

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

**Committees on Appropriations of the House of Representatives and the Senate,
Committee on Energy and Commerce of the House of Representatives,
and
Committee on Health, Education, Labor, and Pensions of the Senate**

**Report to Congress on
Section 317 Immunization Program - Cost Estimates**



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Overview

In its report on the Fiscal Year (FY) 2021 appropriation for the Department of Health and Human Services (HHS), the House Committee on Appropriations states the following:

Cost Estimates — The Committee looks forward to reviewing the fiscal year 2022 report on estimated funding needs of the Section 317 Immunization Program and urges that the report be updated and submitted not later than February 1, 2021. The updated report should include an estimate of optimum State and local operations funding, as well as a discussion of the role of the 317 Program, as coverage for vaccination under public and private resources continues to evolve. The fiscal year 2022 report should include specific information on the estimated cost to fully address evidence-based public health strategies that could be funded through CDC to improve coverage for human papillomavirus and influenza. (House Report 116-450, page 61)

The Centers for Disease Control and Prevention (CDC) prepared this report in response to requests from the House and Senate Appropriations Committees. The following report provides CDC's FY 2022 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 regard to the competing priorities that the CDC Director, the Secretary, and the President must consider when developing the President's Budget.

Introduction

In preparing this report, CDC acknowledges the COVID-19 pandemic's profound impact on the lives of Americans, with over 31 million¹ infected with the SARS-CoV-2 virus and over 551,000 deaths through the week ending 4/17/2021.² Concurrently, the pandemic severely disrupted the U.S. economy, with the loss of millions of jobs and closure of both small and large businesses, adding to the increasing number of people without health insurance.^{3,4} Healthcare use significantly changed as well, as patients were hesitant to visit providers for routine preventive health services including immunization. CDC released a seminal report, [Effects of the COVID-19 Pandemic on Routine Pediatric Vaccine Ordering and Administration — United States, 2020](#), which signaled the decline in routine childhood immunization, including measles-containing vaccine. Subsequent calls to action were issued by CDC and its partners to address these dangerous declines. Data for adult vaccine coverage rates during this time are not yet available.

CDC used funds received through the Coronavirus Aid, Relief, and Economic Security (CARES) Act to support jurisdictions to enhance influenza vaccination for adults (i.e., \$140 million in June 2020) and to prepare for COVID-19 vaccine distribution (i.e., \$200 million in September and \$140 million in December 2020). Another \$3 billion from the Coronavirus Response and Relief Supplemental Appropriations Act of 2021 was awarded in January 2021 to help jurisdictions enhance their infrastructure to enable more timely administration of COVID-19 vaccine to help end the pandemic.

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, there are record high

¹ CDC COVID Data Tracker as of 4/21/21; accessed April 22, 2021.

² NCHS Deaths due to COVID-19; accessed April 22, 2021.

³ Health Insurance Coverage in the United States: 2019 (census.gov); accessed January 19, 2021

⁴ How Many Americans Have Lost Jobs with Employer Health Coverage During the Pandemic?; accessed January 20, 2021.

immunization coverage rates for most childhood vaccines⁵ and increasing coverage rates for adolescent⁶ and adult vaccines.⁷ 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 2). The Section 317 Immunization Program plays an essential 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. The COVID-19 vaccine experience in 2020-2021 has highlighted the importance of infrastructure for vaccine delivery. 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.

The Evolving Role of the Section 317 Immunization Program

Enacted in 1962⁸ 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 Immunization Program provides the majority of financial support for the nation's immunization infrastructure, which is made up of public health experts and systems that implement our nation's immunization policies and programs, as well as a flexible federal supply of vaccine that can be used in response to VPD outbreaks and other urgent vaccine needs.

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 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. The Section 317 Immunization Program is a critical resource in meeting national immunization priorities, such as maintaining high childhood immunization coverage, increasing influenza vaccination coverage across the lifespan, and supporting Americans in making the decision to vaccinate with confidence.

Over its more than fifty-year history, the Section 317 Immunization 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 high immunization coverage rates and low occurrence of VPDs.

⁵ CDC. Vaccination Coverage by Age 24 Months Among Children Born in 2016 and 2017 — National Immunization Survey-Child, United States, 2017–2019. MMWR 2020; 69(42); 1505-1511.

⁶ CDC. National, Regional, State, and Selected Local Area Vaccination Coverage Among Adolescents Aged 13-17 Years--United States, 2019. MMWR. 2020; 69(33);1109-1106.

⁷ CDC. Surveillance of Vaccination Coverage Among Adult Populations - United States, 2015. MMWR-SS 2017;66(11); 1:28

⁸ 42 USC § 247b.

Professional Judgment Estimates

CDC developed the following professional judgment estimates for program operations and vaccine purchase. The approach estimates the costs of prevention opportunities that are in scope for the Section 317 Immunization Program—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.

CDC's FY 2022 professional judgment estimate includes:

- Program operations:
 - State and local: \$819.4 million
 - National: \$213.4 million
 - Total: \$1,032.8 million
- Vaccine purchase:
 - Uninsured adults: \$221.0 million
 - Time-sensitive public health needs: \$184.5 million
 - Total: \$405.5 million

Program Operations

Total Program Operations (Cost per Dose Methodology): \$1,032.8 million (Tables 1, 2, and 3; Appendix 3)

Table 1. Total Operations

State and Local Immunization Program Operations	\$819.4M
National Program Operations	\$213.4M
Total Operations	\$1,032.8M

Methods

In previous reports, CDC used a cost per dose methodology to calculate an overall operations estimate. This report provides updated estimates 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 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 Vaccines for Children (VFC) vaccine doses distributed in FY 2000. Section 317 operations funding supports the state and local public health workforce that implements the Section 317 Immunization Program and VFC. For the 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.

CDC implemented this approach more than 10 years ago as a way to find a more objective approach to creating the estimates for overall immunization program operations. Given that we based the calculations on the baseline year of 2000, we used the Consumer Price Index for all Urban Consumers (CPI-U) to adjust for current day dollars. CDC has used the same methodology each year to ensure consistency for each year’s professional judgement estimate.

In each report, we have applied the CPI cumulatively to the FY 2000 baseline in calculating the projections. Thus, rather than re-calculate the baseline from 2000 to 2022, we add in the CPI-U increase for the new report year, in this case, from FY 2021 to FY 2022. Also, we use the CPI-U medical annual average. Given this has been the approach for more than 10 years, we have again used this methodology in this report to ensure consistency and comparability of the report over time.

State and Local Immunization Program Operations Estimate: \$819.4 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 \$6.65 when adjusted for 2022 dollars using the Bureau of Labor Statistics’ Consumer Price Index⁹. CDC then applied the \$6.65 rate to the total amount of doses projected for the Section 317 and VFC programs in FY 2022, which includes total baseline doses (excluding influenza) adjusted for population growth (52.4 million) and the number of doses of newly recommended vaccines (including influenza) since 2000 for children (61.8 million) and adults (9.0 million).¹⁰

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

Fiscal Year	Doses of Section 317 and VFC Vaccine	State and Local Program Operations Cost per Dose
2000	Baseline Doses, Including Influenza: 52,250,229 ¹	317 Operations: \$132.6 million VFC Operations: \$50 million Total: \$182.6 million Operations/Dose: \$182.6 million/52.3 million = \$3.49
2022	Baseline Doses, Excluding Influenza, Adjusted for Population Growth: 52,410,818 ^{2,3}	
2022	New Doses, Including Influenza Children (0-18): 8,983,759 Adult: 70,805,618 Total New Doses	2000 Operations/Dose, Adjusted for 2022 Dollars ⁴ : \$6.65

⁹ Based on CPI-U provided by Office of Management and Budget (3.9 percent in 2022), and adjusted from \$6.40 in FY 2021

¹⁰ 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.

2022	Total Doses (Baseline Doses Adjusted for Population Growth + New Doses):	123,216,436	Total Program Operations (123,216,436 x \$6.65)	\$819.4M
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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 2022 (3.5 percent, from 4 million to 4.14 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 2022 new doses.

⁴ Adjusted from \$6.40 in FY 2021.

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

1. Stewardship and accountability for publicly purchased vaccine and Section 317 and VFC operations support;
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 Immunization 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 estimate of operations funding.

National Program Operations Estimate: \$213.4 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 \$0.62 when adjusted for 2022 dollars using the Bureau of Labor Statistics' Consumer Price Index.¹¹ CDC then applied the \$0.62 rate to the total number of doses projected for public and private purchase in FY 2022, which includes total baseline doses (excluding influenza) adjusted for population growth (116.3 million) and the number of doses of newly recommended vaccines (including influenza) since 2000 for children (108.1 million) and adults (119.9 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 Influenza: 182,755,410 ¹	National Program Operations: Operations/Dose: \$61.2 million \$61.2 million/182.8 million = \$0.335

¹¹ Based on CPI-U provided by Office of Management and Budget (3.9 percent in 2022), and adjusted from \$0.60 in FY 2021.

2022	Baseline Doses, Excluding Influenza, Adjusted for Population Growth:	116,260,856 ^{2,3}	
2022	New Doses, Including Influenza Children (0- 18): Adult: Total New Doses	108,066,169 119,861,191 227,927,360	2000 Operations/Dose, Adjusted for 2022 Dollars ⁴ : \$0.62
2022	Total Doses (Baseline Doses Adjusted for Population Growth + New Doses):	344,188,216	Total Program Operations (344,188,216 x \$0.62) \$213.4M

¹ Includes 70.4 million influenza doses.

² The projected change in birth cohort from 2000 to 2022 (3.5 percent, from 4 million to 4.14 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 2022 new doses.

⁴ Adjusted from \$0.60 in FY 2021

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 and 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, or widespread adoption of electronic health records systems.

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.^{12 13 14}

Vaccine Purchase

Total Vaccine Purchase: \$405.5 million (Tables 4, 5, 6, and 7; Appendix 4)

The Section 317 Immunization 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

¹² National Immunization Survey: <http://www.cdc.gov/vaccines/imz-managers/nis/index.html>

¹³ Resources for vaccine management: <http://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/manage.html>

¹⁴ Science-based communications tools for the public and healthcare providers:

<http://www.cdc.gov/vaccines/hcp/index.html> <https://www.cdc.gov/vaccines/parents/index.html> <https://www.cdc.gov/vaccines/adults/index.html>

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 Immunization 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 example, in 2017, four states responded to outbreaks of acute hepatitis A virus, with the majority of infections occurring in persons reporting injection or non-injection drug use or homelessness. As part of the response, vaccine clinics were held in a variety of settings including homeless encampments, drug treatment centers, jails, etc.¹⁵ 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

Vaccine Purchase Category	Total Cost	State Funds Used to Purchase Vaccine from Federal Contracts	Total Vaccine Purchase Estimate
Uninsured Adults (all vaccines)	\$259.5M	\$(38.5M)	\$221.0M
Time-Sensitive Vaccine Needs	\$184.5M	N/A	\$184.5M
Total			\$ 405.5M

Uninsured Adult Vaccine Needs: \$221.0 million (Tables 4 and 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 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 2017 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 2022. Uninsured adults aged 19–64 years and living within 200 percent of the federal poverty threshold were included in the final purchase estimates.¹⁶
- Data from the 2012-2019 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 2022).
- 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 2022.

¹⁵ Hepatitis A Virus Outbreaks Associated with Drug Use and Homelessness — California, Kentucky, Michigan, and Utah, 2017 | MMWR (cdc.gov); accessed March 8, 2021.

¹⁶ According to the U.S. Census Bureau, the 2017 federal poverty threshold is \$12,752 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 (\$38.5 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: FY 2022 Estimates

	Uninsured and Within 200 Percent of FPT Population, Total	Final Population, One or Five Cohorts ¹	Population to Vaccinate (Uptake)	Vaccine Cost to Fully Vaccinate an Adult	Total Cost
Adults (19–64 years)					
Influenza for general adult population (19-64)	11,671,892	N/A	4,937,210	\$14.12	\$69,713,405
Influenza for pregnant women	303,337	N/A	215,976	\$14.12	\$3,049,581
Tdap ² for general adult population (19-64)	11,671,892	1,268,684	883,004	\$26.64	\$23,523,227
Tdap for pregnant women	303,337	N/A	202,022	\$26.64	\$5,381,866
HPV (females, 19-45) ³	4,225,366	N/A	78,989	\$442.48	\$34,951,053
HPV (males, 19-45) ³	4,385,018	N/A	74,151	\$442.48	\$32,810,334
Hepatitis B (venue) ^{3,4}	6,954,396	N/A	605,032	\$80.63	\$48,783,730
Hepatitis B (diabetics) ^{3,5}	426,000	N/A	42,600	\$80.63	\$3,434,838
PPV	3,716,330	80,790	22,298	\$65.77	\$1,466,539
PCV13	524,996	N/A	78,749	\$138.07	\$10,872,874
Zoster (50-64)	2,421,849	N/A	121,092	\$210.99	\$25,549,201
Total					\$259.5M

¹ Population in one cohort=Total uninsured population divided by number of cohorts.

² Reflects price of Tdap because CDC recommends that all adults in this population could receive Tdap (instead of Td).

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: \$184.5 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 Immunization Program.

Table 6. Outbreak Response Vaccines: FY 2022 Estimates

	Total	Doses		Vaccine Cost	
		Adult	Child	Adult	Non-VFC Child ¹
MMR	55,000	40,000 (73%)	15,000 (27%)	\$2,050,400	\$172,425
Meningococcal ACWY	20,000	18,000 (90%)	2,000 (10%)	\$1,372,860	\$101,700
Meningococcal B ²	110,000	95,000(86%)	15,000(14%)	\$24,577,450	\$2,318,025
Tdap/DTaP	80,000	32,000 (40%) ³	48,000 (60%) ⁴	\$852,480	\$782,628
Varicella	5,000	1,000 (20%)	4,000 (80%)	\$86,070	\$231,460
Hepatitis A	4,104,486	4,089,486 (99.6%)	15,000 (0.4%)	\$140,964,582	\$165,750
Hepatitis B	1,650	1,650 (100%)	0 (0%)	\$44,352	\$0
				\$169,948,194	\$3,771,988
Total⁵				\$173.7M	

¹ Doses assumed to be for VFC-eligible children (50 percent) were deleted from cost estimate.

² Estimates include outbreak in college/university-based and community-based settings. Average price of 2 dose and 3 dose schedules.

³ All Tdap.

⁴ Assumes 85 percent Tdap and 15 percent DTaP.

⁵ Projected adult vaccine prices (MMR, \$51.26; Meningococcal ACWY, \$76.27; Meningococcal B, \$258.71 (average per series); Tdap, \$26.64; varicella,

\$86.07; hepatitis A, \$34.47; hepatitis B, \$26.88; child vaccine prices (MMR, \$22.99; Meningococcal ACWY, \$101.70; Meningococcal B, \$309.07 (average per series); Tdap, \$34.84; single-antigen DTaP, \$19.97; varicella, \$115.73; hepatitis A, \$22.10; hepatitis B, \$14.78).

The VPDs that typically require substantial numbers of doses of vaccine (i.e., from 1,650-4,104,486 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 55,000 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, 4,104,486 doses of hepatitis A, and 1,650 doses of hepatitis B for outbreak response in FY 2022. The significant increase in estimated doses of Hepatitis A vaccine from the FY 2021 report is based on widespread outbreaks in an increasing number of states.¹⁷ 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)

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	\$15.05
Total						\$10.8M

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) ($0.25 \times 53,000,000$).

² Assuming SLV will be conducted in 50% of lower SES schools, the estimated number of students attending these schools ($0.50 \times 13,250,000$).

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 ($0.60 \times 6,625,000$).

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 ($0.60 \times 3,975,000$ – 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 ($0.30 \times 2,385,000$ – 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 2022.

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,¹⁸ and approximately one-third of school-aged children (5-17 years of age) vaccinated against 2009 H1N1 pandemic influenza were vaccinated at school.¹⁹

Conclusion

¹⁷ Widespread outbreaks of hepatitis A across the U.S. | CDC

¹⁸ National Association of County and City Health Officials, unpublished data, 2011.

¹⁹ CDC, unpublished data, 2011.

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.²⁰ The Section 317 Immunization 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 2022, 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.

As noted above, this Section 317 Immunization Program Report to Congress represents a professional judgment estimate 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 estimate for a comprehensive immunization program is \$1,032.8 million.

Vaccine Purchase

CDC’s estimate is \$405.5 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 estimate are conservative and limit the scope of the Section 317 Immunization Program to only serving as a safety net for financially vulnerable adults. These estimates do not include achieving full coverage in uninsured adults but are based on achieving similar coverage as the general population or a modest increase from current levels.

²⁰ Benefits from Immunization During the Vaccines for Children Program Era — United States, 1994–2013. MMWR, 25 April 2014

Appendix

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

Comparison of 20 th Century Annual Morbidity and Current Morbidity: Vaccine-Preventable Diseases			
Disease	20th Century Annual Morbidity †	2018 Reported Cases † †	Percent Decrease
Smallpox	29,005	0	100%
Diphtheria	21,053	1	> 99%
Measles ¹⁵	530,217	273	> 99%
Mumps	162,344	2251	99%
Pertussis	200,752	13,439	93%
Polio (paralytic)	16,316	0	100%
Rubella	47,745	5	> 99%
Congenital Rubella Syndrome	152	0	100%
Tetanus	580	20	97%
<i>Haemophilus influenzae</i>	20,000	27*	> 99%

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

† † CDC. MMWR January 6, 2017/ 64(52); ND-924 – 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 221 reports of Hib (< 5 years of age) with unknown serotype.

* ¹In 2019, the United States is experiencing outbreaks of measles in several states. Over 1,000 cases have been reported. This is the greatest number of cases reported in the U.S. since 1992 and since measles was declared eliminated in 2000.

Appendix 2: Operations 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 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 Immunization 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 \text{ million} \div 52.3 \text{ 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 \$6.65 when adjusted for 2022 dollars using the Bureau of Labor Statistics' Consumer Price Index provided by the Office of Management and Budget.²¹
- The \$6.65 rate was then applied to the total amount of doses projected for the VFC and 317 programs in FY 2022. The determination of doses needed for FY 2022 was calculated by adding the baseline number of doses delivered in 2000 (adjusted for population changes from 2000 to 2022) to the number of doses of newly recommended vaccines since 2000.²² 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 2022. 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 2017-2019 NIS for childhood vaccines at or above 90 percent coverage and 2019-2020 influenza vaccination coverage estimates. For childhood vaccines where uptake was less than 90 percent, CDC estimated uptake by adding 5 percent to the 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 2011.²³

²¹ Based on CPI-U provided by Office of Management and Budget (3.9 percent in 2022), and adjusted from \$6.40 in FY 2021.

²² 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.

²³ <https://www.cdc.gov/vaccines/vaxview/index.html>

- As a result of these new vaccine recommendations, an additional 70.8 million doses of VFC and Section 317 vaccine will need to be distributed along with the 52.4 million baseline doses (adjusted for population changes from 2000 to 2022).
- The adjusted cost per dose rate of \$6.65 was applied to the projected number of VFC and Section 317 doses needed for FY 2022 (123.2 million), for a total state and local immunization program operations budget of \$819.4 million.

CDC used the following approach to calculate the National Program operations 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 \text{ million} \div 182.8 \text{ 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 \$0.62 when adjusted for 2022 dollars using the Bureau of Labor Statistics' Consumer Price Index provided by the Office of Management and Budget.²⁴
- The \$0.62 rate was then applied to the total amount of Section 317, VFC, state, and private doses projected for FY 2022. The determination of doses needed for FY 2022 was calculated by adding the baseline number of doses delivered in 2000 (adjusted for population changes from 2000 to 2022) 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 2022. 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 2017-2019 NIS for childhood vaccines at or above 90 percent coverage and 2019-2020 influenza vaccination coverage estimates. For childhood vaccines where uptake was less than 90 percent, CDC estimated uptake by adding five 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 2011.²⁵
- As a result of new vaccine recommendations for PCV, influenza, hepatitis A, Tdap, meningococcal, rotavirus, varicella, HPV, and herpes zoster vaccines, an additional 227.9 million doses of Section 317, VFC, state, and private vaccine will need to be distributed along with the 116.3 million baseline doses (adjusted for population changes from 2000 to 2022).
- The adjusted cost per dose rate of \$0.62 was applied to the projected number of Section 317, VFC, state, and private doses needed for FY 2022 (344.2 million), for a total National Program operations budget of \$213.4 million.

²⁴ Based on CPI-U provided by Office of Management and Budget (3.9 percent in 2022), and adjusted from \$0.60 in FY 2021.

²⁵ <https://www.cdc.gov/vaccines/vaxview/index.html>

Appendix 3: Vaccine Purchase for Adult Populations

CDC estimated uptake of PPV and Tdap by adding five percent to the coverage estimate from the 2019 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 for general adult population

- 11,671,892 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 2022 is 42.3 percent. $11,671,892 \times 0.423 = 4,937,210$ adults.
- Based on 2020-2021 flu prebook data (projected orders prior to the start of the influenza season, projected weighted average federal contract price for one dose of adult influenza vaccine in FY 2022 is \$14.12.
- $4,937,210 \times \$14.12 = \$69,713,405$.

Influenza for pregnant women

- 303,337 pregnant women in the U.S. are uninsured who are recommended to receive influenza vaccine.
- Projected uptake for influenza vaccination in pregnant women in FY 2022 is 71.2%. $303,337 \times 0.712 = 215,976$ pregnant women.
- Projected average federal contract price for one dose of influenza vaccine in FY 2022 is \$14.12.
- $215,976 \times \$14.12 = \$3,049,581$.

Tdap for general adult population

- 11,671,892 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.
- Because one dose of Td/Tdap vaccine should be given every 10 years, we adjusted the number of adults recommended for Tdap vaccine that could be vaccinated in FY 2022. $11,671,892 \div 46$ (number of cohorts of persons aged 19 to 64 years) * 5 (5 cohorts are eligible every year) = 1,268,684 adults.
- Projected uptake for Tdap vaccine in 2022, is 69.6%. $1,268,684 \times 0.696 = 883,004$ adults.
- Projected average federal contract price for one dose of Tdap vaccine in FY 2022 is \$26.64.
- $883,004 \times \$26.64 = \$23,523,227$.

Tdap for pregnant women

- 303,337 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 2022 is 69.6%. $303,337 \times 0.696 = 202,022$ pregnant women.
- Projected average federal contract price for one dose of Tdap vaccine in FY 2022 is \$26.64.
- $202,022 \times \$26.64 = \$5,381,866$.

HPV

- 4,225,366 females in the U.S. are aged 19 to 45 years, uninsured, and living within 200 percent of the federal poverty level who are recommended to receive the HPV vaccine. 4,385,018 males in the U.S. are aged 19 to 45 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 by ACIP for females and males older than age 45 years.

- Projected catch-up for HPV vaccine in FY 2022 is 1.9 percent for females and 1.7 percent for males. $4,225,366 \times 0.019 = 78,989$ females and $4,385,018 \times 0.017 = 74,151$ males.
- Projected federal contract price for one dose of HPV vaccine in FY 2022 is \$147.493 (price for Gardasil 9) and \$442.48 for the three doses a person could receive between 19 and 45 years of age.
- $78,989 \times \$442.48 = \$34,951,053$ for females, and $74,151 \times \$442.48 = \$32,810,334$ for males.
- $\$34,951,053 + \$32,810,334 = \$67,761,387$.

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 $6,954,396 \times (1-0.42) = 4,033,549$ adults eligible for hepatitis B vaccination.
- Projected uptake for hepatitis B vaccine for these populations in FY 2022 is 15 percent. $4,033,549 \times 0.15 = 605,032$ adults.
- Projected average federal contract price for one dose of hepatitis B vaccine in FY 2022 is \$26.877 and \$80.63 for the full three-dose series.
- $605,032 \times \$80.63 = \$48,783,730$ 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. $426,000 \times 0.1 = 42,600$ diabetic adults.
- Projected average federal contract price for one dose of hepatitis B vaccine in FY 2022 is \$26.87 and \$80.63 for the full three-dose series.
- $42,600 \times \$80.63 = \$3,434,838$.
- $\$48,783,730 + \$3,434,838 = \$52,218,568$.

Pneumococcal Polysaccharide Vaccine (PPV)

- 3,716,330 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 2022. $3,716,330 \div 46$ (number of cohorts of persons aged 19 to 64 years) = 80,790 adults.
- Projected uptake for PPV vaccine in FY 2022 is 27.6 percent. $80,790 \times 0.276 = 22,298$ adults.
- Projected federal contract price for one dose of PPV vaccine in FY 2022 is \$65.77.
- $22,298 \times \$65.77 = \$1,466,539$.

Pneumococcal Conjugate (PCV13)

- 524,996 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 2022 is 15.0 percent. $524,996 \times 0.15 = 78,749$ adults.
- Projected federal contract price for one dose of PCV13 vaccine in FY 2022 is \$138.07.
- $78,749 \times \$138.07 = \$10,872,874$.

Herpes Zoster

- 2,421,849 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 2022 is 5 percent. $2,421,849 \times 0.05 = 121,092$ adults.
- Projected federal contract price for one dose of Herpes Zoster vaccine in FY 2022 is \$105.495 (price for Shingrix) and \$210.99 for the full two-dose series.
- $121,092 \times \$210.99 = \$25,549,201$.