DEPARTMENT OF HEALTH AND HUMAN SERVICES

CENTERS FOR DISEASE CONTROL AND PREVENTION

# REPORT TO CONGRESS ON SECTION 317 IMMUNIZATION PROGRAM

## Senate Appropriations Committee

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## Overview

In its report on the Fiscal Year (FY) 2014 appropriation for the Department of Health and Human Services (HHS), the Senate Appropriations Committee stated the following:

*The Committee requests an updated report on Federal immunization programs no later than February 1, 2014, to reflect fiscal year 2015 cost estimates, optimum funding to support State and local operations, and a continued discussion of the evolving role of Federal programs as expanded coverage for vaccination becomes more available from private and public sources.(Senate Report 113-71, page 60)*

The Centers for Disease Control and Prevention (CDC) prepared this report in response to this request from the Senate Appropriations Committee. The following report provides discussion about the evolving role of the federal discretionary Section 317 Immunization Program (Section 317) under expanded health insurance coverage, and CDC's FY 2015 professional judgment estimates for a comprehensive immunization program.

This report represents the professional judgment estimates of CDC on the size and scope for a fully implemented Section 317 Immunization Program and is provided without regard to the competing priorities that the CDC Director, the Secretary, and the President must consider as the President's Budget is developed.

## I. Expanded Health Insurance Coverage and the Evolving Role of Section 317

Vaccines are one of the most effective and successful tools for protecting the public's health from 17 vaccine-preventable diseases (VPDs) across the lifespan. In the United States today, we enjoy record high immunization coverage rates for most childhood vaccines[1] and increasing coverage rates for adolescent[2] and adult vaccines[3]. As a result, Americans have benefited from significant reductions in, and in some cases elimination of, once common and deadly diseases such as diphtheria, smallpox, measles, and polio (see Appendix 1). Full implementation of the expanded health provisions of the Affordable Care Act will allow the Section 317 Program to fulfill its public health role in protecting communities from VPDs, including providing a safety net for uninsured adults, responding to outbreaks of VPDs, and ensuring a scientifically sound and robust immunization infrastructure.

However, vaccines alone cannot protect a population. Behind every vaccine given to a child, adolescent, or adult in the United States is a robust public-private partnership that works to develop safe and effective vaccines, make national recommendations for the use of vaccines, pay for the vaccines, assure equitable access to vaccine across all populations, vaccinate target populations, monitor vaccine coverage, assess effectiveness and safety of our national vaccine recommendations and programs, and help providers and the public make informed vaccine decisions. Section 317 is the backbone for the public health functions that help make this partnership so successful.

Enacted in 1962[4] to protect the American people from VPDs, Section 317 has evolved throughout its fifty year history to address our nation's most important vaccination needs and gaps. Today, Section 317 helps support the local, state, and national public health systems and experts that will continue to make essential

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[1] CDC. National, State, and Local Area Vaccination Coverage Among Children Aged 19–35 Months — United States, 2012. MMWR 2013: 62(36);733-740.
[2] CDC. National and State Vaccination Coverage Among Adolescents Aged 13–17 Years — United States, 2012. MMWR 2013: 62(34);685-693.
[3] Noninfluenza Vaccination Coverage Among Adults — United States, 2012. MMWR 2014:63(05);95-102.
[4] 42 USC § 247b.

contributions following the full implementation of the health insurance reforms of the Affordable Care Act. The Affordable Care Act makes important expansions to insurance coverage for immunization services. Following Affordable Care Act implementation, the Section 317 Program will continue to address the public health functions that are necessary to ensure that the right vaccines are given to the right people at the right time to best protect their health, the health of their communities, and prevent resurgence of life-threatening disease. More importantly, Section 317 continues to be the mainstay of the U.S. childhood immunization program—regardless of the payer of the vaccine given—by ensuring that childhood vaccination is accessible, safe and effective, and used in the best way to protect the nation's most precious national resource for the future.

Section 317 provides vaccines and supports the nation's public health infrastructure, which is made up of public health experts and systems that promote immunization recommendations across the lifespan; fosters convenient access for all to recommended vaccinations; provides a safety net for those who cannot otherwise access immunization services; manages vaccine shortages; monitors the safety and effectiveness of vaccines and vaccine policies; prevents disease outbreaks and responds early and rapidly should they occur; and prepares to respond quickly and comprehensively to other urgent vaccine emergencies, such as pandemics. See Appendix 2 for a chart that provides an analysis of the contributions of Section 317 prior to the implementation of the Affordable Care Act health insurance related provisions and CDC's expectations for Section 317 post implementation of the Affordable Care Act.

Throughout its 50 year history, Section 317 has continued to evolve and adapt to meet new challenges and changing needs. The flexibility of the program to respond to immunization priorities and urgent needs will allow it to support the full implementation of expanded health coverage, and maintain high immunization coverage rates and low occurrence of VPDs.

For FY 2015, CDC's priorities for the Section 317 Immunization Program are to:

- Preserve core public health immunization infrastructure at the local, state, and federal levels;
- Maintain an adequate amount of vaccine purchase to provide a vaccination safety net for uninsured adults, and for response to VPD outbreaks and other vaccine urgent needs; and
- Make strategic investments to enhance the immunization infrastructure and evidence base and improve efficiency.

## II. Professional Judgment Budget Estimates

CDC developed the following professional judgment budget estimates for operations funding and vaccine purchase. The estimates in this section reflect a fully implemented program and would require incremental increases in order to achieve programmatic goals. The approach estimates the costs of realizing the prevention opportunities that are in scope for Section 317, accounting for changes in the recommended vaccination schedules, and projecting changes to the immunization financing environment. These estimates cannot account for unanticipated changes in vaccine financing, and are based on the best available information at the time of the estimates.

The FY 2015 professional judgment budget includes:

- Program operations:
  - State and local: $639.3 million
  - National: $149.3 million
  - Total: $788.6 million
- Vaccine purchase:
  - Uninsured adults: $267.4 million
  - Time-sensitive public health needs: $15.0 million
  - Total: $ 282.4 million

### Program Operations

**Total Program Operations (Cost per Dose Methodology): $788.6 million (Tables 1, 2, and 3; Appendix 3)**

**Table 1. Total Operations**

| | |
|---|---|
| State and Local Immunization Program Operations | $639.3 million |
| National Program Operations | $149.3 million |
| **Total Operations** | **$788.6 million** |

*Methods*

In previous reports, CDC used a cost per dose methodology to calculate an overall operations estimate. This report provides updated estimates for state and local immunization program operations and national-level program operations that together support the national immunization program. As in previous reports, FY 2000 was used as a benchmark because it was the last year before the licensure of many new childhood and adult vaccines. Thus, the methodology uses the operations funding available in FY 2000 as a baseline budget for distributing the doses needed to fulfill the vaccine recommendations in place in 2000. For the state and local immunization program operations estimate, the baseline represents the operations funding provided in FY 2000 for all state and local activities required to support the number of Section 317 and VFC vaccine doses distributed in FY 2000. Section 317 operations funding supports the state and local public health workforce that implements Section 317 and VFC. For the national program operations estimate, the baseline represents the operations funding provided in FY 2000 for all national-level activities required to support all vaccine doses (Section 317, VFC, state, and private) distributed in FY 2000.

**State and Local Immunization Program Operations: $639.3 million**

To derive the state and local immunization program operations estimate, CDC calculated the baseline operations cost per dose by dividing the total amount of Section 317 and VFC program operations funding available in FY 2000 ($182.6 million) by the number of Section 317 and VFC vaccine doses

distributed in 2000 (52.3 million). The $3.49 cost per dose rate is equal to $5.23 when adjusted for 2015 dollars using the Bureau of Labor Statistics' Consumer Price Index.[5] CDC then applied the $5.23 rate to the total amount of doses projected for the Section 317 and VFC programs in FY 2015, which includes total baseline doses (excluding influenza) adjusted for population growth (54.1 million) and the number of doses of newly recommended vaccines (including influenza) since 2000 for children (55.5 million) and adults (12.6 million).[6]

**Table 2. Federal Contribution to State and Local Immunization Program Operations (Cost per Dose Methodology)**

| Fiscal Year | Doses of 317 and VFC Vaccine | | State and Local Program Operations Cost per Dose | |
|---|---|---|---|---|
| 2000 | Baseline Doses, Including Flu: | 52,250,229[1] | 317 Operations:<br>VFC Operations:<br>Total:<br><br>Operations/Dose: | $132.6 million<br>$50 million<br>$182.6 million<br><br>$182.6 million/52.3 million = $3.49 |
| 2015 | Baseline Doses, Excluding Flu, Adjusted for Population Growth: | 54,132,141[2,3] | | |
| 2015 | New Doses, Including Flu<br>Children (0-18):<br>Adult:<br>Total New Doses | <br>55,472,636<br>12,629,120<br>68,101,756 | 2000 Operations/Dose, Adjusted for 2015 Dollars: | $5.23 |
| 2015 | Total Doses (Baseline Doses Adjusted for Population Growth + New Doses): | 122,233,897 | Total Program Operations (122,233,897 x $5.23) | **$639,283,281** |

[1] Includes 1.6 million influenza doses purchased with VFC and Section 317 funding in FY 2000.
[2] The projected change in birth cohort from 2000 to 2015 (6.9 percent, from 4 million to 4.27 million) was used to estimate the growth in baseline doses.
[3] Influenza doses distributed in FY 2000 (1.6 million) are excluded to avoid duplication when calculating FY 2015 new doses.

The required activities of Section 317 include five key program areas:

1. Stewardship and accountability for publicly purchased vaccine and Section 317 and VFC operations funding;
2. Assessment of program performance for program improvement;
3. Assurance of access to vaccines;
4. Assurance that immunization information technology supports programmatic goals; and
5. Improvement and maintenance of preparedness readiness.

Section 317 operations infrastructure funding is the primary means of support for all of these activities. As the number of routinely-recommended vaccines increase, the magnitude and complexity of the challenge to assure the timely immunization of individuals increases proportionately. It is this increase in magnitude and complexity that drives the professional judgment of operations funding needed to support Section 317 immunization programs.

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[5] Based on 2015 CPIU provided by Office of Management and Budget (3.8 percent).
[6] Between 2000 and 2011, the following new vaccine and/or new vaccine dose recommendations were made for the childhood and adult populations: PCV (2000), influenza (2004-2007), hepatitis A (2005), Tdap (2005), MCV (first dose 2005, second dose 2010), rotavirus (2006), varicella (2006), HPV (2006 for females, 2011 for males), and herpes zoster (2006).

*Stewardship and Accountability*
Stewardship and accountability involve required activities that protect the federal investment in vaccine and operations funding so that life-saving vaccines are managed, stored, handled, and accounted for correctly. Training, education, and site visits to states' networks of providers help assure meeting these program requirements. State and local immunization program planning is also essential to assure that VFC vaccine is provided only to children entitled to the VFC program and to assure that Section 317 vaccine is not provided routinely to fully insured individuals.

*Program Assessment*
Assessment of program performance is used to provide feedback on state and local immunization program abilities to fully protect children, adolescents, and adults from VPDs. Vaccination coverage data are provided or gathered through the National Immunization Surveys (NIS), the Behavioral Risk Factor Surveillance System (BRFSS), Immunization Information Systems (IIS), and school entry coverage reports. These data are used by Section 317 awardees to identify vaccines that lag in coverage so that the awardees can evaluate and undertake steps to improve coverage and, therefore, improve protection using evidence-based strategies and communication. The Task Force on Community Preventive Services has conducted several reviews of the evidence supporting strategies to improve coverage.[7] Task Force recommendations (e.g., reminder/recall systems, assessment of provider coverage with feedback, and use of IIS) are used by immunization programs to improve coverage of lagging vaccines.

*Vaccine Access*
Assurance of access to vaccines is accomplished by Section 317 awardees' recruitment, education, and maintenance of networks of immunization providers. Currently, over 45,000 provider sites, representing well over 100,000 individual providers, are enrolled in public sector immunization programs. Section 317 awardees use CDC's Advisory Committee on Immunization Practices (ACIP) and HHS' National Vaccine Advisory Committee (NVAC) medical and programmatic standards in their educational outreach to immunization providers. In addition to assurance of access to routinely-recommended vaccines, Section 317 awardees also conduct activities to identify hepatitis B surface antigen positive pregnant women so that the appropriate medical care can be provided to interrupt transmission of hepatitis B virus to infants during child birth.

***Immunization Information Technologies (IT)***
Adequate support for immunization information technology is critical to the stewardship and management of public sector vaccines. As electronic health records (EHRs) become increasingly used, the EHR Incentive Program will help guide EHRs information transmission of immunization data to IIS. The flow of data will be facilitated by the use of 2-dimensional bar codes that accurately and efficiently capture vaccine administration information and transmit from EHR to IIS using Health Level 7 standards. The Task Force on Community Preventive Services recently reviewed the evidence of effectiveness of IIS to improve vaccination coverage levels.[8] The Task Force recommended strongly that the evidence supports their use. Fully integrating the three levels of immunization systems—provider EHRs, state and local Immunization Information Systems, and CDC's Vaccine Tracking System (VTrckS)— will make vaccine visible from manufacturer to CDC's vaccine distributor to the Section 317 awardees' providers. This degree of visibility is critically important to provide stewardship for vaccine and to mitigate the impact of vaccine shortages.

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[7] http://www.thecommunityguide.org/vaccines/index.html
[8] http://www.thecommunityguide.org/vaccines/universally/imminfosystems.html

*Preparedness*
Improving preparedness involves planning, exercising, and evaluating activities that will be used for significant events that require a vaccination response, including pandemics and outbreaks of VPDs. Section 317 awardees work closely with federal, state, and local preparedness programs in these activities. For example, awardees assure sustained elimination of measles, rubella, and polio. During an outbreak response to one of these VPDs, public health and immunization program staff need to work closely with providers and other stakeholders in the community. This may include some or all of the following activities: finding and interviewing patients and tracing contacts, emergency response (e.g., planning and coordinating response, vaccinating contacts, administering immune globulin to contacts, collecting specimens, enforcing isolation and quarantine, developing and analyzing databases, developing information for the public, preparing reports, answering public inquiries, and working with the media), laboratory work, and providing materials (e.g., vaccine and immune globulin, and specimen collection kits or tests). If indicated, vaccination campaigns and clinics may be conducted for at-risk populations.

**National Program Operations Funding: $149.3 million**

To derive the national program operations estimate, CDC calculated the baseline operations cost per dose by dividing the total amount of national program operations funding available in FY 2000 ($61.2 million) by the number of Section 317, VFC, state, and private vaccine doses distributed in FY 2000 (182.8 million). The $0.33 cost per dose rate is equal to $0.49 when adjusted for 2015 dollars using the Bureau of Labor Statistics' Consumer Price Index.[9] CDC then applied the $0.49 rate to the total number of doses projected for public and private purchase in FY 2015, which includes total baseline doses (excluding influenza) adjusted for population growth (120.1 million) and the number of doses of newly recommended vaccines (including influenza) since 2000 for children (95.8 million) and adults (88.8 million). It is important to note that much of the national program operations activity that supports the immunization program is conducted extramurally through collaboration with external entities.

**Table 3. National Program Operations Estimate (Cost per Dose Methodology)**

| Fiscal Year | All Doses | | National Program Operations Cost per Dose | |
|---|---|---|---|---|
| 2000 | Baseline Doses, Including Flu: | 182,755,410[1] | National Program Operations: | $61.2 million |
| | | | Operations/Dose: | $61.2 million/182.8 million = $0.33 |
| 2015 | Baseline Doses, Excluding Flu, Adjusted for Population Growth: | 120,079,198[2,3] | | |
| 2015 | New Doses, Including Flu<br>Children (0-18):<br>Adult:<br>Total New Doses | <br>95,840,709<br>88,787,204<br>184,627,913 | 2000 Operations/Dose, Adjusted for 2014 Dollars: | $0.49 |
| 2015 | Total Doses (Baseline Doses Adjusted for Population Growth + New Doses): | 304,707,112 | Total Program Operations (304,707,112 x $0.49) | **$149,306,485** |

[1] Includes 70.4 million influenza doses.
[2] The projected change in birth cohort from 2000 to 2015 (6.9 percent, from 4 million to 4.27 million) was used to estimate the growth in baseline doses.
[3] Influenza doses distributed in FY 2000 (70.4 million) are excluded to avoid duplication when calculating FY 2015 new doses.

[9] Based on 2015 CPIU provided by Office of Management and Budget (3.8 percent).

There are important programmatic components of the nation's immunization system that are most efficiently and effectively implemented at the national level to support Section 317 awardees, public, and private providers. This includes vaccine management and inventory that enables rapid response to changes in vaccine supply and demand at the national, state, and local levels, and improvements in health information technology systems for information exchange and Meaningful Use.

***Centralized Distribution***
CDC has implemented centralized vaccine distribution of public sector vaccines through a contract with a medical supplies distributor, which has resulted in program efficiencies and cost-savings. Centralized distribution has eliminated the need for multiple state and local vaccine depots, reduced distribution costs, decreased the risks associated with uninsured vaccine storage, and improved visibility into the publicly-purchased vaccine supply and inventory. Centralized distribution also enables much more rapid response to emergencies requiring vaccine, as it gives CDC the ability to ship vaccine anywhere in the United States within approximately 24 hours or less.

***Immunization Information Technologies***
CDC works with the health information technology sector to facilitate integrated systems to support immunization at the federal, state, and local levels. One such effort is VTrckS, which is the vaccine management system implemented to manage the public sector vaccine supply chain. It is a resilient, recoverable, standardized enterprise system that replaced several legacy systems used at the federal, state, and local levels. It includes web-based provider ordering technology with automated awardee approval that allows awardees overall control of the level of visibility and usage by their providers. This system is the largest and most complex vaccine supply chain in the United States. CDC continues to support this and other efforts to modernize and integrate immunization information technologies and systems to improve immunization practice through standardized information exchange and accountability.

National program operations funding at the level of $149.3 million would strengthen the scientific underpinnings of the national immunization program. Vaccine programs rest on a foundation of strong science, which is essential for vaccine policy decision making and for evaluating vaccination recommendations after they are implemented. A comprehensive immunization program requires national-level scientific expertise in VPDs and vaccines, epidemiology and surveillance, statistics, laboratory sciences, health economics, communications, vaccine policy, and applied research. CDC works collaboratively with its state and local partners to strengthen the scientific foundation for immunization recommendations, monitors disease rates to track emerging new threats, and supports communication strategies to reach providers and the public. The following activities would be enhanced:

***Vaccine Effectiveness Studies***
Since 2007, ACIP policy recommendations by the CDC have been in place in the United States to prevent 17 diseases in our population through vaccination. Before vaccines are licensed and recommended for use in the U.S. population, most are tested for safety and efficacy in clinical trials, but the size and locations of these trials are limited and participants may not reflect the heterogeneity of the U.S. population, so vaccine performance may differ under conditions of broad community use. Therefore, post-licensure evaluation of vaccine performance is important to ensure that the national vaccine programs and policies are having the intended public health impact. Evaluation of vaccine effectiveness and impact is particularly important in the years soon after recommendations are made and vaccines are used widely. Long-term and routine monitoring is also crucial to evaluate duration of vaccine-induced immunity, vaccine performance, and disease trends over time. There are many examples in which vaccine policies were refined or revised to maintain optimal population protection, based on these evaluations. This includes recommendations for a routine second dose of varicella vaccine for children and meningococcal vaccine for teens; and, in response to the resurgence of pertussis disease in many

states, recent recommendations for use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis vaccine (Tdap) in pregnant women and evaluations of the effectiveness of Diphtheria, Tetanus, and Acellular Pertussis (DTaP) and Tdap vaccines, including duration of protection over time.

Vaccine effectiveness and impact assessments provide additional information about the return on investments from vaccines, as additional benefits may become apparent post-licensure. For example, use of pneumococcal conjugate 7-valent vaccine (PCV7) in young children produced unexpectedly high levels of community protection resulting in significant declines in disease in all age groups, as demonstrated by active surveillance. As a result of such assessments, national vaccine policy and programs are more informed by a better understanding of the actual societal costs and benefits of implementing the vaccination recommendation. Monitoring suggests that PCV13 vaccine is also having substantial impact on disease in age groups who are not receiving vaccine.

*Disease Surveillance*

Disease surveillance is essential to document vaccine effectiveness and programmatic impact, providing data to monitor and describe disease epidemiology since vaccine introduction. As new vaccines are recommended and the recommended populations for other vaccines are expanded, disease surveillance and vaccine effectiveness monitoring are needed to look at the new recommendations or populations, and may require new approaches. Maintaining or enhancing state public health capacity for VPD surveillance has been challenging. Vaccines may provide protection against only some of the many strains of these pathogens, requiring laboratory confirmation, which can be more expensive. Additional funds would allow an increase in the number of active enhanced and/or population-based disease surveillance activities, tied to a strong laboratory component that can characterize circulating strains and serotypes to monitor for replacement strains. Increased funding would also support epidemiological and laboratory technical assistance to states and localities as needed. For more established vaccination programs, such as those for pertussis and mumps, increased funds would promote the development of new or enhanced diagnostic methods to confirm disease, especially among vaccinated populations. These improved tests and procedures could then be made available to state public health laboratories through collaborations that allow sharing of technology and other testing resources.

*Outbreak Detection and Response*

Maintaining our achievements in the reduction and elimination of VPDs requires ongoing efforts to monitor, detect, and respond to these diseases, especially those with the potential to cause outbreaks and those that have achieved elimination status. Even with the tremendous achievements made in global polio eradication, the United States remains at risk for importation of wild poliovirus. Measles and rubella elimination (interruption of ongoing endemic disease transmission) were declared in the United States in 2000 and 2004 respectively, but the United States is challenged every year with importations of measles and rubella viruses. Measles is one of the most highly contagious infectious diseases, and maintaining surveillance capacity to detect imported cases and provide rapid public health response is needed to prevent outbreaks and re-establishment of endemic disease transmission. These are important activities at the local, state, and national levels and often require substantial state and local resources. In addition, the national program must be able to lead and coordinate a multi-state response when an outbreak crosses state lines. Recent outbreaks of meningitis and mumps in university settings and other tight knit communities have involved coordinated response efforts from local, state, and national levels. Investigation and response to outbreaks is a critical public health function, and allows us to improve our understanding of why outbreaks occurred, how to control them, and how to prevent them in the future. The additional resources would help ensure a rapid and effective outbreak response.

*Vaccine Coverage Assessment*

National and state vaccination coverage rates are currently tracked for children 19-35 months of age, teens, and—for selected vaccines—adults. Implementing new vaccines adds new demands on vaccine

monitoring programs. The methods for monitoring vaccination coverage need to be improved and enhanced, including methods for measuring vaccine coverage and exemption rates at school entry and at selected older grades in middle and high school. For example, the increase in the use of cell phones instead of household landline phones requires new survey methods. Additionally, immunization information systems offer the potential for more rapid monitoring of vaccination trends earlier than survey methods, especially among infants and age groups other than pre-school children.

*Vaccine Safety*

Immunization safety programs are an important component in immunization programs, allowing vaccine safety issues to be identified and public health action to be taken at the earliest possible time. This capacity is also essential for maintaining the public trust in our national immunization program through reducing concerns about vaccinations. CDC is the nation's lead public health agency for maintaining a safe, effective vaccine supply for all children, adolescents, and adults in the United States. Once a vaccine is licensed and recommended for routine use by the ACIP and approved by the CDC Director, monitoring vaccine safety and conducting research to address gaps in scientific knowledge about vaccine-associated adverse events is critical to the successful implementation of the vaccine program. This is particularly important as recommendations are made for newly-licensed vaccines and expanded populations.

CDC's post-licensure immunization safety activities include: monitoring for immunization-associated adverse events, evaluating possible adverse events to determine whether they might be caused by immunization, assessing risk factors for specific adverse events, developing strategies to prevent adverse events, and communicating vaccine risks and benefits to healthcare providers and the public. CDC monitors the number and types of vaccine adverse events reported to the Vaccine Adverse Event Reporting System (VAERS), conducts near-real time monitoring of potential adverse events following immunization and vaccine safety research through its Vaccine Safety Datalink (VSD) and Clinical Immunization Safety Assessment (CISA) projects, and maintains national reference laboratories to support evaluation of suspected vaccine adverse events, especially those due to live viral vaccines.

According to CDC data, 14,903 reports were submitted to VAERS in 2001, while today approximately 25,000 to 30,000 reports are submitted annually—representing an increase of approximately 120 percent in the past decade. CDC continues to improve the efficiency of VAERS through increased electronic reporting. Additional financial resources would further enable CDC to enhance VAERS through IT infrastructure and database improvements allowing increased capacity to manage the increasing number of reports, enhance electronic reporting capabilities to make reporting more accessible and timely, and expand medical and scientific expertise to respond to serious adverse events. In addition, CDC would bolster research efforts to improve the understanding of possible genetic and other risk factors that predispose individuals and/or high-risk subpopulations to vaccine associated adverse events and enhance diagnostic methods for evaluating such suspected adverse events, including rapid methods for differentiating vaccine from wild virus strains. Finally, CDC would strengthen efforts to develop and disseminate systematic, evidence-based vaccine safety assessments to healthcare providers, partners, policy-makers, and the public.

***National Communication Campaign and Provider Education***

Public awareness and provider knowledge of the CDC's immunization recommendations across the lifespan are critical to the success of the national immunization program. This is particularly important when a new vaccine is recommended or an already approved vaccine is recommended for a new population. And as new populations are recommended to receive vaccines, CDC must provide outreach, education, and technical assistance to the providers that serve these populations. CDC also recognizes the continued need to engage the public on questions related to U.S. immunization policy and programs.

With increased resources, CDC would be able to enhance its web presence and make information available in more formats for more audiences (e.g., mobile-ready and Spanish web content), increase the number of public awareness campaigns and partnership activities to raise awareness of VPDs and vaccine availability, better address public questions about vaccine benefits and risks, and increase healthcare provider knowledge about vaccine recommendations. CDC would also be able to conduct additional research to assess public knowledge, attitudes, and beliefs and develop, test, and evaluate broad-based and targeted immunization resources, tools, and messages. This research is critical to ensure that immunization communications efforts support informed decision-making, are culturally appropriate, and have the intended impact.

*ACIP Support*

Since 1962, policy recommendations for the use of vaccines in the United States have been developed by the ACIP for the CDC Director. The committee also provides advice for the control of diseases for which a vaccine is licensed in the United States. The ACIP recommends new vaccines to be incorporated into the routine immunization schedule, recommends vaccine formulations, and reviews older vaccines to update recommendations as needed. CDC provides scientific and technical guidance to the ACIP through subject matter experts, as well logistical and administration support to ensure proper management of this federal advisory committee, and ensures its broad accountability to the public and stakeholders (e.g., via webcasts).

**Vaccine Purchase**

**Total Vaccine Purchase: $282.4 million (Tables 4, 5, 6, and 7; Appendix 4)**

Section 317 provides states with federally-purchased vaccine to ensure access to immunization services for at-need populations including financially vulnerable individuals. The health insurance related provisions of the Affordable Care Act are expected to increase access to immunization for many Americans, particularly underinsured children and adolescents that have been priority populations for Section 317 vaccine. However, Section 317 vaccine is a precious national resource that will continue to fill critical public health needs, such as providing routine vaccination for those with no health insurance, and responding to outbreaks of VPDs and other urgent public health issues. To ensure Section 317 vaccine is being used for these most vulnerable populations, CDC implemented a new vaccine use policy beginning October 1, 2012. This policy clarifies that it is not appropriate for Section 317 vaccine to be used for routine vaccination of children, adolescents, and adults who are considered fully insured. The CDC definition of fully insured is anyone with insurance that covers the cost of vaccine, even if the insurance includes a high deductible or co-pay, or if a claim for the cost of the vaccine and its administration would be denied for payment by the insurance carrier because the plan's deductible had not been met. In an era where federal budgets are strained, and support for critical operational needs is so vital, it is an important aspect of stewardship to take steps to assure that insurance is paying for vaccination of fully insured people.

In addition to serving financially vulnerable adults, the ability of Section 317 to respond to time-sensitive and urgent public health vaccination needs is critical to the prevention of VPDs. In these urgent situations, it is often not feasible to require billing for immunization services. For this reason, CDC is including a professional judgment estimate for the amount of vaccine purchase to meet these time-sensitive public health needs.

**Table 4. Uninsured Adult Vaccine Purchase Summary and Time-Sensitive Vaccine Needs**

| Vaccine Purchase Category | Total Cost | State Funds Used to Purchase Vaccine from Federal Contracts | Total Vaccine Purchase Estimate |
|---|---|---|---|
| Uninsured Adults (all vaccines) | $267,410,472 | ($37,299,449) | $230,111,023 |
| Time-Sensitive Vaccine Needs | $ 15,040,253 | N/A | $15,040,253 |
| Total | | | $245,151,276 |

**Uninsured Adults Vaccine Needs: $267.4 million**

The United States has not been as successful in achieving high vaccination coverage among adults as it has been among children. Historically, the majority of Section 317 funds have been dedicated to the vaccination of children, and a limited amount of funds has been used to vaccinate uninsured adults. Given the limited success with adult vaccination efforts and the importance of reaching this population, CDC's funding estimate is based on the following:

- The vaccine purchase estimates for the uninsured adult population are based on the CDC Director approved, ACIP-recommended vaccines (influenza, Tdap, HPV, hepatitis B, Pneumococcal Polysaccharide Vaccine [PPV], and Herpes Zoster).
- CDC used 2012 U.S. Census data to provide information about population by age and insurance status, adjusted the data for poverty level, and projected the estimate for 2015. Uninsured adults aged 19–64 years and living within 200 percent of the federal poverty threshold were included in the final purchase estimates.[10] At this time, we do not have estimates of the uninsured population in future years based on full implementation of the health coverage provisions of the Affordable Care Act.
- Data from the 2012 National Health Interview Survey were used to estimate the number of individuals considered high-risk for pneumococcal disease.
- The adult population to vaccinate was calculated separately for each vaccine, based on the age recommendations and high-risk specifications particular for that vaccine, the number of doses required to be fully vaccinated, and estimated uptake (uptake estimates were made to predict the percent of adults who would get vaccinated in FY 2015).
- The vaccine purchase estimate subtotal for each vaccine was calculated by multiplying the population to vaccinate by the cost to fully vaccinate an adult projected for FY 2015.
- To determine the final vaccine purchase estimate, the amount of funding contributed by states to purchase adult vaccines from the federal vaccine contracts was removed to ensure the Section 317 vaccine purchase budget did not supplant state funding.

[10] According to the latest data from the U.S. Census Bureau, the 2012 federal poverty threshold is $11,945 for an individual less than 65 years of age.

**Table 5. Adult Vaccines**

| | Uninsured and Within 200 Percent of FPT Population, Total | Final Population, One Cohort [1] | Population to Vaccinate (Uptake) | Vaccine Cost to Fully Vaccinate an Adult | Total Cost |
|---|---|---|---|---|---|
| Adults (19–64 years) | | | | | |
| Influenza | 23,870,584 | 23,870,584 | 8,521,798 | $10.37 | $88,371,045 |
| Tdap [4] for general adult population (19-64) | 23,870,584 | 23,870,584 | 763,859 | $24.69 | $18,859,679 |
| Tdap [4] for pregnant women | 415,048 | 415,048 | 163,944 | $24.69 | $4,047,777 |
| HPV (females, 19-26) [5] | 2,934,844 | 2,934,844 | 146,472 | $281.50 | $41,307,873 |
| HPV (males, 19-21) [5] | 1,076,856 | 1,076,856 | 26,921 | $281.50 | $7,578,262 |
| Hepatitis B (venue) [2, 5] | 6,954,396 | N/A | 605,032 | $78.36 | $47,410,308 |
| Hepatitis B (diabetics) [3, 5] | 691,471 | N/A | 69,147 | $78.36 | $5,418,359 |
| PPV | 9,595,975 | 208,608 | 52,152 | $25.67 | $1,338,742 |
| PCV13 | 1,073,014 | 1,073,014 | 536,537 | 88.43 | 47,443,314 |
| Zoster (60-64) | 1,245,619 | 249,124 | 47,334 | $119.05 | $5,635,113 |
| Total | | | | | $267,410,472 |

[1] Total uninsured population divided by number of cohorts.
[2] Hepatitis B vaccine is based on the recommendation that hepatitis B be universally administered in settings where health care is provided where a high proportion of those being served are at risk for hepatitis B infection (i.e., this estimate is determined by venue).
[3] In 2011, the ACIP recommended that unvaccinated persons aged 19 to 59 years diagnosed with diabetes mellitus be vaccinated with hepatitis B vaccine. Persons aged 60 years and over with diabetes mellitus may be vaccinated at the direction of the treating physician.
[4] Reflects price of Tdap because CDC projects all adults in this population will receive Tdap (instead of Td) in FY 2014.
[5] Hepatitis B and HPV are each three-dose series.

### Time-Sensitive Public Health Needs: $15.0 million

Containment of VPDs is a core mission and responsibility of public health programs. Unlike the VFC vaccine that is restricted to certain, eligible children, Section 317 vaccine does not have eligibility restrictions in its authorization. This flexibility of Section 317 vaccine can serve a critical role in urgent or time-limited situations which are managed through vaccination campaigns that cannot be accomplished through routine vaccination in the primary care system. The amount of Section 317 vaccine needed for these activities is relatively small, but these activities can have a notable impact on states' abilities to control and prevent VPDs.

To develop an estimate for vaccine costs related to time-sensitive public health needs for this professional judgment, subject matter experts were consulted to estimate the number of doses of vaccine needed by awardees on an annual basis for outbreak response and to estimate the vaccine needs to support increasing vaccination capacity for influenza among school aged children, in particular among children not eligible for the VFC program attending schools in financially disadvantaged areas.

It should be noted that time-sensitive public health needs may vary from year to year. It is impossible to predict the number and magnitude of outbreaks or public health emergencies. In addition, support for influenza vaccination capacity reflects a current need that may increase or decrease in the future. New time-sensitive public health needs may also emerge. Having the ability to be flexible and respond to unpredicted vaccination needs will continue to be a critical role for Section 317. Additionally, strategies to allow for the use of Section 317 resources for outbreak vaccine across fiscal years should be considered to ensure these vaccine resources are available when needed for a rapid and successful outbreak response.

**Table 6. Outbreak Response Vaccines**

| | | Doses | | Vaccine Cost | |
|---|---|---|---|---|---|
| | Total | Adult | Child | Adult | Non-VFC Child[1] |
| MMR | 20,000 | 14,000 (70%) | 6,000 (30%) | $538,352 | $62,000 |
| Meningococcal | 15,000 | 10,500 (70%) | 4,500 (30%) | $785,949 | $193,309 |
| Tdap/DTaP | 100,000 | 10,000 (10%) | 90,000 (90%) | $246,912[2] | $1,331,410[3] |
| Varicella | 10,000 | 2,000 (20%) | 8,000 (80%) | $126,156 | $325,268 |
| Hepatitis A | 12,000 | 9,600 (80%) | 2,400 (20%) | $238,408 | $20,129 |
| Hepatitis B | 1,500 | 1,500 (100%) | 0 (0%) | $39,180 | $0 |
| | | | | $1,974,957 | $1,932,116 |
| Total[4] | | | | $3,907,073 | |

[1] Doses assumed to be for VFC-eligible children (50 percent) were deleted from cost estimate.
[2] All Tdap.
[3] Assumes 85 percent Tdap and 15 percent DTaP.
[4] Adult vaccine prices (MMR, $37.05; Meningococcal, $72.11; Tdap, $23.79; hepatitis A, $23.93; hepatitis B, $26.16; varicella, $60.77); child vaccine prices (MMR, $19.91 Meningococcal, 82.77; Tdap, $30.75; single-antigen DTaP, $15.77; hepatitis A, $16.16; hepatitis B, 11.22; varicella,$78.34).

CDC subject matter experts estimated the number of doses of vaccine needed by immunization awardees on an annual basis for outbreak response. The VPDs that typically require substantial numbers of doses of vaccine (i.e., from 1,000-100,000 doses annually) includes pertussis, measles, mumps, hepatitis A, and hepatitis B. Based on a survey conducted of awardees, historical use of vaccine for outbreak response, and professional judgment, CDC estimates it will need 20,000 doses of MMR, 15,000 doses of meningococcal, 100,000 doses of Tdap, 12,000 doses of hepatitis A, 10,000 doses of varicella, and 1,500 doses of hepatitis B for outbreak response in FY 2015. This estimate does not include doses needed for VFC-eligible children.

**Table 7. Expanding Capacity for Influenza Vaccine among School-aged Children (ages 5-17 years)**

| Number of school-aged children nationwide | Children attending lower SES schools[1] | Children attending lower SES schools where SLV conducted[2] | Children vaccinated overall (any location)[3] | Children vaccinated at school[4] | Non-VFC eligible children vaccinated at school[5] | Vaccine cost[6] |
|---|---|---|---|---|---|---|
| 53,000,000 | 13,250,000 | 6,625,000 | 3,975,000 | 2,385,000 | 715,500 | $15.56 |
| | | | | | Total | $11,133,180 |

[1] Approximate number of students nationwide attending lower SES schools, defined as schools where ≥70% of children are eligible for Free or Reduced Price Lunch (FRPL) (0.25*53,000,000).
[2] Assuming SLV will be conducted in 50% of lower SES schools, the estimated number of students attending these schools (0.50*13,250,000).
[3] Assuming 60% of students attending lower SES schools where SLV will be conducted will receive influenza vaccination, projected number of students vaccinated at any location (0.60*6,625,000).
[4] Assuming 60% of vaccinated students attending lower SES schools where SLV will be conducted will be vaccinated at school, projected number of students vaccinated at school (0.60*3,975,000 – This projection is based on a target of 60%, which is higher than most previous experiences with school-located vaccination).
[5] Assuming 30% of students attending lower SES schools who are vaccinated at school are not VFC-eligible, estimated number of non-VFC-eligible students (0.30*2,385,000 -- 30% was selected because, among schools where ≥70% of students are eligible for FRPL, the median percent of students eligible for FRPL is about 80-85%, so 15-20% are not eligible for FRPL. Since the percentage of students eligible for FRPL is greater than the percentage eligible for VFC, the non-VFC eligible percentage was set higher, at 30%).
[6] Assuming 30% TIV and 70% LAIV.

Because the influenza vaccine is universally recommended for all persons over the age of 6 months every year, achieving immunization coverage goals places a significant burden on the primary care system. School-located vaccination (SLV) campaigns have been shown to have the potential to increase routine influenza vaccination among school-aged children. Vaccination of this population in complementary venues, such as schools, has broad support from primary care providers as an adjunct setting.

The utility of SLV campaigns was demonstrated on a large scale in response to the 2009 H1N1 influenza pandemic. In July 2009, the ACIP recommended that school-aged children be considered among the high priority target groups to receive vaccine when it first became available. In response to this recommendation, public health, educational institutions, and other community organizations joined together to hold school-associated clinics throughout the United States, with several states implementing the clinics statewide. In the end, vaccinating children at school appeared to be a successful approach: An estimated 85 percent of local health departments held at least one 2009 H1N1 school-located influenza clinic in their jurisdiction[11], and approximately one-third of school-aged children (5-17 years of age) vaccinated against 2009 H1N1 pandemic influenza were vaccinated at school.[12]

[11] National Association of County and City Health Officials, unpublished data, 2011.
[12] CDC, unpublished data, 2011.

## III. Conclusion

The Section 317 Program plays a critical role in the nation's immunization system. It saves lives as well as dollars, and provides the public with a strong level of protection from VPDs. Targeting vaccines appropriately, ensuring that vaccines are as safe and effective as possible, assessing the impact of expanded immunization programs for children and adults through disease and vaccination coverage surveillance, and detecting and responding to outbreaks of VPDs are all crucial public health functions that will remain in the era of full implementation of the Affordable Care Act and beyond.

For FY 2015, CDC's priorities for the Section 317 Immunization Program are to:

- Preserve core public health immunization infrastructure at the local, state, and federal levels;
- Maintain an adequate amount of vaccine purchase to provide a vaccination safety net for uninsured adults, and for response to VPD outbreaks and other vaccine urgent needs; and
- Make strategic investments to enhance the immunization infrastructure and evidence base and improve efficiency.

This Section 317 report to Congress represents CDC's professional judgment of what is necessary to support a comprehensive, effective immunization program, and does not take into account other competing priorities across the CDC.

**Program Operations**
New vaccines allow for an unprecedented level of protection across the lifespan. New vaccine-preventable diseases require the creation or expansion of important vaccine program infrastructure components at the local, state, and national level. At the same time, the infrastructure for existing vaccines cannot be weakened or new outbreaks of disease can occur. CDC's total operations funding estimate for a comprehensive immunization program is $788.6 million.

**Vaccine Purchase**
CDC's funding estimate is $282.4 million to address time-sensitive public health needs, such as improving influenza vaccination among school-age children; respond to outbreaks of VPDs; and implement the CDC approved ACIP recommended vaccine schedule for uninsured adults. It is important to note the methods we used in calculating this funding estimate are conservative, and limit the scope of the Section 317 Program to only serving as a safety net for financially vulnerable adults. These estimates do not include achieving full coverage in the safety net population, but are based on achieving similar coverage as the general population or a modest increase from current levels.

## Appendix 1: Morbidity Associated with Vaccine-Preventable Diseases, United States

| Comparison of 20th Century Annual Morbidity and Current Morbidity: Vaccine-Preventable Diseases | | | |
|---|---|---|---|
| Disease | 20th Century Annual Morbidity † | 2013 Reported Cases †† | Percent Decrease |
| Smallpox | 29,005 | 0 | 100% |
| Diphtheria | 21,053 | 0 | 100% |
| Measles | 530,217 | 189 | > 99% |
| Mumps | 162,344 | 438 | > 99% |
| Pertussis | 200,752 | 24,231 | 88% |
| Polio (paralytic) | 16,316 | 0 | 100% |
| Rubella | 47,745 | 9 | > 99% |
| Congenital Rubella Syndrome | 152 | 0 | 100% |
| Tetanus | 580 | 19 | 97% |
| *Haemophilus influenzae* | 20,000 | 18* | > 99% |

JAMA. 2007;298(18):2155-2163

† † CDC. MMWR January 3, 2014;62(52);ND-719-ND-732. (MMWR week 52 provisional data)

* Haemophilus influenzae type b (Hib) < 5 years of age. An additional 13 cases of Hib are estimated to have occurred among the 212 reports of Hi (< 5 years of age) with unknown serotype.

| Comparison of Pre-Vaccine Era Estimated Annual Morbidity with Current Estimate: Vaccine-Preventable Diseases | | | |
|---|---|---|---|
| **Disease** | **Pre-Vaccine Era Annual Estimate** | **2012 Estimate (unless otherwise specified)** | **Percent Decrease** |
| **Hepatitis A** | 117,333 † | *2,890 ** | *98%* |
| **Hepatitis B (acute)** | 66,232 † | *18,800 ** | *72%* |
| **Pneumococcus (invasive)** **all ages** | 63,067 † | 31,600 # | 50% |
| **< 5 years of age** | 16,069 † | 1,800 ## | 89% |
| **Rotavirus (hospitalizations, < 3 years of age)** | 62,500 †† | 1,250 ### | 98% |
| **Varicella** | 4,085,120 † | *216,511* #### | *95%* |

† JAMA. 2007;298(18):2155-2163

†† CDC. MMWR. February 6, 2009 / 58(RR02);1-25

* CDC. Viral Hepatitis Surveillance - United States, 2011

# CDC, Active Bacterial Core Surveillance Provisional Report; S. pneumoniae 2012

## CDC. Unpublished, Active Bacterial Core Surveillance

### New Vaccine Surveillance Network 2012 data (unpublished); U.S. rotavirus disease now has biennial pattern

#### CDC. Varicella Program 2012 data (unpublished)

## Appendix 2: Section 317 Immunization Program Pre and Post ACA Comparison Chart

| The Role of Section 317 Immunization Program: Pre and Post Full Implementation of the Affordable Care Act | |
|---|---|
| **Pre-ACA (FY 2013)** | **Post-ACA (FY 2014 and later)** |
| Provide a vaccine safety net for those without access to immunization services. The best way to protect communities from VPDs is to vaccinate all individuals who can safely receive vaccines in order to protect them and to prevent them from transmitting diseases to those who can't be vaccinated.<br><br>Section 317 provides vaccines at no cost for Vaccines for Children (VFC)-eligible underinsured children who do not have access to a Federally Qualified Health Center or Rural Health Clinic, which are the designated VFC providers for underinsured children. Section 317 vaccines can also be used to vaccinate uninsured adults, and both insured and uninsured adults in VPD outbreaks. | Expect shift in safety net population.<br><br>The ACA insurance related provisions and the continuing role of the VFC Program, will likely result in a significant reduction in the population of VFC-eligible underinsured children and adolescents that were previously vaccinated with Section 317 vaccine.<br><br>Section 317 will continue to provide a vaccine safety net. We expect the Section 317 vaccine safety net to will be focused on uninsured, poor adults. The Congressional Budget Office estimates that in FY 2014, approximately 44 million non-elderly adults will remain uninsured, down from an estimated 55 million uninsured non-elderly adults in FY 2013. |
| Conduct the science that provides the evidence-base for national immunization policy, including burden of disease, vaccine effectiveness and safety, economic analyses, and program feasibility.<br><br>Section 317 supports the public health workforce and systems that have contributed to the body of evidence for the immunization recommendations to prevent 17 diseases across the lifespan. | A strong evidence base for national vaccine policy and programs will be as critical post-ACA, particularly as most of these policies now mandate coverage by private insurers and must cover vaccinations without cost-sharing. The need will continue for this important public health function. |
| Collect, analyze, and report scientific data about the effectiveness, safety, and duration of protection of vaccines as they are used in the real-world setting and with larger populations to ensure the effectiveness persists over time and assure safety once vaccines are used in the larger population.<br><br>Section 317 contributes to the availability of important evidence for monitoring and assessing national vaccine policies, and informs any needed changes in these policies as the vaccines are used in the broader population. | Ongoing assessments of vaccine recommendations are critical, and even more so as more Americans have access to immunization services, and as national policy expands to protect Americans from more diseases. The need will continue for this important public health function. |
| Monitor immunization coverage rates to evaluate program effectiveness and identify and reach populations at greater risk for preventable diseases. | Coverage monitoring will continue to be critical in assessing our progress with the implementation of current and future immunization recommendations, |

| The Role of Section 317 Immunization Program: Pre and Post Full Implementation of the Affordable Care Act | |
|---|---|
| **Pre-ACA (FY 2013)** | **Post-ACA (FY 2014 and later)** |
| Section 317 has contributed to our understanding of the priority areas for increased immunization efforts to better protect all Americans from VPDs. Coverage monitoring is also critical for identifying geographic, socio-demographic, and provider and patient beliefs associated with under-immunization. | and making informed decisions about the best use of immunization resources. |
| Communicate the benefits of vaccination through science-based communication campaigns, tools, and resources to aid healthcare providers and the public in making informed vaccine decisions.<br><br>Section 317 supports the development and dissemination of science-based communications campaigns, tools, and resources through multiple venues. These include tailored efforts to decrease racial and ethnic disparities, public campaigns to improve vaccination coverage, and provider and public resources about the benefits of vaccination and risks of VPDs. | Expanded health insurance coverage without cost-sharing for immunization services will be enhanced by ongoing efforts to inform the public about the benefits of recommended vaccines for themselves and their families. The use of new media, social media, and targeted information campaigns will maximize the opportunity expanded insurance coverage under the Affordable Care Act provides. |
| Support health care providers' adherence to current immunization recommendations and use of immunization information technologies and clinical best practices to help them protect their patients and communities from VPDs.<br><br>Section 317 supports the public health systems and experts that implement immunization information systems; collaborates with healthcare providers and professional organizations to develop, assess, and disseminate recommendations and best practices to healthcare providers; and works with providers to ensure appropriate vaccine storage and handling, and implementation of vaccination policies in their practices. | Section 317 will continue to provide the tools, training, monitoring, and feedback to ensure that providers are educated about the importance of vaccination, the vaccine recommendations, and proper management practices. |
| Respond to disease outbreaks by rapidly identifying and investigating cases, conducting surveillance and laboratory testing, and implementing targeted vaccination efforts and other measures to control the spread of disease and prevent future outbreaks.<br><br>Section 317 ensures there is the public health expertise in vaccine-preventable diseases, vaccine programs, and communications at the national, state, | Disease outbreaks can affect anyone, regardless of insurance status. Outbreak response is a critical public health function that will continue as long as VPDs are circulating somewhere in the world.<br><br>Section 317 will continue to be an important public health resource for addressing the underlying causes of disease outbreaks, such as waning immunity and imported diseases. It also provides access to a |

| The Role of Section 317 Immunization Program: Pre and Post Full Implementation of the Affordable Care Act | |
|---|---|
| **Pre-ACA (FY 2013)** | **Post-ACA (FY 2014 and later)** |
| and local levels to respond to threats such as the recent measles and pertussis outbreaks, mumps, and meningococcal meningitis outbreaks.<br><br>In addition, Section 317 vaccine is a critical resource for targeted vaccination in response to these emergencies, and can be used to vaccinate all at-risk members of a community to prevent spread of disease and prevent future outbreaks. | flexible vaccine supply for a rapid public health response to a VPD outbreak. |
| Manage vaccine supply disruptions and shortages to ensure the best public health outcomes until vaccine supply is restored.<br><br>When vaccine shortages occur, the Section 317 program plays a critical role in providing temporarily modified recommendations for use of vaccines to providers as necessary; manages the federal vaccine supply for the best public health outcome; works with manufactures and providers to optimally manage private sector vaccine supply; and monitors the public health effects, such as decreases in vaccine coverage and increases in disease. | Vaccine supply disruptions and shortages can occur for a number of reasons. The public health workforce and systems funded by Section 317 will continue to be an important national asset for managing vaccine supply disruptions and shortages in the future. |
| Safely distribute public sector vaccines to the network of private and public healthcare providers that serve children and adolescents through the mandatory VFC Program.<br><br>Section 317 supports the public health experts and systems that manage and distribute publicly-purchased vaccine. This includes the nearly $4 billion in vaccines purchased each year through the mandatory VFC Program. | The VFC program will continue to be an important program for vaccinating children in the United States. The total size of the population served by the VFC Program is not expected to be significantly impacted by the ACA, although there may be modest changes among the separate eligibility categories; and a significant reduction in the VFC-eligible underinsured population. Section 317 will continue to support the public health experts and systems that are essential to ensure access to vaccines, including VFC vaccines. |

## Appendix 3: Operations Funding Cost per Dose Methodology

In previous reports, CDC used a cost per dose methodology to calculate an overall operations estimate. This report includes separate estimates for state and local immunization program operations and CDC program operations that support the national immunization program. As in previous reports, FY 2000 was used as a benchmark because it was the last year before the licensure of many new childhood and adult vaccines. Thus, the methodology uses the operations funding available in FY 2000 as a baseline budget for distributing the doses needed to fulfill the vaccine recommendations in place in 2000. For the state and local immunization program operations estimate, the baseline represents the operations funding provided in FY 2000 for all state and local activities required to support the number of Section 317 and VFC vaccine doses distributed in FY 2000. For the CDC program operations estimate, the baseline represents the operations funding provided in 2000 for all national-level activities required to support all vaccine doses (Section 317, VFC, state, and private) distributed in 2000.

CDC used the following approach to calculate the state and local immunization program operations funding estimate:

- The budget appropriated to Section 317 state infrastructure/operations in FY 2000 was $132.6 million.
- Because the VFC program was implemented in the context of the Section 317 program, we see this as an integrated public program. CDC has included VFC doses with Section 317 doses in the operations estimates.
- When combined with VFC operations funding ($50 million), the total operations budget available in FY 2000 was $182.6 million.
- The cost per dose ratio was calculated by dividing the total amount of operations funding available for the year ($182.6 million) by the number of Section 317 and VFC vaccine doses distributed in 2000 (52.3 million). $182.6 million ÷ 52.3 million doses = $3.49 in state and local immunization program operations costs per dose of Section 317 and VFC vaccine distributed.
- The $3.49 cost per dose rate is equal to $5.23 when adjusted for 2015 dollars using the Bureau of Labor Statistics' Consumer Price Index provided by the Office of Management and Budget.[13]
- The $5.23 rate was then applied to the total amount of doses projected for the VFC and 317 programs in FY 2015. The determination of doses needed for FY 2015 was calculated by adding the baseline number of doses delivered in 2000 (adjusted for population changes from 2000 to 2015) to the number of doses of newly recommended vaccines since 2000.[14] Because influenza vaccine was distributed in 2000, the number of influenza doses was included in the baseline cost per dose calculation but excluded from the adjustment for population changes to avoid duplication in the calculation of the total amount of doses projected for FY 2015. CDC calculated the number of newly recommended doses by using National Immunization Survey (NIS) data for children and Census and NHIS data for adults. CDC used actual coverage estimates from the 2012 NIS for childhood vaccines at or above 90 percent coverage. For childhood and adult vaccines where uptake was less than 90 percent (with the exception of hepatitis B for adults), CDC estimated uptake by adding 5 percent to the most recent coverage estimate available for that vaccine. CDC used professional judgment to estimate hepatitis B vaccine coverage because the population to vaccinate includes a venue-based population and a high-risk population (diabetes mellitus) that was first recommended for hepatitis B vaccine in 2011.[15]

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[13] Based on 2015 CPIU provided by Office of Management and Budget (3.8 percent).

[14] Between 2000 and 2011, the following new vaccine and/or new vaccine dose recommendations were made for the childhood and adult populations: PCV (2000), influenza (2004-2007), hepatitis A (2005), Tdap (2005), MCV (first dose 2005, second dose 2010), rotavirus (2006), varicella (2006), HPV (2006 for females, 2011 for males), and herpes zoster (2006).

[15] http://www.cdc.gov/vaccines/stats-surv/default.htm (non-influenza coverage estimates, 2010) and http://www.cdc.gov/flu/professionals/vaccination/coverage_1011estimates.htm (influenza coverage estimates, 2010-2011).

- As a result of these new vaccine recommendations, an additional 68.1 million doses of VFC and Section 317 vaccine will need to be distributed along with the 54.1 million baseline doses (adjusted for population changes from 2000 to 2015).
- The adjusted cost per dose rate of $5.23 was applied to the projected number of VFC and Section 317 doses needed for FY 2015 (122.2 million), for a total state and local immunization program operations budget of $639.3 million.

CDC used the following approach to calculate the National Program operations funding estimate:

- The budget appropriated to Section 317 National Program operations in FY 2000 was $61.2 million.
- The cost per dose ratio was calculated by dividing the total amount of operations funding available for the year ($61.2 million) by the number of Section 317, VFC, state, and private vaccine doses distributed in 2000 (182.8 million). $61.2 million ÷ 182.8 million doses = $0.33 in National Program operations costs per dose of Section 317, VFC, state, and private vaccine distributed.
- The $0.33 cost per dose rate is equal to $0.49 when adjusted for 2015 dollars using the Bureau of Labor Statistics' Consumer Price Index provided by the Office of Management and Budget.[16]
- The $0.49 rate was then applied to the total amount of Section 317, VFC, state, and private doses projected for FY 2015. The determination of doses needed for FY 2015 was calculated by adding the baseline number of doses delivered in 2000 (adjusted for population changes from 2000 to 2015) to the number of doses of newly recommended vaccines since 2000. Because influenza vaccine was distributed in 2000, the number of influenza doses was included in the baseline cost per dose calculation but excluded from the adjustment for population changes to avoid duplication in the calculation of the total amount of doses projected for FY 2015. CDC calculated the number of newly recommended doses by using National Immunization Survey (NIS) data for children and Census and NHIS data for adults. CDC used actual coverage estimates from the 2012 NIS for childhood vaccines at or above 90 percent coverage. For childhood and adult vaccines where uptake was less than 90 percent (with the exception of hepatitis B for adults), CDC estimated uptake by adding 5 percent to the most recent coverage estimate available for that vaccine. CDC used professional judgment to estimate hepatitis B vaccine coverage because the population to vaccinate includes a venue-based population and a high-risk population (diabetes mellitus) that was first recommended for hepatitis B vaccine in 2011.[17]
- As a result of these new vaccine recommendations, an additional 184.6 million doses of Section 317, VFC, state, and private vaccine will need to be distributed along with the 120.0 million baseline doses (adjusted for population changes from 2000 to 2015).
- The adjusted cost per dose rate of $0.49 was applied to the projected number of Section 317, VFC, state, and private doses needed for FY 2015 (304.7 million), for a total National Program operations budget of $149.3 million.

[16] Based on 2015 CPIU provided by Office of Management and Budget (3.9 percent).
[17] http://www.cdc.gov/vaccines/stats-surv/nis/default.htm#nis (non-influenza coverage estimates, 2010) and http://www.cdc.gov/flu/professionals/vaccination/coverage_1011estimates.htm (influenza coverage estimates, 2010-2011).

## Appendix 4: Vaccine Purchase for Adult Populations

With the exception of hepatitis B vaccine, CDC estimated uptake by adding 5 percent to the coverage estimate from the 2012 NHIS. CDC used professional judgment to estimate hepatitis B vaccine coverage because the population to vaccinate includes a venue-based population and a high-risk population (diabetes mellitus) that was first recommended for hepatitis B vaccine in 2011.

*Influenza*

- 23,870,584 individuals in the U.S. are aged 19 to 64 years, uninsured, and living within 200 percent of the federal poverty level who are recommended for influenza vaccine (the ACIP now recommends everyone 6 months and older receive an annual influenza vaccine).
- Projected uptake for influenza vaccine in FY 2015 is 35.7 percent. 23,870,584x 0.357 = 8,521,798 adults.
- Based on 2013-2014 flu prebook data, estimated weighted average federal contract price for one dose of adult influenza vaccine in FY 2015 is $10.37.
- 8,521,798 x $10.37= $88,371,045.

*Tdap for general adult population*

- 23,870,584 individuals in the U.S. are aged 19 to 64 years, uninsured, and living within 200 percent of the federal poverty level who are recommended for Tdap vaccine.
- Projected uptake, based on the three year average increase in uptake of Tdap vaccine among adults is 3.2%. 23,870,584 x 0.032 = 763,589 adults.
- Estimated average federal contract price for one dose of Tdap vaccine in FY 2015 is $24.69.
- 763,589 x $24.69= $18,859,679.

*Tdap for pregnant women*

- 415,048 pregnant women in the U.S. are living within 200 percent of the federal poverty level who are recommended to receive Tdap vaccine.
- Projected uptake for Tdap vaccination in pregnant women in FY 2015 is 39.5%. 415,048 x 0.395 = 163,944 pregnant women.
- Estimated average federal contract price for one dose of Tdap vaccine in FY 2015 is $24.69.
- 163,944 x $24.69 = $4,047,777.

*HPV*

- 2,934,844 females in the U.S. are aged 19 to 26 years, uninsured, and living within 200 percent of the federal poverty level who are recommended to receive the HPV vaccine. HPV vaccine is not recommended for females older than age 26 years. 1,076,856 males in the U.S. are aged 19 to 21 years, uninsured, and living within 200 percent of the federal poverty level who are recommended to receive the HPV vaccine.[18]
- Projected catch-up for HPV vaccine in FY 2015 is 5.0 percent for females and 2.5 percent for males. 2,934,844 x 0.05 = 146,742 females, and 1,078,856 x 0.025 = 26,921 males.
- Estimated federal contract price for one dose of HPV vaccine in FY 2015 is $93.83 (price for Gardasil) and $281.50 for the three doses a female could receive between 19 and 26 years of age and a male could receive between the ages of 19 and 21 years of age.
- 146,742 x $281.50= $41,307,873 for females, and 26,921 x $281.50= $7,578,262 for males.
- $41,307,873 + $7,578,262= $48,886,135

[18] Gardisil only, per ACIP recommendations.

*Hepatitis B*

- The population estimate for hepatitis B vaccine was determined based upon the ACIP recommendation for universal adult hepatitis B vaccination in healthcare settings that provide services to a high proportion of individuals at high risk for incident hepatitis B infection (e.g., STD/HIV prevention and treatment clinics, drug treatment centers).
- This high-risk, venue-based population estimate includes all individuals presenting at high-risk sites, and does not attempt to determine insurance or poverty level status to implement the public health approach for high-risk populations.
- 2,763,965 individuals in the U.S. are seen annually in sexually transmitted disease clinics or HIV/AIDS counseling and testing facilities.
- The population estimate for this vaccine was reduced from 2,763,965 to 2,487,569 because some individuals may be seen in more than one type of clinic (i.e., the population estimate removed potential duplication).
- An additional 4,466,827individuals are in drug abuse treatment or are otherwise considered to be among high-risk populations.
- Previous uptake of full vaccination with hepatitis B vaccine for these populations is estimated at 42 percent, based on 2011 NHIS data.
- 2,487,569 + 4,466,827 = 6,954,396 and 6,954,396 x (1-0.42) = 4,033,549 adults eligible for hepatitis B vaccination.
- Projected uptake for hepatitis B vaccine for these populations in FY 2015 is 15 percent. 4,033,549 x 0.15 = 605,032 adults.
- Estimated average federal contract price for one dose of hepatitis B vaccine in FY 2015 is $26.12 and $78.36 for the full three-dose series.
- 605,032 x $78.36 = $47,410,308 for high-risk individuals.
- The population estimate for hepatitis B also incorporated the 2011 ACIP recommendation that unvaccinated persons aged 19 to 59 diagnosed with diabetes mellitus be vaccinated with hepatitis B vaccine. Persons aged 60 years and over with diabetes mellitus may be vaccinated at the direction of the treating physician.
- There are 691,471 adults aged 19 to 64 diagnosed with diabetes mellitus who are uninsured and within 200 percent of the federal poverty level.
- Hepatitis B vaccination uptake for this population is estimated to be 10 percent. 691,471 x 0.1 = 69,147 diabetic adults.
- Estimated average federal contract price for one dose of hepatitis B vaccine in FY 2015 is $26.12 and $78.36 for the full three-dose series.
- 69,147 x $78.36 = $5,418,349.
- $47,410,308+ $5,418,349 = $52,828,667.

*Pneumococcal Polysaccharide Vaccine (PPV)*

- 9,595,975 individuals in the U.S. 19 to 64 years of age are considered high-risk for pneumococcal vaccination, are uninsured, and are living within 200 percent of the federal poverty level.
- Because only one dose of PPV vaccine is recommended for these high-risk populations, we adjusted the number of adults recommended for PPV vaccine that could be vaccinated in FY 2015. 9,595,975 ÷ 46 (number of cohorts of persons aged 19 to 64 years) = 208,608 adults.
- Projected uptake for PPV vaccine in FY 2015 is 25.0 percent. 208,608 x 0.250 = 52,152 adults.
- Estimated average federal contract price for one dose of PPV vaccine in FY 2015 is $25.67
- 52,152 x $25.67 = $1,338,742.

*Pneumococcal Conjugate (PCV13)*

- 1,073,014 individuals in the U.S. 19 to 64 years of age are considered high-risk for pneumococcal conjugate vaccination, are uninsured, and are living within 200 percent of the federal poverty level.
- Projected uptake for PCV13 vaccine in FY 2015 is 50.0 percent. 1,073,014 x 0.50 = 536,507 adults.
- Estimated federal contract price for one dose of PCV13 vaccine in FY 2015 is $88.43
- 536,507 x $88.43 = $47,443,314.

*Herpes Zoster*

- 1,245,619 adults in the U.S. aged 60 to 64 years are uninsured and living within 200 percent of the federal poverty level (most adults 65 years of age and older are eligible for Medicare).
- Because one dose of Herpes Zoster vaccine is recommended, we adjusted the number of adults recommended for Herpes Zoster vaccine that could be vaccinated in FY 2015. 1,245,619 ÷ 5 (number of cohorts of persons aged 60 to 64 years) = 249,124 adults.
- Projected uptake for Herpes Zoster vaccine in FY 2015 is 19.0 percent. 249,124x 0.190 = 47,334 adults.
- Estimated federal contract price for one dose of Herpes Zoster vaccine in FY 2015 is $119.05.
- 47,334 x $119.05 = $5,635,113.