federal decision to deploy. If the incident requires additional pharmaceuticals and/or medical supplies, follow-up Vendor Managed Inventory (VMI) supplies are shipped to arrive within 24 to 36 hours. If the agent responsible for the catastrophic event is well defined, VMI can be tailored to provide pharmaceuticals, supplies and/or products specific to the suspected or confirmed agent(s). In this case, VMI could act as the first option for immediate response from the SNS.

Program Performance Planning

The SNS Program measures its performance in delivering SNS assets and technical support to the scene of a directed deployment through regular exercises and, as in September 2001, in response to actual terrorist events. The SNS Program thoroughly analyzes its performance following each of those activities, assisted by outside consultants, and continues to take actions that will strengthen its response. The program measures performance in State-level preparedness

by monitoring the development of SNS Preparedness functions believed necessary to effectively manage and use deployed SNS assets. Currently there are 12 SNS Preparedness functions. Progress toward function development, as well as overall impact on the ability of the State to perform in an SNS deployment, is carefully measured on an ongoing basis. Following is a key performance measure of the SNS Program:

- ✓ ***100 percent of State public health agencies are prepared to use material contained in the Strategic National Stockpile as demonstrated by the evaluation of standard functions as determined by CDC.***

Means and Strategies

The SNS Preparedness Program Plans have 12 critical functions that must be addressed to effectively use SNS assets. CDC describes these functions in a comprehensive planning guide and video which are available to grantees. To enhance SNS Preparedness Program planning efforts, the SNS Program maintains a staff of Program Services Consultants who provide ongoing technical advice and assistance to all 62 states and large cities that receive CDC BioTerrorism grants and provide the following services:

- ·Annual technical review of applications for funding with feedback and recommendations
- ·Annual site visits and assessments of SNS preparedness
- ·Evaluations of new facilities designated to receive SNS material
- ·Quarterly training courses
- ·Exercise support as requested by the Project Area

Budget and Policy Priorities

In order to clarify for State and local officials a single Federal focal point for both strategic stockpile operations and public health emergency response, the SNS appropriation will be returned to the Department of Health and Human Services, and administration will remain at the CDC. This change will align and parallel the Federal role with the roles of the State and local public health departments, the lead agencies for planning and deployment of the SNS assets. HHS has a long history of strong relationships with State and local public health officials, who rely on the scientific and clinical expertise that exists in HHS. HHS is requesting $400 million for the Strategic National Stockpile for FY 2005, this is an increase of $2.4 million over FY 2004.

External Factors

The following factors external to the SNS Program affect or have affected the program:

- State budget decisions may affect progress toward SNS Preparedness Program development in a number of project areas;

- Preparedness efforts in 2002-2003 focused heavily on planning and preparation for smallpox vaccination campaigns. Preparedness for the use of other SNS assets is not as far along.

Several vital SNS-approved pharmaceuticals are only available from a single domestic manufacturer. When that manufacturer experiences production or quality problems the product can suddenly be in short supply or unavailable.

BIOTERRORISM HOSPITAL PREPAREDNESS PROGRAM

Health Resources and Services Administration

FY 2005 Budget Request: $476 million

FY 2005 Full Cost Budget Request: $476 million

Program Background and Context

The Bioterrorism Hospital Preparedness Program, which is part of the President's Homeland Security Initiative, has the goal of readying hospitals and supporting health care systems to deliver coordinated and effective care to victims of terrorism and other public health emergencies. The program is designed to enable State and regional planning among local hospitals, emergency medical services systems, health centers, poison control centers, and other health care facilities to improve their preparedness to work together to combat terrorist attacks and deal with infectious disease epidemics and other public health emergencies. Through coordination efforts on both the State and Federal levels, the hospital preparedness plans have also been linked with State and local public health preparedness planning funded by the Centers for Disease Control and Prevention, and, where applicable, the Metropolitan Medical Response Systems funded by the Department of Homeland Security.

This program was newly established and funded in FY 2002. A major accomplishment was the successful and expedient award of funding to 59 eligible entities in this first year in response to the national emergency heralded by the anthrax attacks in late 2001. These funds enabled awardees to set up hospital preparedness offices with bioterrorism coordinators and medical advisors, begin their needs assessments of hospital preparedness and begin development of regional preparedness plans. In FY 2003, 62 awards were made to assist awardees to further develop and implement regional preparedness plans. The program has also awarded a contract to establish a national resource center for bioterrorism hospital preparedness. This resource center will serve as a central repository of information, tools, best practices, and technical assistance available to awardees as they implement their work plans.

Communication is a key factor in preparedness. Data from progress reports indicate that all jurisdictions are putting in place mechanisms that address gaps in the communications systems among hospital emergency departments, outpatient facilities, EMS systems and State and local emergency management, public health and law enforcement agencies, and poison control centers. Preliminary data from a recent hospital preparedness survey indicate that 95 percent of the hospitals surveyed had a mechanism in place for rapid receipt and posting of public health alerts.

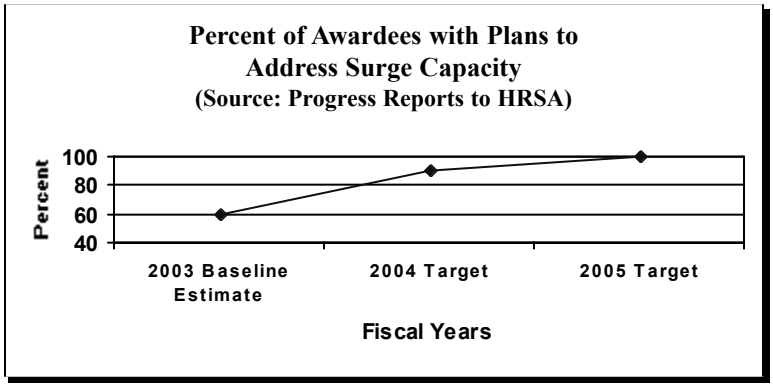
Program Performance Planning

The Bioterrorism Hospital Preparedness Program has five performance goals for FY 2005 that are represented by performance measures covering the following areas: planning and implementation of plans for regional preparedness to address surge capacity due to a terrorist attack or other public health emergency; ability to secure and distribute pharmaceutical resources

required in such emergency events; assessment, acquisition and provision of training related to chemical and radiological response equipment; and demonstration of ability to evaluate, diagnose, and treat adult and pediatric patients in a catastrophic public health emergency. Four of the program's five measures were developed during the FY 2005 PART review process. Data on performance will be obtained from awardees' progress reports, reports of annual drills, and evaluation reports. Information will be validated through site visits and other monitoring and certification procedures by HRSA. HRSA continues to develop and refine measures to determine program success through the PART review process and other evaluation activities. This process will continue over the next year as HRSA integrates its performance and budget processes.

One key performance measure for this program is:

- ✓ ***Increase the percent of awardees that have developed plans to address surge capacity to 100% by FY 2005.***



A terrorist attack or other large-scale emergency could result in a demand for health care that could rapidly overwhelm the resources in a specific region. Surge capacity is the ability to accommodate a large and rapid increase in the number of persons requiring care. It is a major issue for hospitals across the Nation, and is a key to preparedness for biological, chemical, radiological, or explosive incidents, as well as other public health emergencies such as epidemics of infectious diseases or related disorders. The requirement to develop plans to address surge capacity to deal with potential terrorist and other threats is based on the concept that improved outcomes can be achieved when critical components of preparedness are formalized in a plan and organized into a system of care.

With regard to surge capacity, program grantees will address the following issues: (1) hospital bed capacity for both adults and children, (2) capacity for isolation and referral of patients with communicable infections, (3) appropriate staffing, (4) antibiotic and vaccine treatment of adult and pediatric biological exposures, (5) antidote and prophylactic treatment for chemical and radiological exposures, (6) personal protective equipment, (7) capacity for trauma and burn care, (8) capacity for mental health care, (9) communications and information technology, and (10) capacity for mass mortuary activities.

The baseline estimate, developed from awardees' progress reports, is that 59 percent of awardees had developed plans in FY 2003 for a potential epidemic involving at least 500 patients per million population in their jurisdictions. The target for FY 2005 is that 100 percent of awardees will have developed surge capacity plans.

Means and Strategies

In FY 2003, cooperative agreements were made with 62 entities, including 50 States, the District of Columbia, Puerto Rico, three municipalities (New York City, Chicago and Los Angeles County), the Commonwealth of the Northern Mariana Islands, the territories of the Virgin Islands, Guam and American Samoa, the Federated States of Micronesia, and the Republics of Palau and the Marshall Islands. During the first year of the program (FY 2002), the major emphasis in awardees' plans was assessing needs. The program's focus is now on helping awardees to implement their plans to improve surge capacity based on identified needs.

Coordination among hospitals and related service providers and the enhancement of infrastructures are important strategies to enable the health system to mount a collective response with a seamless interaction of various capabilities. Coordination activities also include coordination with the CDC Bioterrorism program in such areas as the development of a statewide incident management system. Other means and strategies include the requirement that awardees address the education and training of health care professionals involved in terrorism response and conduct terrorism preparedness exercises and drills to test the preparedness systems that are developed.

Budget and Policy Priorities

The budget request for FY 2005 is $475.9 million, which includes administrative expenses. Thus, the FY 2005 full cost estimate is also $475.9 million. The budget request is $39 million below FY 2004. Between FY 2002 and FY 2004, a total of $1.2 billion has been made available for these efforts in States, Territories, and certain municipalities. This program continues to be funded in the Public Health and Social Services Emergency Fund, with funds transferred to HRSA.

Prior to this program, there was little public expenditure on hospital and associated health system planning and infrastructure enhancements for responding to mass casualty biological, chemical, radiological, and explosive incidents. Few, if any, hospitals were equipped to handle such events. The FY 2005 budget for the Bioterrorism Hospital Preparedness Program will help to ensure the provision of medical and public health services if these events occur. The requested funds will allow the program to build upon the needs assessments and implementation plans developed by awardees during FY 2003 and FY 2004. HRSA will continue to review regional hospital and public health system preparedness plans and their associated renovation and equipment expenditures, and will monitor progress to ensure that funds are used appropriately and that goals are met.

PART Review

A PART review of the Bioterrorism Hospital Preparedness Program was conducted for the FY 2005 budget. The program was given a rating of Results Not Demonstrated. The assessment found that the purpose and importance of this effort are clear and that the effort is well coordinated with other Federal preparedness efforts. The review also noted that the program has not yet demonstrated results due to its relative newness and the inherent difficulty in measuring preparedness against an event that does not regularly occur. This program, which was only 18 months old at the time of the review, has made significant progress in a very short time.

One concern identified by the assessment is that the distribution formula may not be optimal because it does not consider varying threat levels or states of preparedness. HHS is developing a plan to review the formula and will consider whether the current formula could be improved by including indicators such as level of risk or preparedness. Issues related to evaluation and dissemination of performance information will continue to be addressed as the program moves forward. The PART scores for program purpose, planning and management, and the recognition that the program is too new to adequately assess results warrant the funding investment requested in the FY 2005 budget.

External Factors

There are a variety of factors that make it complicated to develop surge capacity at the regional level. Among the most significant of these are the following:

- It may be relatively easy for an individual hospital to develop surge capacity, but it becomes much more difficult when this is done on a regional basis. Hospitals need to be identified as to their strengths and weaknesses, and the regional system built on that assessment. There will need to be an effort to avoid duplication. Not every hospital needs every capability.

- There is a need to link the hospital system to the public health infrastructure. These two communities have not always had a close pattern of communications and cooperation. In the event of an attack, the health care system will have to be able to mount a collective response with seamless interaction between the State and local health departments, hospitals and other health care entities.

- Even though it may be possible to supplement the number of hospital beds, one of the most difficult issues is identifying staff that can provide appropriate services. There are issues of credentialing, licensure and the general availability of additional staff.

- The needs for surge capacity may be quite different in a situation involving infectious diseases (e.g., need for isolation beds) vs. a situation involving a mass trauma event. Planning for surge capacity requires planning for a variety of scenarios.

FOODS PROGRAM

Food and Drug Administration

FY 2005 Budget Request: $470 million

FY 2005 Full Cost Budget Budget Request: $571 million

Program Background and Context

The Food and Drug Administration's (FDA) Foods Program is responsible for ensuring a safe, nutritious, wholesome, and honestly labeled food supply for the American public. As one facet of upholding this responsibility, the Foods program operates an import inspection and enforcement program through the Office of Regulatory Affairs (ORA) that is responsible for ensuring the safety of food products that are imported into the United States.

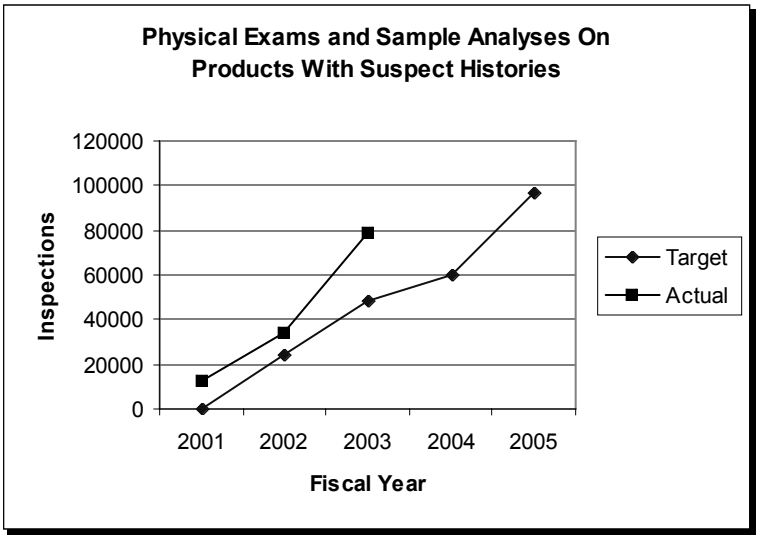
Imports of all FDA-regulated products have been increasing over the last several years. By the end of 2005, it is expected that approximately 10.7 million import line entries will be received. In FY 2001 alone, there were over 70 line entries of items including food products that have been implicated in prior disease outbreaks; food products that could pose a health threat if not processed and handled properly. While FDA used risk-based criteria to identify which import lines among millions should be examined or sampled, it also relied heavily on the inspectors' intuitive judgment. The lessons learned by many import inspectors are lost to the Agency because the import systems do not track the results of decisions in relation to the product implicated. Consequently, when an importer or exporter shifts business from one U.S. port to another, the Agency often must re-learn the lessons learned in the previous port of entry. The Agency's existing systems are unable to receive data that relates to the chain of supply or distribution and shipping data of FDA imports. These weaknesses make it difficult to implement recent amendments to FDA import inspection authority and to facilitate the importation of products that comply with FDA law and regulations.

Although FDA has increased the number of field examinations of food imports from approximately 34,000 to over 78,000 over the last two fiscal years, the actual percentage of examined foods compared to food imports only slightly increased due to the rates of increase of FDA regulated imports. These inspections must be better targeted toward the greatest risk, which requires information system integration and risk-based screening enhancements, to enable the Agency to manage the volume of imported products.

Program Performance Planning

While the Import program at FDA is extensive, this particular goal has only one performance measure. This performance measure is designed to maximize imported product coverage through risk-based targeted inspections. Data collected from the Field Data Systems enable the Agency to determine if targets for the program are being met. The performance measure is listed below:

✓ ***Perform 97,000 physical exams and conduct sample analyses on products with suspect histories.***



Note: No target was set for FY 2001

In FY 2005, FDA will focus much of its resources on examination and follow-up on import shipments that pose the highest potential risks to the U.S. consumer and market. By FY 2004 and FY 2005, FDA expects that the new personnel brought on board in FY 2002 and FY 2003 will have achieved the training and experience necessary to perform tasks consistent with FDA's Import Strategic plan and domestic inspection responsibilities. Thus levels for food import field examinations are targeted at 97,000.

This target is ambitious because beginning in FY 2004 FDA will be developing a more robust physical examination approach that merges the assessment of information integrity with the safety and security of the product. By FY 2005, FDA will have in place a new version of the import field exam. The new exam will routinely include: verification that the imported product is the same as that which was declared; assessment of security concerns related to labeling and source country; and traditional safety concerns. More importantly, these new exams will be conducted on import entries selected using a more rigorous risk assessment and management rubric.

Means and Strategies

Given the continuing explosion in number of import shipments, FDA cannot keep pace with the increasing volume by simply expanding the number of physical examinations. Rather, a significant effort will be launched to develop the appropriate knowledge-based approaches that will assure that FDA is, in fact, addressing the most serious risks. Some strategies for improvement include:

- Filer Evaluation Field Audits: The import filer transmits the required shipment-specific FDA data into the Automated Commercial System, a U.S. Customs comprehensive tracking system used for law enforcement. Within several minutes, the filer receives notification that either their shipment has been released or FDA wishes to review it. This system provides FDA with immediate data on imported products, provides information on potential problems, and maintains national historical data files to develop profiles on specific products, shippers, and manufacturers. Eventually all filers processing entries through Customs' ACS will provide FDA information electronically. Periodically the Operational and Administrative System for Import Support, or OASIS, selects a filer to audit, to ensure the accuracy of the transmitted information. These audits of submitted data are done on a periodic basis depending on the number of entries, quality of the data and other factors;

- Implementation of program with Canada and Mexico to enhance advanced identification of transshipped cargo. This program will give advance notification of cargo which will be transported through the United States, but will not be sold in the United States; and

- Expanding in-bond entry evaluation including performing examinations of in-bond entries at port of arrival and port of entry or export.

The Import Physical Exam goal enhances and improves risk-based targeting of FDA import inspection and enforcement activities toward imported articles that pose the greatest risk to public health, safety and security, and reducing regulatory burdens on importers who have consistently demonstrated an ability to assess, mitigate, and manage such risks.

Budget and Policy Priorities

Total funding for the FDA Foods program in FY 2005 is $470.4 million, an increase of $59.7 million over FY 2004. In FY 2004, FDA will develop a more robust import physical examination approach that merges the assessment of information integrity with the safety and security of the product. With the FY 2005 increase, FDA will implement a new version of the import field exam. The new exam will routinely include: verification that the imported product is the same as that which was declared; assessment of security concerns related to labeling and source country; and traditional safety concerns. More importantly, these new exams will be conducted on import entries selected using a more rigorous risk assessment and management rubric. The full cost of operating the imports program is $571.0 million in FY 2005 and $504.2 million in FY 2004. The FDA imports program supports the Department's strategic goal of Enhancing the ability of the Nation's health care system to effectively respond to bioterrorism and other public health challenges by protecting our Nation's food supply from potential terrorist attacks and threats.

PART Review

The FY 2004 PART shaped FDA FY 2005 planning and budgeting processes by focusing on improving program performance and accountability, and by identifying potential outcome goals and funding strategies. The development of the long-term outcome goals continued during the strategic planning process and culminated with several goals presented during the FY 2005 PART review and incorporated into the initial budget submission to HHS.

The FY 2004 PART noted insufficient Office of Regulatory Affairs effort in a few areas, including foods and medical devices. FDA has taken steps toward improvement and has used PART ratings to strengthen its budget decisions.

The risk of imported products has long been a concern of FDA given the continuing explosion in the number of import shipments to this country. It is also an important part of the Agency's efforts to support the President and Secretary's goal of reducing the terrorist threat to the American public. The FY 2005 President's Budget reflects the increasing priority of this goal, and FDA has taken action by increasing the number of physical exams from 12,000 in FY 2001 to the target of 97,000 in FY 2005.

External Factors

FDA is monitoring regulated products in an environment that has become significantly more complex over the past several years. Contributing to this change are the growth in international trade leading to a tripling of imports during the past 10 years; much more technologically complex and diverse products both domestically and internationally; and increasing use of the internet by industry to develop, distribute and market their products.

Strategic Goal 3: Increase the Percentage of the Nation's Children and Adults Who Have Access to Health Care Services, and Expand Consumer Choices

Disparities in health care and health status within the U.S. population are of great concern to HHS. The Department is working to expand health care to all. In response to the need for a subsidized prescription drug benefit, and better insurance protection, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act (MMA). The Act phases in the prescription drug benefit in FY 2004. The full benefit begins in FY 2006. HHS also seeks to improve satisfaction among Medicare beneficiaries, increase the number of children enrolled in the State Children's Health Insurance Program (SCHIP) and Medicaid, and expand the health care safety net. The FY 2005 budget request will continue to expand access to critical health care services for the uninsured, especially in underserved rural and urban areas.

HHS is committed to raising awareness among minority communities about major health risks prevalent in their specific populations and providing access to information on how to reduce these risks. This commitment also includes efforts to promote cultural competence among practitioners, thereby reducing communication barriers between health care providers and their patients. HHS will continue to conduct and support research to find underlying causes of racial and ethnic health disparities and develop and disseminate effective strategies to reduce them.

HHS will expand access to health care services for targeted populations with special health care needs. HHS will continue targeted efforts to promote organ donation, disseminate Ryan White CARE Act resources to underserved communities and uninsured people, support the development of additional mental health services, and provide outreach to children with special health care needs.

The measures under this goal are indicative of continuing strides HHS is making towards increasing access to health care. Programs included for measurement are the Medicare, Medicaid and SCHIP programs, the Health Center Program, and the Indian Health Service National Diabetes Program.

MEDICARE

Centers For Medicare & Medicaid Services

FY 2005 Budget Request: *$324,597 million*

FY 2005 Full Cost Budget Request: *$330,805 million*

Program Background and Context

Medicare was enacted in 1965 to extend affordable health insurance coverage to the Nation's most vulnerable population, the elderly. In 1972, Medicare was expanded to cover the disabled. The Centers for Medicare and Medicaid Services (CMS) administers Medicare, the Nation's largest health insurance program, which covers more than 41 million Americans. For nearly four decades this program has helped pay medical bills for millions of Americans, providing them with comprehensive health benefits.

The CMS mission is to "assure health care security" for its program beneficiaries. Medicare provides health insurance coverage to the elderly and disabled, ensuring access to the same high quality health care services as the under-65 population. The elderly have health care costs four times that of the under 65 population. The disabled have high total health care expenditures similar to the aged population. Medicare provides a significant public subsidy to finance these health care costs. In the absence of the Medicare program, the elderly and disabled generally do not have sufficient resources to pay for health care.

In early FY 2004, the President signed into law the MMA, that provides enhanced coverage for the lowest income beneficiaries and an immediate prescription drug discount card for all beneficiaries until the full plan is available nationwide. Beginning in 2006, Medicare beneficiaries will have access to a standard Medicare drug benefit. Additionally, the proposal includes savings for many State governments; increased coverage for preventive services; and provisions for modernizing the drug delivery infrastructure, as well as increased flexibility in the administration of Medicare.

Program Performance Planning

The majority of the performance goals in the FY 2005 Annual Performance Plan (APP) represent vast purview of Medicare. The APP has evolved with the enactment of the new Medicare legislation. As a result, CMS has added three new annual performance goals addressing the prescription discount card, the Medicare prescription drug program, and Medicare contracting reform.

With the enactment of the MMA, Medicare will give all Medicare beneficiaries' access to prescription drug coverage and the collective buying power to reduce the amount they currently pay for drugs. The Act provides enhanced coverage for the lowest income beneficiaries and an immediate prescription drug discount card for all people with Medicare. The new prescription drug card goal will monitor the progress of implementation by tracking questions coming into

the 1-800-MEDICARE call center. Based on information received, CMS will modify the print materials and the website as needed.

Beginning in 2006, Medicare beneficiaries will have access to a standard prescription drug benefit. Although drug plan sponsors may change some of the formulary specifications, the benefit offered by each plan must at least be equal in value to the standard benefit. People with limited savings and low income will receive a more generous benefit package. Data collection will begin in 2006 to monitor the effectiveness of the implementation phase.

"Assuring health care security" covers a wide array of activities beginning with paying claims for Medicare-covered beneficiary services. Medicare has three components: Hospital Insurance, Supplementary Medical Insurance, and Medicare Advantage. Medicare processes over one billion fee-for-service claims each year, is the Nation's largest purchaser of health care, and accounts for more than 11 percent of the Federal budget. The claims payment activity is supported by the CMS Medicare Operations budget, which funds its contractors (carriers and fiscal intermediaries) and the information technology needed for claims processing.

One CMS goal is to demonstrate the fiscal integrity of its programs and to be an accountable steward of public funds. CMS demonstrates this ongoing commitment through its Medicare Integrity Program, which helps ensure that Medicare claims are paid properly the first time. These efforts are represented separately under *Strategic Goal 8: Achieve Excellence in Management Practices*, featured later in this volume.

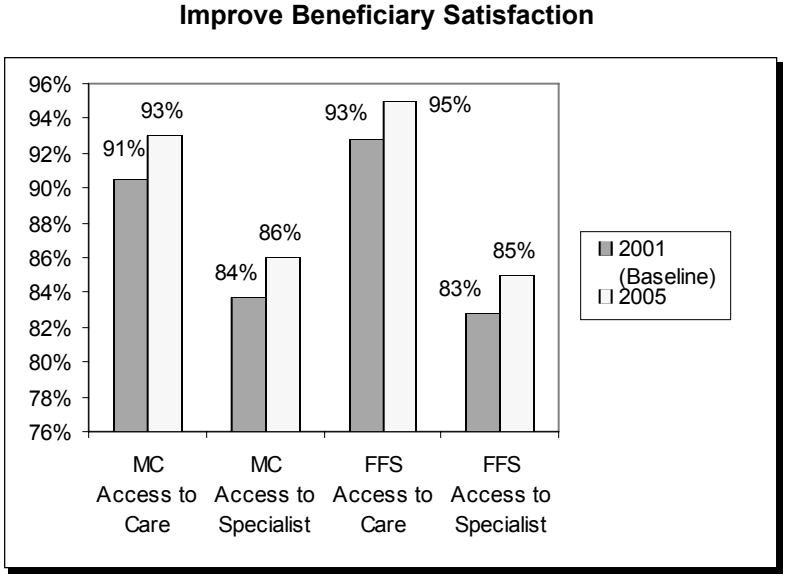
Section 911 of the MMA establishes the Medicare FFS Contracting Reform Initiative (MCRI) that will be implemented over the next several years. Under this provision, CMS will replace the current Medicare fiscal intermediaries and carrier contracts, using competitive procedures, with new Medicare Administrative Contractor (MAC) contracts by October 2011. In accordance with the new legislation, CMS plans to transition 100 percent of the FFS claims workload to the new MACs over the course of FY 2006 through FY 2011. The new contracting reform measure will monitor the progress of CMS efforts, including the development of a timeline and funding strategy for all of the activities.

Through the Quality Improvement Organizations and other State and local partners, CMS collaborates with health care providers and suppliers to promote improved health status, including quality improvement in nursing homes. In addition, through the Survey and Certification program, CMS meets its responsibilities for assuring the safety and quality of medical facilities, laboratories, providers, and suppliers by setting standards, conducting inspections, certifying providers as eligible for program payments, and ensuring that corrective actions are taken where deficiencies are found.

CMS administers comprehensive outreach and education programs to keep beneficiaries informed and aware of the benefits and choices available to them. Through regular and continuous national surveys, CMS continuously seeks to ensure that Medicare beneficiaries are aware of the program and their options, and are satisfied with the care they receive as well.

One ultimate goal of CMS is to assure satisfaction of its primary customer—the Medicare beneficiary. CMS currently measures satisfaction using beneficiary responses to questions regarding access to care and specialists in both fee-for-service (FFS) and managed care (MC). This performance measure is used to improve the already high satisfaction rate beneficiaries have with the Medicare program.

✓ ***Improve Satisfaction of Medicare Beneficiaries with the health care services they receive (managed care, fee-for-service)***



CMS considers survey data on beneficiary access to care and access to a specialist to be valid measures of satisfaction. Our targets are set for a five-year period so that the percentage increases are large enough to be statistically meaningful.

Means and Strategies

CMS will pursue accomplishment of this measure through a combination of the following means and strategies:

- Collecting and sharing annual data from the Consumer Assessment of Health Plans Survey (CAHPS) with health plans and Quality Improvement Organizations for use in better management of health plans.

- Sharing the CAHPS data with Medicare beneficiaries through various means, including the National Medicare & You Education Program.

- Ensuring strategies are in place for CMS to remain a responsive and dynamic Agency that serves the American public. There will also be focused attention on citizen-centered governance in FY 2005 and beyond.

- Emphasizing citizen-centered governance by identifying significant processes and services, expanding resources in a way that enhances service to the public, being accountable stewards of Agency resources, and monitoring and evaluating effectiveness.

- Communicating, collaborating, and cooperating with key customers, both public and private, to help achieve the desired outcomes.

Budget and Policy Priorities

In FY 2005, CMS requests a current law program level totaling $2.8 billion for program management, a 4.1 percent increase over FY 2004. CMS is also proposing two user fees that would provide $205 million in additional offsetting collections. If enacted, these fees will offset the CMS appropriation request by $205 million. Net of proposed and current law user fee collections, the CMS FY 2005 discretionary appropriation request totals $2.5 billion for Medicare Operations, Federal Administration, Medicare Survey and Certification, Research, Demonstrations and Evaluation, and the CMS Revitalization Plan.

CMS FY 2005 budget priorities include:
- Implementing the MMA;
- Educating consumers;
- Reducing the burden on our partners and focusing on poor performers;
- Strategic management of human capital; and
- Improving financial performance.

PART Review

During the FY 2005 PART process, the Medicare program was assessed by OMB and received a score of 74 and a rating of "Moderately Effective." In general, the PART results indicated that CMS has set comprehensive long-term performance goals that reflect the Medicare program's mission across several dimensions including critical care and program efficiency, with ambitious timeframes for meeting these goals. However, OMB indicated that features of the Medicare program reflect its outdated statutory design. OMB commented that the program contained some deficiencies with respect to program and financial management. With enactment of the new MMA in 2003, many of these issues have been addressed. CMS has added three new annual performance goals addressing the prescription discount card, the Medicare prescription drug program, and contracting reform.

External Factors

A significant challenge for CMS is the availability of timely performance data to inform decisions. CMS uses many data systems to measure its performance. Relying on administrative, third-party, and survey data presents certain difficulties. For example, there are inherent time lags between actual data submission, data compilation, and dates for performance reporting. For some data sources (e.g. surveys) there may be a one to two year delay before data are

compiled and analyzed for release. This is especially true of health outcome goals, where data are not available in "real time." In these cases, performance-based decision-making is a challenge.

Prior to the enactment of the MMA, Medicare was criticized as outdated and in need of reform. The major provisions of the new law will include a prescription drug benefit, an interim prescription drug discount card, regulatory reform, contracting reform, the establishment of the Medicare Advantage program and a significant amount of beneficiary and provider education. CMS will be challenged over the next several years to establish regulations, empower stakeholders (providers and contractors), educate health care beneficiaries/consumers, and implement the many provisions included in this new law.

MEDICAID AND STATE CHILDREN'S HEALTH INSURANCE PROGRAM

Centers For Medicare & Medicaid Services

FY 2005 Medicaid Budget Request: *$183,197 million*

FY 2005 Medicaid Full Cost Budget Request: *$183,214 million*

FY 2005 SCHIP Budget Request: *$4,082 million*

FY 2005 SCHIP Full Cost Budget Request: *$4,267 million*

Program Background and Context

Medicaid is a means-tested health car program for low-income Americans, administered by CMS in partnership with the States. It is the primary source of health care for a large population of medically vulnerable Americans, including poor families, people with disabilities, and people with long-term care needs. In coordination with the Medicaid Program, the State Children's Health Insurance Program (SCHIP) has stimulated enormous change in the availability of health care coverage for children.

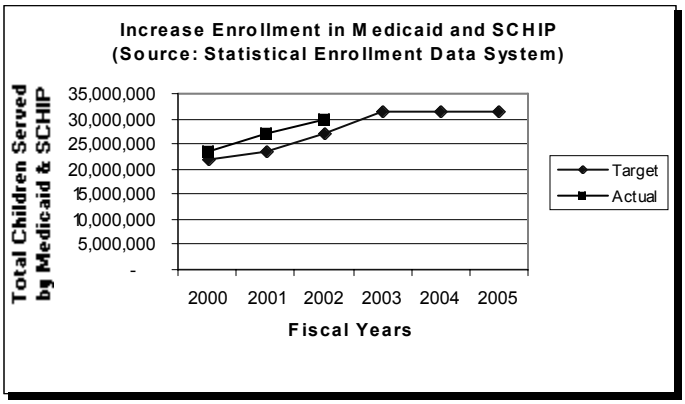
The Balanced Budget Act of 1997 created the State Children's Health Insurance Program under title XXI of the Social Security Act. This program is the largest single expansion of health insurance coverage for children in more than 30 years and improves the access to health care and quality of life for millions of vulnerable children under 19 years of age. Under title XXI, States were given the option to expand Medicaid (title XIX) coverage, set up a separate SCHIP program, or have a combination of both a Medicaid expansion and a separate SCHIP program.

As of September 1999, all States, territories, and the District of Columbia have approved SCHIP plans. CMS continues to review the States' SCHIP plan amendments as the States respond to the challenges of implementing this program. CMS is working with the States to simplify enrollment procedures and to improve outreach activities.

Program Performance Planning

CMS has developed four performance measures related to Medicaid and SCHIP. With respect to SCHIP, in 1997, CMS set the goal of enrolling five million children by FY 2005. To quantify this objective, CMS set annual targets for FY 2000 through FY 2002 to enroll at least one million new children in SCHIP and Medicaid per year. CMS changed the target for FY 2003 to increase enrollment by five percent over the previous year. This change was made because CMS exceeded the annual targets for FY 2000 - FY 2002 and because States were facing fiscal challenges that may have affected program outreach and enrollment. Current economic conditions have made it difficult for the SCHIP program to achieve its enrollment targets. Therefore, CMS is revising its enrollment targets for FY 2004 and FY 2005 to maintain enrollment of children in SCHIP and Medicaid at the previous year's levels. CMS remains confident that the programs' long-term goals and performance targets for FY 2005 will be met. An example of the Medicaid and SCHIP measures is listed below:

✓ ***Increase the number of children enrolled in regular Medicaid and SCHIP***



Means and Strategies

To assure that both Medicaid and SCHIP fulfill their potential, CMS has worked with States, other operating divisions of HHS, other Federal Government agencies and the private sector on a broad array of outreach activities. These activities include providing technical assistance to States, providing new resources to States to help them improve their programs, and promoting the exchange of information among States, community-based organizations, advocacy groups, Government grantees, and private sector groups.

SCHIP has allowed States more flexibility to tailor their children's health insurance programs to individual States' needs under Medicaid. For example:

- Medicaid enrollment has increased, and correspondingly the number of uninsured children has decreased since the inception of SCHIP.

- States are making progress in enrolling more children into Medicaid and SCHIP through better outreach and enrollment simplification efforts.

For SCHIP, the appropriated allotment for FY 2005 is $4.1 billion, an increase of approximately $900 million over the FY 2004 allotment.

Budget and Policy Priorities

Under current law, the estimated Federal share of Medicaid gross obligations is equal to $183.2 billion in FY 2005. These obligations are composed of $172.7 billion for Medicaid benefits, $9.4 billion for Medicaid administrative costs, and $1.2 billion for the Centers for Disease Control Vaccines for Children program.

For FY 2005, the statute authorizes and appropriates $4.1 billion for SCHIP allotments to States, territories, commonwealths, and the District of Columbia. Also in FY 2005, the Balanced Budget Refinement Act of 1999 (BBRA) authorizes and appropriates an additional $32.4 million for SCHIP allotments to commonwealths and territories. The total funds available for CMS to grant to States, commonwealths, and territories for the State Children's Health Insurance Program in FY 2005 will be $4.1 billion. In addition, if any funding from the FY 2002 allotment is not expended by the end of FY 2004, it will become available for redistribution in FY 2005. Also, P.L. 108-74 extended the availability of the SCHIP redistribution funding from the FY 1998, FY 1999 and FY 2000 allotments through the end of FY 2004. It also extended the availability of the FY 2001 allotment through the end of FY 2005.

According to our projections of Medicaid enrollment in FY 2005, 15.2 percent or 43.6 million of the estimated 287.7 million U.S. residents will be enrolled in Medicaid for the equivalent of a full year during FY 2005. The proportion of children and women in the U.S. who are enrolled in the Medicaid program is far higher. The estimated 20.2 million children to be served by Medicaid in FY 2005 represent more than one out of every five children in the Nation.

PART Review

SCHIP was initially evaluated by OMB in the FY 2004 cycle and received a PART score of 71; it was reassessed in the FY 2005 cycle with a score of 66. As a result of OMB's FY 2004 findings, CMS developed an SCHIP Action Plan to address OMB concerns. CMS continues to develop with States a core set of national performance measures to evaluate the quality of care received by low-income children. A new annual performance goal was established to use the information gathered from States to establish formal collaborations that will improve health care delivery and quality for Medicaid and SCHIP populations using reliable and valid performance measures. In addition, CMS plans to expand the Medicaid Payment Error Rate Measurement (PERM) Program developed to measure and ultimately reduce Medicaid payment error rates to measure SCHIP improper payments in FY 2005.

A PART assessment has not been done on the Medicaid program.

External Factors

In the face of recent fiscal challenges, a number of States may be reversing some of their simplification efforts and reducing outreach to try to maintain enrollment. States are using their flexibility to impose waiting lists on SCHIP potential enrollees and reducing eligibility levels while trying to maintain their programs. It is important to note, however, that some States are increasing eligibility and other States are reaching mature stable enrollment under SCHIP. Given the current economic conditions and potential reductions in State programs, increasing enrollment of children will be challenging.

HEALTH CENTER PROGRAM

Health Resources and Services Administration

FY 2005 Budget Request: $1,836 million

FY 2005 Full Cost Budget Request: $1,893 million

Program Background and Context

The Health Center program is a major component of America's health care safety net for the nation's indigent populations. This program, which is more than 35 years old, is a Presidential initiative to increase health care access for those Americans who are most in need. Millions of Americans are uninsured and lack access to a regular source of health care. Health Centers provide regular access to high quality, family oriented, and comprehensive primary and preventive health care regardless of patients' ability to pay. The ultimate goal of the Health Center program is to contribute to improvements in the health status of underserved and vulnerable populations and to the elimination of health disparities. Federal grants to Health Centers provide about 25 percent of their revenues on average, leveraging three dollars for each Federal dollar spent.

FY 2002 was the first year of the President's Health Center initiative to create 1,200 new or expanded Health Center sites and increase the number of clients served by 6.1 million over a five-year period. In the first two years of the initiative, the program has created 490 sites (271 new sites and 219 significantly expanded sites). To further ensure quality of care, in FY 2003, the Health Center program increased funding for Health Disparity Collaboratives, a quality initiative to improve health outcomes for patients with chronic diabetes, cancer, asthma, depression and cardiovascular disease. Nationally, more than 500 centers participate in one or more collaboratives.

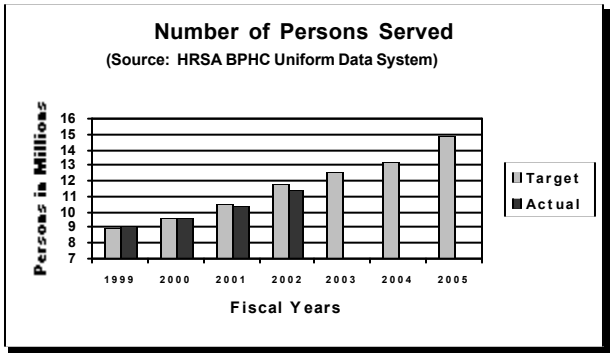
Program Performance Planning

The Health Center program currently has 15 annual performance measures in the Annual Performance Plan that track success in reaching various needy populations, expanding access points, operating efficiently, and providing high quality primary and preventive services. HRSA continues to develop and refine measures to determine program success through PART review and other evaluation activities. This process will continue over the next year as HRSA integrates its performance and budget processes.

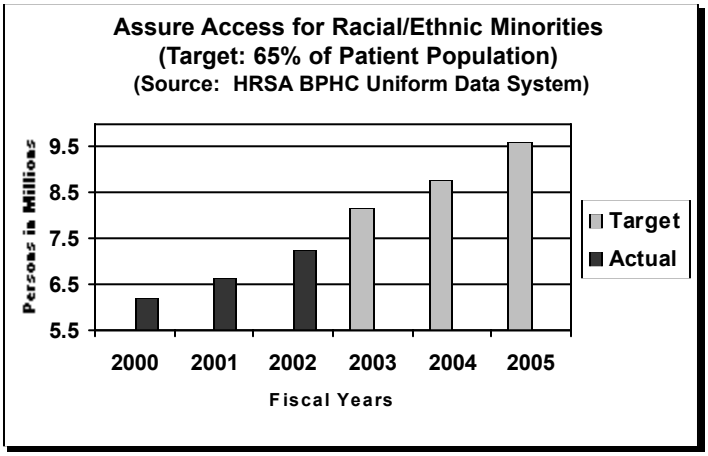
The primary source of performance data is the program's Uniform Data System that collects aggregate administrative, demographic, financial, and utilization data annually from each organization receiving support. These data are regularly validated through over 1,000 automated edit checks and onsite performance reviews. Other data sources include periodic surveys of representative samples of Health Center patients and their medical records, and special performance assessment studies. The Health Center program has recently launched a Sentinel Centers Network comprising a representative sample of all centers. When fully operational, the

Sentinel Centers Network will routinely provide patient-level data for timely investigation of program and policy issues. This will reduce the need for special periodic surveys of Health Center users and medical records. Key performance measures for the Health Center program are:

- ✓ ***In 2005, broaden access to health care services for the uninsured and underserved by funding 332 new and expanded health center sites and increasing to 14.8 million the number of uninsured and underserved persons served by Health Centers.***



- ✓ ***Continue to assure access to preventive and primary care for racial/ethnic minority individuals by serving 9.6 million racial/ethnic minority persons in 2005 (65% of total patients served).***



Growth in the number of persons served by Health Centers is an indicator of improved access to care for the nation's most vulnerable populations. The Health Center program served 11.3 million people in 2002. The increase between 2001 and 2002 of one million additional persons served represents the single largest annual increase in the history of the program. With such increases, the Health Center program is on target for meeting the 5-year growth initiative goal.

Access to health care is key to eliminating health disparities. The number of racial/ethnic minority individuals served by the Health Center program increased from 6.6 million in 2001 to 7.2 million in 2002, continuing a steady growth consistent with the overall growth in program

clients. The proportion of racial/ethnic minority individuals has remained at 64 percent of total clients, only one percentage point below the target of 65 percent. The President's Health Center initiative includes service capacity expansions for existing centers and development of new service sites. Some of these new centers and sites are or will be in underserved rural and frontier areas that do not have large numbers of racial/ethnic minorities, thus impacting the program's ability to maintain and increase the proportion of minority clients served. With substantial and rapid increases in the total number of clients served and expansions in areas with relatively small proportions of racial/ethnic minorities, a racial/ethnic minority representation of 65 percent of the Health Center program total patient population is a challenging performance target.

Means and Strategies

The Health Center program grants support a variety of community-based public and private nonprofit organizations for the operation of health centers, forming Federal, State and community partnerships to assure access to needed care for vulnerable populations. The program has three key overarching strategies for assuring both the viability and value of these essential safety-net resources:

- Expanding the network. Through the President's Health Center initiative, the program will create 1,200 new or significantly expanded health center sites and serve an additional 6.1 million persons by FY 2006.

- Strengthening existing network of centers. While fostering growth in health center sites and clients, the Health Center program strives to maintain the base by supporting existing centers to sustain and enhance both the numbers of persons served and the care provided to them.

- Ensuring high quality. The program engages in continuous quality improvement activities, exemplified by: (1) efforts to increase the number of centers accredited by national accrediting bodies; (2) aggressive risk management practices; and (3) health disparities collaborative that focus on developing and sharing best practices for the treatment and management of chronic diseases that are especially prevalent in the populations served.

Within this framework, the Health Center program emphasizes prevention, early detection and timely intervention, as well as the delivery of culturally and linguistically competent care.

Budget and Policy Priorities

The total budget request for FY 2005 is $1.8 billion, an increase of nearly $219 million over FY 2004. The FY 2005 requested funding will support the President's Health Center initiative by enabling the program to create 332 sites (176 new sites and 156 significantly expanded sites) in areas of greatest need. Total FY 2005 funding will support service to an additional 1.6 million patients over the number served in FY 2004.

PART Review

A PART review of the Health Center program was conducted for the FY 2004 budget. The program was rated Effective, with a score of 85, one of the highest among all government programs assessed that year. The assessment found that the program purpose is clear and designed to have a unique and significant impact, the program uses performance information to improve annual administrative and clinical outcomes, and the program is making progress in achieving its long-term outcome goals. This positive assessment of the Health Center program informed decisions to continue to fund existing centers and develop new centers and expanded sites.

In response to the PART observation that the program has struggled to estimate liabilities to the government that arise from malpractice coverage extended to Health Center employees under the Federal Tort Claims Act, the Health Center program has implemented a new database that enables the program to project liabilities related to tort claims.

External Factors

The future viability and performance of the Health Center program are impacted by the following factors:

- Because the Federal grant funds provide approximately 25 percent of the revenues of Health Centers, they rely heavily on Medicaid, additional patient revenue, and other State and local support for non-patient revenue. Given economic pressure on State budgets, Medicaid and other State funding can be variable, thus affecting the financial stability of some Health Centers.

- The nation's changing demographic profile, particularly the aging of the population, confronts Health Centers with a growing number of persons with chronic diseases and comorbidities. This puts extra pressure on centers to maintain efficiency and productivity in the face of shifts in case-mix.

IHS NATIONAL DIABETES PROGRAM

Indian Health Service

FY 2005 Budget Request: $154 million

FY 2005 Full Cost Budget Request: $154 million

Program Background and Context

The Indian Health Service (IHS) National Diabetes Program is an integral part of the IHS Hospitals and Health Clinics program. The mission of the IHS National Diabetes Program is to develop, document and sustain a public health effort to prevent and control diabetes in American Indian/Alaska Native (AI/AN) people. The program works with communities to prevent and treat diabetes, as well as oversee the Special Diabetes Program for Indians Grant Program (SDPI).

Development of the regional Model Diabetes Programs is a major achievement of the IHS National Diabetes Program. The Model Diabetes Programs are designed to expedite care and provide education to people with diabetes, and also to translate and develop new approaches to diabetes control that serve as models for other Indian communities facing similar problems. In addition, Area Diabetes Consultants within each IHS Area provide consultation and technical assistance related to clinical activities and programmatic issues to Indian, Tribal, and Urban (I/T/U) facilities and SDPI programs.

Moreover, the Indian Health Service has historically included diabetes quality of care measurements within its Annual Performance Plan. The current IHS Strategic Plan includes this performance indicator. IHS emphasis on diabetes care within the Hospital and Health Clinics program recognizes the role of diabetes as a major cofactor in morbidity and as well as the major cause of mortality among AI/AN people.

Program Performance Planning

Six IHS performance goals reflect the commitment of IHS to prevention and control of the diabetic epidemic in AI/AN communities. In FY 2004, IHS modified the Annual Performance Plan diabetic performance indicator to include a complementary indicator-the percentage of patients that are in poor diabetic control. This new indicator (replacing the percentage of diabetics in the service population) allows IHS to emphasize the impact of improved control on costs as well as morbidity.

The IHS Diabetes Program conducts a yearly medical record review of a random sample of over 20,000 charts in I/T/U facilities in order to assess compliance with the IHS Standards of Care for Diabetes. These standards are a set of clinical parameters of care and patient management that have a recognized evidence-based correlation with improved diabetic patient outcomes. This record review is the IHS Diabetes Care and Outcomes Audit and uses a strict protocol to assure statistical integrity and comparability of both process and outcome measures over time.

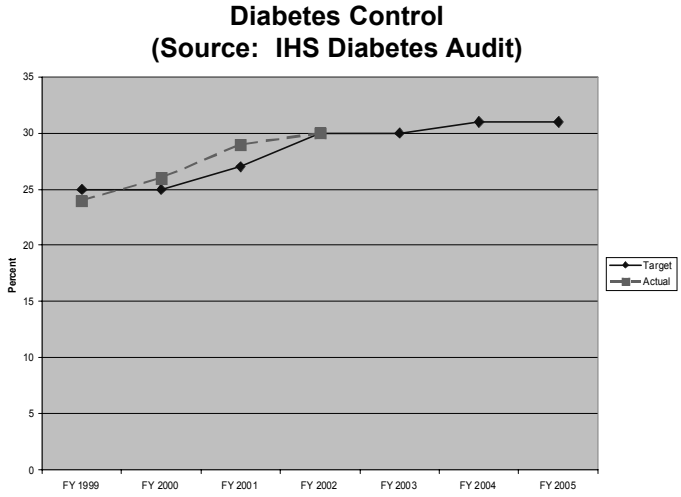
Each year, facility-specific values are reported for each indicator, as well as values for each Area and IHS-wide. Trends over time for I/T/U facilities, service units, Areas and IHS-wide are also constructed for indicators 2-5.

In FY 2003, data for diabetes performance is based upon results from an IHS-developed software application that queries local health information systems (RPMS- Resource and Patient Management System) for clinical quality results. In FY 2003, IHS queried over one million patient charts; over 65,000 charts of diabetics were electronically reviewed to obtain the results of the diabetic indicators.

One key measure of the IHS National Diabetes Program is:

- ✓ ***Maintain the proportion of Indian, Tribal, and Urban (I/T/U) facilities Native American patients with diagnosed diabetes that have demonstrated improved glycemic control blood sugar levels).***

The following chart demonstrates the targeted and actual percentages of AI/AN patients with ideal blood sugar control from 1999 through 2005. Data for actual percentages is reported through 2002.



IHS determined this measure to be a good reflection of diabetes care within the AI/ AN community. Diabetic control is contingent upon access to health care (including lab and appropriate pharmaceuticals), patient education and understanding about the importance of blood sugar control, as well as many patient controlled factors (diet; exercise; medication compliance; for the adolescent diabetic, an increased interest in health; etc). Moreover, if blood sugar is adequately controlled, co-morbidities significantly decrease, resulting in decreased health care costs, as well as increased quality of life.

Targets for the IHS diabetes program continue to be ambitious. Because IHS data indicates at least a 3-4 percent increase in the number of diabetics that receive services through the I/T/U network annually, maintaining the percentage of diabetics in the population who are achieving good blood sugar control reflects an increase in the actual numbers of patients treated.

Means and Strategies

IHS met the 2002 ideal glycemic control indicator. The 2002 performance demonstrated the improvements made compared to the FY 2001 performance level for ideal glycemic control in patients with diagnosed diabetes. The graph above illustrates IHS ongoing ability to improve glycemic control in AI/AN populations, as well as improve the percentage of patients in ideal control.

Glycemic control refers to how well the blood sugars are controlled in a person with diabetes. It is measured with a blood test called the Hemoglobin A1c. The IHS Diabetes Care and Outcomes Audit process divides these levels of control into "Ideal" (<7%); "Good" (7.0-7.9%); "Fair" (8.0-9.9%); "Poor" (10-11.9%); and "Very Poor" (>12%) categories, based on national diabetes care standards. (The diabetic audit of glycemic control is a reliable and consistent data source based on the patient data management software-RPMS-lab package used by the majority of I/T/U facilities, which is externally validated through chart reviews.)

IHS uses several treatment and prevention strategies to achieve glycemic control in the AI/AN population:

- Glucose lowering medications are used to achieve glycemic control. Many new glucose-lowering medications have been introduced on the market for the past 7 years. These medications are potent and quite effective. Efforts to achieve this measure also include the negotiation of wholesale/at cost purchase of newer, more effective (but considerably more expensive) medications for AI/AN diabetic patients.
- Increased emphasis on patient education about nutrition, diet and exercise; this is coupled with the IHS Health Promotion/ Disease Prevention Initiative.
- Availability of 'best of practice' guidelines on the IHS Web site for community and health care facility guidance.
- In addition, IHS has developed and deployed a clinical software application that allows sites to track and provide timely feedback on the achievement of glycemic control, as well as other diabetic indicators.
- The total IHS budget requested for FY 2005 will allow IHS to invest in more potent pharmaceutical agents for its patients with diabetes, increased emphasis on patient education (to include diet and exercise), diabetic case management, and additional electronic diabetic reminders.

Budget and Policy Priorities

Proposed funding levels for FY 2005 represent an estimate of the Hospitals and Clinics budget that supports glycemic control efforts as part of diabetes treatment services. The FY 2005 amount is a slight increase over the FY 2004 estimate because of anticipated pay increases for staffing costs.

The Diabetes program complements the Secretary's Steps to a Healthier U.S. Initiative. Ongoing emphasis on health promotion and disease prevention is inherent in this emphasis on diabetes care. In addition, this indicator is reflective of quality of care to a minority population; program results are consistent with those reported by other health care plans. Providing the requested additional resources will help ensure that IHS can keep pace with the diabetic epidemic in AI/AN communities, and impact the diabetes racial disparity that currently exists.

PART Review

The FY 2004 IHS PART included a review of the IHS Direct Federal Programs. This includes the Hospital and Clinics program, which includes diabetes care activities. PART review results have been shared with all IHS clinical providers and health care facilities. This increased emphasis on sharing performance, and specifically, PART results with local I/T/U facilities has resulted in improved clinical care at this level, which is occurring in conjunction with the targeting of resources to address this critical area of treatment.

The PART review process has also focused attention on the continued importance of assuring valid and reliable performance data addressing diabetic care at all levels of Indian health (i.e., IHS, Tribal and Urban). IHS addressed this issue in both the Urban Indian Health Program and RPMS/IT PART reviews that were part of the FY 2005 budget process.

External Factors

Increasing rates of childhood obesity and the concurrent emergence of Type 2 diabetes in children pose a growing public health concern for IHS. Type 2 diabetes and obesity rates are disproportionately high for AI/AN children: data from 1999 studies showed the prevalence of obesity among AI/AN children to be 39 percent, versus 15 percent for all U.S. children. Recent data indicates that this gap has increased in the past 4 years. The effects of commercial advertising, the convenience and low cost of "fast foods," and the availability of vending machines run counter to many of the healthy lifestyle messages and activities being promoted in American Indian/Alaska Native communities. Consequently, efforts to address childhood obesity will directly affect diabetes program outcomes in the long term.

Strategic Goal 4: Enhance the Capacity and Productivity of the Nation's Health Science Research Enterprise

HHS recognizes the important role research plays in furthering its overall mission of improving the Nation's health. As a result, many of the strategies that HHS has identified as important components in achieving its other strategic goals incorporate a research base. This goal therefore focuses on creating the underlying knowledge and strategies that improve and maintain the research infrastructure that produces advances in health science.

HHS is committed to advancing the understanding of basic biomedical and behavioral science and how to prevent, diagnose, and treat disability and disease. In order to accomplish this objective, HHS will continue to support basic, clinical and applied biomedical, behavioral and health services research that meets stringent criteria for scientific quality through a peer review process. Moreover, HHS has developed and is implementing processes for setting research priorities to ensure that research is responsive to public health needs, scientific opportunities, and advances in technology.

HHS places a high priority on improving the coordination, communication and application of health research results. Strategies to meet this objective include:

- Providing easy access by academia and industry to HHS databases and findings from HHS research while maintaining appropriate privacy and confidentiality protections;

- Establishing partnerships with health professional associations, industry groups, patient representatives, community groups and purchasers of care to more widely disseminate research findings; and

- Supporting translational research to determine how innovative, effective interventions can be applied in actual settings and populations, including the means to reach diverse communities. This research also supports the development of data-based quality of care and outcome measurement systems to track the adoption of evidence-based practices.

HHS commitment to enhancing the capacity and productivity of the Nation's health science research enterprise is demonstrated by the development of the map of the human genome. Investment in this basic science research will provide important information for identifying patterns of genetic variation across all human chromosomes. The following narrative describes key performance measures for the National Institutes of Health (NIH) HapMap Project, which will contribute to research identifying the genetic factors underlying common diseases.

MAP OF GENETIC VARIATION ACROSS ALL HUMAN CHROMOSOMES

National Institutes of Health

FY 2005 Budget Request: $5 million

FY 2005 Full Cost Budget Request: $5 million

Program Background and Context

The mission of the National Institutes of Health (NIH)-to uncover new knowledge that will lead to better health for everyone--derives from Section 301 of the Public Health Service Act. Begun as a one-room Laboratory of Hygiene in 1887, NIH today is one of the world's foremost health research centers. NIH is composed of 27 Institutes and Centers (ICs), whose research activities extend from basic research that explores the fundamental workings of biological systems and behavior, to studies that examine disease and treatments in clinical settings, to prevention, and to population-based analyses of health status and needs. The Office of the Director, NIH, provides leadership, oversight, and coordination for the enterprise.

The ICs are the NIH "visible" to most Americans. Some of the ICs focus on diseases (e.g., cancer, diabetes); others concentrate on organ systems (e.g., heart, eye, kidney), whereas others focus on a stage of life (e.g., children, the aging population). Yet, no less essential to the Nation's health are NIH ICs that address overarching scientific needs and opportunities, for example, sequencing the human genome, an effort that generated knowledge fundamental to the research efforts across all of NIH. In April 2003 the Human Genome Project, led by the National Human Genome Research Institute (NHGRI) of NIH, essentially completed the sequence of the human genome and released it into a publicly accessible database for all to view and use. That same month, the NHGRI published an ambitious "Vision for the Future of Genomic Research" that lays out a bold agenda for the next phase of genomics.

One use of the human genome sequence has been to study the role that genetic variation plays in health and disease. Virtually all diseases have a genetic component. The DNA sequences of any two people are 99.9 percent identical. However, there are at least 10 million DNA sites where people commonly differ in their DNA sequences, and some of these variations greatly affect an individual's risk for disease or response to drugs.

An important goal of genetic research is to identify genes that contribute to disease. For single-gene disorders such as cystic fibrosis or Huntington disease, current methods often are sufficient to find the genes involved. Most people, however, do not have single-gene disorders. Rather, their disorders result from complex interactions of multiple genetic and environmental factors. Unfortunately, strategies that have worked well to map the genes for single-gene disorders generally lack the power to map such multigene disorders, and other approaches are needed.

Several newer strategies should be more successful in identifying the hereditary factors in common diseases such as diabetes, heart disease, and cancer. Many of these approaches depend on understanding the ways in which genetic variations are correlated. Using this information for disease-gene identification will result in considerable savings in time, effort, and cost.

Sites in the genome where individuals differ in their DNA spelling by a single letter are called single nucleotide polymorphisms (SNPs). Recent work has shown that about 10 million SNPs are common in human populations. SNPs are not inherited independently; rather, sets of adjacent SNPs are inherited as blocks. The specific pattern of particular SNP spellings in a block is called a haplotype. Although a region of DNA may contain many SNPs, it takes only a few SNPs to uniquely identify or "tag" each of the haplotypes in the region. This presents the possibility of a major shortcut in identifying hereditary factors in disease. Instead of testing 10 million SNPs, a rigorously chosen subset of about 400,000 SNPs could provide most of the essential information. These "tag SNPs" can be organized in a "HapMap," a catalog of the haplotype blocks and the SNPs that tag them. The HapMap will be an important tool that researchers will use in future studies to identify the genetic factors underlying common diseases.

Program Performance Planning

NIH is using one measure in each fiscal year to assess the performance of the HapMap Project, an international collaboration for which NHGRI serves as the lead agency. The measures will provide useful information for assessing the progress of the HapMap Project. In addition to measures included in the NIH Annual Performance Plan, the Agency has measures of program efficiency, for example, the rate at which SNPs are discovered.

Measurement data will come from:

- Documented samples availability from the non-profit Coriell Institute of Biomedical Research, in New Jersey.

- Publicly accessible databases of SNPs, genotypes, haplotypes, and haplotype maps.

The HapMap Project includes a quality assessment component that uses several criteria to assess the quality and validity of the data. Only data that has undergone extensive validation and quality assessment procedures will be used to develop the HapMap.

Key performance measures for FY 2003, FY 2004, and FY 2005 respectively are as follows:

- ✓ ***Obtain additional consent for genotyping from the donors of existing blood samples taken from US residents of Western and Northern European ancestry, and begin genotyping 300,000 SNPs in those samples.***

- ✓ ***Collect blood samples from populations in Japan, China, and Nigeria; prepare a complete collection of an additional 3 million SNPs and release them in public databases.***

- ✓ ***Develop a first-pass draft haplotype map containing 600,000 SNPs.***

While the measures are objective (they require reaching definitive end-points), they are not quantitative and cannot be presented in a graph.

Developing a first-pass draft haplotype map containing 600,000 SNPs is an ambitious goal because it will pinpoint, for the first time, genetic variations among individuals across all human chromosomes. Genetic variations can then be correlated not only to diseases, but to disorders that arise due to individual responses to medications, the environment, and other factors. The long term benefit of understanding the influence of genetics on health and disease is that interventions can be made more precise and predictable and therefore lead to genuine improvements in public health.

Performance Results

By the end of FY 2003, all of the living donors who provided the previously existing 90 US samples specifically consented to their samples being used for developing the HapMap. Also, a total of six research groups have performed genotyping of 132,000 SNPs in these samples to date.

The HapMap Project has already discovered many more SNPs and is currently ahead of schedule in this regard. These additional SNPs will not only speed the pace of the HapMap project's completion, but they will also greatly enhance other basic biomedical research dependent on SNP analysis.

Means and Strategies

To conduct the HapMap Project, NIH helped initiate and continues to coordinate an international consortium of researchers in Canada, China, Japan, Nigeria, the United Kingdom, and the United States, including eight genotyping research groups, four sample collection groups, five data analysis groups, and a data coordination center. NIH ICs and the Office of the Director solicited cooperative agreement applications for the large-scale genotyping. Also, a group of advisors was established to develop a sampling strategy that meets both the need for high-quality scientific research and the need for the Project to adhere to the highest ethical standards to protect participants.

The types of activities that will be used to accomplish the goal are as follows:

- The consortium will identify an additional three million SNPs needed to fill in areas where the current density of SNPs in public databases is not sufficient.

- The consortium will collect consents and samples from a total of 270 individuals who come from one of four populations (US residents with ancestry from Western and Northern Europe and individuals from Japanese, Han Chinese, or Yoruba (Nigeria) populations).

- The consortium will develop scientific strategies to choose which SNPs to study, assess the quality of the data, and derive haplotypes from the SNP data.

- The genotyping research groups will test the samples for up to one million SNPs to discover the pattern of variation among the samples.

- These genotype data will be analyzed to derive haplotypes, develop the HapMap, and then choose the SNPs that contain the most information on the patterns of genetic variation to make the HapMap most useful for later studies relating genetic variation to health and disease.

Budget and Policy Priorities

The NIH budget request for FY 2005 of $28.6 billion will include $4.6 million needed for accomplishing the performance goals of the HapMap Project. This is a decrease of $4.2 million from the FY 2004 funding level of $8.8 million. The difference between FY 2005 and FY 2004 funding levels is because most of the funds were for upfront investment for sample collection, SNP discovery, and genotyping will have been awarded in FY 2003 and FY 2004. While most of this work will be conducted during FY 2003 and FY 2004, some genotyping, analysis, and continued interaction with the communities will be conducted in FY 2005. The estimated full cost of operating this activity for FY 2005 is $4.8 million, which is fully funded for the FY 2005 Budget. Research Project Grants (RPG's) are the funding mechanism in FY 2005. This funding level will allow the U.S. to fulfill its commitments in the international consortium for HapMap construction.

The HapMap program is an example of the President's support of innovative research that has the potential for far-reaching results. Scientists will expand upon the knowledge that arose from the success of the human genome sequencing project with the HapMap, as they will be able to use it to investigate what variations in the genome sequence are associated with a hereditary disease or disease risk. In turn, this information will provide biomedical researchers a more rational basis for the development of new therapies and prevention strategies. Additionally, these innovations will offer clinicians an improved means for diagnosing disease and a clearer rationale for treatment. Such advancements directly relate to the HHS goal of advancing science and medical research to prevent, diagnose, and treat disease and disability. The budget requested for this program is based on the anticipated results of developing a

first-pass haplotype map containing 600,000 SNPs by 2005. This map will provide the next generation tool to enhance the understanding of hereditary factors that contribute to health and disease. Finally, the HapMap effort illustrates how basic science and medical research can be integrated to enhance the capacity and productivity of the Nation's health science research enterprise

PART Review

This program has not been subjected to PART review.

External Factors

An international consortium of researchers is developing the HapMap. This partnership is vital for undertaking the Project, but could affect the time it takes to complete it. The NIH is supporting analysis of 30 percent of the genome; changes in support of science in the other countries could accelerate or decelerate their efforts and thus the time it takes to finish the entire Project. There are many challenges in collecting blood samples in Japan, China, and Nigeria, so these sample collections could be delayed or even cancelled. The HapMap is based on pilot data showing how genetic variation is organized in parts of the genome; it is possible that the entire genome will turn out to have different patterns than seen initially, so more or fewer SNPs may be needed to develop the HapMap than currently thought. Finally, the study of additional populations from other geographic areas, currently being collected as part of a pilot project, may indicate that additional DNA samples from other parts of the world need to be included in the HapMap to make this powerful research tool applicable to all human population groups.

Strategic Goal 5: Improve the Quality of Health Care Services

Improving the quality of life and health in the United States involves improving the quality of the health care services that people receive. This strategic goal aims to improve the quality of health care services by reducing medical errors, improving consumer and patient protection, and accelerating the development and use of electronic health information. To achieve this goal, HHS will focus on implementing a variety of strategies designed to improve the delivery of health care services including the development and dissemination of evidence based practices, information systems and new technologies for the home and clinical setting, and improved reporting systems for medical errors and adverse events including those related to medical devices and drugs.

Health quality improvement at HHS also means translating new knowledge of effective health services into strategies, educational tools, and information to help clinicians and health care policy makers improve health care quality. HHS will work to expand provider networks to disseminate health care quality information. This health care quality information will also be more widely available through several new channels to promote awareness of consumer and patient protections and choices.

HHS will provide leadership to promote the development of a national health infrastructure that takes advantage of the most current technology available. This will involve attention to the secure and confidential treatment of health information, adoption of national data standards, and research on the applications of a national health information infrastructure that serves consumers, patients, professionals, and other decision makers alike.

Illustrative of HHS commitment to reducing medical errors is the Food and Drug Administration (FDA) Medical Product Surveillance Network System. When fully implemented this system will reduce device-related medical errors, serve as an advanced warning system, and create a two-way communication channel between FDA and the user-facility community.

MEDICAL DEVICES & RADIOLOGICAL HEALTH

Food and Drug Administration

FY 2005 Budget Request: $252 million

FY 2005 Full Cost Budget Request: $305 million

Program Background and Context

The Food and Drug Administration (FDA) Medical Devices and Radiological Health Program is responsible for ensuring the safety and effectiveness of medical devices and eliminating unnecessary human exposure to manmade radiation from medical, occupational, and consumer products.

A key element in the FDA program to regulate medical devices is the post market reporting system through which the Agency receives reports of serious adverse events. Such reporting forms the basis for corrective actions by the Agency, which include warnings to users and product recalls. This is especially true as FDA moves toward less direct involvement in the premarket review of lower-risk devices. The Medical Product Surveillance Network (MedSun) is a surveillance system composed of a network of user facilities that report adverse events associated with medical devices. When fully implemented, MedSun will reduce device-related medical errors; serve as an advanced warning system; create a two-way communication channel between FDA and the user-facility community; and act as a laboratory to investigate questions about the use of medical devices.

Once national representation is achieved among the network of user facilities, MedSun will work to obtain reports about problems with medical devices that constitute a representative profile of user reports. MedSun provides FDA with the health information it needs to identify patient safety concerns. The network is based on the premise that a select group of highly trained reporting facilities can provide high quality, informative reports that can be representative of user facility device problems in general.

An example of the how MedSun can improve the quality of health care services comes from a March 2003 report citing potentially serious problems encountered with amniotic fluid used in amniocentesis. Through FDA investigations into the issue, it was found that a rubber stopper used in two widely used brands of syringes contained toxic elements, creating serious health risks to women undergoing this procedure. FDA worked with the syringe manufacturers to draft a letter to customers about this potential problem and consulted with the American College of Genetics. The College sent an alert about rubber toxicity problems to its membership. Because of the problem that was identified by MedSun, the syringe manufactures are taking steps to improve the product by making changes in the processing of the rubber stoppers.

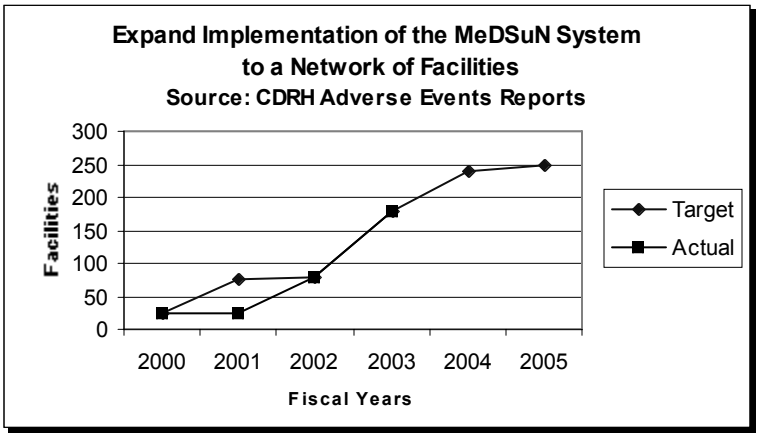
Program Performance Planning

MedSun has a goal to implement a comprehensive program to regulate marketed medical devices using a post market reporting system through which FDA receives reports of problems with medical devices. In addition to its program specific purpose, MedSun is also the FDA pilot for establishing a network of user facilities that will require user reporting for only a subset of facilities. During FY 2001, FDA began feasibility testing with 25 hospitals and worked on software changes needed for website health data security. In FY 2002, FDA adjusted the performance goal downward from 125 facilities to 80 facilities. FDA had to delay recruitment efforts at that time to address various policy issues within the Agency, and to make major software changes needed to respond to new information technology security demands. By the end of 2003, FDA was able to recruit 180 facilities. For 2004, with increased funding, FDA will be able to expand the enrollment to 240 facilities.

The following is the FDA MedSun performance measure for FY 2005:

✓ ***Expand implementation of the MedSun System to a network of 250 facilities.***

Data collected from Adverse Events Reports allows the Agency to determine if targets for the program are being met.



The performance measure is designed to achieve and maintain a desired capacity of reporting systems. MedSun is one part of the FDA long-term outcome goal for increasing the patient population covered by active surveillance.

Means and Strategies

MedSun and linkages with other health care systems form the FDA first line of defense against medical errors. While MedSun was primarily designed to track and analyze adverse events due to medical devices, plans are in place to expand the network to include a study to evaluate

procedures for collecting data on problems with laboratory tests (pathology and in-vitro diagnostic tests) and to evaluate the feasibility of including hospital laboratory staff. The following MedSun activities planned for FY 2005 support achievement of the performance measure and support the Department's initiative to improve the quality of health care services:

- Increase the FY 2005 enrollment to 250 facilities in the MedSun. FDA will reach this level by recruiting a few new facilities and replacing those facilities that choose to rotate out of the system. FDA will use these facilities to determine the effectiveness of various incentives, as laboratories to obtain specific medical product information, and to pilot various types of feedback to encourage facility reporting;

- Expand the lab-reporting project to target surveillance, initially piloted in FY 2003 and FY 2004 into all agreeable MedSun sites. Expansion of the lab-reporting project will allow FDA to evaluate procedures for collecting data on problems with laboratory tests and the feasibility of including hospital laboratory staff.

As funding becomes available from the Center for Devices and Radiological Health (CDRH), MedSun contractors will coordinate with the Center for Drug Evaluation and Research (CDER) to continue implementation of drug MedSun. MedSun is designed to train hospital personnel to accurately identify and report injuries and deaths associated with medical products. The MedSun model, currently designed to track and analyze adverse events due to medical devices, will be expanded to include drug products. Initial work included a feasibility and acceptability assessment of a small regional group of hospital pharmacists about incorporating MedSun and to integrate risk manager reporting on devices with the reporting of adverse drug events and medication errors by hospital pharmacists or other personnel.

Budget and Policy Priorities

Total funding for the Medical Devices and Radiological Health program in FY 2005 is $251.8 million, an increase of $27.1 million over the FY 2004 level. The full cost for operating the Medical Devices and Radiological Health program is $304.7 million in FY 2005 and $272.5 million for FY 2004. The FY 2005 funding increase in the Medical Device and Radiological Health program is provided primarily for pre-market review of medical devices, not increased funding for MedSun. However, within existing resources, MedSun will continue to refine the program and will recruit another 10 facilities into the system for a total of 250 facilities in FY 2005. Implementation of MedSun will result in an enhanced adverse events data system and will provide linkages with other health care systems as the first line of defense against medical errors. MedSun is also the primary surveillance system that supports the Agency's long term outcome goal to increase by 50 percent the patient population covered by active surveillance of medical product safety by 2008. This goal supports the HHS strategic goal of *Improve the Quality of Health Care Services* by identifying adverse events earlier, thereby reducing risks to public health and ensuring the safety of available medical devices.

PART Review

The FY 2004 PART shaped FDA FY 2005 planning and budgeting processes by focusing on improving program performance and accountability, and by identifying potential outcome goals and funding strategies. The FY 2004 PART review and strategic planning process also fashioned the FY 2005 budget request by encouraging Agency management to propose user fees to supplement areas that needed more resources to improve program performance and accountability. The development of the long-term outcome goals continued during the strategic planning process and culminated with several goals presented during the FY 2005 PART review and incorporated into the initial budget submission to HHS.

External Factors

The success of MedSun will continue to be dependent on upon continued participation and the willingness of health care facilities to participate in the program. Although FDA is responsible for the implementation of MedSun, the Agency cannot force facilities to participate in MedSun. FDA will work with the health care community to gain greater participation in MedSun.

Strategic Goal 6: Improve the Economic and Social Well-Being of Individuals, Families, And Communities, Especially Those Most in Need

HHS promotes and supports interventions that help disadvantaged and distressed individuals, families, and communities improve their economic and social well-being. The Department targets interventions toward low-income families, including those receiving Temporary Assistance to Needy Families (TANF), children, the elderly, persons with disabilities, and distressed communities.

To achieve this strategic goal, HHS will continue to support efforts to increase the independence of low-income families, TANF recipients, the disabled, older Americans, Native Americans and refugees. Also, the Department will support community and faith-based organizations that are providing services to individuals transitioning from welfare to self-sufficiency. The Department continues to focus on increasing the proportion of older Americans who stay active, healthy and independent and provide assistance to families who are the mainstay of long-term care for elderly persons.

Representative performance measures discussed in this section include the number of TANF recipients who become newly employed and remain employed and targeting services supported by Administration on Aging programs to elderly residents of rural areas.

TEMPORARY ASSISTANCE FOR NEEDY FAMILIES

Administration for Children and Families

FY 2005 Budget Request: *$17,149 million*

FY 2005 Full Cost Budget Request: *$17,173 million*

Program Background and Context

The purpose of the Administration for Children and Families (ACF) Temporary Assistance for Needy Families (TANF) program is to provide time-limited assistance to needy families; reduce dependency by promoting job readiness, work and marriage; prevent out-of-wedlock pregnancies; and encourage the formation and maintenance of two-parent families. Under Title IV-A of the Social Security Act, as amended by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA), States and Territories receive a block grant allocation and are required to operate their own programs; Tribes have the option to run their own programs. States and Tribes determine eligibility and benefit levels and services offered. ACF provides leadership to help States, Territories and Tribes as they design and implement their programs and move families from welfare to work, while protecting the well-being of children through child care and other services.

Since the enactment of TANF in 1996, millions of families have avoided dependence on welfare in favor of greater independence through work. Employment among low-income single mothers (earning below 200 percent of poverty), reported in the U.S. Census Bureau Current Population Survey (CPS) has increased significantly since 1996. Although it declined slightly in 2002, it is still eight percentage points higher than in 1996 - a remarkable achievement, particularly since it remained high through the brief recession in 2001. Among single mothers with children under age six—a group particularly vulnerable to welfare dependency—employment rates are 13 percentage points higher than in 1996.

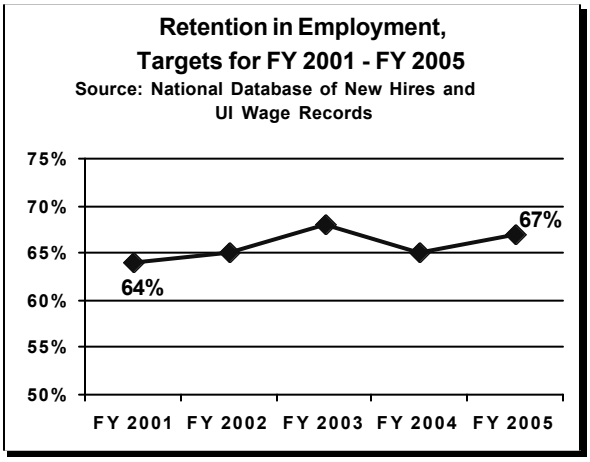
In addition to more low-income single mothers entering the work force, employment data specifically for welfare recipients, which is used to rank States competing for the TANF High Performance Bonus, reflected strong job retention and earnings - 36 percent of unemployed adult welfare recipients entered the work force in FY 2002 and 59 percent of those who started work were still employed six months after getting a job. Average quarterly earnings increased 33 percent for current and former welfare recipients, from $1,935 in the first quarter of employment to $2,578 in the third quarter.

There were 2,032,157 families receiving TANF cash benefits in June 2003, the most recent month for which data are available. The total represents a five percent decrease from January 2001 and a 54 percent decrease from August 1996, when TANF was enacted. A total of 4,955,479 individuals were receiving TANF benefits in June 2003, 9.2 percent fewer than in January 2001 and 60 percent fewer than in August 1996.

Program Performance Planning

The primary goal of the TANF program is to move recipients from welfare to work and self-sufficiency. ACF tracks a number of measures on employment achievement and family formation in support of this goal. TANF shares a common goal with a number of Federal agencies working to improve participants' employment and earnings. In coordination with the Office of Management and Budget, these agencies (ACF/HHS, and the Departments of Labor, Education, Housing and Urban Development, Interior, and Veterans Affairs) developed a common set of four measures for job training and employment. Data for these measures will be based on State Employment Security agency (SESA) wage records and administrative records. (The wage record data are subject to SESA screening and editing procedures, as well as the ACF matching protocol that eliminates duplicate and outlier wage records.) One of these measures, listed below, reflects the TANF core goal to move individuals from welfare to work and self-sufficiency:

✓ ***Increase the percentage of those employed in a quarter that are still employed one and two quarters later. In FY 2005, the target is 67 percent.***



Means and Strategies

ACF will employ various tools and strategies to enhance TANF program performance.

- PRWORA established work participation standards and created a High Performance Bonus incentive system for FY 1999 - FY 2003. State and Territories receive financial rewards for high performance and significant improvement as well as penalties for not meeting the work participation targets on this measure and others. The President's Reauthorization proposal restructures these bonuses to focus on employment achievement. ACF has been operating on continuing resolutions and stand-alone bills that have extended TANF based on current law.

- ACF provides leadership to States, Territories, and Tribes as they design and implement their programs. Efforts include technical assistance and outreach including the use of a Peer Technical Assistance Network.

- The Welfare Peer Technical Assistance (TA) Network provides peer-to-peer technical assistance to public agencies and private organizations operating the TANF program. The Web site also highlights policy relevant research, innovative programs, related links and upcoming events. The objective of the Peer TA Network is to facilitate the sharing of information between and among States and to establish linkages between organizations serving the needs of welfare recipients.

- Examples of technical assistance activities in FY 2003 included:

  - The Healthy Marriage Academy - focused on providing general information and sharing specific information on promising initiatives that promote healthy marriages,
  - The Delta EITC Initiative - focused on increasing the uptake of the Earned Income Tax Credit among low-income families in the Mississippi Delta region. The goal is to move more families in the Mississippi Delta region to work and onto self-sufficiency, and
  - The Urban Partnership - directed toward developing strategies to assist the special needs of ten large urban cities. At the same time, the Partnership provides the opportunity for city leaders to share ideas and discuss issues.
  - ACF also sponsored several targeted technical assistance events across the country on topics requested by States to help them enhance their services for TANF families. Those topics included: children with incarcerated parents, healthy marriages, substance abuse, strengthening Tribal/State collaboration, TANF and Child Welfare Service integration, grandparent housing facilities, strategies to address the child-only caseload, and mental health.

  ACF continues to work closely with States and Tribes as it plans further technical assistance activities.

Budget and Policy Priorities

The Department is requesting $17.1 billion for the TANF program for FY 2005. Building on the success of the 1996 welfare reform program, the FY 2005 budget follows the framework originally proposed in the President's FY 2003 TANF Reauthorization Proposal. The Proposal continues the current block grant funding mechanism and maintains current program funding levels for the following: Family Assistance Grants to States, Tribes, and Territories; Matching Grants to Territories; and Tribal Work Programs. In addition, the Proposal reinstates authority for both the Contingency Fund and Supplemental Grants for Population Increases. While the proposal eliminates the Bonus to Reward Decrease in Illegitimacy and restructures the High Performance Bonus to focus on employment achievement, it creates two new initiatives to support marriage and healthy family development - a matching grant to States and a fund for research, demonstrations, and technical assistance activities. Each of these initiatives would be

funded at $120 million annually, beginning in FY 2005. In addition to the above figure, there is also $6 million in Social Service Research and Demonstration funding which supports a child welfare study under TANF.

External Factors

Performance on the highlighted measure and in the TANF program broadly will be significantly affected by a number of factors which may help or hinder achievement including: 1) the national economy; 2) wage and employment rates; 3) social and demographic trends such as divorce and non-marital birth rates; and 4) increasing proportion of clients with barriers to employment such as lack of fluency in English, mental health problems, substance abuse, disability, or domestic violence.

COMMUNITY BASED SERVICES PROGRAM

Administration on Aging

FY 2005 Budget Request: $1,260 million

FY 2005 Full Cost Budget Request: $1,313 million

Program Background and Context

The Administration on Aging (AoA) Community Based Services Program (CBSP) provides grants to States to provide comprehensive social and supportive services to vulnerable elderly individuals and their family caregivers. CBSP supports a key element of the AoA mission by helping to keep vulnerable elderly individuals in the community, which is where they prefer to live. CBSP supports some of life's most fundamental functions for elderly individuals at risk of institutionalization, including: 1) food for the undernourished; 2) critical transportation for the immobile; 3) respite and support for caregivers; and 4) personal care to those who need assistance with daily functions around the home (e.g., getting in and out of bed).

AoA carries out CBSP through a national aging network that includes 56 state units on aging, 655 area agencies on aging, 243 Indian Tribal organizations and over 29,000 public, private and voluntary direct service providers. The achievement of this community-centered network of providers is reflected in key indicators observed in AoA surveys of elderly clients and caregivers conducted in FY 2002. These surveys found that:

- 86 percent of family caregivers interviewed reported that CBSP services helped them care longer for elders than they could without them.
- 30 percent of elderly CBSP clients are nursing-home eligible due to disabling conditions but are able to remain in the community.

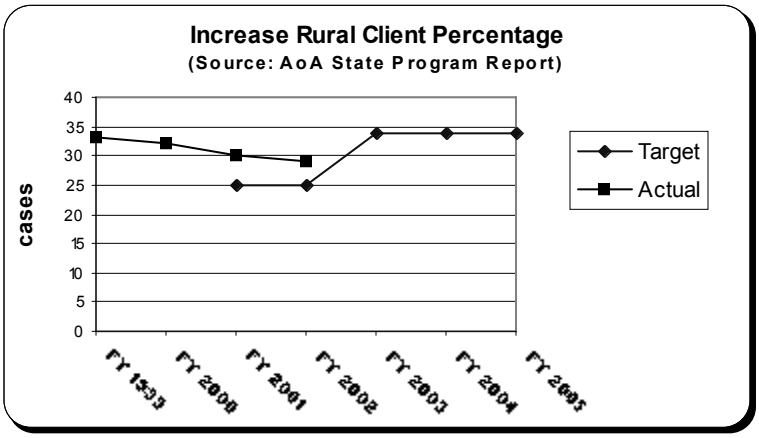
Program Performance Planning

For the CBSP program, AoA has defined three key measures to track critical program performance:

- A program efficiency measure which helps AoA to pursue improvements in the number of individuals served per million dollars of AoA funding;
- A consumer outcome measure which tracks the effects of CBSP services on elderly individuals and caregivers; and
- A targeting measure designed to ensure that CBSP services are provided to vulnerable elders who need them most, including disabled, poor, rural and minority elders.

These measures allow program managers to focus on program outcomes that help to ensure effective program results. The performance indicator representing the AoA targeting measure for FY 2005 is:

✓ ***Increase the percentage of AoA clients who reside in rural areas to 34 percent of all clients.***



This indicator seeks to ensure that critical services are targeted to elderly individuals in rural areas for whom access to care is a challenge. The targeting indicator supports the Older Americans Act specific requirement that States and providers ensure services are provided in rural areas, as well as Secretary Thompson's commitment to addressing the challenge of serving those in areas that are difficult to reach. Data regarding this indicator is gathered from annual State program reports.

AoA pursuit of a significant increase in the percentage of CBSP clients who reside in rural areas is an aggressive performance objective in light of the data above that indicates that this percentage has declined in recent years. This decline in the percentage of clients who live in rural areas should not be viewed with alarm in that it is consistent with Census data, which show a similar trend for all elders in the Nation. Nevertheless, because it is important to target services where access is more difficult, AoA intends to reverse the trend and accomplish this performance goal.

Means and Strategies

AoA intends to accomplish the goal through targeted program integration strategies and the rebalancing of long-term care financing across the country. Targeting services to vulnerable individuals in areas where access is more difficult can be more costly than serving those who live in areas where services are more readily available. AoA has observed that the State and local entities that have had the most success in efficiently integrating multiple funding streams and service infrastructure, and those that provide a higher percentage of long-term care funding to community-based programs, have been better able to devote resources toward serving those in areas where access is a challenge.

AoA integration and rebalancing strategies seek to make such resources available across the network. The strategies reflect the identification and replication of best practices related to the efficient and effective deployment of long-term care resources. Where such resources are efficiently used, higher percentages of vulnerable populations, including those in rural areas, are served.

Budget and Policy Priorities

The budget request for FY 2005 is $1.3 billion. This is a slight increase over the FY 2004 President's Budget. The FY 2005 budget also requests additional funding for discretionary projects that will demonstrate how existing resources can be utilized more effectively to generate better results, while keeping costs down, including:

- An expansion of resource centers that will assist States and communities better integrate program services and funding sources and allocate more resources to difficult to serve populations

- Investments in services integration will help providers to integrate community level service delivery and will enable seniors and caregivers to learn about and access an integrated array of health and social supports

- Health promotion projects that foster implementation of evidenced-based methods.

PART Review

A PART review was conducted on the Community Based Services Program (CBSP) for both the FY 2004 and FY 2005 budgets. The FY 2005 PART rated the CBSP Moderately Effective with a PART score of 81. The PART review found that AoA and its partners are directly impacting the most significant element of their mission: keeping elders in the community. The FY 2005 assessment also notes that AoA improved strategic planning and results management with expanded outcome and efficiency measures. AoA has developed new performance measures that will be used for making future budget decisions, and will allow AoA to better track the success of the innovation activities, which the Agency believes will contribute significantly to improved efficiencies across AoA programs.

External Factors

While it is essential to reach out to elders with critical services, economic factors such as State fiscal pressures and high fuel costs, which can affect the level of transportation services provided, and demographic factors, such as continued declines in rural residence among elders, may influence performance related to this objective.

Strategic Goal 7: Improve the Stability and Healthy Development of Our Nation's Children and Youth

HHS is engaged in a number of efforts to improve the stability and development of our Nation's children and youth. These efforts include promoting family formation and healthy marriages and instituting creative and innovative ways to improve the learning readiness of preschool children. Additionally, the Department aims to increase the involvement and financial support of non-custodial parents in the lives of their children and increase the percentage of children and youth living in a permanent, safe environment.

The Administration for Children and Families (ACF) will continue to promote the availability of childcare services as one of many key strategies to help families achieve economic independence. Research on ways to improve child development and school readiness will continue.

The Child Support Enforcement program assures that support is available to children by locating parents, and establishing paternity and support obligations. It is an integral part of the Department's effort to increase parental responsibility by promoting fathers' involvement in the lives of their children.

The mission of ACF Child Welfare programs, such as Foster Care and Adoption Incentives, is to provide safe and stable environments for those children who cannot remain safely in their own homes. In addition, the programs provide support, such as educational vouchers, to youth transitioning from foster care to independence.

ACF Child Support Enforcement and Child Welfare programs in this section and their representative performance measures illustrate HHS commitment to improving the stability and development of our Nation's children and youth.

CHILD SUPPORT ENFORCEMENT

Administration for Children and Families

FY 2005 Budget Request: *$4,086 million*

FY 2005 Full Cost Budget Request: *$4,128 million*

Program Background and Context

The mission of the ACF Office of Child Support Enforcement (OCSE), as established in Title IV-D of the Social Security Act, is to assure that assistance in obtaining support is available to children by locating parents, establishing paternity and support obligations, and modifying and enforcing those obligations. OCSE works in cooperation with State agencies to implement the program and to achieve performance goals. In addition, OCSE is an integral part of the Department's effort to increase parental responsibility by promoting fathers' involvement in the lives of their children.

The program achievements for FY 2002 of the child support program are as follows:

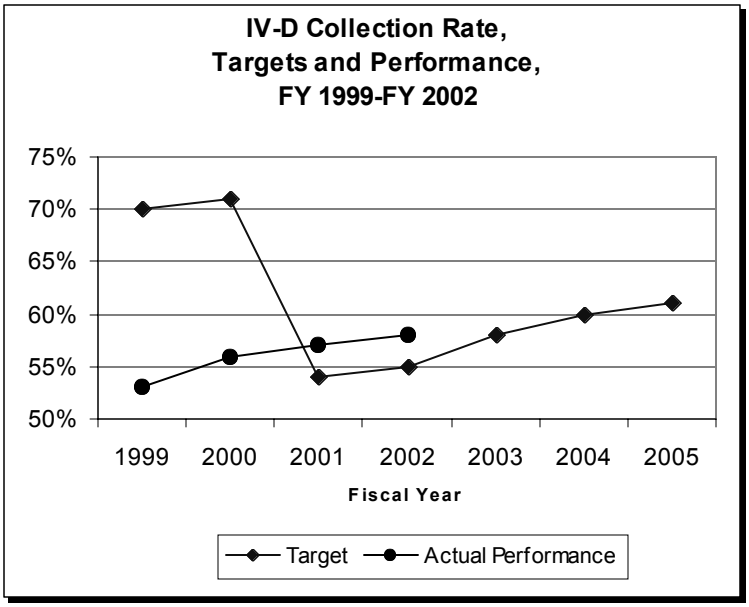
- Increased collections to $20.1 billion, a 40 percent increase from FY 1998.
- Over 1.5 million paternities were established or acknowledged.
- Established 1.2 million support orders, an increase of 6 percent from FY 1998.
- 46 percent of the caseload is families who formerly received public assistance.
- 89 percent of collections went to families.

Program Performance Planning

The program has five performance measures based on paternity establishment, support order establishment, current support collection, past-due cases paying, and cost-effectiveness. These measures are consistent with the performance-based incentive formula mandated by Title IV-D of the Social Security Act, which rewards States for achieving performance targets. The information is provided through administrative data collected by OCSE. Federal auditors conduct data reliability audits of performance data to ensure that States uphold data reliability standards.

The following measure illustrates the program's commitment to assessing program outcomes and improving program performance:

- ✓ ***Increase the Title IV-D collection rate (collections on current support / current support owed) to 61 percent in FY 2005.***



This measure is significant because collections on current support provide a regular and timely source of funds for our clients for their daily living. The target is developed by evaluating historical data to determine an ambitious but reachable percentage. To improve the collection of support for children, ACF is simplifying the payment process, reducing barriers to non-custodial parents providing support payments, increasing the number of cases handled using automated systems, improving interstate case processing, and increasing coordination and integration of services with other agencies.

Means and Strategies

ACF will accomplish its performance measures for Child Support Enforcement through a combination of proven means and strategies.

- Incentive funding to States for performance on five measures, which is mandated by Title IV-D of the Social Security Act. In FY 2003 and FY 2004, OCSE will award States $461 million and $454 million, respectively in incentive payments. Performance and data reliability are clearly improving as a result of fiscal incentives. The new incentive system was phased in over a three year period beginning in FY 2000. In FY 2002, OCSE awarded $450 million in incentive payments.

- The five performance measures are paternity establishment, support order establishment, current support collections, arrears collections, and cost-effectiveness.

- The Federal Parent Locator Service (FPLS), including the National Directory of New Hires and the Federal Case Registry, helps to locate non-custodial parents especially across State lines, as well as their employers and wages. This information also helps States establish more reasonable child support orders, thus increasing the chances for collection and the overall collection rate.

- Federal funds are targeted so that services will reach intended beneficiaries. Collection outcomes are weighted in the incentive program so that States receive more credit for working with low-income public assistance and former public assistance cases, not just potentially high-collection child support cases.

- Investment in program automation, like the Expanded FPLS, enhances the cost-effectiveness of the program by increasing collections. States must meet specific performance and cost effectiveness standards for their automation projects, preventing and/or recovering federal reimbursement for ineffective projects.

- To increase collection of current support, the most effective tool of CSE is wage assignment.

- CSE uses tools, like the passport denial program, State Disbursement Units, Financial Institution Data Matches, the National Directory of New Hires, and the Federal Case Registry, to improve performance on the rate of collection of past-due support.

- OCSE uses liens and the Federal tax refund/Administrative offset program to improve collection in past due collections.

Budget and Policy Priorities

The FY 2005 budget includes an additional $2 million for an annual total of $12 million for access and visitation grants, an estimated 19 additional Tribal child support programs, and $446 million for Federal incentive payments to States. The estimated Federal share of State administrative costs is $3.9 billion.

For FY 2005, ACF is proposing two legislative changes for the Child Support Enforcement program to improve the collection of medical child support by increasing the number of children who receive and maintain medical support coverage. The first proposal assures that IV-D agencies receive notice of a child's loss of health insurance coverage. The second proposal seeks health insurance from either parent, so that more children will have access to continuous health coverage, which will result in healthier children and families.

The FY 2005 President's Budget includes FY 2003 and FY 2004 budget proposals. FY 2004 budget proposals include: new legislative authority to seize funds from bank accounts of delinquent child support obligors in direct response to State difficulties making such seizures in interstate cases; the intercept of gaming proceeds; garnishment of long shore and harbor worker's compensation benefits; FPLS access to insurance settlement databases; increased funding for access and visitation State grant program; and direct access for Indian Tribes to the Federal income tax offset program and the Federal FPLS.

FY 2003 budget proposals include: optional pass-through and disregard; optional simplified distribution; a reduced threshold for passport denial; review and adjustment for child support orders; Social Security Administration benefit match; and a user fee.

PART Review

This program is one of five ACF programs that received PART reviews for the FY 2005 budget. Child Support Enforcement received a rating of Effective with a score of 90 and is the highest rated block/formula grant among all programs reviewed governmentwide. The high score is attributed to its strong mission, established performance measurement and incentive program, demonstrated results, partnerships with State and local government, and integrated budget and performance systems. The above proposals, which seek to enhance medical support for children and improve collection techniques, further strengthen Child Support Enforcement and address PART findings.

External Factors

The following factors may help or hinder the performance of the Child Support Enforcement program: 1) demographic and social trends, such as divorce and non-marital birth rates; 2) wage and employment rates; 3) the national economy; and 4) the five year time limit on TANF benefits, and other State TANF program policies, which make child support critical to family self-sufficiency.

CHILD WELFARE

Administration for Children and Families

FY 2005 Budget Request: $7,897 million

FY 2005 Full Cost Budget Request: $7,898 million

(Budget numbers include mandatory and discretionary program dollars)

Program Background and Context

The purpose of the Administration for Children and Families (ACF) Child Welfare programs is to prevent maltreatment of children in troubled families, protect children from abuse, and find permanent placements for those who cannot safely return to their homes. Through the Child Abuse State Grant and the Community-Based Child Abuse Prevention programs, States receive funds to develop services that prevent the need for a child's removal from the home. Programs such as Foster Care, Adoption Assistance, and Independent Living provide stable environments for those children who cannot remain safely in their homes, assuring the child's safety and well-being while their parents attempt to resolve the problems that led to the out-of-home placement. When the family cannot be reunified, foster care provides a stable environment until the child can be placed permanently with an adoptive family or in a guardianship arrangement. Adoption Assistance funds are available for a one-time payment for the costs of adopting a child as well as for monthly subsidies to adoptive families for care of the child.

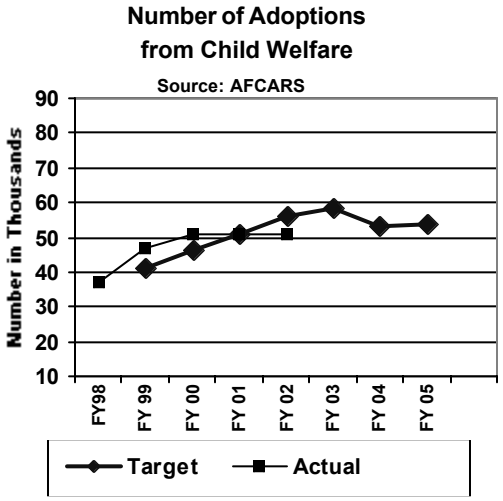
Program Performance Planning

The ACF primary mechanism for performance measurement is the Child and Family Services Reviews (CFSR), which focus on outcomes for children and families in the areas of safety, permanency, and child and family well-being; and systemic factors that directly impact a State's capacity to deliver services leading to improved outcomes. Compliance with statutory requirements and outcome achievement is assessed through qualitative and quantitative case-specific and aggregate data specifically related to the performance measures established for the child welfare programs. In FY 2005, at least one CFSR will have been completed in each State and, where applicable, States will be implementing their Program Improvement Plans.

The Child Welfare program has six performance measures to represent the full spectrum of child welfare from decreasing maltreatment to ensuring permanency and stability. In FY 2002, the most recent year for which data are available, four of the six targets were either met or exceeded. Using State performance related to performance measures, the results of the CFSR, and findings of the PART assessment, ACF has also established two long-term strategic goals on State program improvement and adoption.

Because of the complexity involved, the number of adoptions becomes a measure of how the State system is functioning and its persistence in achieving permanency for children in foster care. It is, therefore, an appropriate goal to highlight.

✓ ***Increase the number of adoptions toward achieving the goal of finalizing 327,000 adoptions between FY 2003-FY 2008. The target for FY 2005 is 62,000 adoptions.***



In following a typical path to adoption, a State must remove a child from his/her home after assessing that the level of risk of harm to the child warrants such action, engage the family in services to ameliorate the level of risk to the child, determine that the family is unable to make the changes needed to reunite the child with his/her family, build and win a case to terminate parental rights, match the child with an appropriate pre-adoptive family, and provide services and supports to that new family unit until the adoption is finalized and post-finalization as warranted.

ACF developed adoption targets by calculating the linear trend in the number of children in foster care on the last day of each fiscal year for FY 2003 through FY 2008. As the graph demonstrates, the number of adoptions has remained constant from 2000 through 2002 at approximately 50,000 adoptions. In these years, the number of children in foster care has been declining while the adoption rate (number of adoptions divided by the number of children in care at the end of the prior year) has been increasing. The FY 2005 target of 62,000 adoptions is a very ambitious target because the rate of adoptions must continue to increase while the number of children in foster care decreases.

Means and Strategies

ACF is employing a number of strategies to improve program performance and facilitate meeting these targets:

- The Adoption Incentive Program, created through the Adoption and Safe Families Act (ASFA) of 1997, authorizes the payment of adoption incentive funds to States that are successful in increasing the number of children who are adopted from the public foster care system. Recently reauthorized through the Adoption Promotion Act of 2003, the program

now emphasizes adopting older children. Analysis of data from AFCARS shows that once a child waiting for adoption reaches nine years old, the child is more likely to continue to wait in foster care than to be adopted. A State will continue to receive $4,000 per adopted child over its baseline for all adoptions out of the public child welfare system and $2,000 per special needs adoption over that baseline. A State will now also receive a $4,000 bonus for each child over the age of nine that is adopted over the State's baseline for older children.

- Under the Child Welfare Program Option proposal, described below, States would be able to use program option funds to facilitate systemic reform in child welfare, increasing the likelihood of meeting the targets for all performance measures.

- ACF will continue to provide States technical assistance as they complete program improvement plans resulting from the CFSR. After the Program Improvement period ends, States will undergo a second review, and will continue this process until they come into compliance with all 14 areas.

- HHS is committed to continuing to seek innovative ways to promote the adoption of children from foster care. The Department has launched an important new tool to promote adoptions called AdoptUSKids, an Internet adoption photolisting. AdoptUSKids was developed through an impressive public/private partnership between the HHS, the National Adoption Center, corporate partners, States, and adoptive families. In its first year, the site featured pictures and descriptions of at least 6,500 children in foster care who need permanent adoptive homes. In addition to featuring waiting children, the secure site maintains a data base of approved adoptive families, raises public awareness and recruits families for waiting children, provides information and referral services to prospective adoptive families, and provides training and technical assistance to States and adoption exchanges. Built into the system are management tools for adoption workers to quickly respond to inquiries from prospective families. In December of 2003, the 2000th child was adopted from the Adopt**US**Kids site.

Budget and Policy Priorities

The FY 2005 budget request for the ACF programs included in this performance program area is $7.9 billion - an increase of $139 million (+1.8 percent) over the FY 2004 level. The most significant increase in the Child Welfare area is in the Child Abuse State Grant and the Community-Based Child Abuse Prevention programs where the request is $107 million, a 95 percent increase over FY 2004. Providing an increase in funding to the State Grant and CBCAB programs will assist States as they implement the prevention-related requirements of the Keeping Children and Families Safe Act of 2003. Increased funding in this area is consistent with the Departmental emphasis on prevention - dedicating resources to prevent the need for intervention services. In FY 2005, ACF also is proposing to amend the Social Security Act to clarify that a child's Title IV-E foster care maintenance payment eligibility is linked inextricably to the custodial relative's home from which the child is removed and is based on whether the child would have been eligible for AFDC in that home as it was in effect on July 16, 1996.

ACF proposes to amend the statute so that the statute and the Department's long-standing interpretation are in full accord.

The Administration continues to support its proposal for the Child Welfare Program Option, which is a plan to improve program performance in child welfare. The proposed program option for Foster Care will provide foster care funds in the form of flexible grants for States choosing to participate. The flexible grants will serve as an incentive to create innovative child welfare programs with an emphasis on providing services that prevent children from being placed in foster care and on strengthening families. States may use these funds for any purposes allowed under Title IV-E Foster Care or Title IV-B (Child Welfare Services and Promoting Safe and Stable Families).

PART Review

The Foster Care program received a PART review for the FY 2004 and 2005 budgets. Preliminary results of the FY 2005 assessment indicate that the overall program score improved from 37 in FY 2004 to 52 in FY 2005. In response to PART findings, the Children's Bureau has proposed a requirement with requisite funding to evaluate States on overall program effectiveness. Additionally, efforts are underway to improve annual achievement of targets and long-term strategic goals. As recommended in the FY 2004 PART review, ACF intends to develop a national error rate for Foster Care and proposes to create a flexible funding program option through which States will have flexibility to implement system reform.

External Factors

Performance will be affected by external factors including: 1) the economy, including employment and wage rates; 2) the success of employment programs implemented under TANF; 3) the success of initiatives which promote healthy marriages and enhanced involvement of fathers in children's lives; 4) the availability of low-cost housing; 5) the availability of substance abuse treatment; and 6) social and demographic trends such as divorce and non-marital births.

Strategic Goal 8: Achieve Excellence in Management Practices

HHS is committed to improving the efficiency and effectiveness of the Department's programs by creating an organization that is citizen-centered and results-oriented. As part of our overall commitment to effective management, HHS is dedicated to successfully meeting the challenges identified in the President's Management Agenda. HHS is committed to improving management of our financial resources; using competition to obtain the best price for the services acquired; improving the management of our human capital and tying human capital goals to program performance goals; using technology wisely and in a cost effective manner; and achieving budget and performance integration.

In implementing the President's Management Agenda HHS is seeking to achieve a variety of reforms. These include: 1) implementing an ambitious restructuring plan aimed at consolidating and automating administrative functions such as human resources management; 2) de-layering organizations and reducing the number of management layers in order to create efficiencies and speed decision-making; 3) implementing a Unified Financial Management System to consolidate multiple systems, eliminate duplication, and improve the management of the Department's financial resources, and implementing initiatives to reduce improper payments in the Department's programs 4) consolidating information technology systems to achieve efficiencies and improve interoperability of the Department's multiple systems; 5) and achieving integration of budget and performance so that funding decisions are results driven.

As part of the One HHS Initiative, the Department has consolidated management of its human resources function, to better focus on the recruitment, retention, and development of a workforce with the skills necessary to carry out our mission now and in the future. The hiring process has been simplified and automated, and leadership succession programs are in place. Top executives, managers and employees alike are held accountable to the Department's mission through performance contracts that link directly to HHS strategic priorities. The Department is also developing a plan to consolidate the Equal Employment Opportunity function department-wide in an effort to achieve efficiencies and improve service deliveries.

The Department continues to make steady progress in improving financial performance, including developing the Unified Financial Management System, and developing and implementing initiatives to estimate payment error rates in Head Start, Child Care, Foster Care, and other HHS programs. HHS has begun work to engage a contractor to provide recovery-auditing services for its contract payments. For FY 2003, the Department earned its fifth consecutive clean and timely audit opinion under a pilot effort by November 15, 2003, 45 days after the end of FY 2003, and one year earlier than the OMB-mandated due date of November 15, 2004.

The Department has also undertaken a major initiative to consolidate information technology systems to achieve efficiencies and improve interoperability of the Department's multiple systems. HHS will also continue to support E-Gov efforts, in concert with the HHS Strategic

Plan and the HHS IT 5-Year Strategic Plan. As applicable, HHS will participate in and contribute resources to PMA E-Gov initiatives, serving as the managing partner for Grants.gov (formerly E-Grants), Consolidated Health Informatics (CHI) and Federal Health Architecture (FHA).

The Department has made strides toward achieving integration of budget and performance so that funding decisions are results driven. HHS has completed its FY 2005 Annual Performance Plan, which highlights key programs and performance measures and presents the total HHS discretionary budget organized by Department Strategic Goal. The Department also has reported the full cost of achieving all performance goals, and used Program Assessment Rating Tool (PART) evaluations to inform budget decisions, program improvements, legislative proposals, and management actions.

The Annual Performance Plan highlights two initiatives to reduce improper payments in HHS programs: the Centers for Medicare & Medicaid Services Medicare Integrity Program and the HHS Office of Inspector General's efforts in this area.

MEDICARE INTEGRITY PROGRAM

Centers for Medicare & Medicaid Services

FY 2005 Budget Request: *$720 million*

FY 2005 Full Cost Budget Request: *$720 million*

Program Background and Context

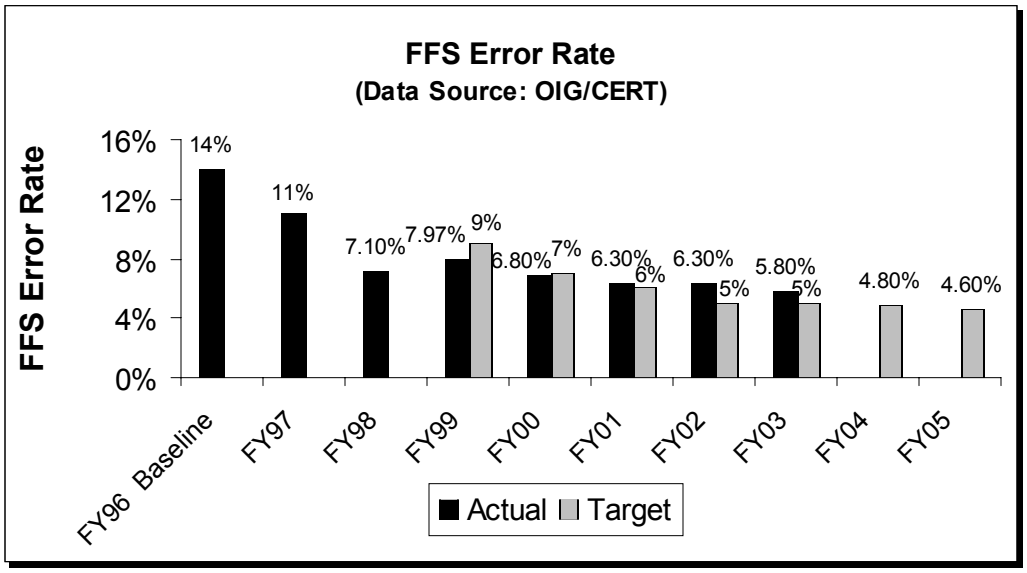
CMS program integrity efforts ensure the Medicare program pays the right amount to legitimate providers for covered, reasonable and necessary services that are provided to eligible beneficiaries. These activities are primarily funded through the Hospital Insurance Trust Fund by the Medicare Integrity Program (MIP), established by the Health Insurance Portability and Accountability Act (HIPAA) of 1996. The MIP includes medical review and benefit integrity activities, provider education and training, Medicare secondary payer activities, and provider audits. CMS overall program integrity efforts are supplemented by funding from the CMS Program Management account and other funds made available from the Health Care Fraud and Abuse Control account (HCFAC).

Program Performance Planning

CMS started measuring the percentage of improper payments made under the Medicare program in 1996 and created a goal to reduce this percentage. CMS now has five goals representing MIP. These include reducing the contractor error rate and improving the provider compliance error rate. For FY 2003 and beyond, the Comprehensive Error Rate Testing (CERT) program is being used to develop the national Medicare claims payment error rate. The CERT program is monitored for compliance by CMS through monthly reports from the contractor.

The following measure illustrates one key programmatic activity of MIP:

- ✓ ***Reduce the Percentage of Improper Payments Made Under the Medicare Fee-for-Service Program***



* The FY 2003 actual figure has been adjusted to account for the high provider non-response experienced in 2003. Had the adjustment not been made, the national paid claims error rate would have been 9.8 percent.

One major CMS goal is to pay claims properly the first time. Paying right the first time saves resources and ensures the proper expenditure of limited Medicare trust fund dollars. During the PART review process, CMS worked with OMB to set ambitious annual targets for its program integrity goals for FY 2004 and beyond. CMS is confident that by addressing specific high-risk areas, it will achieve success in reaching these aggressive annual targets.

Means and Strategies

The complexity of Medicare payment systems and policies and the number of contractors, providers, and insurers involved in the Medicare fee-for-service program create vulnerabilities. CMS has implemented an error rate reduction plan designed to minimize these vulnerabilities and reduce the Medicare claims payment error rate. Other efforts designed to reduce Medicare's improper payment rate include improving customer service, clarifying documentation guidelines, strengthening enrollment, and improving industry compliance.

In addition to the national error rate, CERT outcomes include contractor-specific error rates, as well as a Medicare provider compliance error rate. These rates will allow CMS to quickly identify emerging trends in managing Medicare contractor performance.

CMS medical review activities will emphasize appropriate corrective actions for identified claims payment errors. In addition, CMS will stress a quality improvement program, to ensure that the decisions made by medical review staff are accurate and consistent, and provide a

thorough and efficient medical review process. This approach will enable CMS to reduce the claims payment error rate and assure providers and beneficiaries that it is operating the program in a responsible manner.

In provider education and training, CMS will emphasize educational activities that communicate appropriate billing practices in compliance with Medicare rules, regulations, and manual instructions. Sharing data analysis with local medical societies, professional associations, and other provider organizations will be used to effectively target CMS efforts.

In support of MIP activities, improved provider enrollment will ensure that CMS enrolls only legitimate providers. Plans are being developed or are already underway to: provide stricter standards and stronger conditions of participation, conduct onsite visits to verify legitimacy and compliance with standards, increase the frequency of reenrollment, and collect better ownership and financial solvency information.

Budget and Policy Priorities

For FY 2005, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) provides $720 million for MIP. The following figures indicate the costs for each of the MIP activities for FY 2004 and FY 2005.

	FY 2004	FY 2005
Medical Review	$163 million	$163 million
Benefit Integrity	$127 million	$127 million
Audit	$204 million	$204 million
HMO Audits	$ 9 million	$ 9 million
Medicare Secondary Payer	$147 million	$147 million
Provider Education and Training	$ 70 million	$ 70 million

PART Review

The FY 2004 Medicare Integrity Program PART assessment found that the program has a clear purpose, is managed well overall and relies on performance measures that are directly relevant to the program purpose. This is reflected in the reduction of the Medicare error rate, which has declined from 14 percent of fee-for-service payments in 1996 to 5.8* percent in FY 2003. MIP received one of the highest scores (85) of all programs reviewed by OMB.

The assessment noted that CMS is developing sub-national performance measures to produce contractor, provider and benefit-specific error rates, and developing provider compliance rates to identify providers who need assistance with accurate billing. The assessment also noted that, although CMS has an effective national performance measure, it did not require Medicare fiscal

*This figure has been adjusted to account for the high provider non-response experienced in 2003. Had the adjustment not been made, the national paid claims error rate would have been 9.8 percent.

intermediaries and carriers to commit to specific error rates. CMS contracts with fiscal intermediaries and carriers on a cost basis and budgets most MIP funds based on activity level. As a result, very few of these contracts relate pay to performance. New Medicare contracting reform changes enacted in the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) will allow CMS to competitively bid for these contracts that were previously cost-based contracts.

CMS intends to further reduce the Medicare fee-for-service error rate to four percent by FY 2008. Furthermore, CMS committed to the following two new program integrity goals in the FY 2004 Annual Performance Plan:

- Reduce the Medicare Contractor Error Rate (MIP9-04): By FY 2008, all Medicare contractors will have an error rate less than or equal to the previous year's actual unadjusted national paid claims error rate.

- Decrease the Medicare Provider Compliance Error Rate (MIP10-04): By FY 2008, CMS will significantly improve the Medicare provider compliance error rate.

For the FY 2005 PART assessment, MIP maintained the same score.

External Factors

The ability of MIP to leverage private sector entities through its contracting authority has proven to be effective. Additionally, new Medicare contractor reform legislation will further enhance MIP effectiveness. On December 8, 2003, Congress enacted the MMA. Section 911 of the Act establishes the Medicare fee-for-service Contracting Reform Initiative (MCRI) that will be implemented over the next several years. Under this provision, CMS will replace the current Medicare fiscal intermediary and carrier contracts, using competitive procedures, with new MAC contracts by October 2011. The new Medicare Administrative Contractor (MAC) contracts may be renewed annually based on performance for a period of five years, but they must be re-competed every five years.

OFFICE OF INSPECTOR GENERAL

Office of the Secretary

FY 2005 Budget Request, Mandatory Portion: *$160 million**

FY 2005 Mandatory Full Cost Budget Request: *$160 million*

FY 2005 Budget Request, Discretionary Account: $40 million

FY 2005 Discretionary Full Cost Budget Request: $40 million

Program Background and Context

The purpose of the Office of Inspector General (OIG) is to detect fraud, waste, and abuse, and recommend policies designed to promote economy, efficiency, and effectiveness in Department of Health and Human Services (HHS) programs. It accomplishes its purpose by conducting and supervising audits, inspections, and investigations, and providing guidance to the health care industry. Approximately 80 percent of OIG resources are devoted to Medicare and Medicaid under the Health Care Fraud and Abuse Control Program (HCFAC), which was mandated in 1996 by the health care fraud and abuse provisions of the Health Insurance Portability and Accountability Act (HIPAA). The HCFAC Program is a joint responsibility of HHS and the Department of Justice. Its purpose is to coordinate Federal, State, and local law enforcement activities with respect to health care fraud and abuse, including the conduct of investigations, audits, evaluations, and inspections relating to the delivery of and payment for health care in the United States. The program came about in response to the need to intensify pursuit of the large and growing level of health care fraud and abuse, and to take aggressive action to reduce the risk of insolvency of the Medicare Trust Fund.

The remaining nearly 20 percent of the OIG operating budget is dedicated to fighting fraud, waste, and abuse in all other HHS programs; specifically, all public health, human services, and research programs, as well as general Departmental oversight.

For FY 2003, the OIG reported savings of over $23 billion, comprised of nearly $21.7 billion in implemented recommendations and other actions to put funds to better use, and nearly $1.4 billion in investigative receivables, and recoveries or receivables attributable to audits. Viewed as a ratio of savings to operating costs (return on investment), the OIG saved 117 times its operating cost in FY 2003, thus continuing a long established pattern of effectiveness and efficiency in carrying out its mission.

Program Performance Planning

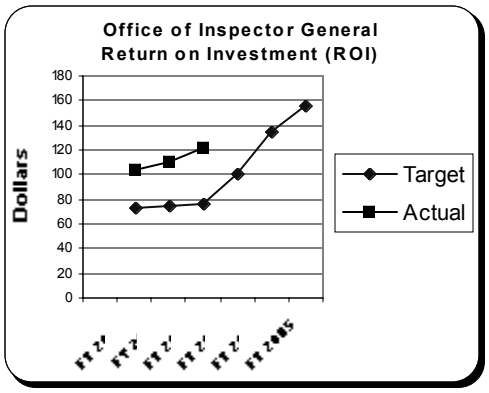
The OIG uses return on investment (ROI) as its key performance measure. ROI is an outcome-oriented measure of OIG efficiency. Savings, its numerator, is a measure of outcome, and by relating it to the cost of operating the OIG, it is a measure of efficiency and cost-effectiveness.

* FY 2005 HCFAC funding will be determined beginning in mid-September 2004. By current law, OIG HCFAC funding ranges from $150–$160 million.

The savings that are used to calculate ROI consist of expected recoveries of funds resulting from successful prosecutions in the courts and out of court settlements, and savings from funds not expended as a result of OIG audits, investigations, and inspections, as determined by the Congressional Budget Office. ROI provides a clear focus on results for OIG managers as they direct the program and allocate its resources.

Because of the unique and innovative nature of the HCFAC Program, which started in 1997, the ROI target was initially conservative. After several years of exceeding its targets, the OIG strove to make them more challenging. The OIG adopted a three-year moving average to recognize the multi-year characteristic of the work that lends itself to that approach, and set goals that exceeded the levels already achieved. The target is to increase by 10 percent expected recoveries, and achieve a fixed dollar increase in saving resulting from the implementation of OIG legislative and administrative recommendations.

- ✓ ***Achieve Return on Investment (Expected Recoveries and Savings from Funds Not Expended per Dollar Invested in the OIG) in FY 2005 of $154.***



Means and Strategies

The work of the OIG consists primarily of conducting and supervising audits; investigating allegations of fraud and abuse; performing evaluations/inspections; assisting U.S. Attorneys, and others, in case development; providing guidance to the health care industry; and championing its cost saving and management improvement recommendations. All of these means and strategies are labor intensive, therefore, it is essential for the OIG to develop, retain, and, where necessary, fill vacancies with talented staff; target resources by careful work planning to achieve the most impact on high priority problems; and use modern technology in ways that increase the organization's efficiency and effectiveness.

Budget and Policy Priorities

The mandatory portion of the budget request (the HCFAC budget account) for FY 2005 will be determined beginning in mid-September of 2004 and the discretionary FY 2005 request for the discretionary account is $40.3 million. The HCFAC request is $160 million, the maximum amount allowed by HIPAA since FY 2003.

While the OIG is actively engaged in support of all Presidential and Secretarial initiatives as part of its Department-wide oversight mission, it is most prominent in its work in support of achievement of excellence in HHS management practices. It is under the latter HHS strategic goal that all its work to uncover fraud, waste, and abuse, and contribute to improved efficiency and effectiveness of HHS programs resides.

PART Review

The HCFAC Program was reviewed as part of the FY 2004 budget. OMB concluded that return on investment was not sufficient to demonstrate performance of this program, and recommended that additional measures, using an objective baseline are necessary, which can be used to make resource allocation decisions. The OIG expects to conclude its performance measure review by the end of June 2004.

External Factors

OIG work in any given year, and therefore the budget for that year, cannot be associated with the results reported for that year. The reasons for this are the multi-year periods usually needed to complete legal actions and commence collection efforts, and the time needed for OIG legislative and administrative recommendations to be implemented. Obviously, the level of performance reported in any given year, though the result of work that spans several years, is linked to the levels of funding over the relevant preceding years.

It is also important to emphasize that OIG returns are highly dependent on the success of the U.S. Attorneys and other components of the Department of Justice, the States, Congress, and HHS Operating Divisions to prosecute criminal cases successfully, arrive at civil settlements, enact necessary legislation, recover misspent funds, or implement recommendations for program improvements.