DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

Senate Appropriations Committee

REPORT TO CONGRESS ON SECTION 317 IMMUNIZATION PROGRAM

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Overview

In its report on the Fiscal Year (FY) 2018 appropriation for the Department of Health and Human Services (HHS), the Senate Appropriations Committee states the following:

Cost Estimates.—The Committee looks forward to reviewing the fiscal year 2018 report on estimated funding needs of the Section 317 Immunization Program and requests that the report be updated and submitted not later than February 1, 2018, to reflect fiscal year 2019 cost estimates. The updated report should also include an estimate of optimum State and local operations funding, as well as a discussion of the evolving role of the 317 program as expanded coverage for vaccination becomes available from private and public sources over the next several years. (Senate Report 115-150. P.57).

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 CDC’s FY 2019 professional judgment estimates for a comprehensive immunization program, which includes estimates on the size and scope for a fully implemented Section 317 Immunization Program. This report is not a budget document and is provided without taking into account competing priorities that the CDC Director, the Secretary, and the President must consider when developing the President’s Budget.

I. Introduction

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 vaccines1 and increasing coverage rates for adolescent2 and adult vaccines3. 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). The Section 317 Immunization Program plays a critical 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; makes national recommendations for the use of vaccines; pays for the vaccines; assures equitable access to vaccines across all populations; vaccinates target populations; monitors vaccine coverage; assesses effectiveness and safety of our national vaccine recommendations and programs; and helps providers and the public make informed vaccine decisions.

II. The Evolving Role of the Section 317 Immunization Program

Enacted in 19624 to protect the American people from VPDs, the Section 317 Immunization Program has evolved throughout its more than fifty year history to address our nation’s most important vaccination needs. Today, the Section 317 Program helps support the nation’s public health infrastructure, which is made up of public health experts and systems critical to the success of our nation’s immunization program. This public health infrastructure promotes immunization recommendations across the lifespan; fosters convenient access to recommended vaccinations; supports science-based communication efforts to convey the benefits of vaccines to the public to aid individuals in making informed vaccine decisions to protect themselves and their loved ones; conducts outreach to

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4 42 USC § 247b.
educate healthcare providers about current immunization policy and clinical best practices to help them protect their patients and communities from VPDs; 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.

Current CDC 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 other vaccine urgent needs;
- Effectively respond to VPD outbreaks, including 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; and
- Make strategic investments to enhance the immunization infrastructure and evidence base and improve efficiency.

While childhood vaccination is largely covered through public and private insurance, there continues to be a gap in adult immunization coverage. The Congressional Budget Office estimated an average of 27 million people under age 65 were projected to be uninsured in 2016, with the number of estimated uninsured reaching approximately 28 million in 2026. While those who are uninsured from birth through 18 years of age are eligible for vaccines through the Vaccines for Children (VFC) Program, the Section 317 Program provides a vaccine safety net for poor, uninsured adults 19 years of age and older. In addition, the Section 317 Program provides a flexible, federal supply of vaccine that can be used in response to VPD outbreaks and other urgent vaccine needs. In 2017, CDC provided technical support to over 80 vaccine-preventable disease investigations and conducted over 1,100 laboratory tests in support of these investigations.

The Section 317 Program continues 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. Importantly, the Section 317 Program 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 for all Americans.

The Section 317 Program 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 allows it to support the full implementation of expanded health coverage and maintain high immunization coverage rates and low occurrence of VPDs.

III. Professional Judgment Estimates

CDC developed the following professional judgment estimates for program operations funding and vaccine purchase. The estimates in this section reflect a fully implemented program and would require incremental increases to achieve programmatic goals. This Section 317 Program Report to Congress represents a professional judgment of what is necessary to support a fully implemented, comprehensive immunization program and is provided without taking into account competing priorities that the CDC Director, the Secretary and the President must consider when developing the President’s Budget. The approach estimates the costs of prevention opportunities that are in scope for the Section 317 Program—accounting for changes in the recommended vaccination schedules and projecting changes to the immunization financing environment. These estimates cannot

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6 Vaccines for Children Program http://www.cdc.gov/vaccines/programs/vfc/index.html
account for unanticipated changes in vaccine financing and are based on the best available information at the time of the estimates.

CDC’s FY 2019 professional judgment estimates include:

- **Program operations:**
  - State and local: $685.2 million
  - National: $169.4 million
  - Total: $854.6 million
- **Vaccine purchase:**
  - Uninsured adults: $178.7 million
  - Time-sensitive public health needs: $66.5 million
  - Total: $245.2 million

**Program Operations**

**Total Program Operations (Cost per Dose Methodology):** $854.6 million (Tables 1, 2, and 3; Appendix 2)

**Table 1. Total Operations**

| State and Local Immunization Program Operations | $685.2 M |
| National Program Operations                   | $169.4 M |
| **Total Operations**                           | **$854.6 M** |

**Methods**

In previous reports, CDC used a cost per dose methodology to calculate an overall operations estimate. This report provides updated estimates for federal funding needed to fully support immunization program operations conducted at the state, local, and national levels 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 needs operations funding available in FY 2000 as a baseline estimate 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 the Section 317 Program and VFC. For the funding estimate for program operations conducted at the national-level, 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 Funding: $685.2 million (Table 2)**

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 FY 2000 (52.3 million). The $3.49 cost per dose rate is equal to $5.93 when adjusted for 2019 dollars using the Bureau of Labor Statistics’ Consumer Price Index.\(^7\) CDC then applied the $5.93 rate to the total amount of doses projected for the Section 317 and VFC programs in FY 2019, which includes total baseline doses (excluding influenza) adjusted for population growth (51.7 million) and the number of doses of newly recommended vaccines (including influenza) since 2000 for children (56.1 million) and adults (7.7 million).\(^8\)

\(^7\) Based on CPIU provided by Office of Management and Budget (4.1 percent in 2019).

\(^8\) Between 2000 and 2015, the following new vaccine and/or new vaccine dose recommendations were made for the childhood and adult populations: PCV, influenza, hepatitis A, Tdap, meningococcal, rotavirus, varicella, HPV, and herpes zoster.
Table 2. Federal Contribution to State and Local Immunization Program Operations (Cost per Dose Methodology)

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Doses of Section 317 and VFC Vaccine</th>
<th>State and Local Program Operations Cost per Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>Baseline Doses, Including Flu:</td>
<td>317 Operations: $132.6 million</td>
</tr>
<tr>
<td></td>
<td>52,250,229¹</td>
<td>VFC Operations: $50 million</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Total: $182.6 million</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Operations/Dose: $182.6 million/52.3 million</td>
</tr>
<tr>
<td></td>
<td></td>
<td>= $3.49</td>
</tr>
<tr>
<td></td>
<td>51,705,970²³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>56,134,514</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Adult:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>7,700,161</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total New Doses:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>63,834,675</td>
<td></td>
</tr>
<tr>
<td>2019</td>
<td>Total Doses (Baseline Doses Adjusted for Population Growth + New Doses):</td>
<td>Total Program Operations (115,540,645 x $5.93) $685.2M</td>
</tr>
<tr>
<td></td>
<td>115,540,645</td>
<td></td>
</tr>
</tbody>
</table>

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 2019 (2.1 percent, from 4 million to 4.08 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 2019 new doses.

The required activities of the Section 317 Program 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 Program 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 ensure 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.

National Program Operations Funding: $169.4 million (Table 3)

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 $0.335 cost per dose rate is equal to $0.56 when adjusted for 2019 dollars using the Bureau of Labor Statistics' Consumer Price Index.⁹ CDC then applied the $0.56 rate to the total number of doses projected for public and private purchase in FY 2019, which includes total baseline doses (excluding influenza) adjusted for population growth (114.7 million) and the number of doses of newly recommended vaccines (including influenza) since 2000 for children (97.4 million) and adults (90.3 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.

⁹ Based on CPI-U provided by Office of Management and Budget (4.1 percent in 2019).
<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>All Doses</th>
<th>National Program Operations Cost per Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>Baseline Doses, Including Flu: 182,755,410&lt;sup&gt;1&lt;/sup&gt;</td>
<td>National Program Operations: $61.2 million</td>
</tr>
<tr>
<td></td>
<td>Operations/Dose: $61.2 million/182.8 million = $0.335</td>
<td></td>
</tr>
<tr>
<td>2019</td>
<td>New Doses, including Flu Children (0-18): 97,439,536 Adult: 90,325,065 Total New Doses 187,764,601</td>
<td>Total Program Operations (302,461,919 x $0.56) $169.4M</td>
</tr>
<tr>
<td>2019</td>
<td>Total Doses (Baseline Doses Adjusted for Population Growth + New Doses): 302,461,919</td>
<td></td>
</tr>
</tbody>
</table>

<sup>1</sup> Includes 70.4 million influenza doses.

<sup>2</sup> The projected change in birth cohort from 2000 to 2019 (2.1 percent, from 4 million to 4.08 million) was used to estimate the growth in baseline doses.

<sup>3</sup> Influenza doses distributed in FY 2000 (70.4 million) are excluded to avoid duplication when calculating FY 2019 new doses.

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.

National program operations funding at the level of $169.4 million would also 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.<sup>10,11,12</sup>


Vaccine Purchase

Total Vaccine Purchase: $245.2 million (Tables 4, 5, 6, and 7; Appendix 3)

The Section 317 Program provides states with federally-purchased vaccine to ensure access to immunization services for at-need populations, and is a 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. CDC maintains a vaccine use policy 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 for vaccines. The CDC definition of fully insured for vaccines 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 addition to serving financially vulnerable adults, the Section 317 program’s ability to respond to time-sensitive and urgent public health vaccination needs is critical to the prevention of VPDs, when it is often not feasible to bill 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. Vaccine Purchase Summary: Uninsured Adult Vaccine and Time-Sensitive Needs

<table>
<thead>
<tr>
<th>Vaccine Purchase Category</th>
<th>Total Cost</th>
<th>State Funds Used to Purchase Vaccine from Federal Contracts</th>
<th>Total Vaccine Purchase Estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uninsured Adults (all vaccines)</td>
<td>$208.7M</td>
<td>$(30.0M)</td>
<td>$178.7M</td>
</tr>
<tr>
<td>Time-Sensitive Vaccine Needs</td>
<td>$66.5M</td>
<td>N/A</td>
<td>$66.5M</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td>$245.2M</td>
</tr>
</tbody>
</table>

Uninsured Adult Vaccine Needs: $178.7 million (Table 5)

The United States has not been as successful in achieving high vaccination coverage among adults as it has been among children. 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, Advisory Committee on Immunization Practices (ACIP)-recommended vaccines (influenza, tetanus, diphtheria, pertussis (Tdap), human papillomavirus (HPV), hepatitis B, Pneumococcal Polysaccharide Vaccine [PPV], Herpes Zoster, and Pneumococcal Conjugate Vaccine (PCV13)).
- CDC used 2015 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 2019. Uninsured adults aged 19–64 years and living within 200 percent of the Federal poverty threshold were included in the final purchase estimates.13
- Data from the 2012-2015 National Health Interview Surveys 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 2019).
- 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 2019.

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13 According to the U.S. Census Bureau, the 2015 federal poverty threshold is $12,331 for an individual less than 65 years of age.
To determine the final vaccine purchase estimate, the amount of funding contributed by states to purchase adult vaccines from the federal vaccine contracts ($30.0 million) was removed from the estimated vaccine purchase costs in Tables 4 and 5 to ensure the Section 317 vaccine purchase estimate did not supplant state funding.

Table 5. Adult Vaccines

<table>
<thead>
<tr>
<th>Adults (19–64 years)</th>
<th>Uninsured and Within 200 Percent of Federal Poverty Level Population, Total</th>
<th>Final Population, One Cohort ¹</th>
<th>Population to Vaccinate (Uptake)</th>
<th>Vaccine Cost to Fully Vaccinate an Adult</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza</td>
<td>13,018,048</td>
<td>N/A</td>
<td>4,725,551</td>
<td>$13.47</td>
<td>63,653,172</td>
</tr>
<tr>
<td>Tdap² for general adult population (19–64)</td>
<td>13,018,048</td>
<td>N/A</td>
<td>390,541</td>
<td>$26.57</td>
<td>10,376,674</td>
</tr>
<tr>
<td>Tdap² for pregnant women</td>
<td>327,022</td>
<td>N/A</td>
<td>192,289</td>
<td>$26.57</td>
<td>5,109,119</td>
</tr>
<tr>
<td>HPV (females, 19-26)³</td>
<td>1,452,595</td>
<td>N/A</td>
<td>74,082</td>
<td>$380.42</td>
<td>28,182,274</td>
</tr>
<tr>
<td>HPV (males, 19-21)³</td>
<td>518,872</td>
<td>N/A</td>
<td>21,793</td>
<td>$380.42</td>
<td>8,290,493</td>
</tr>
<tr>
<td>Hepatitis B (venue)³,⁴</td>
<td>6,954,396</td>
<td>N/A</td>
<td>605,032</td>
<td>$86.24</td>
<td>52,177,960</td>
</tr>
<tr>
<td>Hepatitis B (diabetics)³,⁵</td>
<td>426,000</td>
<td>N/A</td>
<td>42,600</td>
<td>$86.24</td>
<td>3,673,824</td>
</tr>
<tr>
<td>PPV</td>
<td>5,149,940</td>
<td>111,955</td>
<td>31,347</td>
<td>$28.53</td>
<td>894,330</td>
</tr>
<tr>
<td>PCV13</td>
<td>581,503</td>
<td>N/A</td>
<td>87,225</td>
<td>$105.36</td>
<td>9,190,026</td>
</tr>
<tr>
<td>Zoster (50-64)</td>
<td>2,635,155</td>
<td>N/A</td>
<td>131,758</td>
<td>$206.47</td>
<td>27,204,074</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td></td>
<td><strong>$208.7M</strong></td>
<td></td>
</tr>
</tbody>
</table>

¹ Total uninsured population divided by number of cohorts.
² Reflects price of Tdap because CDC recommends that all adults in this population receive Tdap (instead ofTd).
³ Hepatitis B and HPV are each three-dose series.
⁴ 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).
⁵ 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.

Time-Sensitive Public Health Needs: $66.5 million (Tables 6 and 7)

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, CDC subject matter experts estimated the number of doses of vaccine needed by immunization awardees on an annual basis for outbreak response and 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 the Section 317 Program. Additionally, strategies to allow for the use of Section 317 resources for outbreak vaccine across fiscal years could be considered to ensure these vaccine resources are available when needed for a rapid and successful outbreak response.

Table 6. Outbreak Response Vaccines: FY 2019 Estimates

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Adult</th>
<th>Child</th>
<th>Doses</th>
<th>Vaccine Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Adult</td>
</tr>
<tr>
<td>MMR</td>
<td>45,000</td>
<td>30,000 (67%)</td>
<td>15,000 (33%)</td>
<td>$1,309,200</td>
<td>$163,875</td>
</tr>
<tr>
<td>Meningococcal ACWY</td>
<td>20,000</td>
<td>18,000 (90%)</td>
<td>2,000 (10%)</td>
<td>$1,414,800</td>
<td>$94,770</td>
</tr>
<tr>
<td>Meningococcal B$</td>
<td>110,000</td>
<td>95,000 (86%)</td>
<td>15,000 (14%)</td>
<td>$23,788,950</td>
<td>$2,184,300</td>
</tr>
<tr>
<td>Tdap/DTaP</td>
<td>80,000</td>
<td>32,000 (40%)$</td>
<td>48,000 (60%)$</td>
<td>$850,240</td>
<td>$741,672</td>
</tr>
<tr>
<td>Varicella</td>
<td>5,000</td>
<td>1,000 (20%)</td>
<td>4,000 (80%)</td>
<td>$72,400</td>
<td>$196,800</td>
</tr>
<tr>
<td>Hepatitis A</td>
<td>834,000</td>
<td>819,000 (98%)</td>
<td>15,000 (2%)</td>
<td>$23,865,660</td>
<td>$148,950</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>1,500</td>
<td>1,500 (100%)</td>
<td>0 (0%)</td>
<td>$43,121</td>
<td>$0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Total $51,344,371</td>
<td>$3,530,367</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>$54.9M</td>
<td></td>
</tr>
</tbody>
</table>

$Doses assumed to be for VFC-eligible children (50 percent) were deleted from cost estimate.
$Estimates include outbreak in college/university-based and community-based settings. Average price of 2 dose and 3 dose schedule
$All Tdap.
$Projected adult vaccine prices (MMR, $43.64; Meningococcal ACWY, $78.60; Meningococcal B, $230.41 (average per series); Tdap, $26.57; varicella, $72.40; hepatitis A, $29.14; hepatitis B, $28.747; child vaccine prices (MMR, $21.85; Meningococcal ACWY, $94.77; Meningococcal B, $291.24 (average per series); Tdap, $33.09; single-antigen DTaP, $18.51; varicella, $98.40; hepatitis A, $19.80; hepatitis B, $13.05).

The VPDs that typically require substantial numbers of doses of vaccine (i.e., from 1,500-834,000 doses annually) include measles, mumps, meningococcal, pertussis, varicella, 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 45,000 doses of Measles, Mumps, and Rubella (MMR), 20,000 doses of meningococcal ACWY, 110,000 doses of meningococcal B, 80,000 doses of Tdap/DTaP, 5,000 doses of varicella, 834,000 doses of hepatitis A, and 1,500 doses of hepatitis B for outbreak response in FY 2019. The cost estimate does not include costs needed for VFC-eligible children.
Table 7. Expanding Capacity for Influenza Vaccine among School-aged Children (ages 5-17 years)

<table>
<thead>
<tr>
<th>Number of school-aged children nationwide</th>
<th>Children attending lower SES schools(^1)</th>
<th>Children attending lower SES schools where SLV(^{*}) conducted(^2)</th>
<th>Children vaccinated overall (any location)(^3)</th>
<th>Children vaccinated at school(^4)</th>
<th>Non-VFC eligible children vaccinated at school(^5)</th>
<th>Vaccine cost(^6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>53,000,000</td>
<td>13,250,000</td>
<td>6,625,000</td>
<td>3,975,000</td>
<td>2,385,000</td>
<td>715,500</td>
<td>$16.23</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>$11.6M</td>
</tr>
</tbody>
</table>

\(1\) Approximate number of students nationwide attending lower socioeconomic status (SES) schools, defined as schools where \(\geq 70\%\) 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 \(\geq 70\%\) 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%).

\(6\) Projected weighted average federal contract price and adjusted to 2019.

The influenza vaccine is universally recommended for all persons over the age of 6 months every year, and 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. 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\(^14\), and approximately one-third of school-aged children (5-17 years of age) vaccinated against 2009 H1N1 pandemic influenza were vaccinated at school.\(^15\)

IV. Conclusion

Immunization continues to be one of the most cost-effective public health interventions. CDC estimates that, among children born during 1994—2016, vaccination will prevent an estimated 381 million illnesses, 24.5 million hospitalizations, and 855,000 early deaths over the course of their lifetimes, at a net savings of $360 billion in direct costs and $1.65 trillion in total societal costs.\(^16\) The Section 317 Program plays a critical role in the nation’s immunization system. 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 supported by the Section 317 Immunization program.

For FY 2019, 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,

\(^{14}\) National Association of County and City Health Officials, unpublished data, 2011.

\(^{15}\) CDC, unpublished data, 2011.

\(^{16}\) Benefits from Immunization During the Vaccines for Children Program Era — United States, 1994—2013. MMWR, 25 April 2014

12
• Make strategic investments to enhance the immunization infrastructure and evidence base and improve efficiency.

As noted above, this Section 317 Program Report to Congress represents a professional judgment of what is necessary to support a fully implemented, comprehensive immunization program and is provided without taking into account competing priorities that the CDC Director, the Secretary, and the President must consider when developing the President’s Budget.

Program Operations
New vaccines allow for an unprecedented level of protection across the lifespan. New VPDs require the creation or expansion of important vaccine program infrastructure components at the local, state, and national levels. 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 $854.6 million.

Vaccine Purchase
CDC’s funding estimate is $245.2 million to address time-sensitive public health needs, such as improving influenza vaccination among school-age children; responding to outbreaks of VPDs; and implementing the CDC approved ACIP recommended vaccine schedule for uninsured adults. It is important to note the methods CDC 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

<table>
<thead>
<tr>
<th>Disease</th>
<th>20th Century Annual Morbidity †</th>
<th>2016 Reported Cases ††</th>
<th>Percent Decrease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smallpox</td>
<td>29,005</td>
<td>0</td>
<td>100%</td>
</tr>
<tr>
<td>Diphtheria</td>
<td>21,053</td>
<td>0</td>
<td>100%</td>
</tr>
<tr>
<td>Measles</td>
<td>530,217</td>
<td>69</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>Mumps</td>
<td>162,344</td>
<td>5,311</td>
<td>99%</td>
</tr>
<tr>
<td>Pertussis</td>
<td>200,752</td>
<td>15,737</td>
<td>91%</td>
</tr>
<tr>
<td>Polio (paralytic)</td>
<td>16,316</td>
<td>0</td>
<td>100%</td>
</tr>
<tr>
<td>Rubella</td>
<td>47,745</td>
<td>5</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>Congenital Rubella Syndrome</td>
<td>152</td>
<td>1</td>
<td>99%</td>
</tr>
<tr>
<td>Tetanus</td>
<td>580</td>
<td>33</td>
<td>96%</td>
</tr>
<tr>
<td>Haemophilus influenzae</td>
<td>20,000</td>
<td>22*</td>
<td>&gt;99%</td>
</tr>
</tbody>
</table>

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

†† CDC. MMWR. January 6, 2017; 66(52);ND:925 – ND:941. (MMWR 2016 week 52 provisional data)

* Haemophilus influenzae type b (Hib) < 5 years of age. An additional 11 cases of Hib are estimated to have occurred among the 223 reports of Hib (< 5 years of age) with unknown serotype.
Appendix 2: 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 estimate 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 funding 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 funding 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 $5.93 when adjusted for 2019 dollars using the Bureau of Labor Statistics' Consumer Price Index provided by the Office of Management and Budget.  
- The $5.93 rate was then applied to the total amount of doses projected for the VFC and 317 programs in FY 2019. The determination of doses needed for FY 2019 was calculated by adding the baseline number of doses delivered in 2000 (adjusted for population changes from 2000 to 2019) 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 2019. CDC calculated the number of newly recommended doses by using National Immunization Survey (NIS) data for children and Census and National Health Interview Survey (NHIS) data for adults. CDC used actual coverage estimates from the 2015 NIS for childhood vaccines at or above 90 percent coverage and 2015-16 flu vaccination coverage estimates. For childhood vaccines where uptake was less than 90 percent, PPV and herpes zoster vaccine, 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.
- As a result of these new vaccine recommendations, an additional 63.8 million doses of VFC and Section 317 vaccine will need to be distributed along with the 51.7 million baseline doses (adjusted for population changes from 2000 to 2019).

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17 Based on CPIU provided by Office of Management and Budget (4.1 percent in 2019).
18 Between 2000 and 2015, the following new vaccine and/or new vaccine dose recommendations were made for the childhood and adult populations: PCV, influenza, hepatitis A, Tdap, meningococcal, rotavirus, varicella, HPV, and herpes zoster.
19 https://www.cdc.gov/vaccines/vaxview/index.html
• The adjusted cost per dose rate of $5.93 was applied to the projected number of VFC and Section 317 doses needed for FY 2019 (115.5 million), for a total state and local immunization program operations estimate of $685.2 million.

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

• The funding 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 = $0.335 in National Program operations costs per dose of Section 317, VFC, state, and private vaccine distributed.
• The $0.335 cost per dose rate is equal to $0.56 when adjusted for 2019 dollars using the Bureau of Labor Statistics’ Consumer Price Index provided by the Office of Management and Budget.20
• The $0.56 rate was then applied to the total amount of Section 317, VFC, state, and private doses projected for FY 2019. The determination of doses needed for FY 2019 was calculated by adding the baseline number of doses delivered in 2000 (adjusted for population changes from 2000 to 2019) 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 2019. 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 2015 NIS for childhood vaccines at or above 90 percent coverage and 2015-16 flu vaccination coverage estimates. For childhood vaccines where uptake was less than 90 percent, 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 2011.21
• As a result of these new vaccine recommendations, an additional 187.8 million doses of Section 317, VFC, state, and private vaccine will need to be distributed along with the 114.7 million baseline doses (adjusted for population changes from 2000 to 2019).
• The adjusted cost per dose rate of $0.56 was applied to the projected number of Section 317, VFC, state, and private doses needed for FY 2019 (302.5 million), for a total National Program operations estimate of $169.4 million.

20 Based on CPI-U provided by Office of Management and Budget (4.1 percent in 2019).
21 https://www.cdc.gov/vaccines/vaxview/index.html
Appendix 3: Vaccine Purchase for Adult Populations

CDC estimated uptake of PPV by adding 5 percent to the coverage estimate from the 2015 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

- 13,018,048 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 2019 is 36.3 percent. 13,018,048 x 0.363 = 4,725,551 adults.
- Based on 2017-2018 flu prebook data (projected orders prior to the start of the flu season), projected weighted average federal contract price for one dose of adult influenza vaccine in FY 2019 is $13.47.
- 4,725,551 x $13.47 = $63,653,172.

Tdap for general adult population

- 13,018,048 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 catch-up for Tdap vaccine in 2019, based on the three year average increase in uptake of Tdap vaccine among adults, is 3.0%. 13,018,048 x 0.030 = 390,541 adults.
- Projected average federal contract price for one dose of Tdap vaccine in FY 2019 is $26.57.
- 390,541 x $26.57 = $10,376,674.

Tdap for pregnant women

- 327,022 pregnant women in the U.S. are uninsured who are recommended to receive Tdap vaccine.
- Projected uptake for Tdap vaccination in pregnant women in FY 2019 is 58.8%. 327,022 x 0.588 = 192,289 pregnant women.
- Projected average federal contract price for one dose of Tdap vaccine in FY 2019 is $26.57.
- 192,289 x $26.57 = $5,109,119.

HPV

- 1,452,595 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. 518,872 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.
- Projected catch-up for HPV vaccine in FY 2019 is 5.1 percent for females and 4.2 percent for males. 1,452,595 x 0.051 = 74,082 females and 518,872 x 0.042 = 21,793 males.
- Projected federal contract price for one dose of HPV vaccine in FY 2019 is $126.807 (price for Gardasil 9) and $380.42 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.
- 74,082 x $380.42 = $28,182,274 for females, and 21,793 x $380.42 = $8,290,493 for males.
- $28,182,274 + $8,290,493 = $36,472,767.
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 4,466,827 individuals 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 2019 is 15 percent. 4,033,549 x 0.15 = 605,032 adults.
- Projected average federal contract price for one dose of hepatitis B vaccine in FY 2019 is $28.747 and $86.24 for the full three-dose series.
- 605,032 x $86.24 = $52,177,960 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 426,000 adults aged 19 to 59 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. 426,000 x 0.1 = 42,600 diabetic adults.
- Projected average federal contract price for one dose of hepatitis B vaccine in FY 2019 is $28.747 and $86.24 for the full three-dose series.
- 42,600 x $86.24 = $3,673,824.
- $52,177,960 + $3,673,824= $55,851,784.

Pneumococcal Polysaccharide Vaccine (PPV)

- 5,149,940 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 2019. 5,149,940 ÷ 46 (number of cohorts of persons aged 19 to 64 years) = 111,955 adults.
- Projected uptake for PPV vaccine in FY 2019 is 28.0 percent. 111,955 x 0.280 = 31,347 adults.
- Projected federal contract price for one dose of PPV vaccine in FY 2019 is $28.53.
Pneumococcal Conjugate (PCV13)
- 581,503 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 2019 is 15.0 percent. 581,503 x 0.15 = 87,225 adults.
- Projected federal contract price for one dose of PCV13 vaccine in FY 2019 is $105.36.
- 87,225 x $105.36 = $9,190,026.

Herpes Zoster
- 2,635,155 adults in the U.S. aged 50 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).
- Projected uptake for new Herpes Zoster vaccine (Shingrix) in FY 2019 is 5 percent. 2,635,155 x 0.05 = 131,758 adults. Note, Zostavax is no longer in the CDC contract due to the new ACIP preferential recommendation for Shingrix.
- Projected federal contract price for one dose of Herpes Zoster vaccine in FY 2019 is $103.235 (price for Shingrix) and $206.47 for the full two-dose series.
- 131,758 x $206.47 = $27,204,074.