



**DEPARTMENT  
of HEALTH  
and HUMAN  
SERVICES**

**Fiscal Year  
2007**

**Centers for Disease Control  
and Prevention**

*Justification of  
Estimates for  
Appropriation Committees*

**IMMUNIZATION**

**AUTHORIZING LEGISLATION**

Grants: PHS § 317(a), 317(j), 317(k)(1); Prevention activities: PHS §§ 301, 307, 310, 311, 317, 327, 340C, 352, 2125, 2126, Title XXI; Subtitle 1 – National Vaccine Program § 1928 of Social Security Act (42 U.S.C. § 1396s).

Immunization (Dollars in Thousands)	FY 2005 Actual	FY 2006 Appropriation	FY 2007 Estimate	FY 2007 +/- FY 2006
Discretionary Immunization Program, Current Law	\$480,238	\$507,078	\$494,575	(\$12,503)
<i>Section 241, PHS Evaluation Transfer</i>	\$12,794	\$12,794	\$12,794	\$0
<b>Subtotal, Discretionary Immunization Program (Current Law)</b>	<b>\$493,032</b>	<b>\$519,872</b>	<b>\$507,369</b>	<b>(\$12,503)</b>
Proposed Law Changes <sup>1,2</sup>	\$0	\$0	(\$100,000)	(\$100,000)
<b>Subtotal, Discretionary Immunization Program (Proposed Law)<sup>1</sup></b>	<b>\$493,032</b>	<b>\$519,872</b>	<b>\$407,369</b>	<b>(\$112,503)</b>
Vaccines for Children (VFC) (Current Law)	\$1,503,127	\$1,957,963	\$2,006,445	\$48,482
Proposed Law Changes <sup>1,2</sup>	\$0	\$0	\$140,000	\$140,000
VFC (Proposed Law) <sup>1,2</sup>	\$1,503,127	\$1,957,963	\$2,146,445	\$188,482
<b>Total Immunization (Current Law)</b>	<b>\$1,996,159</b>	<b>\$2,477,835</b>	<b>\$2,513,814</b>	<b>\$35,979</b>
<b>Total Immunization (Proposed Law)<sup>1,2</sup></b>	<b>\$1,996,159</b>	<b>\$2,477,835</b>	<b>\$2,553,814</b>	<b>\$75,979</b>

<sup>1</sup>The FY 2007 Estimate reflects the Proposed Law transfer of \$100 million from the Section 317 Program to the Vaccines for Children program.

<sup>2</sup>Funding for VFC in FY 2005 reflects obligations. FY 2006 funding includes carryover of \$60 million from FY 2005.

**STATEMENT OF THE BUDGET**

The FY 2007 President's Budget reflects a total proposed law level of \$2,553,814,000 for Immunization, an increase of \$75,979,000 above the FY 2006 total funding level of \$2,477,835,000. The FY 2007 President's Budget reflects a total current law level of \$2,513,814,000, an increase of \$35,979,000 above the FY 2006 total funding level of \$2,477,835,000.

**PROGRAM DESCRIPTION**

The mission of CDC's Immunization program is to prevent disease, disability and death in children, adolescents and adults through vaccination. Many life-threatening and/or debilitating infectious diseases, including diphtheria, measles, mumps, and pertussis, were once common in this country. Now, widespread use of vaccines, particularly among children, has resulted in continuing low levels of these diseases.

Appropriate administration of safe and effective vaccines is one of the most successful and cost-effective public health tools for preventing disease, disability, and death and for reducing economic costs resulting from vaccine-preventable diseases. To maintain this success, CDC provides national leadership in the ongoing effort to protect children, adolescents and adults from vaccine-preventable diseases and to ensure the safety of vaccines. The responsibilities are many but focus on the goal of ensuring that every person, of every age, in every part of the country is protected from vaccine-preventable diseases.

CDC strives to ensure control of vaccine-preventable diseases by working with partners to develop national immunization policy, ensure high quality immunization services, increase community participation, education and partnerships, improve systems to monitor disease and vaccination coverage, and improve vaccines and vaccine use.

In carrying out its mission, CDC:

- Awards grants through the Section 317 of the Public Health Service Act and the Vaccines for Children (VFC) Program to assist state and local health departments in purchasing safe and effective vaccines and in planning, developing, and conducting childhood immunization programs.
  - The Section 317 program provides vaccines for children, adolescents and adults who primarily present at local health departments for immunization services but are not eligible for the VFC program. These populations are predominately underinsured (i.e., their insurance does not cover immunization), insured but they cannot afford high deductibles, or the working poor. Vaccines are provided to adolescents and adults, as funding allows, but to a much lesser extent than children.
  - The VFC program serves children without insurance, those eligible for Medicaid, American Indian/Alaska Native children, and children who are underinsured and receive care through Federally Qualified Health Clinics. Under the VFC program, federally purchased vaccines are distributed to public health clinics and enrolled private providers, enabling vaccination of all eligible children.
- Provides technical, epidemiological, educational, statistical and scientific assistance to state and local health departments.
- Collaborates with three advisory bodies to issue a single schedule of routine childhood immunizations: the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP). The schedule is continually evaluated to ensure the highest level of effectiveness, efficiency, and safety in childhood immunizations. Upon recommendation by ACIP, CDC includes new vaccines in the Vaccines for Children Program so that they are available to all eligible children.
- Develops an Adult Immunization Schedule to offer a summary of immunization recommendations for adults. The schedule is endorsed by ACIP, AAFP, and the American Academy of Obstetricians and Gynecologists.
- Strives to ensure a six month supply of recommended vaccines will be available for all U.S. children through a national pediatric stockpile.
- Strives for vaccine safety by monitoring harmful effects, conducting scientific research to evaluate the safety of vaccines, communicating the benefits and risks of vaccines to the public.
- Conducts research and operational programs for the prevention and control of vaccine-preventable diseases.
- Supports a nationwide framework for effective surveillance of diseases for which effective immunizing agents are available.

Vaccines are one of the most successful and cost-effective public health tools for preventing disease and death.

COST-EFFECTIVENESS OF CHILDHOOD VACCINES	
For every \$1 spent on an individual vaccine:	
•	DTaP saves \$27
•	MMR saves \$26
•	Perinatal Hepatitis B saves \$14.70
•	Varicella saves \$5.40
For every \$1 spent:	
•	Inactivated Polio (IPV) saves \$5.45
•	Childhood Series (7 vaccines) saves \$16.50*

\* (DTaP, Td, Hib, IPV, MMR, Hep B and Varicella)

Source: various peer reviewed publications. Direct and indirect savings included.

Despite great success and achievements, there are challenges:

- Nearly one million two-year-olds in the United States have not received one or more of the recommended vaccines. Even though coverage levels for preschool immunization are high in many states, pockets of need, or areas within each state and major city where substantial numbers of under immunized children reside, continue to exist.

- Every day in the United States, approximately 11,000 babies are born who will need up to 25 vaccinations before they are two years old to be protected against 13 vaccine-preventable diseases. New vaccines, although greatly beneficial to public health, complicate an already complex immunization schedule and make it increasingly difficult to ensure complete immunization.
- The burden of vaccine-preventable diseases in adults in the United States is staggering. Approximately 43,000 U.S. adults die annually of vaccine-preventable diseases. Pneumonia and influenza were the fifth leading cause of death in all persons aged 65 and older based on 2000 national mortality data. One of the greatest challenges is extending the success in childhood immunization to the adult population.
- Vaccine production difficulties can have a great impact on immunization programs and policies. In the 2005-2006 influenza season, a delay and decreased vaccine production by one manufacturer resulted in a mismatch between supply and demand for influenza vaccine that left a number of providers, hospitals, long term care facilities, and vaccine distributors without sufficient vaccine. CDC works to influence influenza vaccine distribution and use through recommendations and guidelines and extensive collaborations; however, there are limits to what CDC can accomplish in this role because influenza vaccine distribution and administration is a mostly private sector enterprise. Challenges will continue as new groups are recommended for influenza vaccination and there is an increase in vaccine usage. CDC is committed to working closely with partners to develop strategies to address these challenges.
- Immunizations are subject to a higher standard of safety than other medical interventions because they are given to healthy people. Actively monitoring and assuring the safety of vaccines is essential for maintaining public confidence in immunizations, thereby preserving high coverage levels and preventing a resurgence of vaccine-preventable diseases.

CDC is committed to:

- Promoting immunization at every stage of life: CDC works with health care providers, partners, and state and local government agencies to ensure that childhood immunizations remain at high levels. As childhood immunization coverage continues to increase, the incidence of vaccine-preventable diseases declines significantly.
- Achieving high vaccination coverage rates for adolescents and adults: This includes working with private health care providers, state and local health departments and other partners to foster awareness of immunization recommendations and increase vaccine knowledge.
- Providing effective, proactive leadership on vaccines and immunization: CDC provides effective, proactive leadership in the immunization arena by fostering sound vaccine recommendations and policies, conducting quality research, developing and distributing educational material, and enlisting and engaging the contributions of a wide range of professional groups and other organizations.
- Strengthening immunization science and communicating the results: CDC undertakes and promotes a wide range of scientific activities, including tracking and monitoring diseases, disease outbreak investigations, evaluations of health care delivery methods and systems, and social and behavioral science research. Importantly, CDC works to translate research findings into actions and recommendations and to communicate these to the appropriate audiences.
- Fostering and establishing partnerships and collaboration: CDC works with local, state, and national partner organizations to increase awareness of immunization recommendations, foster the development and implementation of effective immunization programs, and achieve high immunization coverage levels. CDC also develops partnerships with community organizations and private health care providers to increase awareness of immunization recommendations and the use of "best practices."
- Providing effective, responsive immunization education and information. CDC helps health departments, physicians, nurses, and other health care providers attain the knowledge and skills needed to effectively implement immunization recommendations. Patient-education materials are also provided to assist health care providers in educating parents, adolescents and adults about the importance, benefits and risks of immunization recommendations.
- Assisting states as they further develop and refine their pandemic preparedness and emergency response plans and identifying innovative approaches to common problems.

Immunization has been cited as one of the top ten public health achievements of the 20th century. In the U.S., vaccine-preventable diseases are at or near record low levels. Beginning in 1962, when the first national effort to improve the immunization status of children was proposed by Congress, CDC has counted immunization among its most vital programs, recognizing it as a core public health activity and perhaps the best example of effective primary prevention.

Vaccines have reduced cases of all vaccine-preventable diseases by more than 97 percent from peak levels before vaccines were available, saving lives and treatment and hospitalization costs (see table below).

INDIGENOUS CASES OF VACCINE PREVENTABLE DISEASES IN THE U.S. FINAL REPORTS FOR 2002, 2003 AND 2004					
	Highest # of Cases	2002 <sup>1</sup>	2003 <sup>1</sup>	2004 <sup>1</sup>	2010 Goal
Diphtheria <sup>2</sup>	206,939	0	0	0	0
Measles <sup>3</sup>	894,134	26	32	11	0
Mumps <sup>3</sup>	152,209	253	222	245	0
Pertussis <sup>4</sup>	265,269	4,109	3,719	6,850	2,000
Polio <sup>3</sup> (paralytic, wild-type)	21,269	0	0	0	0
Rubella <sup>3</sup>	57,686	10	7	7	0
Congenital Rubella Syndrome (CRS) <sup>5</sup>	20,000	1	1	0	0
Tetanus <sup>2</sup>	1,733*	6	6	6	0

<sup>1</sup> 2002-2004 cases correspond to Healthy People 2010 and GPRA age targets

<sup>2</sup> Persons under 35 years of age reported 2002-2004

<sup>3</sup> All ages reported

<sup>4</sup> Children under 7 years of age reported 2002-2004

<sup>5</sup> Children under one year of age reported 2002-2004 Estimated

### PERFORMANCE ANALYSIS

To reflect the public health impact achieved by the Immunization activity, the following performance measure has been selected as a highlight of the program's performance plan:

Performance Goal	Results	Context
1. Achieve or sustain immunization coverage of at least 90 percent in children 19- to 35-months of age for: 4 + doses DTaP vaccine <sup>1</sup> 3 + doses <i>Haemophilus influenzae</i> type B (Hib) vaccine 1 + dose MMR vaccine <sup>2</sup> 3 + doses hepatitis B vaccine 3 + doses polio vaccine 1 + dose varicella vaccine 4 + doses pneumococcal conjugate vaccine (PCV7) <sup>3</sup>	The target of 90 percent coverage was met in 2004 for most of the vaccines except varicella and four doses of DTaP. Varicella is the most recently introduced vaccine that has a measurable target. Varicella rates are rising, with coverage at only 43 percent in 1998 reaching 88 percent in 2004.	Appropriate administration of safe and effective vaccines is one of the most successful and cost effective public health tools in preventing disease, disability, and death and reducing the economic costs resulting from vaccine-preventable disease. Immunizing children by two years of age helps to accomplish the goal of reducing the number of indigenous cases of vaccine preventable disease.

<sup>1</sup> Due to a shortage to vaccine and temporary change in recommendations, reported by 3 doses from 2002-2003

<sup>2</sup> Includes any measles containing vaccine

<sup>3</sup> Performance targets for newly recommended vaccines, such as pneumococcal conjugate vaccine and influenza vaccine are reported in GPRA 5 years after ACIP recommendations. Measures for PCV7 will begin in 2006 and influenza in 2009.

In 2004, the coverage rate for four doses of DTaP containing vaccine did not achieve the 90 percent goal. However, the coverage rate for the fourth dose has steadily increased since the change to a four dose schedule, as recommended by the ACIP in 1991. This goal continues to be difficult to achieve because it requires that the fourth dose be given to the child between 15 and 18 months of age. The administration of DTaP tends to coincide with regular well-baby visits through the third dose; however, the fourth dose does not, requiring a visit specifically for this purpose. Coverage rates are 96 percent for the first three DTaP doses. Although the first three doses are considered to be most critical, CDC and the ACIP feel strongly that the fourth and a fifth dose administered at four to six years of age are important for full vaccination protection. Varying state requirements for the four-dose vaccine schedule may have also led to a slower increase in coverage.

#### Current Activities:

Awarding Grants to States for Vaccine Purchase: Vaccine grants support the purchase of ACIP recommended vaccines through CDC's consolidated vaccine purchase contracts available to state and local health departments.

Awarding Grants to States for Operations/Infrastructure activities including:

- Implementing the unprecedented number of new vaccine recommendations for children, adolescents and adults which were approved by ACIP in 2005. New vaccines and/or expanded recommendations include: 1) Use of Meningococcal Vaccine (MCV4) for adolescents and college freshmen to protect against meningococcal disease in adolescence and young adulthood. 2) Replacement of the Td booster with the more comprehensive Tetanus, diphtheria, and pertussis (Tdap) vaccine, to reduce the number of cases of pertussis (whooping cough) in infants, adolescents and adults. 3) Universal use of Hepatitis A vaccine and lowering the age indication for vaccine to 12 months of age. Previously, the Hepatitis A vaccine was recommended for use in only certain high risk groups and children living in states, communities or counties with high annual incidence of hepatitis A during 1987-1997. 4) Use of the combination Measles Mumps Rubella Varicella (MMRV) vaccine to protect children against these four vaccine preventable diseases.

Raising and sustaining vaccination coverage levels through the technical assistance CDC provides which is based on evidence-based immunization strategies that have been scientifically proven to sustain and raise vaccination coverage levels such as:

- Identifying and improving coverage in "pockets of need" (areas within each state and major city where substantial numbers of under-immunized children reside), where the risks of vaccine-preventable disease outbreaks are increased. The development and use of state-based registries will help identify high-risk and under-immunized populations.
- Using reminder and recall systems to improve immunization levels in children and adults (the development and use of state-based registries that include reminder/recall components provide critical information needed to improve and sustain coverage).
- Conducting Assessing vaccination coverage levels and practices in public and private provider settings, providing Feedback, encouraging Incentives for improved performance, and eXchange of information to stimulate competition between providers (AFIX).
- Operating vaccine distribution systems, processing vaccine orders from the states and from physicians in the private sector who participate in the VFC program, conducting provider recruitment and enrollment activities, conducting the AFIX strategy with VFC-enrolled private and public providers, and developing and implementing vaccine accountability and evaluation plans.

Conducting prevention activities, supported by cooperative agreements, contracts, in house research, technical assistance and consultation, and planning and evaluation in cooperation with states and local agencies. Prevention activities include:

- Collecting vaccination coverage data at the national, state, and local levels (with this information, the impact of national, state, and local policies and programs can be evaluated and monitored; the results provide an essential means of monitoring progress toward Healthy People 2010 objectives).
- Conducting operational research to develop new and improved immunization delivery strategies to raise or sustain coverage levels.
- Researching the occurrence and scientific basis for infrequent adverse events following vaccination.
- Conducting surveillance of vaccine preventable infectious diseases to detect and respond more rapidly to outbreaks and other changes in disease incidence.
- Assessing vaccination coverage levels in adults and conducting research to determine strategies for raising coverage levels.
- Increasing community participation, education, and partnerships through public information campaigns.
- Increasing education and training for providers and partnerships with community based and professional organizations, national minority organizations, and other federal agencies.

Creating and managing stockpiles and improving the vaccine purchase and distribution process:

- Leveraging commercial best practices to address all aspects of vaccine procurement, ordering, distribution and management and achieve cost savings and efficiencies, through the Vaccine Management Business Improvement Project (VMBIP). VMBIP is a comprehensive review and update of the public pediatric vaccine supply chain from the distribution of vaccine by the manufacturer to the point of administration (either public clinic or private provider's office).

- Maintaining a contractual mechanism for the consolidated purchase of vaccine for states and local agencies with their own supplemental funds as well as federal funds provided through grants.
- Ensuring that a six month national supply of all recommended childhood vaccines is available for use in case of supply disruptions or outbreaks of vaccine-preventable diseases. CDC has a legislative mandate to create this stockpile and since its inception in 1983, the pediatric vaccine stockpiles have been accessed as many as twelve times.
- Purchasing a strategic reserve of influenza vaccine in the event of a vaccine shortage or increased demand. This vaccine may be distributed to state health departments for distribution to providers serving VFC eligible children if demand warrants this use of the vaccine. Alternatively, this vaccine can be borrowed by the manufacturer for sale outside the VFC program, with repayment to CDC for all doses sold. CDC first received funding for this activity in FY 2004.

Continuous monitoring of vaccines and ongoing assessment of immunization benefits and risks is a vital component of sound immunization policies and recommendations affecting the health of our nation. As a national leader in vaccine safety, CDC conducts several vaccine safety activities including:

- Managing the Vaccine Adverse Event Reporting System (VAERS), in collaboration with the Food and Drug Administration, which serves as an early warning system to detect problems that may be related to vaccines.
- Supporting the Vaccine Safety Datalink (VSD) project, a large linked database containing comprehensive medical and immunization histories of approximately 5.5 million people annually to enable vaccine safety research studies comparing incidence of health problems between vaccinated and unvaccinated people.
- Providing in depth, standardized clinical evaluations for individuals with unusual or severe vaccine adverse events through the Clinical Immunization Safety Assessment (CISA) Network to
- Developing case definitions for adverse events following vaccination through the support of the Brighton Collaboration an international collaborative effort.
- Promoting safer, simpler, and swifter vaccine delivery technologies to overcome potential dangers and drawbacks of using needle-syringe to administer vaccine through the Vaccine Technology Development (VAXDEV) Activity.
- Determining perceptions and develops interventions that help individuals make informed decisions about vaccinations through the Vaccine Acceptance and Risk Perception Activity.

Significant Accomplishments:

- The nation's childhood immunization coverage rates are at record high levels for every vaccine and for all the vaccination series measures. As childhood immunization coverage rates increase, cases of vaccine preventable diseases decline significantly. For example, during the 1990s, approximately 11,000 hospitalizations and 100 deaths occurred each year due to varicella. CDC has made great progress in educating health care providers and the public about the benefits of varicella vaccine. Coverage for varicella vaccine reached 88 percent in 2004 as opposed to only 43 percent in 1998.

VACCINATION COVERAGE LEVELS AMONG CHILDREN AGED 19 - 35 MONTHS, NATIONAL IMMUNIZATION SURVEY, U.S.								
Vaccine/ Dose	1998 (%)	1999 (%)	2000 (%)	2001 (%)	2002 (%)	2003 (%)	2004 (%)	2010 Goal
DTP 4*+	84	83	82	82	82/95	85/96	86	90
Polio 3+	91	90	90	89	90	92	92	90
Hib 3+	93	94	93	93	93	94	94	90
MMR 1+	92	92	91	91	92	93	93	90
Hepatitis B 3+	87	88	90	89	90	92	92	90
Varicella	43	58	68	76	81	85	88	90

\* In 2002 and 2003, CDC temporarily modified reporting on DTaP from four doses to three doses because vaccine shortages limited the availability of the fourth dose.

- An economic evaluation of the impact of seven vaccines (DTaP, Td, Hib, polio, MMR, hepatitis B, and varicella) routinely given as part of the childhood immunization schedule found that vaccines are tremendously cost effective. Routine childhood vaccination with these seven vaccines, which prevent over 14 million cases of disease and over 33,500 deaths over the lifetime of children born in any given year, resulted in annual cost saving of \$10 billion in direct medical cost and over \$40 billion in indirect societal costs. This study in the Archive of Pediatrics and Adolescent Medicine is the first time the seven vaccine series has been examined together with a common methodology.
- In March 2005, CDC announced a major public health milestone—the elimination of the rubella virus in the U.S. Once a common disease in this country, rubella is now a rare threat. This remarkable achievement is a tribute to having a safe and effective vaccine and a successful immunization program. The rubella virus is an infectious agent that causes birth defects known as congenital rubella syndrome if a woman becomes infected during pregnancy. Babies with CRS may suffer from blindness, deafness, heart defects and mental retardation. Implementation of rubella control programs in other countries in the Americas since the late 1990s likely decreased importations of rubella into the US and contributed to the decline in cases since 2001. In spite of the remarkable achievement, the US should continue its current efforts and vigilance against rubella and CRS to ensure that elimination of rubella is maintained.
- Despite the devastation caused by Hurricane Katrina, the Immunization Information Systems (IIS) in Louisiana, Alabama, and Mississippi remained operational to ensure stability and accessibility for other grantees needing immunization histories for displaced children. IISs are systems that record all shots on all children given by providers in a state or city catchment area. Many IISs also have functions and features needed by an immunization program (e.g. vaccine inventory management, adverse event reporting etc.) as well as interoperability with other health information systems including Electronic Medical Records (EMR). Because of these systems, schools or health agencies outside of the three Hurricane Katrina-impacted states were able to contact their own state or local immunization information system to access records of children displaced by the hurricane. The connections established by immunization information systems enabled many immunization histories to be retrieved thereby reducing or eliminating the need for costly re-vaccination of Hurricane Katrina displaced children.
- CDC's consolidated vaccine purchase contracts provide access to pediatric, adolescent and adult vaccines for state and local health departments to secure a uniform price for vaccines for the 64 state and local immunization programs (grantees) supported by federal, state and local tax dollars. Substantially reduced prices afforded by these consolidated contracts saved over \$885 million in 2005 when compared to what would have been paid at private sector vaccine prices. Purchases through CDC contracts accounted for approximately 54 percent of all childhood vaccine used in the United States in 2004.
- The VFC program enables children to receive vaccines at their physicians' offices where they receive regular care instead of being referred to the local health department. One study (*Fairbrother and Colleagues*) showed that VFC resulted in vaccination levels increasing by 23 percent in inner city New York.
- As part of a broad reorganization of CDC, the Immunization Safety Branch was renamed the Immunization Safety Office and moved from the National Immunization Program into CDC's Office of the Director, Office of the Chief Science Officer in 2005. The reorganization was undertaken as part of CDC's efforts to build a more robust immunization safety activity. The immunization safety office identifies possible vaccine side effects through a multi-faceted approach.
- In 2005 findings from the VAERS have resulted in educational efforts targeted to health care providers and changes to the newly licensed meningococcal conjugate vaccine (Menactra®) vaccine's recommendations and instructions for use.
- In response to the influenza vaccine shortfall and resulting prioritization of influenza vaccine in 2004-2005, the VSD conducted a rapid assessment of influenza vaccination coverage among HMO members in Northern California.
- The Clinical Immunization Safety Assessment Network began enrolling subjects in the newly established centralized registry of clinical data and repository of biological specimens, which will be important in increasing our understanding of virologic, immunologic and genetic markers for post-vaccination adverse events.

## **RATIONALE FOR THE BUDGET**

The FY 2007 President's Budget reflects a total proposed law level of \$2,553,814,000 for Immunization, an increase of \$75,979,000 above the FY 2006 total funding level of \$2,477,835,000. The FY 2007 President's Budget reflects a total current law level of \$2,513,814,000, an increase of \$35,979,000 above the FY 2006 total funding level of \$2,477,835,000.

### **SECTION 317 PROGRAM**

#### *CURRENT LAW*

The FY 2007 discretionary immunization current law estimate of \$507,369,000 reflects a decrease of \$12,503,000 below the FY 2006 Enacted level of \$519,872,000.

#### Fund States to Increase Demand for Influenza Vaccine (+\$19.8 million)

Demand for influenza vaccine is variable and relatively low given the number of people who are at increased risk for complications from influenza. With increased funding of \$20 million, CDC will increase the demand for and uptake of annual influenza vaccine, particularly to accommodate high-risk populations. Increasing vaccine demand will stimulate vaccine manufacturers to produce additional vaccine, thereby increasing vaccine production capacity and helping the nation's preparedness for a pandemic.

#### Pay Raise (+\$1.2 million)

The request includes funds to cover the projected FY 2007 increase.

#### Bulk Monovalent Influenza Vaccine (-\$29.7 million)

The FY 2006 appropriation contained \$29.7 million in no-year funding for CDC to enter into back-end sales guarantee contracts with vaccine manufacturers to maintain a more stable influenza vaccine supply. As these funds can be utilized in future years, additional funds will not be necessary in FY 2007. Additionally, bulk monovalent vaccine purchased in FY 2006 may be used for the 2007/2008 influenza season should the strain remain the same.

#### Administrative and Information Technology (IT) Savings (-\$3.8 million)

An administrative savings will be realized in areas related to travel, equipment, consultant contracts, and cost savings due to a new and more efficient method of processing of interagency agreements. This savings has been applied across CDC's budget lines. The FY 2007 President's Budget also includes an IT savings, realized based on select systems moving from the development phase into implementation and operations as well as greater internal efficiencies realized in areas related to IT.

#### *PROPOSED LAW:*

The FY 2007 discretionary proposed law budget request of \$407,369,000 for Immunization represents a decrease of \$112,503,000 below the FY 2006 Enacted level of \$519,872,000. The proposed law request reflects a proposed law transfer of \$100,000,000 from the Section 317 program to the VFC program (described below) and a program decrease of \$12,503,000, as described previously.

#### Vaccine Purchase Grants (-\$100.0 million)

Currently, underinsured children can receive vaccines purchased with VFC program funds only at Community Health Centers and Federally Qualified Health Centers. The change to VFC legislation proposes allowing these children to receive VFC vaccine at a state or local public health clinic. Amending the VFC authorizing legislation to expand access points for these children could decrease the amount of discretionary vaccine purchase appropriations needed by \$100 million. Also, the proposed legislation would ensure these children have rapid access to new vaccines such as PCV. This reduction in the amount of discretionary funding needed would be contingent upon passage of the proposed amendment to the VFC legislation.

### **VFC PROGRAM**

In FY 2007, CDC requests a total proposed law funding level of \$2,146,445,000 for the VFC program. The request represents an increase of \$188,482,000 over the FY 2006 estimate of \$1,957,963,000.

**CURRENT LAW:**

The FY 2007 current law estimate for VFC is \$2,006,445,000. This reflects an increase of \$48,482,000 above the FY 2006 estimate of \$1,957,963,000.

Increased VFC Need (+\$48.5 million)

Increases in FY 2007 over FY 2006 reflect estimated price increases for vaccines and the addition of MCV and a larger target of Hepatitis A Vaccine into the pediatric vaccine stockpile. MCV and wider usage of Hepatitis A vaccine was recommended for inclusion in the VFC program in 2005. Due to the addition of these vaccines, more funds are necessary for anticipated stockpile purchases.

**PROPOSED LAW:**

The FY 2006 proposed law estimate of \$2,146,445,000 represents an increase of \$188,482,000 over the current law request. The proposed law request reflects a proposed law increase of \$140,000,000 to the VFC program offset by \$100,000,000 in savings from the Section 317 program, as well as a program increase of \$48,482,000, as described previously.

VFC Vaccine Purchase (+\$140.0 million)

Currently, underinsured children can receive vaccines purchased with VFC program funds only at Community Health Centers and Federally Qualified Health Centers. The change to VFC legislation proposed allowing these children to receive VFC vaccine at a state or local public health clinic. Amending the VFC authorizing legislation to expand access points for these children could increase the amount of VFC vaccine purchase funds available by \$140 million. Also, the proposed legislation would ensure these children have rapid access to new vaccines such as PCV.

**OUTPUT TABLE\***

OUTPUT TABLE	FY 2005 ACTUAL	FY 2006 APPROPRIATION	FY 2007 ESTIMATE	FY 2007 +/- FY 2006 APPROPRIATION
317 Vaccine Purchase Grants				
# of PCV doses purchased <sup>1</sup>	1.1M	1.1M	1.1M	0
# of routine influenza doses purchased <sup>1</sup>	1.6M	1.6M	1.6M	0
State Operations/Infrastructure Grants				
Number of states with 90 percent or greater coverage for 3+ Hib	50	50	50	0
Number of states with 90 percent or greater coverage for 1+ MMR	50	50	50	0
Prevention Activities				
Support clinical evaluations to study newly hypothesized or alleged vaccine related syndromes	80	80	80	0
Registries participating in safety monitoring with VAERS	17	17	17	0
Case reports submitted by immunization registries	275	275	275	0
CISA centers in operation	7	7	7	0

NARRATIVE BY ACTIVITY  
INFECTIOUS DISEASES  
IMMUNIZATION

OUTPUT TABLE	FY 2005 ACTUAL	FY 2006 APPROPRIATION	FY 2007 ESTIMATE	FY 2007 +/- FY 2006 APPROPRIATION
VFC Vaccine				
Number of PCV doses purchased <sup>1</sup>	8.3M	9.5M	9.1M <sup>2</sup>	(.4M)
Number of influenza vaccine doses purchased for routine administration <sup>1</sup>	5.0M	9.8M	9.8M	0

\*Any GPRA-related outputs have been removed and are further detailed in the Detail of Performance Analysis section of the Performance Budget.

<sup>1</sup> Based on Current Law

<sup>2</sup> The total number of PCV doses purchased declined due to a smaller catch-up cohort in 2007, than 2006.

**FUNCTIONAL TABLE**

Immunization Budget by Functional Activity (Dollars in Thousands)	FY 2005 Actual	FY 2006 Appropriation	FY 2007 Estimate	FY 2007 +/- FY 2006
<b><u>317 Immunization Program</u></b>				
Vaccine Purchase Grants (Current Law)	\$234,897	\$263,023	\$232,456	(\$30,567)
Vaccine Purchase Grants (Proposed Law) <sup>1</sup>	\$234,897	\$263,023	\$132,456	(\$130,567)
State Operations/Infrastructure Grants	\$195,798	\$193,840	\$192,480	(\$1,360)
<b>Subtotal, 317 Immunization Program (Current Law) -</b>	<b>\$430,695</b>	<b>\$456,863</b>	<b>\$424,936</b>	<b>(\$31,927)</b>
<b>Subtotal, 317 Immunization Program (Proposed Law)<sup>1</sup> -</b>	<b>\$430,695</b>	<b>\$456,863</b>	<b>\$324,936</b>	<b>(\$131,927)</b>
<b><u>Program Operations</u></b>				
Vaccine Tracking	\$4,960	\$4,910	\$4,876	(\$34)
Prevention Activities	\$57,377	\$58,099	\$77,557	\$19,458
<b>Subtotal, Program Operations -</b>	<b>\$62,337</b>	<b>\$63,009</b>	<b>\$82,433</b>	<b>\$19,424</b>
<b>Total (Current Law) -</b>	<b>\$493,032</b>	<b>\$519,872</b>	<b>\$507,369</b>	<b>(\$12,503)</b>
<b>Total (Proposed Law)<sup>1</sup> -</b>	<b>\$493,032</b>	<b>\$519,872</b>	<b>\$407,369</b>	<b>(\$112,503)</b>

<sup>1</sup>The FY 2007 Estimate reflects the Proposed Law transfer of \$100 million from the Section 317 Program to the Vaccines for Children program.

laboratories to purchase state-of-the-art equipment needed to perform more accurate and rapid laboratory testing and confirmation for TB and multi-drug resistant TB.

**Goal 11, Performance Measure 4:**

Completion of treatment for latent TB infection among contacts of infectious TB cases is a cornerstone of U.S. efforts to reduce TB and eliminate the disease, second only to ensuring that those with active TB complete treatment with appropriate drugs. Contacts of smear-positive TB patients are at high risk of developing TB and therefore must be screened for infection. If infected, these contacts should be offered complete treatment for latent infection. Performance reporting dates for FY 2002 – 2006 have been revised to accurately reflect the time lag in reporting data to CDC. In 2000, CDC adopted a new system for reporting on this measure. As a result, baseline data is substantially lower than that gathered under the previous system. Previous targets were set with a different data system which reflected a much higher baseline. The FY 2007 target has been revised in consideration of the new baseline data.

Through cooperative agreements with state and local health departments, CDC supports identifying and examining contacts of persons with active TB, as well as completing treatment for contacts who have latent TB infection. CDC is designing training for health department TB staff to improve their skills in this area. CDC is also working with the Health Resources and Services Administration (HRSA) and other federally funded programs serving groups at high risk for TB to facilitate testing and completion of treatment of latent TB infection.

**IMMUNIZATION**

Efficiency Measure	FY	Target	Result
1. Establish a target range for VFC and Section 317 funds requested by grantees for assessing vaccination coverage levels and providing feedback (AFIX) in healthcare provider office and clinic settings, and continue to monitor progress toward achieving the AFIX cost range. [E]	2007	Continue to reassess grantee progress toward achieving target range of AFIX visit costs and quality.	12/2008
	2006	Continue to provide feedback to grantees on methods to improve quality factors and decrease AFIX visit costs.	12/2007
	2005	Identify quality factors that are associated with grantee funding requests within the estimated baseline cost ranges for the different methods of implementing AFIX visits.	12/2006
	2004	Establish estimated baseline cost ranges for the different methods of implementing AFIX visits.	2/2006
<b>Data Source:</b> Grantee annual reports, budget submissions and supplemental surveys will be used to gather this information.			
<b>Data Validation:</b> Data submitted from grantees will be tracked and analyzed by the CDC program consultants working with the grantees.			
<b>Cross Reference:</b> HHS-8			

**Efficiency Measure 1:**

AFIX (Assessing immunization coverage levels in public and private provider settings, providing Feedback, encouraging Incentives to motivate providers to improve performance or for improved performance and eXchange of information on best practices) is a proven quality improvement strategy for increasing vaccination rates. CDC will establish estimated target ranges for the cost per visit for the various methods of implementing AFIX by reviewing grantee expenditure data in conjunction with data submitted annually on the number of AFIX visits completed. CDC will encourage grantees to align their AFIX visit costs with the target range for the implementation method, so that additional AFIX visits can be conducted with the subsequent cost savings. The efficiency measure was revised because the original efficiency measure was only designed for the Section 317 Immunization Grant Program. The revised efficiency measure will address both funding streams for AFIX, Section 317 and the Vaccines for Children (VFC) Program. CDC is close to establishing estimated baseline cost ranges per visit for the different methods of implementing AFIX. The reporting date was changed from December 2005 to February 2006 due to process delays.

<b>GOAL 1: REDUCE THE NUMBER OF INDIGENOUS CASES OF VACCINE-PREVENTABLE DISEASES.</b>				
Measure	FY	Target	Result	
1. The number of indigenous cases of paralytic polio <sup>1</sup> , rubella <sup>1</sup> , measles <sup>1</sup> , <i>Haemophilus influenzae</i> invasive disease (type b and unknown types) <sup>2</sup> , diphtheria <sup>3</sup> , congenital rubella syndrome <sup>4</sup> , and tetanus <sup>3</sup> will remain at or be reduced to 0 by 2010. [O]		<i>Paralytic Polio</i>	<i>Paralytic Polio</i>	
	2007	0	9/2008	
	2006	0	9/2007	
	2005	0	9/2006	
	2004	0	0 (Met)	
	2003	0	0 (Met)	
	2002	0	0 (Met)	
			<i>Rubella</i>	<i>Rubella</i>
	2007	15	9/2008	
	2006	15	9/2007	
	2005	15	9/2006	
	2004	15	10 (Exceeded)	
	2003	15	7 (Exceeded)	
	2002	20	10 (Exceeded)	
			<i>Measles</i>	<i>Measles</i>
	2007	50	9/2008	
	2006	50	9/2007	
	2005	50	9/2006	
	2004	50	11 (Exceeded)	
	2003	50	32 (Exceeded)	
	2002	60	26 (Exceeded)	
			<i>Haemophilus influenzae</i>	<i>Haemophilus influenzae</i>
	2007	150	9/2008	
	2006	150	9/2007	
	2005	150	9/2006	
	2004	150	196 b + unknown (Unmet)	
	2003	175	259 b+unknown (Unmet)	
	2002	175	187 b+unknown (Unmet)	
			<i>Diphtheria</i>	<i>Diphtheria</i>
	2007	5	9/2008	
	2006	5	9/2007	
	2005	5	9/2006	
	2004	5	0 (Exceeded)	
	2003	5	0 (Exceeded)	
	2002	5	0 (Exceeded)	
			<i>Congenital rubella Syndrome</i>	<i>Congenital rubella Syndrome</i>
	2007	5	9/2008	
	2006	5	9/2007	
	2005	5	9/2006	

<b>GOAL 1: REDUCE THE NUMBER OF INDIGENOUS CASES OF VACCINE-PREVENTABLE DISEASES.</b>			
Measure	FY	Target	Result
	2004	5	0 (Exceeded)
	2003	5	1 (Exceeded)
	2002	5	1 (Exceeded)
		<i>Tetanus</i>	<i>Tetanus</i>
	2007	25	9/2008
	2006	25	9/2007
	2005	25	9/2006
	2004	25	6 (Exceeded)
	2003	25	6 (Exceeded)
	2002	25	6 (Exceeded)
2. Reduce the number of indigenous cases of mumps in persons of all ages from 666 (1998 baseline) to 0 by 2010. [O]		<i>Mumps</i>	<i>Mumps</i>
	2007	200	9/2008
	2006	200	9/2007
	2005	200	9/2006
	2004	200	245 (Unmet)
	2003	250	222 (Exceeded)
	2002	250	253 (Unmet)
3. Reduce the number of indigenous cases of pertussis among children under 7 years of age. [O]		<i>Pertussis</i>	<i>Pertussis</i>
	2007	2,300	9/2008
	2006	2,300	9/2007
	2005	2,300	9/2006
	2004	2,300	6,850 (Unmet)
	2003	2,500	3,719 (Unmet)
	2002	2,500	4,109 (Unmet)
<b>Data Source:</b> National Notifiable Disease Surveillance System (NNDSS), National Congenital Rubella Syndrome Registry (NCRSR), Active Bacterial Core Surveillance (ABCs), Emerging Infections Programs.			
<b>Data Validation:</b> NNDSS - CDC receives reports of notifiable diseases from the 50 state health departments, New York City, the District of Columbia, and five U.S. Territories. These reports are initiated when health-care providers suspect or diagnose a case of a notifiable disease. Clinical laboratories also report results consistent with reportable diseases. Reporting of nationally notifiable diseases to CDC by the states is voluntary and only mandated (i.e., by state legislation or regulation) at the state level. All case reports, especially for low incidence and internationally quarantinable diseases, must be verified by the appropriate state officials. NNDSS case counts are likely incomplete, and therefore, these data are considered to represent a minimum number of cases. State reporting practices and some administrative procedures used in processing the NNDSS data may impact surveillance data reports and analyses. CDC staff provides technical assistance relevant for data verification to ensure data accuracy, completeness, and timeliness, specifically, assistance includes: computer specifications and software for reporting from state and territorial health departments, development and implementation of procedures to validate surveillance data, and identification of incomplete records, transmission errors, and deviations from expected numbers. NCRSR - CDC maintains the NCRSR with supplemental information to NNDSS. The registry includes data only on cases classified as confirmed or compatible. Cases are also classified as indigenous (exposure within the United States) and imported (exposure outside the United States) and are tabulated by year of birth. In contrast, cases reported to the NNDSS are tabulated by year of report. ABCs is an active laboratory and population-based surveillance system for invasive bacterial pathogens of public health importance, and currently operates in 10 sites in the U.S. For each case of invasive disease in the surveillance population, a case report with basic demographic information is completed and bacterial isolates are sent to CDC and other reference laboratories for additional laboratory evaluation. The ABCs program provides routine laboratory audits to ensure the completeness of data collection. Each month, CDC staff review data and communicate potential errors to state personnel for evaluation. Performance standards for active surveillance have been established in each site to permit aggregation of data collected via somewhat different approaches. Detailed instructions for completion of case report forms ensure consistency across sites. Timeliness and completeness of reporting in ABCs is evaluated using threshold percentages of isolate collection and enrollment into special studies. Surveillance "fatigue" or operational problems are assessed using			

GOAL 1: REDUCE THE NUMBER OF INDIGENOUS CASES OF VACCINE-PREVENTABLE DISEASES.			
Measure	FY	Target	Result
isolate shipping schedules, audit sensitivities, and the timeliness of the audit data being completed by set deadlines.			
Cross Reference: <u>Measure 1</u> - HHS-1, HP-14.1a, 14.1b, 14.1c, 14.1e, 14.1h, 14.1i, 14.1j, PART, 500-1; <u>Measure 2</u> - HHS-1, HP-14.1f, 500-1; <u>Measure 3</u> - HHS-1, HP-14.1g, 500-1			

<sup>1</sup> All ages.  
<sup>2</sup> Children under five years of age.  
<sup>3</sup> Persons under 35 years of age.  
<sup>4</sup> Children under one year of age.

**Goal 1, Performance Measure 1:**

Haemophilus influenzae type B (Hib) – Conjugate vaccines for the prevention of Hib are highly effective. Hib is no longer the leading cause of meningitis among children younger than five years old in the U.S. The number of possible cases reported decreased from 259 cases in 2003 to 196 cases in 2004. However, the FY 2004 target of 175 cases remains unmet. In accordance with the Healthy People 2010 goal, this measure includes both type b cases and those with unknown serotypes. The number of cases with unknown serotypes that are actually type b cannot be confirmed. Neither Healthy People 2010 targets nor GPRA targets have been adjusted to adjust for cases with unknown serotype. Therefore, while this goal remains unmet, the actual number of type b cases (both serotyped and not) for which the vaccine would have been effective may have remained the same or even decreased; the increase in cases from 2002 – 2003 may be explained by these disease reporting challenges. To address this issue of incomplete serotyping, CDC is working with state partners to provide technical assistance for enhanced Hib surveillance and laboratory support.

**Goal 1, Performance Measure 2:**

CDC exceeded its mumps disease reduction target in 2003, yet the goal was not met in 2004. However, there have been great strides in reducing mumps; the 1998 baseline of 666 cases has been reduced by almost two-thirds to 245 confirmed and probably indigenous cases in 2004. At this time, it is not clear whether the increased number of mumps reports in 2004 is due to increased awareness and enhanced surveillance, or due to an actual increase in disease. Continued monitoring over time will clarify this trend.

**Goal 1, Performance Measure 3:**

Pertussis (whooping cough) is a highly contagious, vaccine-preventable bacterial illness characterized by prolonged and severe cough and sometimes pneumonia. Although pertussis affects all age groups, complications and death are most frequently recognized among unvaccinated infants. The 2004 target was to reduce the number of pertussis cases among children under seven years of age to 2,300. The actual number of cases in this age group was 6,850. Most of these cases occurred among children who are not fully protected from disease. Children are not fully protected until they receive four doses of the vaccine by 15-18 months. Many cases occur among infants who are exposed to disease before they receive their first vaccination at two months of age. Introduction in 2005 of adolescent and adult versions of improved acellular pertussis vaccines with tetanus and diphtheria booster (Tdap vaccine) provides new opportunities for reducing severe pertussis and its complications in all age groups in the U.S. In addition, to propel efforts to regain control of pertussis in the U.S., CDC convened a meeting and an international panel of pertussis experts to develop a plan to improve control of pertussis in the U.S. Four publications are forthcoming which will guide the deliberations of four expert working groups. The interactions of the participants and especially the feedback provided by CDC's constituents suggest the panel generated new energy and new collaborations needed to reduce the pertussis disease burden in the U.S.

GOAL 2: ENSURE THAT 2-YEAR-OLDS ARE APPROPRIATELY VACCINATED.			
Measure	FY	Target	Result
1. Achieve or sustain immunization coverage of at least 90% in children 19- to 35-months of age for: -4 doses DTaP vaccine <sup>1</sup> -3 doses Hib vaccine -1 dose MMR vaccine <sup>2</sup> -3 doses hepatitis B vaccine -3 doses polio vaccine -1 dose varicella vaccine -4 doses pneumococcal conjugate vaccine	2007	90% coverage	8/2008
	2006	90% coverage	8/2007
	2005	90% coverage	8/2006
	2004	90% coverage	DTaP 86%; Hib 94%; MMR 93%; Hepatitis B 92%; Polio 92%; Varicella 88% (Exceeded, with the exception of DTaP and Varicella)

<b>GOAL 2: ENSURE THAT 2-YEAR-OLDS ARE APPROPRIATELY VACCINATED.</b>			
(PCV7) <sup>3</sup>	2003	90% coverage	DTaP 96%; Hib 94%; MMR 93%; Hepatitis B 92%; Polio 92%; Varicella 85% (Exceeded, with the exception of Varicella)
	2002	90% coverage	DTaP 95%; Hib 93%; MMR 91%; Hepatitis B 90%; Polio 90%; Varicella 81% (Exceeded, with the exception of Varicella)
<b>Data Source:</b> Data are collected through the National Immunization Survey (NIS) and reflect calendar years.			
<b>Data Validation:</b> The NIS 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, a telephone-based survey, is administered by random-digit-dialing to find households with children aged 19 to 35 months. Parents or guardians are asked about the vaccines—with dates—that appear on the child's "shot card" kept in the home, and demographic and socioeconomic information is also collected. At the end of the interview with parents or guardians, survey administrators request permission to contact the child's vaccination providers. Providers are then contacted by mail to provide a record of all immunizations given to the child. Examples of quality control procedures include 100% verification of all entered data with a sub-sample of records independently entered. The quarterly data files are reviewed for consistency and completeness by CDC's National Immunization Program, Immunization Services Division - Assessment Branch and CDC's National Center for Health Statistics' (NCHS) Office of Research and Methodology. NCHS also conducts a separate qualitative assessment of 10% of the records. Random monitoring by supervisors of interviewers' questionnaire administration styles and data entry accuracy occurs daily. Annual methodology reports are available to the public for review.			
<b>Cross Reference:</b> HHS-1, HP-14.24a, PART, PAR, 500-1			

<sup>1</sup> Due to a shortage in vaccine and temporary change in recommendations, 3 doses were reported from 2002 – 2003.

<sup>2</sup> Includes any measles-containing vaccine.

<sup>3</sup> Performance targets for any newly recommended vaccines, such as pneumococcal conjugate vaccine and influenza vaccine, are reported in GPRA five years after ACIP recommendation. Measures for pneumococcal conjugate vaccine (PCV7) will begin in 2006 and influenza in 2009.

**Goal 2, Performance Measure 1:**

The ACIP Recommended Childhood and Adolescent Immunization Schedule recommends routine vaccination of children for these diseases. The target of 90 percent coverage was met in 2004 for most of the vaccines, except varicella and Diphtheria-Tetanus-acellular Pertussis (DTaP).

In 2004, the coverage rate for four doses of DTaP containing vaccine did not yet achieve the 90 percent goal. However, the coverage rate for the fourth dose has steadily increased since the change to a four dose schedule, as recommended by the ACIP in 1991. This goal continues to be difficult to achieve because it requires that the fourth dose be given to the child between 15 and 18 months of age. The administration of DTaP tends to coincide with regular well-baby visits through the third dose; however, the fourth dose does not, requiring a visit specifically for this purpose. Coverage rates are 96 percent for the first three DTaP doses. Although the first three doses are considered to be most critical, CDC and the ACIP feel strongly that the fourth and fifth doses are important for full vaccination. Varying state requirements for the four-dose vaccine schedule may have also led to a slower increase in coverage. In 2002 and 2003, CDC modified reporting on DTaP from four doses to three doses because vaccine shortages limited the availability of the fourth dose. This change was made because the ACIP recommends that if this vaccine is in short supply, or not available, the fourth dose of DTaP may be dropped. The performance reporting change was temporary and reporting for the fourth dose has now been implemented.

Varicella is the most recently introduced vaccine that has a measurable target. Varicella vaccination rates are rising with coverage at only 43 percent in 1998 and reaching 88 percent in 2004. CDC is close to meeting the 90 percent varicella vaccines coverage goal, which is especially impressive this soon after the introduction of this particular vaccine, since a child that has already been exposed to chickenpox does not receive the varicella vaccine. The prevention of pneumococcal infections with PCV is becoming more important because of problems with treatment due to antibiotic resistance. ACIP added PCV to the 2001 Recommended Childhood Immunization Schedule. As this vaccine was recently recommended, accountability for performance targets will begin in 2006. The vaccination coverage level for PCV in 2004 is 73.2 percent.

<b>GOAL 3: INCREASE THE PROPORTION OF ADULTS WHO ARE VACCINATED ANNUALLY AGAINST INFLUENZA (FLU) AND EVER VACCINATED AGAINST PNEUMOCOCCAL DISEASE.</b>			
Measure	FY	Target	Result
1. Increase the rate of flu and pneumococcal pneumonia vaccination in persons 65 years of age and older.	2007	Flu 74%; pneumococcal 69%	1/2009
	2006	Flu 74%; pneumococcal 69%	1/2008
	2005	Flu 74%; pneumococcal 69%	1/2007
	2004	Flu 74%; pneumococcal 69%	Flu 65% (Unmet); Pneumococcal 57% (Unmet)
	2003	Flu 74%; pneumococcal 69%	Flu 66% (Unmet); pneumococcal 56% (Unmet)
	2002	Flu 74%; pneumococcal 66%	Flu 66% (Unmet); pneumococcal 55% (Unmet)
2. Achieve a vaccination rate of 60% among non-institutionalized high-risk adults aged 18 to 64 years for flu and pneumococcal pneumonia by 2010.	2007	Flu 32%; pneumococcal 22%	1/2009
	2006	Flu 32%; pneumococcal 22%	1/2008
	2005	Flu 32%; pneumococcal 22%	1/2007
	2004	Flu 32%; pneumococcal 22%	Flu 35% (Met); pneumococcal 21% (Unmet)
	2003	Flu 32%; pneumococcal 22%	Flu 34% (Met); pneumococcal 21% (Unmet)
	2002	Flu 32%; pneumococcal 22%	Flu 32% (Met); pneumococcal 19% (Unmet)
<b>Data Source:</b> NHIS.			
<b>Data Validation:</b> NHIS is a cross-sectional household interview survey. Households chosen for interviews are a probability sample representative of the target population. The annual response rate is >90% of eligible households in the sample. The NHIS has three modules: 1) The basic module remains largely unchanged from year to year and allows for trend analysis. Data from more than one year can also be pooled to increase the sample size for analytic purposes. The basic module contains a family core, a sample adult core, and a child core through which data are collected on the family unit and from one randomly selected adult and child. 2) Periodic modules collect more detailed information on some of the topics included in the basic module. 3) Topical modules respond to new data needs as they arise. Data are collected through a personal household interview conducted by staff employed and trained by the U.S. Bureau of the Census according to procedures delineated by CDC. Data are reviewed and analyzed extensively to ensure their validity and reliability. The survey sample is designed to yield estimates that are representative and that have acceptably small variations. Before the actual survey, cognitive testing is performed by CDC's Questionnaire Design Research laboratory, and pretests are conducted in the field. Once collected, data are carefully edited, checked, and compared to data from earlier surveys and/or independent sources. Staff members calculate descriptive statistics and perform in-depth analyses, which result in feedback on the analytic usefulness of the data.			
<b>Cross Reference:</b> <a href="#">Measure 1</a> - HHS-1, HP-14.29a, 14.29b, 500-1; <a href="#">Measure 2</a> - HHS-1, HP-14.29c, 14.29d, 500-1			

**Goal 3, Performance Measure 1:**

During the past decade, vaccination coverage levels among older adults increased steadily as CDC implemented national strategies and promoted adult and adolescent immunization among healthcare providers and state and local governments. Influenza vaccination coverage levels among the elderly have increased from 30 percent in 1989 to 65 percent in 2004. However, data suggest that influenza vaccination levels may have reached a plateau. The vaccine shortage in 2004-2005, delays in distribution of influenza vaccine supplies during the 2000-2001 and 2003-2004 seasons, and to a lesser degree in the 2001-2002 season, posed additional challenges to increasing coverage levels. Because large gaps remain between existing coverage levels and some of the targets for subsequent years, CDC has decided to maintain an influenza vaccination target of 74 percent for 2005, 2006 and 2007.

An increasing proportion of older adults also reported receipt of pneumococcal vaccination, from 15 percent in 1989 to 57 percent in 2004. However, the goal of 69 percent for 2004 was not met. Adult vaccination rates are slowly increasing and CDC has worked with the Centers for Medicaid and Medicare Services to raise the reimbursement rate for influenza and pneumococcal vaccines. The same challenges apply to pneumococcal vaccination in adults as influenza vaccination. Because large gaps remain between existing coverage levels and some of the targets for subsequent years, CDC has decided to maintain the same targets for 2005, 2006 and 2007 for pneumococcal vaccination in this age group.

**Goal 3, Performance Measure 2:**

The ACIP Recommended Adult Immunization Schedule recommends vaccination for influenza for adults at high risk of complications each year and pneumococcal vaccination for those persons at high risk. Current levels of coverage among adults vary widely among different age, risk, and racial and ethnic groups. High-risk adults aged 18 to 64 years may not have insurance coverage for influenza and pneumococcal vaccines. These vaccines are covered by Medicare, thus vaccinating greater numbers of adults 65 years of age and older is feasible. Persons with high-risk conditions, such as heart disease and diabetes, remain at increased risk from these diseases. For this population the influenza vaccination goal has been met, and CDC and its partners are close to meeting the pneumococcal vaccination goal for high risk adults aged 18 to 46 years.

<b>GOAL 4: IMPROVE VACCINE SAFETY SURVEILLANCE.</b>			
Measure	FY	Target	Result
1. By 2010, improve capacity to conduct vaccine safety studies by increasing the number of persons in the Vaccine Safety Datalink (VSD) databases to 13 million.	<i>2007</i>	<b>10 million</b>	6/2008
	<i>2006</i>	10 million	6/2007
	<i>2005</i>	10 million	6/2006
	<i>2004</i>	10 million	7.5 million (Unmet)
	<i>2003</i>	10 million	7.5 million (Unmet)
	<i>2002</i>	Baseline	7.5 million
<b>Data Source:</b> Vaccine Safety Datalink (VSD).			
<b>Data Validation:</b> SAS computer programs developed by CDC analysts are submitted to the HMO sites at least once a quarter. The SAS programs are used to determine estimates of the performance measure. The programs also make several comparisons to check the quality of the estimates.			
<b>Cross Reference:</b> HHS-1, 2, 4, HP-14.31, 500-3			

**Goal 4, Performance Measure 1:**

The Vaccine Safety Datalink (VSD) project is a collaborative effort involving CDC and several large health maintenance organizations (HMOs). The VSD was established primarily to assess vaccine safety issues in the U.S. through analyses of Large-Linked Databases (LLDB) collected at the HMOs as part of their routine administration of health services. The databases contain the vaccination and medical records of millions of children and adults. VSD is an example of a LLDB that includes information on more than seven million people. The performance target for this goal was not met in FY 2004 because increasing populations in LLDBs is contingent on cooperating entities, resources, and technologies.

CDC's Vaccine Safety Activity relocated to the Office of the Chief Science Officer (OCSO) on April 21, 2005. This performance measure reflects one aspect of CDC's vaccine safety surveillance. CDC's vaccine safety activities are not limited to this one project.