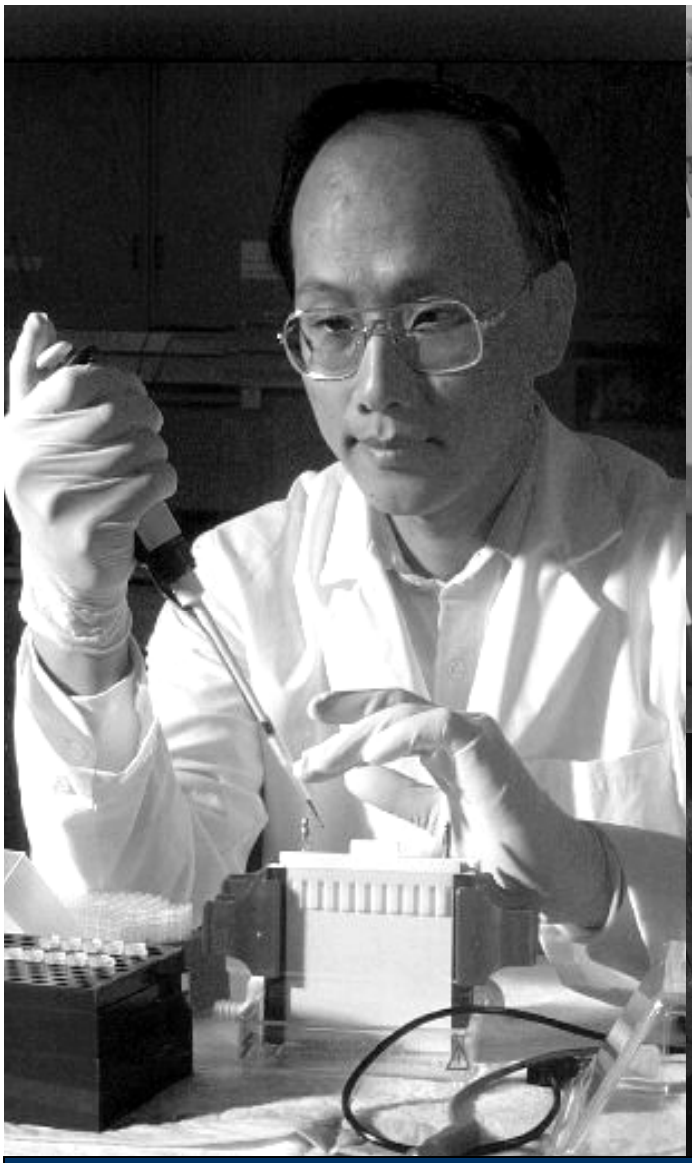


Program Performance Report



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Program Performance Report

Overview

The Department of Health and Human Services (HHS) is the one of the largest Federal agencies, the Nation's largest health insurer, and the largest grant-making agency in the Federal Government. The Department protects and promotes the health and well-being of all Americans and provides world leadership in biomedical and public health sciences. The programs of the Department impact all Americans, whether through direct services, scientific advances, or information that helps them choose medical care, medicine, or even food. Through Medicare and Medicaid, for example, HHS oversees the administration of the Nation's largest health insurance programs, which provide care to about one in every four Americans. Medicare serves approximately 42 million elderly and disabled Americans, while Medicaid, a joint Federal-State program, provides health coverage for 42.9 million low-income people. Through numerous grants and other financing arrangements with public and private service providers, HHS is committed to improving health and human service outcomes and the economic independence of individuals and families throughout the U.S.

In fiscal year (FY) 2004, HHS published an updated *Strategic Plan*, which outlines the Department's strategic direction over the next 5 years. The plan's eight strategic goals guide HHS in accomplishing its mission to protect and improve the health and well-being of the American public. These goals provide a focus for HHS investments and serve as a framework for the measures that track the Department's performance.

HHS administers its programs in coordination with partners in the States and local communities. In fact, the overwhelming majority of the approximately $550 billion expended for HHS programs in FY 2004 will be spent by these program partners. Therefore, the strategic goals, performance goals, and results in the HHS *Strategic Plan* and the annual performance plans and reports reflect the combined commitment and effort of HHS programs and their State, local, Tribal, and non-governmental partners. A copy of the HHS *Strategic Plan FY 2004 – FY 2009* is available at http://aspe.hhs.gov/hhsplan/.

Data and Performance Measurement

Sound information is essential to HHS' mission of enhancing the health and well-being of Americans. For every HHS performance measure, whether providing for effective health and human services or for fostering sustained advances in the sciences or public health system, reliable and readily available information is necessary for planning, measuring results, and making sound decisions. Accordingly, the Department plays an essential role in producing data for decision making for health and human services programs, both as a direct producer and as a partner in data collection with the States, grantees, and other governmental agencies. The HHS Data Council maintains on its website (http://aspe.hhs.gov/datacncl/index.shtml) a directory of all of the major data systems supported by HHS Agencies, both programmatic and multi-purpose data systems and surveys. These data systems support most of the performance measurement objectives in HHS programs as well as broad health and social outcome indicators.

HHS' programs and agencies rely upon data for program management, policy decision making, and intervention development. The Government Performance and Results Act of 1993 (GPRA) emphasizes the importance of data for decision making and creates an incentive for staff throughout HHS to refine the Department's data systems. HHS programs work extensively with partners in State, local, and Tribal

governments, grantees, and Medicare contractors in program implementation and data collection. The Department continuously identifies enhancements to the systems that improve the timeliness, completeness, and accuracy of data and enables employees to move to more sophisticated performance measures.

HHS has taken a number of steps to address key data needs in a coordinated fashion, promote a HHS-wide strategy on data issues, and strengthen the Department's ability to work in collaboration with private sector entities, State and local governments, and other partners. The HHS Data Council serves as the principal senior level internal forum on health and human services data policy, and serves as the focal point for HHS data policy initiatives. Currently, the Data Council and its working groups are focusing efforts on the following:

- HHS data collection strategy, coordination, priorities, and planning;
- Cross-HHS budget review, prioritization, and coordination of data collection investments in the budget planning process;
- National health data standards (e.g., Health Insurance Portability and Accountability Act standards, clinical data standards and statistical standards;
- Data privacy and confidentiality issues, policies, and best practices;
- HHS data quality policies and practices, including peer review policies; and
- Selected national health information infrastructure issues.

As a result, HHS had made improvements in many data collection systems and in HHS-wide data planning and integration, including HHS survey integration efforts. As the result of Council recommendations, for example, the President's FY 2005 budget for HHS includes a major statistical data investment. In addition, integrated, user-friendly access to and availability of the vast data resources in HHS is being improved through the creation of the Data Council's Gateway to Data and Statistics on the Internet. Additional Department-wide initiatives developed by the Council include the HHS data quality initiative, improvements in geocoding standards and practices, data access and dissemination, statistical confidentiality, and coordination of data collection activities.

However, new data needs for performance measurement are arising, and a number of critical data gaps remain. Additional challenges for performance related data include:

- Producing data on a timelier basis and with a frequency relevant to the periods over which performance is being measured;
- Continuously appraising and updating systems to reflect innovations and changes in the delivery of health and human services to the American public;
- Systematically obtaining accurate, reliable data at the State and local level where many HHS programs are implemented;
- Developing appropriate performance measurement methodologies to capture the progress of program efforts to produce measurable results;
- Producing information with sufficient quality and precision to detect what may be relatively small but important changes in key performance indicators; and
- Achieving major changes in complex data collection systems in a timely and affordable manner.

To address these needs from the collective Department-wide perspective in the annual budget process, the HHS Data Council works closely with the Office of Budget to review, coordinate, and prioritize all proposed investment requests to improve data and information for decision making and to ensure that data systems are responsive to performance measurement needs and Secretarial priorities. In addition, the Council continually reviews plans for major data collection activities.

Similarly, throughout HHS, data is being made available to Agencies and partners for planning, decision making, and measuring results. These efforts include developing new data collection systems, enhancing current data collection systems, eliminating systems that are no longer relevant, combining reporting where possible, and building capacity to collect data at the State and local levels.

Throughout this report, when current year performance data is not available, a date that the data will become available is provided. As required by Office of Management and Budget (OMB) guidance, HHS will report the results of all performance measures in future reports submitted to Congress.

Guide to Section II

The pages that follow provide an overview of performance measurement at HHS. The Department manages hundreds of programs, and the ones included in this report highlight the many ways that HHS is leading Americans to better health, safety, and well-being. This section highlights the efforts and accomplishments of dedicated program staff in a sample of program areas and provides information on the measures and goals of a few example HHS programs. To accomplish that, HHS selected programs that represent each of the Department's eight strategic goals, and each of the agencies that make up the Department. For a comprehensive view of all performance goals for all HHS program activities, including the latest performance results, see the FY 2005 performance plans and reports included in the budget justification to Congress for the individual HHS agencies or the FY 2006 performance budgets that will be submitted to Congress in February 2005.

Qualified staff with a thorough knowledge of program content and current operations, including financial and management control procedures, performed the data review process for data reported in Section II. Assurance of the accuracy of data for Section II was achieved through data verification processes inherent in the recurring usage and updates of the data and tables. Analysts, managers, and executives in the HHS Agencies and in the Office of Budget verified the data reported on an ongoing basis. Section II data and narratives received a thorough review within the Office of Budget by budget and program branch chiefs with budget and performance responsibilities. Performance management and assessment activities related to GPRA, the Performance Assessment Rating Tool (PART), and other performance related activities include assurances of the accuracy of data which are documented in the Data Verification and Validation section in the Agencies' annual performance plans and reports. These assurances are achieved through a first-level evaluation of data by Agency and Department GPRA and PART coordinators, followed by a second-level review and verification by specifically appointed managers and evaluators.

In developing the programs and measures reported in the FY 2004 *Performance and Accountability Report (PAR)*, HHS attempted to provide the best set of representative measures for HHS programs. Staff developed side-by-side comparisons of the strategic plan indicators and the FY 2005 performance plan measures and engaged Agency and Office of Budget analysts and managers in discussions regarding the measures and programs to be included in the *PAR*. Budget and performance coordinators compared the strategic plan indicators to the priorities of the President and the Secretary in an effort to ensure that all HHS Agencies and all major priorities were included on the FY 2004 *PAR* list. This effort resulted in selecting measures for the FY 2004 *PAR* that best represent the work and activities of HHS Agencies that occurred during FY 2004. However, the selected measures do not always match up neatly with either the

Department's *Strategic Plan* or the FY 2004 *Performance Plan*. This is because at the time the FY 2004 *Performance Plan* was prepared, HHS was still developing its performance budget plans and had not completed its current FY 2004 - 2009 *Strategic Plan*. In some cases, measures found in the FY 2005 *Performance Plan* were more representative of the work and direction the Agency was moving in FY 2004. This process resulted in the list of 22 highlighted programs reported in Section II.

In this section of the PAR, HHS presents detailed performance information for 22 highlighted programs organized by the Department's eight strategic goals. Each goal overview includes an introduction to the goal and a list of the selected programs and performance measures supporting the goal. Following the overview is a description of the program; a snapshot of the program's performance targets and results for four fiscal years; a discussion of the program performance and results; a description of the data sources; and, if applicable, a summary of the results program evaluations and PART reviews for each program. The PART is an evaluation tool developed by OMB used for reviewing program performance. As a result of a PART review, a program receives a rating as well as OMB recommendations for program improvements. In many cases these recommendations may involve a more comprehensive program evaluation or changes in program legislation. For information on the PART ratings for all HHS programs assessed during the FY 2004 and FY 2005 budget processes, please see Appendix I.

To find information about a specific goal, the reader can look at the page footer and find the desired goal.

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 HealthierUS* 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 U.S. 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 Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (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 immunization program protects the population from a wide variety of infectious diseases, including Diphtheria, Measles, Mumps, and Pertussis.

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 overall recommendations, the FY 2005 budget request makes a fourth installment on the President's drug treatment initiative, and HHS continues to work with Office of National Drug Control Policy to implement an effective drug prevention strategy that will increase the number of clients served.

- Selected Program 1.a: Centers for Disease Control and Prevention (CDC) National Immunization Program
    - Performance Measure 1.a: Achieve or sustain immunization coverage of at least 90 percent in children 19- to 35- months of age for: 4 doses Diphtheria Tetanus acellular Pertussis (DTaP) vaccine, 3 doses Haemophilus Influenzae type B (Hib) vaccine, 1 dose Measles, Mumps, and Rubella (MMR) vaccine, 3 doses Hepatitis B vaccine, 3 doses Polio vaccine, 1 dose Varicella vaccine, and 4 doses Pneumococcal Conjugate (PCV7) vaccine.
- Selected Program 1.b: CDC HIV/AIDS Prevention in the U.S.
    - Performance Measure 1.b.1: Reduce the number of HIV infection cases diagnosed each year among people under 25 years of age.
    - Performance Measure 1.b.2: Decrease the number of perinatally acquired AIDS cases, from the 1998 base of 235 cases.
- Selected Program 1.c: Substance Abuse and Mental Health Services Administration (SAMHSA) Substance Abuse Prevention and Treatment Block Grant
    - Performance Measure 1.c: Number of clients served.
- Selected Program 1.d: Centers for Medicare & Medicaid Services (CMS) Quality Improvement Organizations
    - Performance Measure 1.d.1: Increase annual Influenza vaccinations in Medicare beneficiaries age 65 and older to 72.5 percent over baseline (FY 1994 –59 percent).
    - Performance Measure 1.d.2: Increase lifetime Pneumococcal vaccinations in Medicare beneficiaries age 65 and older to 69 percent over baseline (FY 1994 – 24.6 percent).

1.A National Immunization Program

Centers for Disease Control and Prevention (CDC)

The Program

Through the National Immunization program, CDC protects the health of children and adults from disability and disease associated with vaccine-preventable diseases by developing and implementing immunization programs and monitoring vaccine use. The program focuses on the following areas: childhood, adolescent, and adult immunization; global Polio eradication; global Measles control; and vaccine safety. Vaccines are responsible for the control of many infectious diseases that were once common in the U.S., including Diphtheria, Measles, Mumps, and Pertussis. Today, many vaccines are available to protect children and adults against these and other life-threatening and debilitating diseases. CDC 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. CDC also plays a critical role in developing immunization policy by providing technical and scientific support to policymaking advisory groups, such as the Advisory Committee on Immunization Practices (ACIP).

Immediately following the notification by Chiron that its vaccine would not be available for the 2004-2005 Influenza season, HHS, and its component Agencies, including CDC, began working to address the Influenza vaccine shortage. HHS and CDC worked with the other major vaccine producer, Aventis Pasteur, to develop a plan for ensuring that the available Influenza vaccine would reach the most vulnerable populations. CDC is continuing to work with Aventis Pasteur, State, and local health departments and other partners in an effort to provide Influenza vaccine to geographic areas and high-risk individuals in need. CDC also collects and reports information on Influenza activity in the U.S. each week from October through May. The U.S. Influenza surveillance system has four separate components that allow CDC to find out when and where Influenza is circulating; determine what type of Influenza viruses are circulating; detect changes in the Influenza viruses; track Influenza-related illness; and measure the impact Influenza is having on deaths in the U.S.

Snapshot

1.a – Performance Measure: Achieve or sustain immunization coverage of at least 90% in children 19- to 35- months of age for [1]: 4 doses DTaP vaccine [2] 3 doses Hib vaccine 1 dose MMR vaccine [3] 3 doses Hepatitis B vaccine 3 doses Polio vaccine 1 dose Varicella vaccine [4] 4 doses PCV7 [4].		
Year	**Target**	**Actual**
2001	90% coverage	DTaP – 94% coverage Hib – 93% coverage MMR – 91% coverage Hepatitis B – 89% coverage Polio – 89% coverage Varicella – 76% coverage
2002	90% coverage	DTaP – 95% coverage Hib – 93% coverage MMR – 91% coverage Hepatitis B – 90% coverage Polio – 90% coverage Varicella – 81% coverage
2003	90% coverage	DTaP – 96% coverage Hib – 94% coverage MMR – 93% coverage Hepatitis B – 92% coverage Polio – 92% coverage Varicella – 85% coverage
2004	90% immunization coverage	Data available 08/2005

[1] Data are collected through the National Immunization Survey and reflect calendar years.

[2] Due to a shortage of vaccine and temporary change in recommendations, reported three doses from 2002 – 2003.

[3] Includes any Measles-containing vaccine.

[4] Performance targets for newly recommended vaccines are reported in GPRA 5 years after ACIP recommendation. Measures for Varicella began in 2001. Performance reporting PCV7 will begin in 2006.

Discussion of Results and Performance

One of CDC's immunization goals is to ensure that 2-year-olds are appropriately vaccinated. New cases of most vaccine-preventable disease have decreased approximately 99 percent from peak pre-vaccine levels, which has saved lives and reduced treatment and hospitalization costs. As CDC's immunization activities increase childhood immunization coverage, the incidence of vaccine-preventable diseases declines significantly. Vaccination coverage levels are at 90 percent or higher for most individual vaccines such as Measles, Polio, Hib, and Hepatitis B, and three doses of DTaP. Examples of the success of immunizations include:

- Measles is a highly infectious, viral illness that can cause severe Pneumonia, diarrhea, Encephalitis, and death. Measles is no longer endemic in the U.S.
- Only one child in the U.S. was born with Congenital Rubella Syndrome in 2003.

- Rubella cases have declined from 57,600 in 1969, when the vaccine was first available, to a total of seven cases in 2003.
- Hib cases have dropped more than 99 percent among children younger than age 5 since the Hib vaccine was introduced in 1990, and it is no longer the leading cause of meningitis among children younger than 5 years of age in the U.S.
- There have not been any cases of Polio reported in the U.S. since 1979.

In 2002 and 2003, CDC modified the measure for DTaP from four doses to three doses because vaccine shortages limited the availability of the fourth dose to children. The ACIP recommends that if this vaccine is in short supply, or not available, the fourth dose of DTaP may be dropped. The first three doses are considered the most critical to prevent disease. The change was temporary and the measure returned to four doses in 2004.

In 1996, the ACIP introduced the Varicella vaccine to the Recommended Childhood Immunization Schedule. By 2003, Varicella vaccine coverage levels reached 85 percent for most[1] racial and ethnic groups compared with a 26 percent coverage level in 1997.

ACIP added PCV7 to the 2001 Recommended Childhood Immunization Schedule. Accountability for PCV7 performance targets begins in FY 2006. PCV7 already is impacting the incidence of invasive Pneumococcal disease. According to a recently published study, the incidence of invasive Pneumococcal disease was 77 percent lower among white children less than 2 years of age and 89 percent lower among black children less than 2 years of age in 2002, as compared to 1998-1999 averages. Overall, this vaccine is projected to prevent more than 1 million episodes of childhood illness and approximately 120 deaths among children annually. Preventing Pneumococcal infections with vaccine is becoming more important because of problems with treatment as a result of increasing antibiotic resistance.

Data Source: The National Immunization Survey

Data for the immunization coverage performance comes from the National Immunization Survey (NIS), which uses a nationally representative sample and provides estimates of vaccination coverage rates that are weighted to represent the entire population, nationally, and by region, State, and selected large metropolitan areas. The NIS was established to provide an ongoing, consistent data set for analyzing vaccination coverage among young children in the U.S. and disseminating this information to interested public health partners. The NIS provides calendar year data. The immunization coverage rates for 2004 will be available in August 2005.

Program Evaluations

In response to OMB's recommendation, CDC is undergoing a comprehensive independent evaluation of the Section 317 Immunization Grant program. This program awards 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. These grants are only a part of HHS immunization program activities to assure the

[1] Only American Indian/Alaska Natives had a coverage rate of 81 percent, which is below the national average for varicella vaccine.

implementation of effective immunization practices and proper use of vaccines to achieve high vaccination coverage levels and decrease the burden of vaccine preventable diseases.

An independent contractor will provide recommendations to improve the efficiency of the Section 317 Grant program. The comprehensive evaluation has three phases. In phase one, the program mission, performance measures and objectives, and how CDC is implementing the mission and objectives and grantees will be evaluated. In phase two, the operations and management procedures, including the grant allocation decision-making process, will be evaluated. In the final phase, the program efficiency and accountability will be evaluated, and methods for improving efficiency of management and operations will be identified. The independent evaluation will be completed in June 2006; results will be known then.

Separate from evaluation activities initiated following the Section 317 Grant program PART review, an independent evaluation and business process improvement project is also underway to improve the Vaccines for Children (VFC) program. CDC is initiating a business process improvement project to strengthen the efficiency and accountability of vaccine management systems.

Although the Section 317 Grant program and the VFC program serve two distinct groups who would not otherwise be immunized, the evaluation and improvement project focuses on the vaccine delivery, program management, and service delivery functions of the VFC program, which are similar to the Section 317 Grant program.

Thus far, a set of recommendations has been developed to improve the business processes. Business process improvements should result in improved efficiencies, accountability, and cost savings for the VFC program and the Section 317 Grant program.

PART Review and Recommendations

The Section 317 Immunization Grant program received an "Adequate" PART rating from OMB during the FY 2004 budget process. The FY 2004 PART assessment determined the program has strong management practices and was successful in improving vaccination coverage levels among children. OMB made the following recommendations to improve program management and planning and better demonstrate program outcomes and results:

- Participate in regular independent evaluations of program effectiveness;
- Establish processes and procedures to measure and/or improve program efficiency; and
- Improve mechanisms linking the program's budget for State immunization program and operations activities to program performance.

CDC is addressing these recommendations through program improvements and management initiatives.

For more information on this program's performance, please see pages II-119 through II-134 of CDC's *Revised Final FY 2004 GRPA Annual Performance Plan*.

1.B HIV/AIDS Prevention in the U.S.

Centers for Disease Control and Prevention (CDC)

The Program

HIV remains a deadly infection for which there is no cure. Over 500,000 Americans have died of AIDS and an estimated 850,000 to 950,000 are currently infected with the virus. 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, as the Federal agency charged with preventing HIV infection, 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 nonprofit groups, and the private sector.

CDC's core set of HIV prevention activities includes surveillance, research, intervention, capacity building, and evaluation. Surveillance provides demographic, laboratory, clinical, and behavioral data that are used to identify populations at greatest risk for HIV infection. These data also help CDC estimate the size and scope of the epidemic.

Snapshot

1.b.1 – Performance Measure: Reduce the number of HIV infection cases diagnosed each year among people under 25 years of age. [1,2]

Year	Target [3]	Actual
2001	Not applicable	2,241 cases [4]
2002	Not applicable	2,926 cases [4]
2003	Not applicable	2,331 cases [4]
2004	Overall: 1,900 reported cases	Data available 08/2005

[1] CDC will continue to revise baseline and targets when data from more States with adequate HIV reporting systems are available.

[2] Data are from 25 states with confidential, name-based HIV reporting. Beginning in 2006, all reported data will be from 30 areas with confidential, name-based HIV reporting.

[3] This measure was first reported in FY 2004 and therefore, targets begin in FY 2004. However, actual performance is shown for previous years because the data was available, even though it was not reported in the form of a measure.

[4] All data have been modified to update annual "actual performance" numbers based on the most recent HIV and AIDS surveillance data. Therefore, some values have changed for prior years.

1.b.2 – Performance Measure: Decrease the number of perinatally acquired AIDS cases, from the 1998 base of 235 cases.

Year	Target	Actual
2001	151 cases	100 cases [5]
2002	141 cases	90 cases
2003	<139 cases	58 cases
2004	<100 cases	Data available 08/2005

[5] All data have been modified to update annual "actual performance" numbers based on the most recent HIV and AIDS surveillance data. Therefore, some values have changed for prior years.

Discussion of Results and Performance

CDC's overarching goal in HIV is to reduce by 25 percent the number of new HIV infections in the U.S., as measured by 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. The following measures indicate CDC's progress toward achieving this overarching goal.

HIV Diagnoses Among People Under 25 Years of Age

The number of HIV infection cases among persons under 25 years of age diagnosed each year is the best data available to monitor new HIV infections. HIV infections occurring in this group are likely to have been acquired recently and thus are a relatively good proxy measure of HIV incidence. In addition, these data enable CDC to look at yearly trends in a meaningful way.

Data are from a national surveillance system that collects demographic, clinical, and behavioral information on all AIDS cases diagnosed in the U.S. as well as HIV cases diagnosed in States with HIV reporting requirements. FY 2004 targets were set when only 25 States had stable, confidential name-based HIV reporting. Beginning in 2006, data will be reported from 30 areas with confidential, name-based HIV reporting. This measure continues to be refined and has undergone revisions in previously reported data. In 2003, there were 2,331 cases reported in 25 areas with confidential, name-based reporting. Data for 2004 will be available in August 2005. FY 2004 was the first year that a target was set for this measure.

Perinatally Acquired AIDS

A dramatic reduction in perinatal (mother-to-child) HIV transmission cases has been noted in the U.S., a result of the widespread implementation of the Public Health Service (PHS) recommendations made in 1994 and 1995. Recommendations included routinely counseling and voluntarily testing pregnant women for HIV, and offering zidovudine (AZT) to infected women during pregnancy and delivery, and to their infants post-partum. Further decreasing perinatal HIV transmission is one of four strategies included in CDC's new Advancing HIV Prevention initiative. To support this key strategy, CDC issued recommendations that clinicians routinely screen all pregnant women for HIV infection and that jurisdictions with statutory barriers to such routine prenatal screening consider revising them.

Surveillance data reported through December 2003 show sharply declining trends in perinatal AIDS cases. This decline was strongly associated with increasing zidovudine use in pregnant women who were aware of their HIV status. More recently, improved treatment also has likely delayed onset of AIDS for HIV-infected children. With efforts to maximally reduce perinatal HIV transmission and increase treatment for those infected, the number of cases is likely to remain low. However, declines may be affected by treatment failures and missed opportunities to prevent transmission. Data for 2003 continues to show low levels of perinatally acquired AIDS cases, from 90 in 2002 to 58 in 2003. Data for 2004 will be available in August 2005.

Program Evaluations

In 2000, the Institute of Medicine reviewed CDC and other HHS Agencies' HIV prevention activities to provide recommendations to CDC and other agencies on how to improve their activities. Twice in the past 10 years, CDC has convened an external review panel to look at CDC's existing activities and provide recommendations for the future. The first led to reorganization (merging surveillance with prevention programs), and the most recent one led to the current HIV prevention strategic plan. CDC also has some ongoing studies, including HHS' Office of Inspector General (OIG) audit of HIV prevention programs.

PART Review and Recommendations

CDC's domestic HIV/AIDS prevention program received a rating of "Results Not Demonstrated" from OMB's PART review during the FY 2004 budget process. As a result of that review, OMB provided a number of recommendations for the program, which CDC is working to implement. They are:

- Develop methods to estimate the level of resources required to reach program goals;
- Hold Federal managers accountable for program performance;
- Develop incentives and procedures to measure and achieve efficiencies and cost effectiveness in program execution;
- Improve oversight of grantee activities; and
- Collect data on program performance and make it available publicly.

CDC is working to implement OMB's recommendations and reports regularly to OMB on achieving milestones established for each recommendation.

For more information on this program's performance, please see pages II-83 through II-102 of CDC's *Revised Final FY 2004 GRPA Annual Performance Plan*.

1.C Substance Abuse Prevention and Treatment Block Grant

Substance Abuse and Mental Health Services Administration (SAMHSA)

The Program

The goal of SAMHSA's Substance Abuse Prevention and Treatment Block Grant is to improve the health of the Nation by bringing effective alcohol and drug treatment and prevention services to every community through a block grant to the States. The effects of substance use disorders are seen in permanent damage to the Nation's children, the transmission of HIV/AIDS and other communicable diseases, criminal involvement, premature and preventable deaths, and economic and social consequences estimated to cost the Nation more than $294 billion each year. The block grant supports and expands substance abuse prevention and treatment, while providing maximum flexibility to the States. States and territories may expend block grant funds only for the purpose of planning, carrying out, and evaluating activities related to these services. The block grant is the cornerstone of States' substance abuse programs and is an integral part of the President's drug treatment initiative. States are heavily dependent upon block grant funding for substance abuse services that are urgently needed.

Snapshot

1.c– Performance Measure: Number of clients served.

Year	Target	Actual
2001	1,635,422 clients	1,739,796 clients [1]
2002	1,751,537 clients	1,882,584 [2]
2003	1,884,654 clients	Data available 09/2005
2004	1,925,345 clients	Data available 09/2006

[1] Source: SAMHSA, Office of Applied Studies. Treatment Episode Data Set (TEDS): 1992-2001. National Admissions to Substance Abuse Treatment Services, Drug Abuse Services Information System (DASIS) Series: S-20, HHS Publication No. (SMA) 03-3778, Rockville, MD, 2003. p. 79. (Issued as proxy for this measure)

[2] Source: SAMHSA, Office of Applied Studies. Treatment Episode Data Set (TEDS): 1992-2002. National Admissions to Substance Abuse Treatment

Services, DASIS Series: S-23, HHS Publication No. (SMA) 04-3965, Rockville, MD, 2004, p. 71 (Issued as a proxy for this measure)

Discussion of Results and Performance

The FY 2002 target for increasing the number of clients served was exceeded. Data collected by the Drug Abuse Services Information System-Treatment Episode Data Set (DASIS-TEDS) information system showed that SAMHSA served 7 percent more clients than the target for FY 2002. FY 2002 is the most recent year for which data are currently available, because of the time required for States to report data on the number of admissions in any given year. FY 2003 data will be available in September 2005; FY 2004 data will be available in September 2006; and FY 2005 data will be available in September 2007. Targets have been met for all years for which data are available.

The proxy data reported represent treatment admissions data. These data are used as a proxy for persons served because many States currently are unable to employ a unique client identifier, which is necessary in order to track unduplicated numbers of clients served. States are working toward providing unduplicated counts of the number of clients served. SAMHSA expects that the 2003 and 2004 goals will be met. The

estimated number of clients served shows progress in increasing service delivery in support of the President's drug treatment initiative. Limitations to DASIS-TEDS data fall into two broad categories: those related to the scope of the data collection system (e.g., the fact that DASIS-TEDS collects data on admissions rather than individuals), and those related to the difficulties of aggregating data from highly diverse State data collection systems.

The following external factors affect the performance of the block grant:

- The status of the national economy, including changes in employment and insurance coverage for substance abuse and mental health services;
- The amount of resources that States and communities are able to allocate to prevention and treatment of substance abuse; and
- The variation in the supply of (and demand for) illegal drugs such as heroin and cocaine, as well as new addictive substances.

Program Evaluations

An evaluability assessment for the block grant program is underway, with results expected in December 2004. A comprehensive evaluation will then be performed, with results expected in late 2006.

PART Review and Recommendations

The block grant received a PART review in the FY 2005 budget cycle. The review identified strengths, such as program purpose, need for program, and program design. It scored a rating of "Ineffective." The review identified a number of areas for improvement, with the main area being related to performance measures.

The assessment found that SAMHSA faces continuing challenges in collecting performance data. SAMHSA will address this problem over time by implementing new measures and improving data collection, analysis, and utilization. Several new performance measures were identified that will be used for making future budget and other management decisions. These measures were implemented later in FY 2003. SAMHSA has made significant progress with the States in identifying other needed performance measures for the block grant. States will begin reporting data on the newly developed cost band and long-term outcome measures in FY 2005. SAMHSA also 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. SAMHSA has initiated funding for a national evaluation of the block grant.

For more information on this program's performance, please see page 88 of SAMHSA's *Revised Final FY 2004 GRPA Annual Performance Plan*.

1.D Quality Improvement Organizations

Centers for Medicare & Medicaid Services (CMS)

The Program

Under the Quality Improvement Organization (QIO) program, CMS contracts with 53 independent physician organizations (one in each State, the District of Columbia, Puerto Rico, and the Virgin Islands) to ensure that medical care paid for under the Medicare program is reasonable and medically necessary, meets professionally recognized standards of health care, and is provided in the most economical setting. The QIO responsibilities are defined specifically in the scope of work portion of the contract. Each scope of work is 3 years in duration and can vary the activities the QIOs perform. Funding patterns tend to vary substantially from year to year. The QIO program is funded directly from the Medicare Trust Funds, rather than through the annual Congressional appropriations process.

Snapshot

1.d.1– Performance Measure: Increase annual Influenza vaccinations in Medicare beneficiaries age 65 and older to 72.5% over baseline (FY 1994 –59%).

Year	Target	Actual
2001	72.0%	67.4%
2002	72.0%	69.0%
2003	72.5%	Data available 12/2004
2004	72.5%	Data available 12/2005

1.d.2– Performance Measure: Increase lifetime Pneumococcal vaccinations in Medicare beneficiaries age 65 and older to 69% over baseline (FY 1994 – 24.6%).

Year	Target	Actual
2001	63.0%	63.3%
2002	66.0%	64.6%
2003	67.0%	Data available 12/2004
2004	69.0%	Data available 12/2005

Discussion of Results and Performance

In 2001 and 2002 the National Center for Health Statistics reported Influenza and Pneumonia to be the primary causes of death for a significant number of older adults. For all persons age 65 or older, the ACIP and other leading authorities recommend lifetime vaccination for Pneumococcal Pneumonia and annual vaccination for Influenza. Consistent with HHS' strategic plan goals and through the collaborative efforts of CMS, CDC, and the National Coalition for Adult Immunization, the Department is working to improve adult immunization rates in the Medicare population.

Manufacturing and distribution shortages of the Flu vaccine have affected HHS' ability to reach Influenza targets. Since the timing of the Pneumococcal vaccination usually occurs at the same time as the Flu vaccination, performance in this area is affected as well. Other external challenges to meeting this goal include reported public concerns about the side effects and general safety of immunizations, fueled by reports of potential side effects of the Smallpox vaccine. Producing the specific strain needed in a given Flu season also has been a challenge that has affected supply.

Most recently, for the 2004-2005 Flu season, CMS and CDC are actively addressing the impact of the unanticipated 2004 Flu vaccine shortage; its effect on achievement of CMS' 2004 target is unknown.

During the 2003-2004 Flu season, all 50 States experienced early outbreaks of Influenza and many cases of the Flu, which created great demand among the public to seek immunizations, especially for children who were being hit hard by the epidemic. In December, as a result of the public's demand for Flu vaccine, the CDC changed its public health recommendation for the remaining vaccine from offering to all people to targeting high-risk individuals for immunization. There remain external challenges to increasing the Influenza and Pneumococcal vaccination rates; however, CMS has taken several steps, which should help to reduce known barriers to Flu and Pneumoccocal vaccinations and which, hopefully, will be reflected by higher rates in the next few years' data:

- Increased use of standing orders in Fall 2002 to include nursing homes, hospitals, and home health agencies serving Medicare and Medicaid beneficiaries;
- Raised reimbursement rates in 2003 for Influenza and Pneumococcal immunizations;
- Exempted paper roster billing for Medicare-covered vaccinations from the Health Insurance Portability and Accountability Act standards rules (to remove administrative barriers); and
- Medicare contractor-published notice in physician/provider newsletters and websites encouraging physicians and providers to order Influenza vaccine early in anticipation of increased demand in Fall 2004.

QIOs also are working in collaboration with beneficiaries, providers, managed care plans, community groups, and other interested partners to design and implement immunization quality improvement projects. These projects are conducted in hospitals, long-term care facilities, dialysis facilities, physician offices, home health agencies, and public health clinics. They combine education for health care workers, a plan for identifying high-risk patients, and efforts to remove administrative and financial barriers that prevent patients from receiving Influenza and Pneumococcal vaccines.

Program Evaluations

There are no independent evaluations of the QIO program 2004. Per the MMA, the Institute of Medicine is evaluating the QIO program and its report is due for release in June 2005.

For more information on this program's performance, please see pages V-31 through V-53 of CMS' *Revised Final FY 2004 GRPA Annual Performance Plan*.

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 the Nation's health and food supply by enhancing preparedness and response capabilities.

The Office of the Assistant Secretary for Public Health Emergency Preparedness 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. This office serves as the focal point within HHS for these activities, directing and coordinating the development and implementation of a comprehensive HHS strategy.

CDC has an integral role in strengthening State and local public health infrastructure to effectively respond to emergencies. The Health Resources and Services Administration (HRSA) works to prepare hospitals and other medical facilities for the health consequences of bioterrorism and other mass casualty events. The Food and Drug Administration (FDA) 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 the Nation's food supply and prevent food-borne illness.

- Selected Program 2.a: CDC Terrorism Preparedness and Emergency Response
    - Performance Measure 2.a.1: Enhance preparedness by ensuring State, territorial, and local jurisdiction projects have written plans to respond to biological, chemical, radiological, and mass trauma hazards related to terrorism.
    - Performance Measure 2.a.2: 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.
- Selected Program 2.b: HRSA Bioterrorism Hospital Preparedness
    - Performance Measure 2.b: Increase the percent of awardees that have developed plans to address surge capacity to 100 percent.
- Selected Program 2.c: FDA Foods Program
    - Performance Measure 2.c: Perform 60,000 import field exams and conduct sample analyses on products with suspect histories.

2.A Terrorism Preparedness and Emergency Response Program

Centers for Disease Control and Prevention (CDC)

The Program

CDC's mission in this area is to prevent death, disability, disease, and injury associated with urgent health threats by improving preparedness of the public health system, the health care delivery system, and the public through excellence in science and services.

CDC's comprehensive terrorism preparedness and emergency response program comprises three key components:

- Detection activities assure the ability to detect an event so intervention can begin as early as possible to minimize mass trauma;
- Investigative and response activities ensure plans and systems are in place to respond to and contain a public health event; and
- Control, containment, and recovery activities ensure, among other activities, State and local government's ability to quickly receive and distribute the Strategic National Stockpile, a national repository of life-saving pharmaceuticals, medical material, and equipment.

In addition, CDC is focusing on its readiness capability so that the Agency, at a moment's notice and on a 24/7 basis, can support State and local response and ensure that HHS' State and local partners have the resources they need to be prepared.

As part of the system to quickly recognize and react to disease outbreaks, CDC has begun to invest in strengthening early detection and containment of biological public health threats with the biosurveillance initiative. The initiative, which began in FY 2004 and will be more fully implemented by the end of FY 2005, brings epidemiology tools into the 21st century by connecting multiple data sources into a fully functioning, real-time surveillance system. Federal, State, and local health officials will have access to real-time data that potentially could be the first sign of a public health emergency (naturally-occurring or intentional).

Snapshot

2.a.1– Performance Measure: Enhance preparedness by ensuring State, territorial, and local jurisdiction projects have written plans to respond to biological, chemical, radiological, and mass trauma hazards related to terrorism.

Year	Target	Actual
2001	Not applicable	Not applicable
2002	Not applicable	Not applicable
2003	Not applicable	Not applicable
2004	50% of the 62 State, territorial, and local jurisdictions funded by CDC have these written plans.	Data available 12/2004

2.a.2 – Performance Measure: 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. [1]		
Year	Target	Actual
2001	Not applicable	Not applicable
2002	Not applicable	Not applicable
2003	Not applicable	Not applicable
2004 [2]	Not applicable	Not applicable

1] CDC and OMB established this measure during the FY 2005 PART review of the Division of State and Local Readiness. Though work has begun, actual progress regarding the performance measure will be reported beginning in December 2005.

[2] Although this measure was not reported in the FY 2004 *Consolidated Performance Plan* (because there is no FY 2004 data), HHS and CDC will include the measure going forward and therefore it is included in the FY 2004 PAR.

Discussion of Results and Performance

Performance Measure 2a1:

The continuation guidance for the *Cooperative Agreement on Public Health Preparedness and Response for Bioterrorism – Budget Year Five* requires that all awardees develop or enhance scalable plans supporting local, Statewide, and regional response to incidents of bioterrorism, infectious disease outbreaks, and other public health threats and emergencies.

As of May 2004, 100 percent of the State-based projects had written response plans covering at least one of the Category A biological agents, chemical agents, or radiation. Specifically, the following percentages of awardees indicate they have Statewide response plans for the listed agent: Anthrax: 67 percent, Botulism: 59 percent, Plague: 61 percent, Smallpox: 98 percent, Tularemia: 61 percent, Nerve Agents: 30 percent, Blood Agents: 28 percent, Blister Agents: 28 percent, Radiation/Nuclear: 56 percent, and Influenza (pandemic Flu): 75 percent. CDC's objective is to have awardees routinely exercise the written response plans.

Performance Measure 2a2:

CDC and OMB established this measure during the FY 2005 PART review of the State and Local Preparedness program. Though work has begun, actual progress regarding the performance measure will be reported beginning in December 2005. CDC's continuation guidance outlines critical and enhanced capacities necessary for preparedness and prioritized recipient activities, as well as critical benchmarks for awardees to attain during the funding periods. Notwithstanding CDC's guidance, awardees have asked Federal agencies to define what it actually means to be "prepared" and for more assistance in defining, reaching, and demonstrating adequate levels of public health preparedness.

In response to requests from awardees, CDC initiated the Public Health Preparedness Indicators project (now termed Evidence-Based Performance Goals for Public Health Disaster Preparedness). This project defines and establishes a fundamental level of public health preparedness by providing a framework for the cooperative agreement guidance, allowing for the evaluation of the program's progress, and enabling more targeted technical assistance. To establish draft goals, indicators, and measures, CDC relied on:

- Subject matter expertise input from internal and external experts; and
- Review of scientific literature to identify lessons learned.

The performance goals are evidence-based, and subject to revision. Field investigations initiated in May 2004 will facilitate an initial round of revisions. Information gleaned will be used to draft an evaluation tool that can be used by a third-party evaluator at the State and local level. In addition, CDC's FY 2005 cooperative agreement guidance will be based on the final goals, indicators, and measures.

Program Evaluations

The CDC Office of Terrorism Preparedness and Emergency Response has been evaluated numerous times by the Government Accountability Office (GAO), the OIG, and the OIG's Office of Evaluation and Inspections. The completed evaluations have resulted in recommendations, which have provided CDC the opportunity to examine and report on the progress made in addressing them. Recent audits and evaluations have focused on bioterrorism preparedness in State and local jurisdictions, the Statewide 24/7 urgent disease reporting systems, and the Strategic National Stockpile.

PART Review and Recommendations

CDC's Division of State and Local Readiness received a rating of "Results Not Demonstrated" from OMB's PART review during the FY 2005 budget process. OMB recommended independent program evaluations to inform strategic planning and program management.

CDC is working to implement OMB's recommendations and reports regularly to OMB on achieving milestones established for each recommendation.

For more information on this program's performance, please see pages II-201 through II-225 of CDC's *Revised Final FY 2004 GRPA Annual Performance Plan*.

2.B National Bioterrorism Hospital Preparedness Program

Health Resources and Services Administration (HRSA)

The Program

The goal of the Bioterrorism Hospital Preparedness program, which is part of the President's Homeland Security initiative, is to ready hospitals and supporting health care systems to deliver coordinated and effective care to victims of terrorism and other public health emergencies. The Nation has lacked sufficiently adequate plans and infrastructure to respond to challenges that terrorist acts and other events with mass casualties may pose. A GAO investigation (Report 03-373) found widespread deficiencies in capacity, communication, and coordination elements essential to preparedness and response.

The Hospital Preparedness program, established in FY 2002, enables State and regional planning among local hospitals, emergency medical services systems, Health Centers, poison control centers, and other health care facilities, in order to improve their preparedness to work together to combat terrorist attacks and deal with infectious disease epidemics and other mass public health emergencies. As appropriate, this program works in concert with CDC's Public Health Preparedness and Response for Bioterrorism program and the Metropolitan Medical Response Systems program of the Department of Homeland Security.

Snapshot

2.b – Performance Measure: Increase the percent of awardees that have developed plans to address surge capacity to 100 percent.		
Year	Target	Actual
2001	Not applicable	Not applicable [1]
2002	Not applicable	Not applicable [1]
2003	Not applicable	59% of awardees (estimated baseline)
2004	90% of awardees	89% of awardees

[1] This program was established in FY 2002.

Discussion of Results and Performance

A terrorist attack or other large-scale public health 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. 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.

Plans for surge capacity must address the following issues: (1) hospital bed capacity for 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.

By FY 2004, 89 percent of Hospital Preparedness program awardees had developed surge capacity plans, based on information from the awardees' March 2004 semiannual progress reports. This represents an increase from an estimated baseline of 59 percent in FY 2003 and is only one percentage point below the FY 2004 target. The goal is that 100 percent of awardees will have plans to respond to a surge capacity of 500 patients per million population by 2005. In the future, the program will track various aspects of the implementation of these plans.

Program Evaluations

The Hospital Preparedness program did not have any independent evaluations completed in FY 2004.

PART Review and Recommendations

During the FY 2005 budget process, OMB conducted a PART review for the Bioterrorism Hospital Preparedness program. The program received 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 indicated 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 occur regularly. The program notes, in this context, the added challenge of measuring the relatively new and evolving concept of preparedness. The assessment recommended that the program work with State and local representatives to ensure that performance information will be available. This work is underway.

For more information on this program's performance, please see pages 192 through 199 of HRSA's *Revised Final FY 2004 GRPA Annual Performance Plan*.

2.C Foods Program

Food and Drug Administration (FDA)

The Program

The Foods program promotes and protects the public's health by ensuring that the U.S. food supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and properly labeled. The program regulates all food except meat, poultry, and frozen and dried eggs, which are regulated by the U.S. Department of Agriculture. As a result of the terrorist attacks of September 11, 2001, and the passage of the Bioterrorism Act of 2002, the program took on a food security/defense role further to improve the protection of the Nation's food supply, which is among the world's safest.

The program regulates $417 billion worth of domestic food, $49 billion worth of imported foods, and $59 billion (including $4 billion imported) worth of cosmetics and toiletries sold across State lines. This regulation takes place from the products' point of U.S. entry or processing to their point of sale, with approximately 60,000 food establishments (includes more than 33,000 U.S. food manufacturers and processors and over 22,000 food warehouses) and 2,600 cosmetic firms.

FDA's performance goal is to ensure that imported food products meet its standards. With more than 7 million food import entries each year, FDA has targeted import examination resources towards shipments that are believed to be at greater risk for safety and security concerns. This performance goal supports the Department's Strategic Goal 2: Enhance the ability of the Nation's health care system to effectively respond to bioterrorism and other public health challenges, its Objective 2.2 - Improve the safety of food, drugs, biological products, and medical devices, and FDA's Strategic Goal - Counterterrorism.

Snapshot

2.c– Performance Measure: Perform 60,000 import field exams and conduct sample analyses on products with suspect histories.

Year	Target	Actual
2001	Not applicable	Not applicable
2002	Increase food import surveillance by hiring 300 new investigators and analysts who will increase the number of import field exams by 97% to 24,000 exams and conduct sample analyses on products with suspect histories.	Hired 600 new investigators and analysts; 34,447 exams conducted
2003	Increase exams by 100% to 48,000 exams	78,659 [1] exams
2004	60,000 exams	70,926 exams

[1] The FY 2003 unanticipated increase was due to Operation Liberty Shield, a one-time multi-department, multi-agency national plan that allowed FDA to leverage its resources with its State and other Federal Government partners, allowing it to achieve this high level of performance.

Discussion of Results and Performance

Starting in FY 2004, FDA expects that the counterterrorism staff brought on board in FY 2002 and 2003 will have achieved the training and experience necessary to perform import activities. The Agency will continue

to better target its import examination resources toward shipments that are believed to be at greater risk for safety and security concerns.

The FY 2004 performance target is to conduct 60,000 import field exams and FDA exceeded this target by conducting 70,926 exams.

While the original performance target for FY 2003 was 48,000 exams, FDA performed a total of 78,659 exams in that year due largely to the extraordinary effort under the Operation Liberty Shield, a one-time multi-department, multi-agency national exercise designed to increase protections for America's citizens and infrastructure. The FY 2004 target was adjusted to 60,000 exams to reflect resource changes and new requirements for implementing the Bioterrorism Act of 2002. Regardless of the increase, FDA continues to believe the best approach is to devote resources to better targeting and following through on suspect import entries rather than significantly expanding import coverage.

Program Evaluations

GAO issued three program evaluation reports in FY 2004. One report addressed the progress made to improve FDA's imported seafood safety program and two reports addressed the implementation of the food safety provisions under the Bioterrorism Act of 2002. While progress has been made in improving the imported seafood safety program, GAO asked FDA to consider several options for augmenting Agency resources. GAO also found that FDA had complied with applicable requirements for promulgating the rules for registration of food facilities and for prior notice of imported foods coming to U.S.

PART Review and Recommendations

During the FY 2004 budget process, the Foods program received a PART review as an individual program. The assessment recommended that the Foods program develop long-term outcome goals. The program developed these goals, which led to a significant increase in the PART score for the FY 2005 budget process during which FDA was evaluated as an entire Agency. FDA's overall rating is "Moderately Effective."

For more information on this program's performance, please see Part 2 pages 35 through 37 of FDA's *Revised Final FY 2004 Annual Performance Plan, Congressional Justification*, January 2004.

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. 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.

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 Comprehensive AIDS Resources Emergency (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, SCHIP, Health Centers, and the Indian Health Service's (IHS) National Diabetes programs.

- Selected Program 3.a: CMS Medicare Program
    - 3.a– Performance Measure: By the end of calendar year (CY) 2004 (FY 2005), improve satisfaction of Medicare beneficiaries with the health care services they receive in Managed Care (MC) and Fee-for-Service (FFS) over CY 2000 baseline: MC access to care – 93.0% (Baseline 90.5%); MC access to specialist – 86.0% (Baseline 83.7%); FFS access to care – 95.0% (Baseline 92.8%); and FFS access to specialist – 85.0% (Baseline 82.8%).
- Selected Program 3.b: CMS Medicaid and State Children's Health Insurance Program
    - 3.b– Performance Measure: Increase the number of children enrolled in regular Medicaid or SCHIP.
- Selected Program 3.c: HRSA Health Center Program
    - 3.c.1– Performance Measure: Increase the infrastructure of the Health Center program to support an increase in utilization, via new or expanded sites.
    - 3.c.2– Performance Measure: Increase number of uninsured and underserved persons served by Health Centers.
    - 3.c.3– Performance Measure: Continue to assure access to preventive and primary care for racial/ethnic minorities (number and percent of total clients).

- Selected Program 3.d: IHS National Diabetes Program
    - 3.d– Performance Measure: Increase the proportion of patients with diagnosed Diabetes that have demonstrated improved glycemic control.
- Selected Program 3.e: CMS Medicare
    - 3.e – Performance Measure: Implement the new Medicare-Endorsed Prescription Drug Card.

3.A Medicare Program

Centers for Medicare & Medicaid Services (CMS)

The Program

CMS administers Medicare, the Nation's largest health insurance program, which covers approximately 42 million Americans. Medicare provides health insurance to people age 65 and over, those who have permanent kidney failure, and certain people with disabilities. For nearly four decades, this program has helped pay medical bills for millions of Americans, providing them with comprehensive health benefits they can count on. Ensuring health care security for beneficiaries is CMS' primary mission. CMS strives to encourage choice in the Medicare beneficiary community for medical coverage while maintaining high-quality care and ensuring fairness of the program to its beneficiaries.

Snapshot

3.a– Performance Measure: By the end of CY 2004 (FY 2005), improve satisfaction of Medicare beneficiaries with the health care services they receive in MC and FFS over CY 2000 baseline.
- MC access to care – 93.0% (Baseline 90.5%)
- MC access to specialist – 86.0% (Baseline 83.7%)
- FFS access to care – 95.0% (Baseline 92.8%)
- FFS access to specialist – 85.0% (Baseline 82.8%)

Year	Target	Actual
2001	Collect and share data	Collect and share data toward FY 2005 targets (Goal met)
2002	Collect and share data	Collect and share data toward FY 2005 targets (Goal met)
2003	Collect and share data	Collect and share data toward FY 2005 targets (Goal met)
2004	Collect and share data toward FY 2005 targets	Collect and share data toward FY 2005 targets (Goal met)

Discussion of Results and Performance

A fundamental CMS goal is to assure satisfaction in the Medicare-related experiences of beneficiaries in accessing care for illnesses and injuries when needed, including their access to care of specialists. In response to the need to standardize the measurement of and monitor beneficiaries' experience and satisfaction with the care they receive through Medicare, CMS developed a series of data collection activities under the Consumer Assessment Health Plans Surveys. CMS fields these surveys annually to representative samples of beneficiaries enrolled in each Medicare managed care plan as well as those enrolled in the original Medicare FFS plan and shares results with health plans, Medicare beneficiaries through various means, including the National Medicare & You Education Program (NMEP), and with QIOs at the annual American Health Quality Association meetings.

Provision of Consumer Assessment Health Plans Surveys performance information assists beneficiaries in their health plan choices under Medicare. Annual development of specific performance measures also

permits use of these surveys as a tool for monitoring beneficiary experiences in and satisfaction with differing care delivery modes and in different regions of the country. Plan-specific measures provide direct incentives for MC plans to improve performance and health services quality. FFS measures, reported by geographic area, assist in development of strategies to improve care quality through targeted interventions implemented either directly by CMS or through other partners. The performance indicators and satisfaction measures disseminated through the NMEP also are part of a long-term strategy to monitor and evaluate the use of specific services provided through Medicare, and improve consumer satisfaction regarding the services received. CMS conducts research on the use and understanding of these measures by beneficiaries as well as the effectiveness of specific initiatives monitored by these measures in improving service quality. The baselines for both MC and FFS satisfaction are already fairly high. Given this type of survey for a large group of people and considering the unrelated factors that could influence responses, a target of 100 percent satisfaction is unrealistic. Nonetheless, the targets are challenging and are set for a 5-year period for the percentage increases to be large enough to be statistically detected.

Program Evaluations

For the Medicare program goals, no independent evaluations were completed in FY 2004.

For more information on this program's performance, please see pages V-17 through V-30 of CMS' *Revised Final FY 2004 GRPA Annual Performance Plan*.

3.B Medicaid and State Children's Health Insurance Program (SCHIP)

Centers for Medicare & Medicaid Services (CMS)

The Program

CMS, in partnership with the States and territories, administers Medicaid, a means-tested health care program for low-income Americans. Over the years, Congress incrementally expanded Medicaid well beyond the traditional population of the low-income elderly and the blind-disabled. Today, Medicaid is the primary source of health care for a much larger population of medically-vulnerable Americans, including low-income families, the disabled, and persons with developmental disabilities requiring long-term care.

SCHIP was created through the Balanced Budget Act of 1997 to address the fact that the nearly 11 million American children (one in seven) were uninsured and therefore at increased risk for preventable health problems. This program represents the largest single expansion of health insurance coverage for children in more than 30 years and aims to improve the quality of life for millions of vulnerable children less than 19 years of age. Many of these children were in working families that earned too little to afford private insurance on their own, but too much to qualify for Medicaid. The funds distributed for SCHIP cover insurance costs, reasonable administrative costs, and outreach services to get children enrolled. Title XXI of the Social Security Act gave States the option to expand their Medicaid program, establish a separate SCHIP, or use a combination of both. CMS' goal is to increase the number of children (up to age 19 for SCHIP; age 21 for Medicaid) enrolled in regular Medicaid or SCHIP.

Snapshot

3.b– Performance Measure: Increase the number of children enrolled in regular Medicaid or SCHIP.		
Year	Target	Actual
2001	+1,000,000 children over FY 2000	+ 2,640,000 children
2002	+1,000,000 children over FY 2001	+ 3,250,000 children
2003	+5% over FY 2002	+1,600,000 children (+ 5.1%)
2004	Maintain enrollment at FY 2003 levels	Data available 02/2005

Discussion of Results and Performance

The implementation of SCHIP enhanced the availability of health care coverage for children. The energy invested by States and territories, communities, and the Federal Government resulted in significant expansions in coverage, as well as new systems for enrolling children. Many States have eliminated barriers that prevent families from enrolling in Medicaid and SCHIP. For example, some States simplified application forms and eliminated income verification requirements. Also, a number of States have expanded eligibility to provide coverage to other populations (i.e., parents, families with incomes at higher levels of the Federal poverty level, etc.) as a way to increase enrollment in Medicaid and SCHIP.

The main goal of SCHIP is to provide health assistance to uninsured, low-income children and to increase enrollment; however current economic conditions have made it difficult for CMS to achieve its enrollment targets for SCHIP. Therefore, CMS revised its GPRA enrollment targets for FY 2004 to maintain enrollment of children in SCHIP and Medicaid at the FY 2003 levels. In the face of recent fiscal challenges, a number of States are limiting outreach efforts in SCHIP and Medicaid in order to maintain current

eligibility levels. In addition, several States are imposing waiting lists on potential enrollees and increasing cost sharing in their SCHIPs to try to maintain enrollment in their programs during these difficult economic times.

Since the inception of SCHIP, there has been a substantial increase in Medicaid enrollment, partly due to the mass media and outreach campaigns in the early years of SCHIP. Additionally, SCHIP requires States to screen all SCHIP applicants for Medicaid eligibility, resulting in increased enrollment for children.

CMS continues to work with States to ensure that their programs are designed to best meet the needs of their children and provides extensive technical assistance to States that need to modify their programs. In addition, CMS published a regulation in 2002, which allows States to provide health care coverage under SCHIP to pregnant women for children who are not yet born.

Program Evaluations

"A Comparison of Children's Uninsurance Rates Across the States 1995 - 97 to 2000 – 02," State Health Access Data Assistance Center, February 2004.

- ". . . seventeen States experienced a statistically significant decrease in their rate of uninsured children [from 1995 – 1997 to 2000 – 2002].
- ". . the Current Population Survey's (CPS) three-year average uninsurance estimates show that more American children had health insurance coverage in 2000-02 than in 1995-97. In 2002, approximately 10.2 million children did not have health insurance, down from over 11.5 million in 1997. This suggests that SCHIP may be helping to reduce the total number of children without health insurance coverage."

"Early Release of Selected Estimates Based on Data From the January-March 2004 National Health Interview Survey," National Center for Health Statistics, September 2004.

- For children under age 18 years, the percent of those who were uninsured decreased from 13.9% in 1997 to 8.8% in early 2004.

"SCHIP: States' Progress in Reducing the Number of Uninsured Children," OIG, August 2004.

- Of the 22 States that provided data on change in the number of uninsured children, 17 States reported a decrease, 3 reported an increase, and 2 reported no change in the number of uninsured children. Several national data sources show a reduction in the national number of uninsured children.

For more information on this program's performance, please see pages V-85 through V-89 of CMS' *Revised Final FY 2004 GPRA Annual Performance Plan*.

3.C Health Center Program

Health Resources and Services Administration (HRSA)

The Program

The Health Center program is a major component of America's health care safety net for the Nation's indigent, underserved, and vulnerable populations. This program, which is more than 35 years old, is a Presidential initiative to increase health care access for those Americans most in need. Millions of Americans are uninsured and lack access to a regular source of health care. These and others also face non-financial barriers to receipt of appropriate care. Health Centers provide regular access to high quality, family-oriented, and comprehensive primary and preventive health care regardless of patients' ability to pay while also reducing other barriers to care. 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. The program provides grants to a variety of community-based public and private nonprofit organizations for the operation of Health Centers. These grants provide about 25 percent of Health Centers' revenues on average, leveraging $3 for each Health Center program dollar spent.

Snapshot

3.c.1– Performance Measure: Increase the infrastructure of the Health Center program to support an increase in utilization, via new or expanded sites.

Year	Target	Actual
2001	Not applicable	Not applicable [1]
2002	260	302
2003	180	188
2004	124	129

[1] Data were not tracked in this way prior to the Presidential Health Centers growth initiative, which began in 2002. In 2001 there were 3,317 comprehensive primary care Health Center sites.

3.c.2– Performance Measure: Increase number of uninsured and underserved persons served by Health Centers.

Year	Target	Actual
2001	10.5 million	10.3 million
2002	11.8 million	11.3 million
2003	12.5 million	12.4 million
2004	13.2 million	Data available 08/2005

3.c.3– Performance Measure: Continue to assure access to preventive and primary care for racial/ethnic minorities (Number and percent of total clients).

Year	Target	Actual
2001	6.8M (65%)	6.6M (64%)
2002	7.6M (65%)	7.2M (64%)
2003	8.2M (65%)	7.9M (64%)
2004	8.6M (65%)	Data available 08/2005

Discussion of Results and Performance

The President's Health Centers initiative began in FY 2002 with the goal of creating 1,200 new or expanded Health Center sites and increasing the number of clients served by 6.1 million over a 5-year period. In the first 3 years of the initiative, FY 2002 – FY 2004, the program funded 619 new or significantly expanded sites, exceeding the target each year.

Growth in the number of persons served by Health Centers is an indicator of expanded access to care for the Nation's most vulnerable populations. The Health Center program served 12.4 million persons in 2003, achieving more than 99 percent of its target even though it generally takes several years for newly established sites to become fully operational. This represented a growth of more than 1 million persons over the previous year, one of the largest single-year increases in the program's history and the second consecutive year in which the number of persons served rose by 1 million persons or more. FY 2004 information is expected in August 2005.

Access to care is key to eliminating health disparities. The number of racial/ethnic minority individuals served by the Health Center program increased from 7.2 million in 2002 to 7.9 million in 2003, continuing a steady growth consistent with the overall growth in program clients. The proportion of racial/ethnic minority individuals has remained steady at 64 percent of total clients. This is only one percentage point below the target of 65 percent and an important achievement given the growth in the program. The President's Health Centers initiative includes expansions for existing centers and development of new service sites. Some of these new sites are or will be in underserved rural areas that do not have large numbers of racial/ethnic minorities. The substantial and rapid increases in the total number of clients served and expansions in areas with relatively small proportions of racial/ethnic minorities impact the program's ability to maintain and increase the proportion of minority clients served. Therefore, a racial/ethnic minority representation of 65 percent of the Health Center program's total client population is a challenging performance target. FY 2004 information is expected in August 2005.

Data on new and expanded sites are obtained from grant award information. Data on persons served and their demographic characteristics come from 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 automated edit checks and onsite performance reviews.

Program Evaluations

MDS Associates completed a study comparing Health Center Medicaid beneficiaries and non-Health Center beneficiaries who also had a usual source of care. Hospital admissions and emergency room visits for a set of 19 ambulatory care sensitive conditions were examined using Medicaid claims data for 1,580,855 Medicaid beneficiaries in 59 service areas across four States. These are conditions for which hospitalization is potentially avoidable and are widely recognized as indicators of access to and quality of primary care. The study showed that Health Center Medicaid beneficiaries are 11 percent less likely to be inappropriately hospitalized and 19 percent less likely to seek care from emergency rooms for these conditions compared to Medicaid beneficiaries who sought regular and usual care from other sources.

PART Review and Recommendations

A PART review of the Health Center program was conducted for the FY 2004 budget. The program received the highest possible rating of "Effective." 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.

For more information on this program's performance, please see pages 19 – 40 of HRSA's *Revised Final FY 2004 GRPA Annual Performance Plan*.

3.D National Diabetes Program

Indian Health Service (IHS)

The Program

The 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 and Alaska Native people. The program works with communities to prevent and treat Diabetes, as well as oversee the Special Diabetes Program for Indians (SDPI) grant program. IHS encourages local efforts to improve Diabetes-related health outcomes through lifestyle intervention and appropriate medication use through orientation, training, and monitoring provided by area Diabetes consultants.

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 facilities and SDPI programs.

Emphasis on Diabetes care within HHS' Hospital and Health Clinics budget recognizes the role of Diabetes as a major cofactor in morbidity and as well as one of the major causes of mortality among American Indian and Alaska Native people. Meeting performance indicators in this program reflects an increase in the percentage of these patients who have access to quality clinical care within the IHS system.

Snapshot

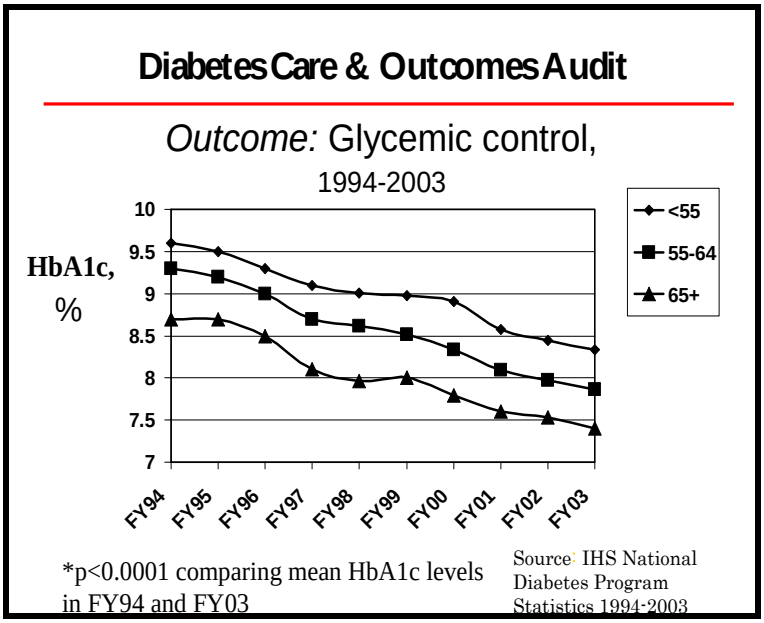
3.d– Performance Measure: Increase the proportion of patients with diagnosed Diabetes that have demonstrated improved glycemic control (defined as ideal control).		
Year	**Target**	**Actual**
2001	Improve from FY 2000 (26%)	29%
2002	Improve from FY 2001 (29%)	30%/25%* [1]
2003	Maintain at FY 2002 level (30%/25%)	31%/28%* [1]
2004	+1% over FY 2003 level (32%/29%*)[1]	Data available 11/2004 from GPRA + Diabetic audit data will be available by third quarter FY 2005.

[1] GPRA+ data; Data has historically been obtained from the diabetic audit. Starting in FY 2002, a new software application was deployed to allow for data extraction for clinical GPRA indicators, GPRA+. The * represents the result of data obtained from GPRA+.

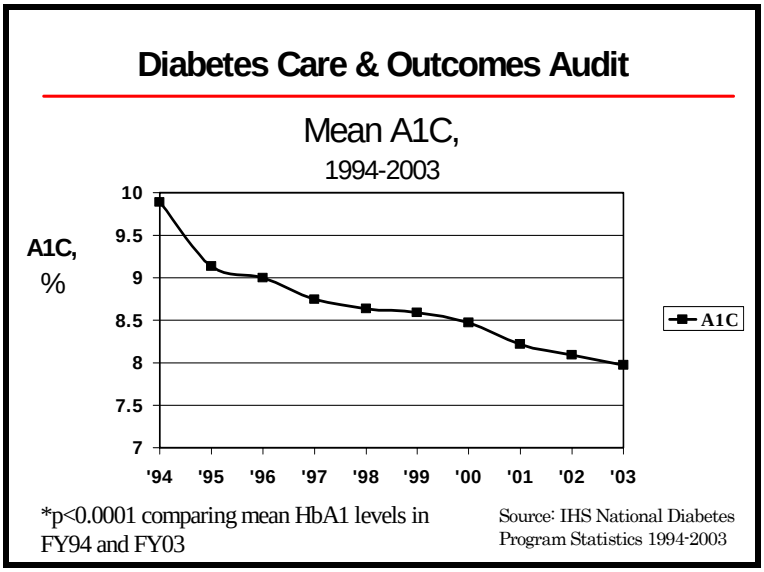
Discussion of Results and Performance

The FY 2003 indicator was to maintain the proportion of American Indian and Alaska Native patients that have improved glycemic control. IHS met and surpassed the 2003 ideal glycemic control indicator. The 2003 performance enabled IHS to improve the FY 2002 performance level for ideal glycemic control in patients with diagnosed Diabetes by 1 percent. Two data sources (the diabetic audit of glycemic control as well as an electronic health information system application (GPRA+), provide reliable and consistent performance information. These two data sources show consistent improvement in performance on this measure; in addition, the diabetic audit of over 11,000 diabetic patients substantiates the electronic audit of over 60,000 diabetic patients.

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 (HbA1c). The IHS Diabetes Care and Outcomes Audit process divides these levels of control into "Ideal" (<7 percent); "Good" (7.0-7.9 percent); "Fair" (8.0-9.9 percent); "Poor" (10-11.9 percent); and "Very Poor" (>12 percent) categories, based on national Diabetes care standards. The attached graph illustrates IHS' ongoing ability to improve glycemic control in American Indian and Alaska Native populations, as well as improve the percentage of patients in ideal control.



HbA1c measures the glucose level (sugar content) of a patient's blood. A lower HbA1c percentage indicates better blood sugar control. These graphs illustrate improving glycemic control among the IHS population, broken into age categories for patients 55 years and older, and among the population as a whole.

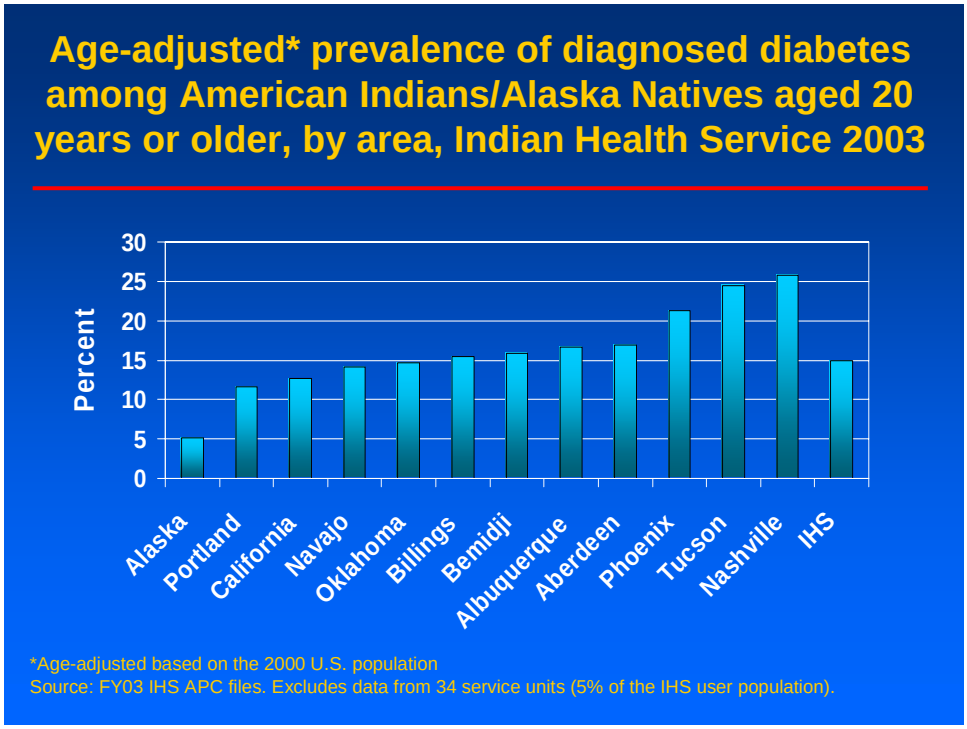


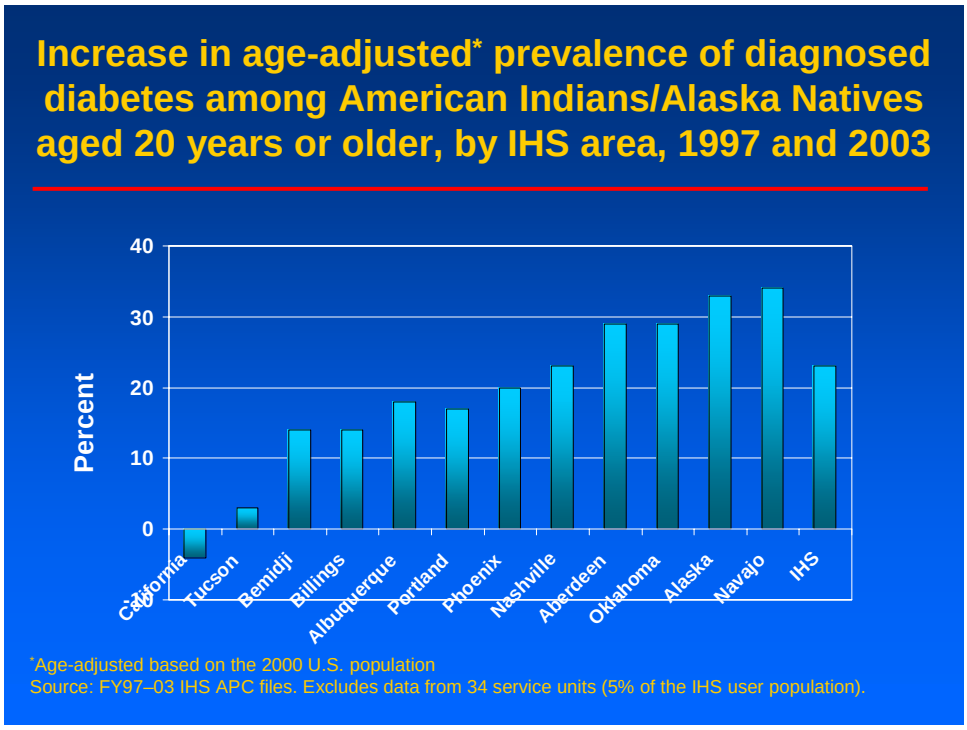
Note: Obtained from Diabetes audit data.

IHS uses several treatment and prevention strategies to achieve glycemic control in the American Indian/Alaska Native population:

- Glucose lowering medications: Many new glucose-lowering medications have been introduced on the market in the past 7 years. These medications are potent and quite effective;
- Negotiation of wholesale/at cost purchase of newer, more effective medications for American Indian/Alaska Native diabetic patients;
- Increased emphasis on patient education about nutrition, diet, and exercise, coupled with the efforts of the IHS health promotion/ disease prevention initiative;
- Increased availability of "best of practice" guidelines on the IHS website for community and health care facility guidance; and
- Enhancement of a clinical software application (GPRA+) that allows sites to track and provide timely feedback on the achievement of glycemic control, as well as other diabetic indicators.

IHS targets continue to be ambitious in overcoming the Diabetes epidemic in American Indian/Alaska Native populations. Since 1997, the number of patients with Diabetes served by the IHS, Tribal, and urban system has increased by 45 percent (review of Diabetes program data by Diabetes statisticians).





Program Evaluations

IHS has not conducted an independent evaluation of the Diabetes program during FY 2004.

PART Review and Recommendations

During the FY 2004 budget process, the IHS PART included a review of the IHS Direct Federal programs and the Hospital and Clinics Budget, where the funding for Diabetes care resides. The program received a rating of "Moderately Effective." IHS shared the PART review results with the clinical providers and health care facilities, where quality care improvements are operationalized. These improved trends in Diabetes care demonstrate the public health impact made possible when local, program, and Departmental initiatives are focused on a common outcome. 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 the Indian health system (i.e., IHS, Tribal and urban); performance data collection, thus, was addressed in both the Urban Indian Health program and Resource Management Patient System/Information Technology PART reviews during the FY 2005 budget process. In addition, the FY 2006 Facilities PART included this measure as one of its annual and long-term strategic goals for illustrating the impact of new facilities on the health status of communities.

For more information on this program's performance, please see pages 1-18 and 1-33 of IHS's *Revised Final FY 2004 GRPA Annual Performance Plan*.

3.E Medicare

Centers for Medicare & Medicaid Services (CMS)

The Program

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, as signed by the President on December 8, 2003, creates a new Part D of Medicare. MMA provides Medicare beneficiaries for the first time in the history of the Medicare program access to prescription drug coverage beginning in 2006. It also allows beneficiaries to save now on prescription drugs, with the Medicare-Approved Prescription Drug Discount Card program. Both the Prescription Drug Discount Card program and the full drug benefit provide enhanced benefits for the lowest income Medicare beneficiaries.

The Medicare-Approved Prescription Drug Discount Card program began in June 2004 and will phase out as the full drug benefit becomes available nationwide in 2006. The card program was estimated to save beneficiaries from 10 percent to 25 percent on most drugs. The cards are delivering actual savings better than originally projected. Savings range from 11 percent to 18 percent for brand-name drugs and 37 percent to 65 percent for generic drugs.

Snapshot

3.e – Performance Measure: Implement the New Medicare-Approved Prescription Drug Card Program.		
Year	**Target**	**Actual**
2001	Not applicable	Not applicable
2002	Not applicable	Not applicable
2003	Not applicable	Not applicable
2004	Implement the new Medicare-Approved Prescription Drug Discount Card program through the development and publication of the requirements for the Medicare-Approved Prescription Drug Discount Card program, solicitation and approval of applications from prescription drug discount card program sponsors, and provision of information to people with Medicare about the program.	06/01/2004 (Goal met)

Discussion of Results and Performance

CMS published the "Interim Final Rule" for the drug card program within 1 week of the implementing legislation and met its statutory deadline for implementing the program within 6 months. In April 2004, CMS launched the "price compare" website, which allows anyone, anywhere, to compare nationwide drug prices that are updated weekly. This level of price transparency and private and public sector cooperation is unprecedented. CMS entered into over 70 new contracts with private sector organizations establishing Medicare-approved drug cards, and amended over 80 contracts with existing Medicare Advantage plans that offer exclusive drug cards to their members. In May 2004, the first month that beneficiaries could enroll in a card program, the 1-800 Medicare toll-free number received 3.8 million calls. This is an

unprecedented record call volume as a result of prescription drug discount card inquiries. As of July 15, 2004, 4 million beneficiaries have enrolled in the drug card program and enrollment is increasing steadily.

In addition to implementing the discount card program, CMS published a "Notice of Proposed Rulemaking" in July-August 2004 to implement the full prescription drug benefit and is currently working on finalizing the rule. CMS is working closely with the Internal Revenue Service, Social Security Administration, and the Department of the Treasury in designing this program. CMS will meet the statutorily required implementation date of January 1, 2006 for the new benefit. To implement it, CMS will contract with Prescription Drug Plan sponsors that, in turn, will provide insurance coverage for Medicare beneficiaries for outpatient prescription drugs. CMS is also responsible for reviewing and evaluating Prescription Drug Plan bids, estimating plan benchmarks, calculating true out-of-pocket costs to beneficiaries, and overseeing low-income subsidies. CMS plans a number of mailings to beneficiaries in 2005 and 2006, including an expanded *Medicare & You* handbook, and to maintain call center staffing at elevated levels commensurate with beneficiary demand. CMS is working closely with State Pharmacy Assistance programs to implement the new Part D benefit.

For more information on this program's performance, please see pages V-17 through V-30 of CMS' *Revised Final FY 2004 GRPA Annual Performance Plan*.

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 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. 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' 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

- Selected Program 4.a: NIH International HapMap Project
    - 4.a – Performance Measure: By 2005, create the next generation map of the human genome, a so-called haplotype map (HapMap), by identifying the patterns of genetic variation across all human chromosomes.
- Selected Program 4.b: NIH Biodefense Research Program
    - 4.b – Performance Measure: By 2004, develop two new animal models to use in research on at least one agent of bioterror.

4.A International HapMap Project

National Institutes of Health (NIH)

The Program

Understanding how genetic variations are inherited in Deoxyribose Nucleic Acid (DNA) "blocks" or "haplotypes," can achieve considerable savings in time, effort, and cost in uncovering the hereditary factors in disease. 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 in 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 identify or "tag" each of the haplotypes in the region uniquely. 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 the essential information.

Most common haplotypes occur in all human populations, although their frequencies may vary considerably. Initial studies also indicate that the boundaries between the blocks are remarkably similar among populations in Europe, Asia, and Africa. These data indicate that a human haplotype map (HapMap) built with samples from these three geographic areas would apply to most populations in the world, although additional testing of this conclusion is needed.

NIH has taken a leadership role in the development of the HapMap, a catalog of the haplotype blocks and the SNPs that tag them. The HapMap is a tool that researchers can use to find the genes and variants that contribute to many diseases or disease risk. In addition, the HapMap will be a powerful resource for studying the genetic factors contributing to variation in individual response to disease once it does occur, as well as to drugs and vaccines. As the numbers of identified SNPs increase, they will be catalogued and made available to the research community to enhance the capacity and productivity of scientists studying the genetic basis of disease.

Snapshot

4.a – Performance Measure: By 2005, create the next generation map of the human genome, a so-called haplotype map (HapMap), by identifying the patterns of genetic variation across all human chromosomes. Baseline: 2.4 million SNPs in database		
Year	**Target**	**Actual**
2001	Not applicable	Not applicable
2002	Not applicable	Not applicable
2003	For existing blood samples from U.S. residents of Western and Northern European ancestry, obtain additional consent from the donors for this new use and begin genotyping 300,000 single nucleotide polymorphisms (SNPs, sites in the human genome where individuals differ by a single letter) in those samples.	All needed consents obtained and genotyping performed on 132,000 SNPs.
2004	Collect samples from populations in Japan, China, and Nigeria; complete collection of additional 3 million SNPs and release in public databases. Target: 3 million SNPs	Collection of samples from populations in China, Nigeria and Japan has been completed. NIH collected and publicly released 7.8 million additional SNPs. Actual: 7.8 million SNPs

Discussion of Results and Performance

In FY 2004, NIH met and greatly exceeded the target to collect and publicly release 3 million additional SNPs. Collection of samples from populations in China, Nigeria, and Japan has been completed.

The consortium originally had planned to identify an additional 3 million new SNPs to fill in areas where the current density of SNPs in public databases is not sufficient, but due to advances in technology the project has already identified a total of 7.8 million new SNPs. The consortium is collecting samples and consent from 270 individuals from four populations (U.S. residents with ancestry from Western and Northern Europe, Yoruba in Nigeria, Chinese, and Japanese). The consortium is also developing scientific strategies to choose which SNPs to study, to assess the quality of the data, and to derive haplotypes from the SNP data.

Because this goal was initiated in 2002, performance data was first available in 2003. In 2003, all of the living donors who provided the (previously existing) 90 U.S. samples used for the project specifically consented to their samples being used for developing the HapMap. Since some of the samples are from deceased individuals, they did not need to be reconsented. A total of six research groups performed genotyping for 132,000 SNPs during 2003.

The SNPs are obtained from an international consortium of researchers that included targeted laboratories round the world. In order to ensure the SNP accuracy and completeness, samples are sequenced according to approved protocols. Further, the data is passed through a data analysis group that follows a universal algorithm to maintain accuracy and preciseness of the haplotypes.

Program Evaluations

Independent evaluation for the HapMap is carried out by the National Advisory Council for Human Genome Research (NACHGR), an independent advisory group that advises the National Human Genome Research Institute (NHGRI), on genetics, genomic research, training and programs related to the human genome initiatives including the International HapMap project. The NACHGR meets three times a year, in February, May and September. At each meeting, the council reviews progress that has been made in achieving the goals of HapMap, and makes recommendations for future progress.

For example, in May 2004, the NACHGR approved the release of an RFA to solicit applications to augment the HapMap project. As a result of advances in genotyping technology, NHGRI was able to fund a large increase in the number of SNPs genotyped for the HapMap, since this genotyping will occur at a lower cost per SNP than had been anticipated when the HapMap was begun in 2002.

An NIH independent advisory group has also been created specifically to provide advice to the NIH about the progress of the International HapMap project. The advisors are not part of the HapMap project, but attend the HapMap Steering Committee meetings, which occur two to three times a year, and provide advice to NIH staff at each meeting. In December 2003, the HapMap advisory group provided important advice on quality assessment, allocation of funds and on areas of analysis for future genotyping regions.

For more information on this program's performance, please see pages 28 and 112 through 115 of NIH's *Revised Final FY 2004 GRPA Annual Performance Plan*.

4.B Biodefense Research Program

National Institutes of Health (NIH)

The Program

Deliberate exposure of the U.S. civilian population to *Bacillus anthracis* (Anthrax) spores revealed a gap in the Nation's overall preparedness against bioterrorism. These attacks uncovered a need for tests to rapidly diagnose, vaccines and immunotherapies to prevent, and drugs and biologics to cure disease caused by agents of bioterrorism. New products and ideas, however, must be thoroughly tested in the laboratory to ensure that they are safe and that they work.

The use of *in vitro* and animal models is an established means to test the safety and effectiveness of new treatments and products in the laboratory prior to testing them in human clinical trials. Appropriately, validated animal models are critically needed for biodefense research for the development and testing of vaccines, therapeutics, and prevention strategies and for the preclinical safety testing that will be required to speed the development of new-generation products. FDA's newly implemented Animal Efficacy Rule will allow testing of biodefense therapies and vaccines in animal models (either in a single well-characterized animal model or in two different animal models) to suffice for FDA approval of new products, since in most cases, human clinical trials to test efficacy are not possible due to ethical considerations. This effort directly applies to the HHS strategic goal of enhancing the capacity and productivity of the Nation's health science research enterprise.

Snapshot

4.b – Performance Measure: By 2004, develop two new animal models to use in research on at least one agent of bioterror.
Baseline: 8 animal models available

Year	Target	Actual
2001	Not applicable	Not applicable
2002	Not applicable	Not applicable
2003	Conduct validation studies of new monkey models of Smallpox by employing them in testing of new Smallpox vaccines and therapies.	Cynomolgus monkeys were tested for protection against human Variola and Monkeypox after being administered the Modified Vaccinia Ankara or Dryvax Smallpox vaccines.
2004	Expand by 25% the animal model resources available for use by the research community and for licensing products under the FDA Animal Efficacy Rule. Target: +2 animal models	Four new models for viral Hemorrhagic fevers, two models for West Nile virus (Category B agent), and a model of flea-borne Plague transmission have been developed. Actual: +7 animal models

Discussion of Results and Performance

NIH exceeded the FY 2004 target. Under a coordinated network of contracts, NIH supports the development of animal models and screening of compounds for activity against orthopoxviruses (murine models of Vaccinia, Cowpox, and Ectromelia) and respiratory viruses (murine models of Influenza A and

B). A contract with Utah State University was expanded to include viral Hemorrhagic fevers and Encephalitis.

Models for Category A Select Agents include: a mouse model for testing antivirals against Bunyaviruses (e.g., Hantavirus and Rift Valley Fever virus) using Punta Toro virus as a representative virus; a hamster model for testing antivirals treatment against Arenaviruses (e.g., Lassa Fever virus and Junin virus) using Pichinde virus as a representative virus; and a mouse model for testing antivirals against Flaviviruses (e.g., Dengue virus) using Banzi virus as a representative virus.

Models for Category B Select Agents include: a mouse model for testing antivirals against Togaviruses (e.g., Eastern, Western and Venezuelan Equine Encephalitis) using Semliki Forest virus as a representative virus; and mouse and hamster models for testing antivirals against West Nile virus.

In addition, National Institute of Allergy and Infectious Diseases intramural scientists developed a flea-to-mouse Plague transmission model for use in testing new candidate vaccines against flea-borne Plague. This model mimics the natural transmission route of Bubonic Plague through the bites of infected fleas. The flea-to-mouse model provides a more realistic test setting than previously used methods, enabling a better assessment of a vaccine's ability to protect against a real-world challenge.

Because this goal was initiated in 2002, performance data is available only from 2003 to date. The FY 2003 target was met. Both human Variola and Monkeypox models have been tested for protection against disease when administered the Modified Vaccinia Ankara or Dryvax Smallpox vaccines and for positive response to the antiviral drug cidofovir. Specifically, scientists at U.S. Army Medical Research Institute of Infectious Diseases and CDC developed two models to study Smallpox in cynomolgus monkeys–one with human Variola virus and one with Monkeypox virus. In FY 2003, these models were employed to test new Smallpox vaccines and therapeutics. Both models are an improvement over previous animal models because they are less susceptible to the pulmonary infections that prevented animals in previous models from progressing to systemic disease like that seen in humans. Researchers found the Monkeypox model to be particularly promising. After intravenous challenge with Monkeypox virus, the Monkeypox model animals die of a disease that is very similar to human Smallpox but which progresses over a shorter period of time. This achievement is a critical step in developing an effective response to bioterrorism and other public health challenges. A *bona fide* animal model allows testing of multiple potential vaccines and other therapies against Smallpox, thus increasing NIH's capacity to develop an FDA-approved product(s) against a bioterrorist microbial.

Program Evaluations

There was no independent evaluation of this program in FY 2004 and the program has not been assessed by PART.

For more information on this program's performance, please see pages 22 and 73 through 76 of NIH's *Revised Final FY 2004 GRPA Annual Performance Plan*.

Strategic Goal 5:

Improve the Quality of Healthcare Services

Improving the quality of life and health in the U.S. 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, increasing the quality and quantity of preventive care, and improving consumer and patient protection. To achieve this goal, HHS implements numerous strategies designed to improve the delivery of health care services. These include 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.

Illustrative of HHS commitment to reducing medical errors is the FDA's Medical Product Surveillance Network System (MedSun). When fully implemented, MedSun 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. HHS also developed a train-the-trainer program to implement a system to increase delivery of clinical preventive services. Finally, HHS partnered with appropriate professional organizations and produced fact sheets that promoted evidenced-based clinical prevention.

- Selected Program 5.a: FDA Medical Devices and Radiological Health
    - 5.a – Performance Measure: Expand implementation of MedSun to a network of 240 facilities.
- Selected Program 5.b: Agency for Healthcare Research and Quality (AHRQ) Prevention Portfolio
    - 5.b.1 – Performance Measure: Improve the quality and quantity of preventive care delivered in the clinical setting for the patient population.
    - 5.b.2 – Performance Measure: Increase the number of partnerships that will adopt and promote evidence-based clinical prevention.

5.A Medical Devices and Radiological Health

Food and Drug Administration (FDA)

The Program

FDA's Medical Devices and Radiological Health program is responsible for ensuring the safety and effectiveness of medical devices and eliminating unnecessary human exposure to man-made radiation from medical, occupational, and consumer products.

A key element in any comprehensive program to regulate medical devices is a postmarket reporting system on serious adverse events. Such reporting forms the basis for public health actions by the Agency, which include risk communication messages to users and product recalls. Questions of interest for marketed devices include long-term safety, performance in community practice, change in use setting, rare or unexpected events, and rates of anticipated adverse events, user error, and off-label use.

Overview of the Performance Goal

The FDA Modernization Act mandates that FDA replace universal user facility reporting with MedSun, composed of a network of user facilities constituting a representative profile of user reports. When fully implemented, MedSun will serve as an advance warning system for device problems, a laboratory for research, and a two-way communication channel between FDA and the user-facility community that will improve patient safety through recognition and management of use-related errors and offer feedback to manufacturers to improve device design.

MedSun is designed to improve FDA decision making about device problems by generating more useful and diverse reports from trained, engaged reporters. Reports on close calls allow FDA to evaluate a device issue before patient injury occurs. Better information allows timelier signal detection and enhances FDA's ability to analyze and react to problems. A key component of MedSun is to offer easily accessible information related to safe device use. MedSun participants receive a continuous stream of feedback including newsletters, educational materials, publications, and other information.

MedSun includes collaborations with a number of other FDA's Center for Devices and Radiological Health (CDRH) components and initiatives to expand the active surveillance. A recent substudy piloted expanded reporting procedures for collecting data on problems with laboratory tests. A new collaboration with the CDRH Home Healthcare Committee will allow better communication exchange between the FDA and Home Healthcare agencies.

The MedSun performance goal supports the Department's Strategic Goal 5 – Improve Quality of Healthcare Services, its Objective 5.1 – Reduce Medical Errors, and FDA's Strategic Goal – Patient and Consumer Safety. It also supports FDA's long-term outcome goal (Increase by 50 percent the patient population covered by active surveillance of medical product safety by 2008) to increase the percent of the population covered by active surveillance, which will allow for more rapid identification and analysis of adverse events. MedSun is a critical component towards achieving this long-term goal.

Snapshot

5.a – Performance Measure: Expand implementation of MedSun to a network of 240 facilities.		
Year	Target	Actual
2001	Recruit a total of 75 hospitals to report adverse medical device events.	FDA began feasibility testing with 25 hospitals and worked on software changes needed for website health data security.
2002	Implement MedSun by recruiting a total of 80 facilities for the network.	FDA recruited, trained and had 80 facilities participating in the network
2003	Build a MedSun hospital network of 180 facilities.	FDA recruited, trained and had 206 functioning facilities for the network.
2004	Build a MedSun hospital network of 240 facilities.	FDA recruited, trained and had 299 functioning facilities for the network.

Discussion of Results and Performance

The FY 2004 performance target is to expand the MedSun network to 240 facilities. FDA exceeded this performance target by having 299 functioning facilities for the network. Of the 299 facilities, 257 were hospitals with over 100 beds, 22 were other facilities, and 20 were nursing homes.

In FY 2003, the Agency met its goal by recruiting a total of 206 facilities into the MedSun system. In FY 2002, FDA recruited, trained, and had functioning 80 facilities for the network. In FY 2001, FDA did not meet the goal of recruiting 75 hospitals, as most of the effort that year was focused on resolving internal policy issues and addressing information technology security requirements. During FY 2002, FDA extended software development to accommodate an Internet-based reporting system (interactive web-based form and database), and took steps to ensure that facilities reporting information had Internet access to secure servers.

Program Evaluations

GAO issued one program evaluation report that examined the timeliness of medical device application reviews. GAO found that FDA had limited data that could be used to measure the Agency's performance against most of the Medical Device User Fee and Modernization Act performance goals. Despite the limited data, FDA has designed its performance measures to track the percentage of actions taken within the required review times. GAO acknowledges that FDA's results could change as the Agency completes its actions on all applications for which the goals apply.

PART Review and Recommendations

The Medical Device and Radiological Health program received PART evaluations for the FY 2004 budget process. During the FY 2005 budget process, FDA was evaluated as a single program. MedSun was not evaluated in either of these reviews. Findings from the FY 2004 PART assessment include the following:

- CDRH achieved a high score for its planning efforts. CDRH's list of annual performance goals allows for measurement of performance results;

- CDRH does have "strategic goals" (such as "Protect the public health by keeping marketed products safe") that aim to produce long-term improvements. However, there is no way to measure progress on those strategic goals. Thus the program cannot currently prove long-term results;
- Financial management is sound, and managers take meaningful steps to address management problems;
- In recent years, CDRH has shown some improvement in the review of new medical devices, but further performance improvements are needed;
- Inspection coverage for medical device manufacturers is poor, and falls far below the statutory expectation each year. CDRH focuses inspection coverage on highest priority establishments; and
- CDRH uses performance data to recommend program improvements.

To address these findings, FDA has:

- Established new, measurable long-term performance goals for CDRH;
- Improved current annual performance goals for the review of new products. CDRH continues to develop new annual goals that measure time to completion of CDRH review, an important review process milestone. Past goals measured an intermediate step in the review process; and
- Increased funding for medical device reviews through medical device review user fees.

For more information on this program's performance, please see pages 117 and 121-122 of FDA's *Revised Final FY 2004 Annual Performance Plan*, Congressional Justification, January 2004.

5.B Prevention Portfolio

Agency for Healthcare Research and Quality (AHRQ)

The Program

The Prevention Portfolio mission is to increase the adoption and delivery of evidence-based clinical prevention services to improve the health of all Americans.

The Prevention Portfolio provides the unique service of generating evidence-based clinical prevention recommendations and facilitating their dissemination and implementation. These efforts fully support the AHRQ's mission by improving the effectiveness and efficiency of health care delivery. Furthermore, the Prevention Portfolio promotes patient safety by providing evidence-based recommendations for essential and nonessential clinical preventive services.

The Prevention Portfolio is comprised of products and services that address the mission of the portfolio. The U.S. Preventive Services Task Force (USPSTF) is an independent panel of experts in primary care and prevention that systematically reviews the evidence of effectiveness and develops recommendations for clinical preventive services. These recommendations serve as the basis for the products produced within this portfolio. Specifically, USPSTF recommendations are disseminated in print through journal publications or electronically on the AHRQ website. Other products target more specific audiences. Fact sheets, clinical pocket guides, and checklists provide consumers and providers with easily assessable evidence-based information. The Prevention Portfolio also is expanding its electronic dissemination capacity. These include prevention topic list-serves and web-based programs that can be downloaded to personal handheld devices.

Snapshot

5.b.1 – Performance Measure: Improve the quality and quantity of preventive care delivered in the clinical setting for the patient population.

Year	Target	Actual
2001	Not applicable	Not applicable
2002	Not applicable	Not applicable
2003	Not applicable	Not applicable
2004	Increase continuing medical education activities by developing a train-the-trainer program for implementing a system to increase delivery of clinical preventive services.	Completed

5.b.2 – Performance Measure: Increase the number of partnerships that will adopt and promote evidence-based clinical prevention. [1]		
Year	Target	Actual
2001	Not applicable	Not applicable
2002	Not applicable	Not applicable
2003	Not applicable	Not applicable
2004	Produce fact sheets for adolescents, seniors, children. Partner with appropriate professional societies and advocacy groups.	Data available 1/2005

[1] 5.b.2 is a new measure. The Prevention Portfolio revised its measures during FY 2004 to include this new outcome measure. The results will be reported in the FY 2006 performance budget submission to Congress.

Discussion of Results and Performance

Legislative authority and Agency directives guide the activities of the Prevention Portfolio. AHRQ, as required by its reauthorization legislation in 2000, has assumed responsibility for supporting the USPSTF as part of the Agency's mission to enhance the quality, appropriateness, and effectiveness of health care services. From the initial inception of the USPSTF under the auspices of the Public Health Service, Office of Disease Prevention and Health Promotion, Federal support has been critical to ensuring both the quality of USPSTF products and the broad participation of relevant professional groups and government agencies. AHRQ's current support of the task force typifies the Agency's strategy of improving health care by assuring that decision makers have access to the evidence they need to draw conclusions about the most effective and efficient screening, diagnostic, and therapeutic choices. AHRQ's support of the fask force also provides opportunities for public and private partners to translate evidence generated from research into recommendations, clinical practice guidelines, continuing education, and quality assurance or improvement measures.

The task force issued recommendations in the area of clinical prevention. These recommendations lead to primary publications in journals and secondary publications. The task force evidence-based recommendations focus on effectiveness of clinical preventive services in the primary care setting. The task force uses a rigorous process to review and synthesize the evidence. These recommendations relate to routine care provided in the primary care setting with proven long-term benefit to the patient, such as decreased morbidity or mortality. Other organizations developing clinical prevention guidelines may produce recommendations in contrast to the USPSTF. These differences are a result of the use of different outcome measures, effectiveness outside the primary care setting or among a high-risk population. Full recommendations and rationale can be obtained at the USPSTF website: http://www.preventiveservices.ahrq.gov.

Program Evaluations

The Prevention Portfolio did not undergo an independent evaluation in FY 2004 and it has not been assessed using PART.

For more information on this program's performance, please see page 13 of AHRQ's *Revised Final FY 2004 GRPA Annual Performance Plan*.

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 empower disadvantaged and distressed individuals, families, and communities to improve their economic and social well-being. HHS targets efforts toward low-income families, including those receiving Temporary Assistance to Needy Families (TANF), children, the elderly, people with disabilities, Native Americans, and distressed communities.

ACF's Office of Family Assistance and the Administration on Aging's (AoA's) Community-Based Services program illustrate HHS' commitment to self-sufficiency. ACF's TANF program promotes work and self-sufficiency to improve the economic well-being of individuals and families through State- and Tribal-administered programs. The Community-Based Services program ensures that local services are provided to seniors who are at risk of losing their independence.

- Selected Program 6.a: ACF Temporary Assistance to Needy Families
    - 6.a – Performance Measure: Percentage of those (current/former TANF recipients) employed in a quarter that were still employed one and two quarters later.
- Selected Program 6.b: AoA Community-Based Services Program
    - 6.b – Performance Measure: A significant percentage of Older Americans Act Title III service recipients live in rural areas.

6.A Temporary Assistance for Needy Families (TANF)

Administration for Children and Families (ACF)

The Program

The purpose of TANF is to reduce dependency by promoting job readiness, employment, and marriage. It is also designed to prevent out-of-wedlock pregnancies and to encourage the formation and maintenance of two-parent families. Title IV-A of the Social Security Act, as amended by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA), requires that States and territories administer programs; Tribes have the option to administer their own programs. States, territories, and Tribes each receive a block grant allocation with a requirement for States to maintain a historical level of State spending (for welfare and other services for low-income families) known as Maintenance of Effort. The block grant covers benefits, administrative expenses, and services. States, territories, and tribes determine eligibility and benefit levels as well as services provided to needy families.

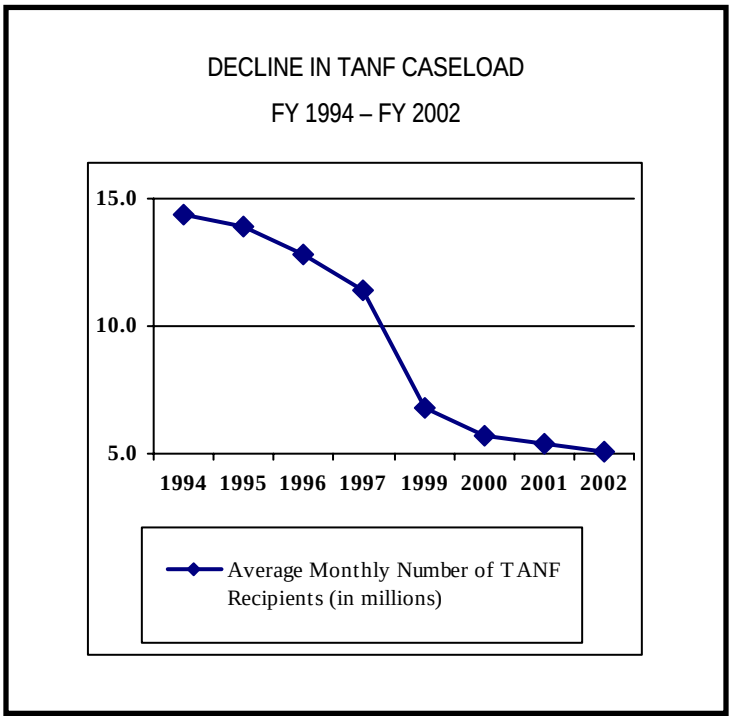
PRWORA dramatically changed the Nation's welfare system into one that requires employment while time-limiting assistance. The TANF program replaced the former Aid to Families with Dependent Children, Job Opportunities and Basic Skills Training, and Emergency Assistance programs, ending the Federal entitlement to assistance.

Snapshot

6.a – Performance Measure: Percentage of those (current/former TANF recipients) employed in a quarter that were still employed one and two quarters later.		
Year	Target	Actual
2001	64% of TANF recipients	63% of TANF recipients
2002	65% of TANF recipients	59% of TANF recipients
2003	68% of TANF recipients	59% of TANF recipients
2004	65% of TANF recipients	Data available 09/2005

Discussion of Results and Performance

Overall, record numbers of people are moving off welfare. Since the August 1996 passage of the law, recipient caseloads are down by 60.7 percent. From March 2003 to March 2004, the number of recipients declined 1.3 percent.



Note: The annual figure is computed by taking the average of the 12 months for the calendar year.

Many are moving from welfare to work. In 2003, 34 percent of adult TANF recipients became newly employed (this is down from 43 percent in 1999 when the economy was very robust). While obtaining a job is an important first step on the path to self-sufficiency, maintaining employment is crucial. Initially, the job retention measure was limited to job retention over one subsequent quarter. However, in 2000, ACF decided to stretch the target and revised the measure to job retention over two subsequent quarters. Job retention rates were 77 percent in 1999 (when the measure was over one quarter). Using this more ambitious job retention measure, job retention rates were 58 percent in 2000, 63 percent in 2001, and 59 percent in 2002. While the ACF target for job retention was achieved in 2000, these targets have not been met in the years following. In 2003, 59 percent of current/former TANF recipients were employed for two consecutive quarters after the first quarter.

While State agencies are reporting that the proportion of clients with barriers is growing, States have increased TANF and Maintenance of Effort funding for supportive services to assist clients to overcome these barriers. ACF is funding major new evaluation projects to increase its knowledge about the most effective strategies for helping hard to employ parents find and sustain employment. In addition, the proposed TANF reauthorization legislation would require States to describe strategies they would/are employing to assist clients to overcome these barriers, develop performance indicators to measure the effect of these strategies, and report the results of these efforts. The proposed legislation would also allow States to count up to 3 months of drug and alcohol treatment/rehabilitation toward the work requirement and up to 16 hours of the 40-hour requirement for activities associated with removing employment barriers.

Source Documentation

For a number of major programs, including TANF, ACF is largely dependent on State administrative systems for collecting performance data. There is generally a 1 - 2 year lag in data collection. For more information on the FY 2003 results, see the following website on FY 2003 High Performance Bonus Awards to States: http://www.acf.hhs.gov/programs/ofa/HPB/2003/tab3a.htm. States can receive high performance bonus awards for success on the work-related GPRA measures discussed in this report: job entry, job retention, and job earnings

Program Evaluations

The results of several independent evaluative studies on TANF were published in 2004. Major findings from these studies included the following: there was little evidence that welfare reform resulted in widespread harm or benefit to school-aged children, but there was some negative impact on teen-agers; program changes resulted in earnings and employment increasing, particularly in mixed-activity programs, consistent across all subgroups; the Jobs-Plus program of the Department of Housing and Urban Development, with its place-based strategy for assisting sizable numbers of public housing residents with employment, showed mixed results; "cyclers" constituted only 9 percent of the caseload and fared better than long-term recipients, but not as well as short-term recipients; the percentage of cyclers increased following PRWORA; welfare dependence among welfare-to-work enrollees fell sharply during the year following program entry; end-of-year household incomes were low and poverty rates high for welfare-to-work enrollees in this study during this period; and poverty was typically about 20 percentage points lower among enrollees who were employed than among those who were not employed.

For more information on this program's performance, please see pages M12 through M22 of ACF's *Revised Final FY 2004 GRPA Annual Performance Plan*.

6.B Community-Based Services Program

Administration on Aging (AoA)

The Program

AoA's Community-Based Services program provides grants to States to provide comprehensive social and supportive services to vulnerable elderly individuals and their family caregivers. AoA and a network of State, Tribal, and local service entities provide essential home and community-based services across the country to help keep America's rapidly growing older population healthy, secure, and independent. Services provided to elders most in need include but are not limited to: meals, transportation, caregiver support, personal care, information and assistance, and health promotion.

Through its programs, AoA directly supports HHS' strategic goal to improve the economic and social well-being of individuals, families, and communities, especially those most in need. To track performance related to the HHS goal, AoA has defined program goals and objectives that focus on protecting the independence and well-being of older Americans. To ensure accountability for serving elderly individuals in greatest need, AoA has established a set of performance outcome measures that focus on program efficiency, client impact, and program targeting to older individuals who require care.

To ensure that AoA programs serve populations in need, the Agency employs "targeting" measures, including one to increase the percentage of AoA clients who reside in rural areas. It is a challenge to provide needed home and community-based services in rural areas, where access is limited, distances are great, and service infrastructure is often wanting. Targeting services to vulnerable elderly individuals, such as those in rural areas, ensures that AoA and the aging network are directly focusing on the HHS goal to serve those in need and the mission of the Agency to help elderly individuals to maintain their independence in the community.

Snapshot

6.b – Performance Measure: A significant percentage of Older Americans Act (OAA) Title III service recipients live in rural areas.		
Year	Target	Actual
2001	25% of clients	30% of clients
2002	25% of clients	28% of clients
2003	34% of clients	28% of clients
2004	34% of clients	Data available 09/2005

The States will provide performance data for FY 2004 to AoA beginning in January 2005, and validated and verified data for FY 2004 are expected to be available for analysis by September 2005.

The source documentation for the data is administrative records collected and aggregated by State Units on Aging, through the State Program Report. The data submitted to AoA annually are part of the National Aging Program Information System.

Discussion of Results and Performance

Performance data for prior years for which AoA used this measure in its GPRA program (FY 2001 and 2002), indicate that AoA met its performance targets.

- In FY 2001, AoA targeted that 25 percent of OAA clients would reside in rural areas. Data for FY 2001 indicate that 30 percent of OAA client resided in rural areas.
- In FY 2002, AoA targeted that 25 percent of OAA clients would reside in rural areas. Data for FY 2002 indicate that 28 percent of OAA clients resided in rural areas.
- Data for the two years prior to FY 2001 (FYs 1999 and 2000) indicate that over 30 percent of OAA clients resided in rural areas.

In FY 2001, AoA initiated processes to improve the timeliness and quality of State Program Report data under the National Aging Program Information System. At that time, there was a 28-month lag between the end of the fiscal year and when data were available for analysis. To reduce this time lag, and to improve the quality of the data, AoA initiated a new central and regional office review process to foster the timely identification and correction of erroneous data. The AoA verification and validation process has resulted in more intense data review at the Federal and State levels, and has reduced the data lag from 28 months to 10 months.

Beginning with the FY 2003 performance year, AoA established more ambitious performance targets for this performance measure because of the importance of targeting services to elderly individuals in rural areas. Recognizing that the FY 2003 target was particularly aggressive, AoA is not surprised that it did not meet the target in the first full year of the implementation of added efforts to target rural areas. Nevertheless, AoA will maintain the aggressive targets for FY 2004 and beyond, and expects in the near future to begin to achieve these targets, because there are efforts in States and communities across the Nation to increase the targeting of resources to rural areas through funding formula modifications and other program initiatives.

Program Evaluations

AoA has no independent program evaluations completed during this fiscal year that would inform the Community-Based Services program.

PART Review and Recommendations

In the FY 2005 budget process, AoA's Community-Based Services program received a rating of "Moderately Effective" during the PART review, which was a significant improvement over the FY 2004 assessment "Results Not Demonstrated". AoA achieved the improved score through enhancements to its strategic plan, the development of efficiency measures, and the assignment of ambitious performance targets, such as the one for serving older persons in rural areas. AoA has continued to make improvements in response to the FY 2005 PART review by conducting detailed program evaluations for its program activities, and by better linking PART results and performance results to program budget requests.

For more information on this program's performance, please see pages 16 through 22 of AoA's *Revised Final FY 2004 GRPA Annual Performance Plan*.

Strategic Goal 7:

Improve the Stability and Healthy Development of Our Nation's Children and Youth

HHS is taking steps to improve the stability and healthy development of the Nation's children and youth. These include promoting family formation, healthy marriages, and instituting creative and innovative ways to improve the school readiness of children. ACF's Child Support Enforcement (CSE) and Child Welfare programs demonstrate this commitment to the Nation's children and youth. The CSE program ensures that support is available to children by locating parents, establishing paternity, and enforcing 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 Child Welfare programs, such as Foster Care, Adoption Assistance, and Adoption Incentives, provide safe and stable environments for vulnerable children. The Head Start program promotes school readiness by enhancing the social and cognitive development of children through educational, health, nutritional, social, and other services.

- Selected Program 7.a: ACF Child Support Enforcement
    - 7.a – Performance Measure: Increase the Title IV-D collection rate (collections on current support/current support owed).
- Selected Program 7.b: ACF Child Welfare
    - 7.b – Performance Measure: Increase the number of adoptions toward achieving the goal of finalizing 327,000 adoptions between FY 2003 - FY 2008.
- Selected Program 7.c: ACF Head Start
    - 7.c – Performance Measure: Achieve goal of at least 80 percent of children completing the Head Start program rated by parent as being in excellent or very good health.

7.A Child Support Enforcement

Administration for Children and Families (ACF)

The Program

The mission of CSE is to ensure that children receive the financial and medical support they need by locating parents, establishing paternity, and enforcing support obligations. Child support is an important source of income for providing quality of life for children and for families striving for self-sufficiency.

The Office of CSE works in collaboration with State agencies. The CSE program is administered by State and local governments, but funded in part by the Federal Government, which reimburses States for 66 percent of administrative costs and 90 percent of paternity laboratory costs. The Federal role is to provide direction, guidance, technical assistance, oversight, and some critical services to States' CSE programs for activities mandated under Title IV-D of the Social Security Act.

The PRWORA is having a dramatic impact on the child support program. This law added major new responsibilities and provided a number of enforcement tools to ensure that both parents financially support children.

One key provision of PRWORA is that all States must have a program to collect information about newly hired employees to a State Directory of New Hires. States match new hire reports against their child support records to locate parents, establish orders, or modify existing orders. To address the large number of cases where the parent who owes child support works in another State, PRWORA established the National Directory of New Hires, a national repository of records from the State Directory of New Hires, quarterly wage and unemployment insurance data from the State Employment Security Agencies, and new hire and quarterly wage data from Federal agencies.

Another mandate from PRWORA was the creation of the Federal Case Registry. This registry is a national database that includes all child support cases handled by State child support agencies, and all support orders established or modified on or after October 1, 1998. It assists States in locating parties who live in different States to establish, modify, or enforce child support obligations, establish paternity, enforce State law regarding parental kidnapping, and establish or enforce child custody or visitation determinations.

PRWORA also provided enforcement tools, some particularly important for collecting past-due child support. One tool is the financial institution data match, which is an additional means for locating the assets of individuals owing child support obligations. State child support programs may issue liens or levies on the accounts of the non-custodial parent (NCP) to collect past-due child support. Another tool provided to States and the Federal Government is passport denial. PRWORA requires the Secretary of State to refuse issuance of a passport to any person certified by HHS as owning greater than $5,000 in child support debt.

Snapshot

7.a – Performance Measure: Increase the Title IV-D collection rate (collections on current support/current support owed).		
Year	Target	Actual
2001	54%	57%
2002	55%	58%
2003	58%	58% [1]
2004	60%	Data available 09/2005

[1] FY 2003 data is preliminary.

Discussion of Results and Performance

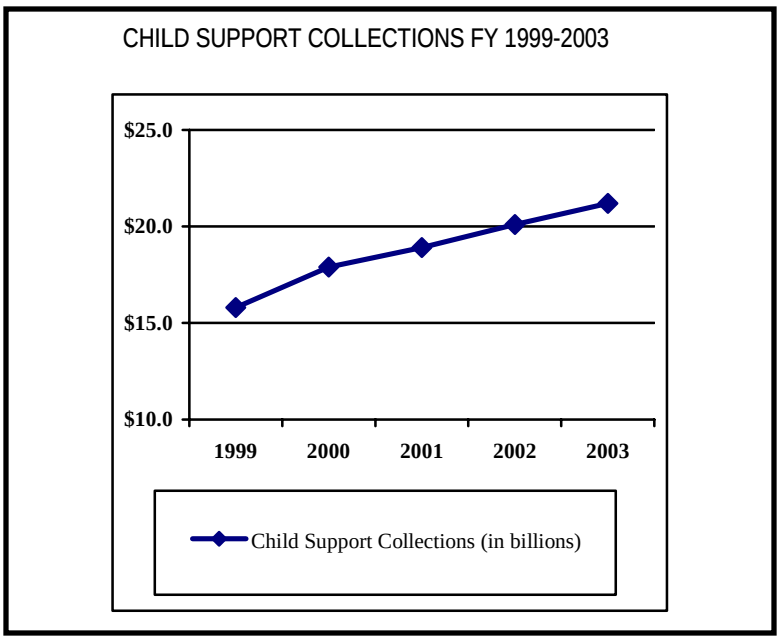
CSE has five performance measures: four outcome measures and one efficiency measure. In FY 2002, the latest year for which final performance data is available, the child support program met its targets for three out of the five measures.

The three measures ACF/ CSE met were:

- Increase the Title IV-D collection rate for current support: CSE achieved a 58 percent Title IV-D collection rate, in FY 2002 and FY 2003 (according to preliminary data). This is an improvement from FY 1999 when the collection rate was 53 percent;
- Increase the percentage of Title IV-D cases having support orders: CSE increased the percentage of cases with orders to 70 percent in FY 2002 (target 64 percent); and
- Increase the percentage of paying cases among Title IV-D arrearage cases: CSE also increased the percentage of paying cases among those with past-due support to 60 percent in FY 2002 (target 55 percent).

CSE just missed the targets for "maintain the paternity establishment percentage among children born out of wedlock," achieving 95 percent in FY 2002 (target 97 percent), and for the efficiency measure, "increase the cost-effectiveness ratio (total dollars collected per dollar expended)," collecting $4.13 in child support for every dollar invested (target $4.20).

Total child support collections reached a record high of $20 billion in FY 2002. Child support professionals of the Title IV-D program collected $326,000 for each full-time equivalent staff member. In addition, 89 percent of collections went to families in FY 2002. Payments distributed to families increased nearly 8 percent since FY 2001. Families who formerly received public assistance comprise the largest group of clients in CSE's caseload (46 percent). Overall, new collection tools and program improvements, such as new hire reporting and increasing Statewide automation, have increased collections but they have not been fully implemented in all States.



Note: FY 2003 data is preliminary. For more information on child support collections, refer to the following website: http://www.acf.hhs.gov/programs/cse/pubs/2004/reports/preliminary_data/.

Source Documentation

For a number of major programs, including CSE, ACF is largely dependent on State administrative systems for collecting performance data. There is generally a 1 - 2 year lag in data collection. As a result, the latest final performance information within this report is for FY 2002. FY 2003 final data is expected to be available by January 2005.

In terms of data quality and reliability, States currently maintain information on the necessary data elements for CSE program measures. Most States use an automated system to maintain these data, while a few maintain the data manually. All States were required to have a comprehensive, Statewide automated CSE system in place by October 1, 1997. Forty-four States and four territories indicated compliance with the single Statewide child support enforcement automation requirements of the Family Support Act of 1998. See http://www.acf.dhhs.gov/programs/cse/stsys/revised.htm for further documentation. Data reliability audits are conducted annually.

Program Evaluations

An independent evaluation of the Office of CSE Responsible Fatherhood project found that more than 52 percent of the NCPs needed help with employment or increasing incomes. Employment at the sites significantly increased from between 8 and 33 percent, with earnings rising significantly from between 25 and 250 percent. More than 57 percent of the NCPs needed assistance with child support. Increases in those making any child support payment ranged from 4 to 31 percent. Fifty-one percent of fathers wanted help getting to see their children more often, and their interests were also in improving parenting skills (39 percent) and improving the relationship with the child's mother (30 percent).

PART Review and Recommendations

CSE received a PART assessment during the FY 2005 budget cycle. The program received a rating of "Effective." OMB recommended that the program continue to build on its success in child support collection, improve medical support enforcement, and encourage responsible parenthood.

For more information on this program's performance, please see pages M47 through M57 of ACF's *Revised Final FY 2004 GRPA Annual Performance Plan*.

7.B Child Welfare

Administration for Children and Families (ACF)

The Program

The purpose of ACF's Child Welfare programs, under Titles IV-B and IV-E of the Social Security Act, is to prevent maltreatment of children, provide in-home services for at-risk children and families, find temporary placements for children who must be removed from their homes, and achieve safe and stable permanent outcomes for children removed from their homes. Foster Care provides stable environments for those children who cannot remain safely in their homes, and ensure children's safety and well-being while their parents attempt to resolve the difficulties that led to the out-of-home placement. When the family cannot be reunified, it 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. In December 2003, President Bush signed the Adoption Promotion Act of 2003, which reauthorizes the adoption incentive payments program first created by the Adoption and Safe Families Act of 1997. The Act creates enhanced incentives for "older child adoptions," namely adoption from foster care of children who are 9 years of age or older. It maintains the existing incentives for other foster children.

Snapshot

7.b – Performance Measure: Increase the number of adoptions toward achieving the goal of finalizing 327,000 adoptions between FY 2003 - FY 2008.		
Year	Target	Actual
2001	51,000 adoptions	50,000 adoptions
2002	56,000 adoptions	53,000 adoptions
2003	58,500 adoptions	49,000 adoptions [1]
2004	53,000 adoptions	Data available 09/2005

[1] Data source is the Adoption and Foster Care Analysis Reporting System; 2003 estimate based on data submitted by States as of 8/1/2004.

Discussion of Results and Performance

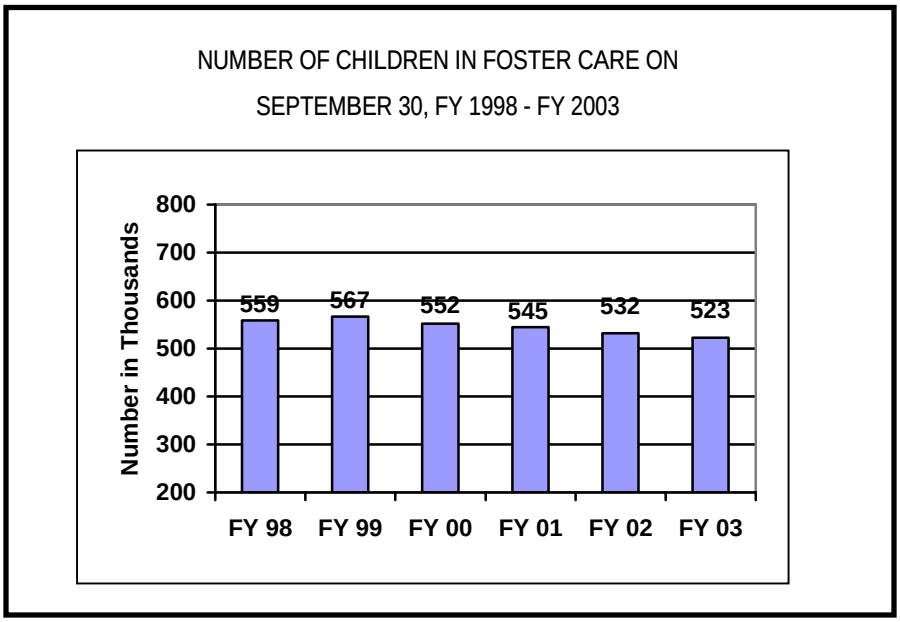
ACF's Foster Care and Adoption programs have five measures, all with established targets. ACF receives data from the States on adoptions and foster care through the Adoption and Foster Care Analysis and Reporting System. ACF is awaiting FY 2003 performance results for two of the measures (increase the percent of children who exit foster care within 2 years of placement either through guardianship or adoption and decrease the percent of children who exit foster care through emancipation) to determine whether targets have been achieved. Of the other three measures for which FY 2003 data are available, two have met or exceeded targets, while one fell short.

ACF met the FY 2002 target of 67 percent for the measure to maintain the percentage of children who exit the foster care system through reunification within 1 year of placement. The FY 2006 target for this measure is 68 percent. Also, ACF exceeded the FY 2002 target for the measure to maintain the percentage of children, who had been in care less than 12 months, to no more than two placement settings, by achieving an 82 percent rate, which was above the target of 62 percent. The FY 2006 target for this measure is 80 percent.

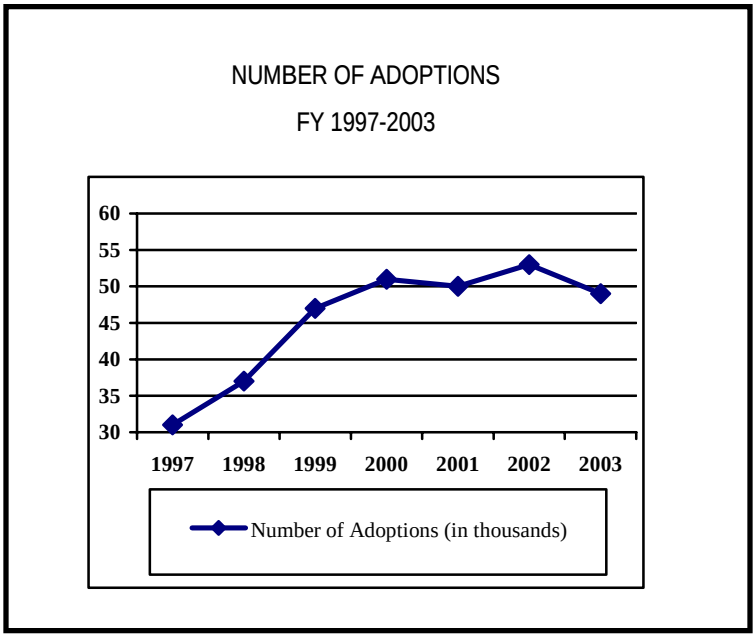
There were 49,000 adoptions in FY 2003. Since 2000, the number of adoptions annually has flattened and annual targets have not been met. The FY 2003 target of 58,500 adoptions was not met, in part, because the decline in the total number of children in foster care during the period was not anticipated. The number of children in care declined from 567,000 in FY 1999 to 523,000 in FY 2003 (see the figure below). In addition, targets did not take into account that the average age of the children waiting for adoption would increase by almost 1 year during this same period, making it more challenging to find adoptive homes for the children. ACF adjusted adoption targets for future years to reflect this new information and, starting in FY 2004, anticipates a much slower rate of growth in the number of adoptions.

ACF also changed the performance measure for adoptions to: increase the number of adoptions toward achieving the goal of finalizing 327,000 adoptions between FY 2003 - FY 2008.

The previous measure was derived from the goal of doubling the number of adoptions over a 5-year period, thereby emphasizing the specific year in which an adoption was finalized rather than the finalization of the adoption itself. For example, the target number of adoptions in performance measures from FY 1999 through FY 2002 was 194,000. The actual number of adoptions finalized was 199,000 – 5,000 more than projected. The adoption rate (number of adoptions divided by the number of children in care at the end of the prior year) actually increased from 8.4 percent in FY 1999 to 9.7 percent in FY 2002.



Note: Estimates are based on data submitted by States as of 8/1/2004.
Data source: Adoption and Foster Care Analysis and Reporting System



Note: Estimates are based on data submitted by States as of 8/1/2004.
Data source: Adoption and Foster Care Analysis and Reporting System

Source Documentation

States report foster care and adoption data for September 30 of any year, under regulation, to ACF electronically by November 14. ACF processes the data, assesses it for errors and compliance with regulatory standards, and transmits the results back to the States. Based on these results and other information provided by the Department, many States submit revised data to insure that accurate data are submitted. Although States may re-submit foster care data at any time, there are two other times States typically re-submit data. States may resubmit data to ensure that the data used for this purpose are accurate. The resubmitted data are then processed and made available to the statistical analysts in May. The analysts review the data to determine which States' data are useable in this plan.

In terms of data quality, both Adoption and Foster Care Analysis and Reporting System and the National Child Abuse and Neglect Data System conduct extensive edit-checks for internal reliability. For the Adoption and Foster Care Analysis and Reporting System, more than 700 edit-checks are conducted each time data are submitted, a minimum of two times a year per State, to improve data quality. In addition, all edit-check programs are shared with the States. Finally, compliance reviews for the system currently are being piloted, and Statewide Automated Child Welfare Information System systems are undergoing reviews to determine the status of their operation.

To view Adoption and Foster Care Analysis and Reporting System data, refer to the following website: http://www.acf.hhs.gov/programs/cb/dis/afcars/.

Program Evaluations

An independent evaluation report completed in 2004 on the Termination of Parental Rights (TPR) for Older Foster Children found that youth move more rapidly to TPR than before the Adoption and Safe Family Act was passed. TPR is necessary in order to move a child to adoption. Parental noncompliance with treatment plans was found to be a key factor in moving TPR more rapidly. Practices and results varied widely by State.

PART Review and Recommendations

OMB assessed the Foster Care program using PART during the FY 2004 budget process. OMB reassessed the program during the FY 2005 budget process and the program's rating improved to "Adequate." OMB recommended that the program develop and introduce legislation that would permit the flexible use of funding so that dollars may be programmed to meet program goals, and include funding for independent evaluation.

For more information on this program's performance, please see pages M92 through M104 of ACF's *Revised Final FY 2004 GRPA Annual Performance Plan*.

7.C Head Start

Administration for Children and Families (ACF)

The Program

Intended primarily for preschoolers from low-income families, the basic philosophy guiding the Head Start program is that children benefit from high quality early childhood experiences. Head Start promotes school readiness by enhancing the social and cognitive development of children through the provision of educational, health, nutritional, social, and other services. Programs emphasize cognitive, language, and socio-emotional development to enable each child to develop and function at his or her highest potential. Head Start engages parents in their children's learning and helps parents to make progress toward their educational, literacy, and employment goals.

Head Start continues to emphasize its role as a national laboratory to test and refine educational approaches, and to use child outcomes to help guide program development. Recognition of emerging research, changing needs, and developing trends enable the Head Start Bureau to make resources available for targeted programmatic improvements. Head Start conducts research, demonstration, and evaluation activities to test innovative program models and to assess program effectiveness. In FY 1994, the Early Head Start program was established in recognition of mounting evidence that the earliest years, from birth to 3 years of age, matter a great deal to children's growth and development.

Snapshot

7.c – Performance Measure: Achieve goal of at least 80% of children completing the Head Start program rated by parent as being in excellent or very good health.		
Year	Target	Actual
2001	80% of children	79% of children
2002	80% of children	79% of children
2003	80% of children	Data available 12/2005
2004	80% of children	Data available 12/2006

Discussion of Results and Performance

In the past few years, the Head Start program almost has achieved its target to have 80 percent of children, who were rated as having excellent or good health by their parents, complete the program. In 2001 and 2002, the program reached a 79 percent completion rate.

Overall, children in Head Start programs are gaining in word knowledge, emergent literacy, language, mathematics, and social skills. However, the program's target goals in each of these areas have not been met. In 2002:

- In word knowledge, the target was to achieve at least an average 34 percent or 12.0-scale point increase. The program actually achieved a 32 percent or 10.0-scale point gain.
- In letter identification, the target was to reach a 70 percent or a 3.4-scale point gain; however, the program only received a 38 percent or a 2.0-scale point gain.

- In mathematical skills, the goal was to achieve 52 percent or a 4.0-scale point increase; however Head Start only gained 43 percent or 3.0-scale points.
- In social skills, the goal was to gain 14 percent or 2.0-scale points. The actual gain was 13 percent or 1.9-scale points.

Source documentation

The Family and Child Experiences Survey is a longitudinal study of a nationally representative sample of 3,200 children and families in 40 Head Start programs, which provides data for the Head Start child outcomes measures. OMB granted approval for the study in July 1997, following a field test of 2,400 children in the spring of 1997. Full implementation began in the fall of 1997 and includes assessment of the same children before and after their Head Start experience (whether 1 or 2 years), as well as in the spring of kindergarten and the spring of first grade. Data sources include parent interviews, staff interviews, teacher questionnaires, classroom observations, and direct child assessments.

Program Evaluations

The data presented in this PAR came from the independent evaluation, Family And Child Experiences Survey (FACES). Additional data concerning the children, the quality of the classroom, and the parents were also reported in FACES and the Quality Research Consortium Data Coordination Center's report; e.g., some types of program enhancements (teacher training and individualizing assessment interventions) had favorable impacts on children's outcomes.

PART Review and Recommendations

Head Start received a PART assessment during the FY 2004 budget cycle, receiving a rating of "Results Not Demonstrated". OMB recommended that the program:

- Create a new system to assess every Head Start center on its success in preparing children for schools;
- Propose legislation to better integrate Head Start, child care, and State-operated preschool programs;
- Develop annual performance measures that assess the progress of individual grantees in improving school readiness;
- Better measure the impact on children; and
- Provide inflationary increases in program funding for 2004.

For more information on this program's performance, please see page M77 through M91 of ACF's *Revised Final FY 2004 GRPA Annual Performance Plan*.

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. To achieve this goal, HHS is dedicated to successfully meeting the challenges identified in the President's Management Agenda. HHS is improving management of financial resources; using competition to obtain the best price for the services acquired; improving the management of 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.

Illustrative of HHS commitment to achieve excellence in management practices are CMS' Medicare Integrity program and the OIG's Healthcare Fraud and Abuse Control programs. The Medicare Integrity program ensures the right Medicare amounts are paid to a legitimate provider for an eligible beneficiary. Similarly, the Healthcare Fraud and Abuse Control (HCFAC) program conducts and supervises audits, inspections, and investigations of HHS programs, and provides guidance to the health care industry.

- Selected Program 8.a: CMS Medicare Integrity Program
    - 8.a – Performance Measure: Reduce the percentage of improper payments made under the Medicare Fee-for-Service Error Rate.
- Selected Program 8.b: Office of Inspector General
    - 8.b – Performance Measure: Returns per budget dollar invested in the OIG.

8.A Medicare Integrity Program

Centers for Medicare & Medicaid Services (CMS)

The Program

CMS' program integrity efforts ensure the Medicare program pays the right amount to a legitimate provider for covered, reasonable, and necessary services that are provided to an eligible beneficiary. CMS' program integrity activities are funded primarily through the Medicare Integrity program, established by the Health Insurance Portability and Accountability Act of 1996. The program includes medical review and benefit integrity activities, provider education and training, Medicare Secondary Payer, and provider audits. CMS' overall program integrity efforts are supplemented by funding from CMS' program management account and other funds made available from the HCFAC account.

Snapshot

8.a – Performance Measure: Reduce the percentage of improper payments made under the Medicare Fee-for-Service error rate.		
Year	Target	Actual
2001	6.0%	6.3%
2002	5.0%	6.3%
2003	5.0%	9.8% [1]
2004	4.8%	9.3% [2]

[1] HHS reported an unadjusted paid claims error rate of 9.8 percent, and an adjusted paid claims error rate of 5.8 percent in FY 2003.

[2]Per Improper Payments Information Act (IPIA) requirements, HHS began reporting on gross results in FY 2004. The FY 2004 gross (under- and over-payments) result was 10.1 percent. FY 2004 net results are shown above for the purposes of comparison.

Discussion of Results and Performance

This goal's purpose is to identify the rate of improper payments and implement corrective actions needed to reduce the percentage of improper payments made under the Medicare FFS program. One of CMS' key goals is to pay claims properly the first time. This means paying the right amount to legitimate providers, for covered, reasonable and necessary services provided to eligible beneficiaries. Paying claims right the first time saves resources required to recover improper payments and ensures the proper expenditure of valuable Medicare Trust Fund dollars.

The Medicare FFS improper payment estimate is derived from two programs: the Comprehensive Error Rate Testing (CERT) Program and the Hospital Payment Monitoring Program (HPMP). Each component represents about 50 percent of the erroneous payments. The CERT Program calculates the error rate for Carriers, Durable Medical Equipment Regional Carriers and non-Prospective Payment System (PPS) inpatient hospital claims submitted to Fiscal Intermediaries (FIs). The HPMP calculates the error rate for PPS inpatient hospital claims submitted to the FIs. The OIG-approved methodology includes:

- Randomly selecting about 160,000 claims;
- Requesting medical records from providers on these claims;
- Reviewing the claims and medical records for compliance with Medicare coverage, coding, and billing rules; and
- Treating non-response by a provider as an error.

HHS reported an unadjusted paid claims error rate of 9.8 percent, or $19.6 billion in net improper payments ($21.5 billion gross), and an adjusted paid claims error rate of 5.8 percent, or $11.6 billion during FY 2003. During FY 2004, HHS worked to develop and implement appropriate corrective action. Further, for FY 2004, HHS determined a paid claims error rate of 10.1 percent, or $21.7 billion, in gross improper payments. To facilitate comparability with prior year results, HHS determined an FY 2004 net paid claims error rate of 9.3 percent, as shown in the table above (see note 2).

HHS will continue to take corrective action to address causes related to the national Medicare Fee-For-Service (FFS) paid claim error rate and also continue to work toward reducing the rate. Further, HHS will determine a national Medicare FFS error rate in FY 2005.

Program Evaluations

The OIG conducted an evaluation entitled "Review of Providers' Responsiveness to Requests for Medical Records Under the Comprehensive Error Rate Testing Program" (A-01-04-00517). This document is available at http://oig.hhs.gov/oas/reports/region1/10400517.pdf. The objective of the review was to continue monitoring the rate of response by Medicare providers to requests for medical records during the FY 2004 CERT process. The OIG found that the remaining non response rate would not have a significant impact on the reliability of CMS' estimate of the FY 2004 Medicare FFS error rate. A number of recommendations for improvement were listed in the report, all of which will be adopted by CMS.

For more information on this program's performance, please see page V-99 of CMS's *Revised Final FY 2004 GRPA Annual Performance Plan*.

8.B Office of Inspector General (OIG)

The Program

The primary function of the OIG is to detect and prevent fraud and abuse and to recommend policies designed to promote economy, efficiency, and effectiveness in the administration of HHS and its programs. OIG accomplishes its purpose by conducting and supervising audits, inspections, and investigations of HHS programs, and providing guidance to the health care industry. Approximately 80 percent of OIG resources are devoted to the Health Care Fraud and Abuse Control (HCFAC) program, a mandatory program established by the Health Insurance Portability and Accountability Act of 1996. It is a joint program of HHS and the Department of Justice (DOJ), and its purpose is to coordinate Federal, State, and local law enforcement activities with respect to health care fraud and abuse, including the conducting of investigations, audits, evaluations, and inspections relating to the delivery of and payment for health care in the U.S. According to former Senator William Cohen, chief author and sponsor of the legislation, it "…simply provides adequate resources for prosecutors and investigators, long-strapped by budget cuts and understaffing, to go after serious patterns and cases of abuse." The remaining approximately 20 percent of OIG resources are allocated to audits, investigations, and inspections of other HHS programs, including its public health and human services programs, and general Departmental oversight.

Snapshot

8.b – Performance Measure: Returns per budget dollar invested in the OIG.		
Year	Target	Actual [1]
2001	$75	$110
2002	$79	$121
2003	$114	$117
2004	$136	Data available 01/2005

[1] The source of the results data will be the HHS OIG *Semiannual Report to the Congress* to be issued October 2004. The results contained in the OIG *Semiannual Report to the Congress* are gleaned from the audit, investigations, and inspection data systems of the OIG.

Discussion of Results and Performance

Return on investment has long been the primary measure of the effectiveness and efficiency of the OIG. The ratio is calculated by dividing the documented savings for the fiscal year by the OIG budget for that year. Fiscal year saving is calculated by summing expected recoveries from investigations that are successfully prosecuted by the DOJ, settlements that occur in lieu of criminal prosecution, monetary penalties, audit disallowances, and savings from funds not expended as a result of legislative and administrative actions stimulated by OIG audits and inspection reports.

In FY 2003, the return was $117 saved per dollar invested in the OIG. This result surpassed the goal of $114:1 and continued the OIG record of returns that exceed its cost of operation by a very wide margin. The results for FY 2004 will be included in the FY 2006 performance budget.

Program Evaluations

The OIG undergoes two types of independent evaluations: a bi-annual GAO audit of the HCFAC program (which includes the OIG's HCFAC program and HHS' and DOJ's HCFAC activities), as required by

Congress until FY 2004; and peer review by an OIG from another Federal agency. The most recent GAO audit covered FY 2002 and FY 2003. Work on this audit began Summer 2003 and ended Fall 2004. As of this date, the report for this audit has not yet been published. There was no GAO audit for FY 2004 or OIG peer review during FY 2004.

For more information on this program's performance, please see pages 18-19 in OIG's *Revised Final FY 2004 GRPA Annual Performance Plan*.

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