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**Assuring Vaccination of Children and Adolescents without Financial Barriers:
Recommendations from the National Vaccine Advisory Committee (NVAC)
U.S. Department of Health and Human Services**

Report developed by the NVAC Vaccine Financing Working Group

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**Assuring Vaccination of Children and Adolescents without Financial Barriers
A Report of the National Vaccine Advisory Committee**

I. Purposes of this report

In September 2006, the National Vaccine Advisory Committee (NVAC) formed a Vaccine Financing Working Group (VFWG) to examine the current state of financing routinely recommended vaccinations for children and adolescents in the United States, to define any financial barriers to effective delivery of vaccines, and to explore policy options to address these barriers. This Report contains NVAC recommendations based on the Working Group's findings and conclusions, and includes recommendations developed by the NVAC Adolescent Working Group. It takes into account public comments and extensive stakeholder input received. The overall goal of the Report is to ensure that all children and adolescents have access to all routinely recommended vaccinations without financial barriers.

Concerns about the stresses on the vaccine financing and delivery system are widespread but often anecdotal. There is a need to better define the root causes and the magnitude of the problem in the current public and private sector vaccine financing system in the U.S. Among the questions of interest are:

- 1) In light of the number of new child and adolescent vaccine recommendations made since 2004, is the existing system of public sector financing for vaccine purchase and administration optimal to support both current and future vaccination schedules?
- 2) What does it cost physicians and other clinicians to vaccinate children and adolescents?
- 3) What financial reimbursements do physicians and other clinicians receive for vaccinating children and adolescents?
- 4) Based on costs and reimbursements, is the current business case for providers delivering pediatric and adolescent vaccines favorable or unfavorable?
 - a) How has the business case changed in light of newly recommended vaccines?
 - b) Is the concern that some providers will cease to administer vaccines justified?
- 5) What factors are most important in determining the costs associated with vaccines and vaccine administration?
- 6) What are the roles of governments, vaccine manufacturers, insurers and healthcare purchasers, and consumers in financing vaccines for children and adolescents?

Given the limited amount of data to address the questions above, the purposes of this Report are twofold. First, current challenges in child and adolescent vaccine financing and delivery in the public and private sectors are described. These challenges are viewed from the perspective of key stakeholders: physicians and other clinicians; vaccine manufacturers and distributors; insurers, employers, and other health care purchasers; consumers; and state and local governments; all of which had representation on the VFWG. In a number of cases, collection of primary data on the current vaccine delivery system was necessary to answer the questions outlined above.

Second, recommendations for addressing these challenges are identified and discussed.

These recommendations are directed to various stakeholders – policy makers in government, health professionals’ organizations, and industry groups – to ensure access to vaccines recommended for routine use among children and adolescents without financial barriers. These recommendations are meant to be consistent with a policy environment that promotes both continued investment in developing new vaccines and new vaccine technology, and continued access to affordable health insurance for all children and adolescents, with coverage of vaccination benefits as defined in health insurance plan contracts and paid by employers through health insurers. These recommendations, if implemented, should also serve to end what has become an *ad hoc* prioritization of universally recommended childhood and adolescent vaccines taking place throughout the U.S. based on financial considerations, described in further detail below.¹³

II. Vaccine Financing Working Group (VFWG) process and methods

The charge from NVAC to the VFWG was to explore all options with regard to vaccine financing, and to propose potential solutions for NVAC’s consideration. Specifically, the VFWG was charged to obtain input from stakeholders on the challenges to creating optimal approaches to vaccine financing in both the public and private sectors, and the impact of these approaches on access to recommended vaccines; and to present findings and proposed recommendations to the full NVAC for discussion and voting. This process was unique in the breadth of stakeholder representation on the working group (see Appendix 4) and the several rounds of public comment that were undertaken to assure broad input. Concurrent with the VFWG process, the Adolescent Working Group developed a report and recommendations to improve vaccination of adolescents. Their draft report included vaccine financing recommendations, which were considered as part of the VFWG process.

To carry out its charge, the VFWG undertook a number of activities. First, it conducted a literature review of the current vaccine financing system in the United States and challenges to financing delivery of child and adolescent vaccines (see section VI). In addition, early deliberations of the VFWG suggested the need for more, systematically collected data on the nature and extent of the problem. Conclusions and recommendations in this Report are based in part on new data from studies initiated by the American Academy of Pediatrics (AAP) and the Centers for Disease Control and Prevention (CDC), detailing the cost to provide childhood and adolescent vaccination. The VFWG also invited input in the form of presentations from key stakeholders at working group meetings. Members of the VFWG participated in the February 2007 National Vaccine Congress co-sponsored by the American Medical Association (AMA), the Infectious Diseases Society of America (IDSA), and AAP to address these issues. Finally, at the request of the VFWG, National Vaccine Program Office (NVPO) and CDC staff conducted a series of open-ended interviews with each of the major vaccine manufacturers and, with the assistance of America’s Health Insurance Plans (AHIP), surveyed and interviewed a small convenience sample of health insurance plans selected

by AHIP. These interviews sought to determine each organization's understanding of the current state of vaccine financing and invited them to suggest possible solutions.

In addition, NVAC held a key stakeholders meeting in Rockville, MD on April 29 and 30, 2008. The goal of the meeting was to obtain stakeholder input and to discuss conclusions, possible solutions, and guidelines. Panels of representatives from each stakeholder group gave informational presentations and provided feedback on proposed conclusions and recommendations developed by the VFWG, including identifying preferred solutions to support child and adolescent vaccine delivery. This input, along with comments received after public review, was used to refine the information presented in this Report and, to the extent possible, to identify a consensus set of proposed solutions addressing the financial issues surrounding childhood and adolescent vaccination. The Report and recommendations were presented to NVAC at its September 16, 2008 meeting and were adopted by a unanimous vote of the Committee. These recommendations will be analyzed with regard to their fiscal impact, and this analysis will be presented at the February 2009 NVAC meeting. The recommendations will be formally presented to the Assistant Secretary for Health for endorsement and determination of implementation steps.

In its deliberations, the VFWG sought to fully explore and define a range of recommendations and their pros and cons. This Report summarizes those recommendations that were felt by the VFWG to best represent the group's consensus on effective solutions to vaccine financing difficulties, while also being acceptable to a diverse group of stakeholders. Every recommendation is accompanied by a list of pros and cons that reflects issues identified during deliberations of the VFWG. The recommendations put forward in this Report are unique in that they represent the consensus of a group of stakeholders that includes government health officials, providers, and consumers as well as vaccine manufacturers, health insurers and employer groups. Recommendations developed with the input of all stakeholders encourage cooperative action toward mutually agreed-upon goals and promote support of all stakeholders for these solutions to the vaccine financing problem.

III. Introduction: the promise of vaccines

Vaccines are unique public health tools. Because most vaccine-preventable diseases (VPD) are communicable diseases which are transmitted from person-to-person, a vaccinated child not only receives personal protection but also provides protection to other children and adults in society.¹⁻² The greater the proportion of people in a population who become immune to a communicable disease through vaccination, the less likely it is that sustained disease transmission can occur, a concept referred to as herd immunity. Children, adolescents, and adults who are not protected by vaccines (because they are too young or too old to be vaccinated, have compromised immune systems that prevent them from being vaccinated or blunt the immune response to vaccines, have medical contraindications to vaccination, or for other reasons) are still indirectly protected by vaccination because they are not exposed to infectious agents when there are high levels of vaccination coverage among children around them.³ Unvaccinated persons

are at risk of exposure, infection, and disease if vaccination coverage is not maintained at optimal levels.² Over the lifetime of each birth cohort in the United States, routine vaccination of children and adolescents prevent 14 million VPD cases and 33,000 VPD deaths (Table 1).⁴ Vaccines provide unique public benefits to persons who have not been vaccinated and warrant the most vigorous efforts by society to remove barriers to vaccination and to achieve the highest possible levels of coverage. Requirements that children be vaccinated to attend school are an example of how society recognizes the unique role of vaccination.

In the 20th century, vaccines have reduced morbidity and mortality from many vaccine-preventable diseases to record lows (Table 2). Vaccines for children recommended prior to 2000 are cost-saving: every dollar spent on vaccinating children saves more than \$5 in medical costs and more than \$11 in societal costs (e.g. lost productivity).⁴ In total, over the lifetime of each birth cohort in the United States, these vaccines save society \$43 billion including \$10 billion in direct medical costs (Table 1).⁴ The vaccines introduced for routine use in children and adolescents in 2000 and thereafter are cost-effective^a with respect to other routinely recommended preventive services, but unlike previously recommended vaccines, are not cost-saving (Table 3). Vaccination of children and adolescents can save employers money by reducing lost workdays of employees who miss work to care for their ill children.⁵ Providing recommended vaccines is also beneficial for health care purchasers, as each fully vaccinated child reduces the likelihood that any payer will later incur costs to treat that person for many vaccine-preventable diseases.

Because vaccines are effective and often cost-saving, vaccination is a top-ranked clinical preventive service in the U.S. In 2006, Partnership for Prevention rankings of 25 widely recommended clinical preventive services gave childhood vaccination a perfect score, based on clinically preventable disease burden and cost-effectiveness.⁷ Because vaccinations are so important and multiple vaccine doses are recommended, they serve to draw patients into health care provider offices, where they receive other recommended preventive services.⁸ Underimmunization is a marker for delay in recommended preventive services such as blood-lead and anemia screening, and promoting vaccination in the medical home may offer opportunities to increase uptake of these services as well.⁹ Despite the importance of vaccines, there is growing concern that parents may forgo vaccination of their children because the perceived risks of vaccines are greater than the perceived risks of the diseases they prevent; this is particularly true as attitudes toward risk change at the population level.¹⁰

Access to a stable supply of recommended vaccines from vaccine manufacturers is an important part of assuring high levels of vaccination coverage for children and adolescents. Although the estimated \$10 billion dollar global market for vaccines is only approximately 1.5 percent of total pharmaceutical revenues, the vaccine segment of the market is growing at a rapid rate.¹¹⁻¹⁴ This steady growth is partly due to the expanded

^a In cost-effectiveness analysis, all costs are related to a single common effect. Results are usually stated as additional cost expended per health outcome achieved. Average cost-effectiveness is the total cost of an intervention (e.g., vaccination) divided by the health outcomes produced by that intervention.⁶

use of vaccines worldwide, but also due to the higher prices of newer vaccines.¹¹ Wyeth's Prevnar®, introduced to the vaccine market in 2000, marked the first high-revenue generating vaccine: 2005 sales totaled \$1.5 billion, an increase of 43% over the previous year, and in October 2007 Prevnar® became the first vaccine to achieve \$2 billion in annual global sales.¹⁵⁻¹⁶ One year following FDA approval, sales of Merck's Gardasil® vaccine reached \$1.5 billion, accounting for more than one-third of Merck's \$4.3 billion in total vaccine sales in 2007.¹⁷ Sanofi-aventis, the parent company of vaccine manufacturer Sanofi Pasteur, expects to double its global vaccine sales to \$34 billion by 2016 and to continue investment in vaccine development.¹⁸ Strong growth in the vaccine industry is reflected in significant investments by vaccine manufacturers in manufacturing infrastructure, production, and creation of new and innovative approaches to vaccine development.¹⁹⁻²⁰

Other changes in the market include the growing number of combination vaccines being developed and licensed, and the rise of alternative vaccine delivery technologies. Substantial efforts are going into the development of new vaccines, some of which are in Phase II and III clinical trials and could be added to the routine immunization schedule for children and adolescents in the next ten years.²¹ To take advantage of these developments, a system is needed to finance both current and future vaccines so that children and adolescents can be protected from disease with minimal lag time following vaccine licensure and national recommendations for routine use.

Since 1999 there have been 8 new recommendations for routine vaccine use among children and adolescents in the U.S. Vaccines recommended include pneumococcal conjugate, varicella (second dose), rotavirus, meningococcal conjugate, hepatitis A, tetanus-diphtheria-acellular pertussis, human papillomavirus, and annual influenza vaccines. Some of these vaccines are the most expensive ever to go on the market. The cost at the federal contract price to fully vaccinate a child through age 18 years has risen from \$223 in 1995 to \$1,105 for males and \$1,407 for females in 2008, an increase of 396% and 531%, respectively (Figure 1, data adjusted to 2008 dollars). The cost of vaccine doses purchased in the private sector is likely to be higher. The cost of administering vaccines has also risen with the number of vaccines and vaccine doses that need to be managed, as well as new costs including those related to vaccine storage and management and to entering vaccination data into immunization information systems (IIS). These increased costs have raised concerns about the ability of the current public and private vaccine delivery systems to maintain access to all vaccines recommended for routine use in children and adolescents without financial barriers.

IV. The current system for financing vaccinations in the United States

Vaccine purchase

The current vaccine financing system in the United States is a mixed public and private sector effort, which funds the purchase and administration of recommended vaccines for children and adolescents. Currently, the public sector purchases vaccines for approximately 55% of the birth cohort through three major sources of public sector

funding: the Vaccines for Children (VFC) program, the Section 317 federal discretionary grant program to states (317 program), and state funds (Figure 2). VFC is an entitlement for children up to age 19 served by Medicaid, those without health insurance, and American Indians and Alaska Natives. In addition, children and adolescents who are underinsured^b can receive VFC vaccines only at sites designated as Federally Qualified Health Centers (FQHCs) or Rural Health Clinics (RHCs). The Advisory Committee on Immunization Practices (ACIP) votes to include a recommended vaccine in the VFC program, and federal financing is automatic once CDC negotiates a federal contract to purchase the vaccine. VFC providers receive shipments of vaccine for eligible patients at no cost. Each year, approximately 48% of the birth cohort is covered by the VFC program.

All states use the 317 program to cover non-VFC eligible children and adolescents – usually those who go to public health departments for vaccination – who may be underinsured or fully insured. In contrast to VFC, the 317 program is not an entitlement, but is dependent on annual discretionary appropriations determined by Congress. In recent years, these annual appropriations have not increased commensurate with the scope of new vaccine recommendations.²² The 317 program budget for vaccine purchase is currently 1/10th the size of VFC (Figure 3), and 317 funding has been shrinking over time relative to VFC funds for vaccine purchase: 35% of total federal funds for vaccine purchase in FY2000 came from the 317 program vs. only 10% in FY2007.

State funds have also been used to purchase vaccines for children and adolescents not eligible for VFC. A combination of state and 317 program funds has been used by a number of states to purchase all recommended vaccines for all children in the state including the privately insured (called “universal purchase” states); recently, the number of states that exercise this option has been decreasing due to increasing vaccine costs.²³ If current economic circumstances reduce state discretionary funds available for immunization programs, the implementation of universal vaccine purchase programs may continue to decline.

Private sector vaccine purchase accounts for about 45%-50% of the pediatric vaccines sold annually in the U.S. (Figure 2), a proportion that has remained relatively constant over the 14-year life of the VFC program (CDC unpublished data). The business model requiring office-based physicians and other clinicians to purchase a pharmaceutical product that is administered to almost every patient in specific age groups is essentially unique in medicine. Much more common is a model in which a provider writes a prescription and the patient fills the prescription at a pharmacy. With vaccines for children and adolescents served in the private sector, physicians and other clinicians typically negotiate vaccine price with vaccine distributors or manufacturers and negotiate

^b Underinsured children are defined as those children who are enrolled in and entitled to benefits under a health insurance plan, but for whom benefits are not available with respect to the cost of one or more vaccines. Children whose insurance covers only selected vaccines are categorized as underinsured with respect to the vaccines not covered, and are VFC-eligible for those non-covered vaccines only. Children whose insurance caps vaccine coverage at a certain amount – once that amount is reached – are also categorized as underinsured.

reimbursement for vaccination with health insurers, then bill insurers for reimbursement following administration of vaccine to a patient.

This up-front vaccine inventory purchase can be costly and, for many practices, has led to a need for more active management of their vaccine inventory. A reimbursement model in which vaccine distributors purchase vaccine on consignment from manufacturers, assuming up-front inventory costs on behalf of physicians, is being tested by some vaccine distributors. Alternative vaccine delivery venues such as pharmacies or retail clinics may utilize other business approaches, but data on vaccine administration in such venues are limited.

Vaccine administration

In addition to payment for the vaccine itself, physicians and other clinicians are reimbursed for the administration of vaccines to children and adolescents. In the public sector, reimbursement for vaccine administration is available only for VFC-eligible children enrolled in Medicaid, approximately 81% of VFC vaccine recipients in 2006 (Figure 4).²⁴ In the fee-for-service Medicaid program, vaccine administration reimbursement rates are set by state Medicaid agencies. The federal government will match state expenditures up to a federally established maximum vaccine administration rate (cap). The current vaccine administration reimbursement caps were set by the federal Centers for Medicare and Medicaid Services (CMS) in 1994 and have not been modified since then. Current state-specific vaccine administration reimbursements (state plus federal share) range from a low of \$2 in some states to almost \$18 per vaccination in others, with a median of \$9.45 per dose (Table 4). (By comparison, the average Medicare Part B reimbursement for influenza vaccine administration, unadjusted for geographic region, was \$19.33 in 2007.)²⁵ Most states do not contribute enough state funds to draw the maximum federal matching contribution allowable (based on the federal medical assistance percentages, or FMAPs^c) for vaccine administration (Table 4). In Medicaid managed care or other forms of non-fee-for-service payment, vaccine administration reimbursement is typically based on a similar negotiation process to that used in private health insurance plans (see below). Many children and adolescents vaccinated in public sector settings are under- or uninsured; privately insured children may also receive vaccines at public health departments.²⁶ However, there is no publicly-funded vaccine administration reimbursement available for these children in these settings.

In the private sector, reimbursement for vaccine administration is sought by physicians and other clinicians from commercial health insurers, if the family has health insurance, or from individual families (i.e. self-pay patients). As with reimbursement for vaccine purchase, providers and insurers negotiate mutually acceptable reimbursement terms for vaccine administration. Vaccine administration may be reimbursed by fee-for-service payments based on the AMA's Current Procedural Technology (CPT) billing codes or

^c The Federal Medical Assistance Percentages (FMAPs) are used in determining the amount of federal matching funds for state expenditures on assistance payments for certain social services, and state medical and medical insurance expenditures. The Social Security Act requires the Secretary of Health and Human Services to calculate and publish the FMAPs each year.

may be included in a standard office visit rate as it is for capitated insurance plans. CPT codes for vaccine administration cover a wide range of costs associated with vaccine delivery including counseling, scheduling, preparing the patient chart, billing, greeting the patient, taking vital signs, obtaining a vaccine history, presenting Vaccine Information Sheets, preparing and administering the vaccine, and observing for adverse events.²⁷ Reimbursements made based on Medicare's Resource-Based Relative Value Scale (RBRVS) also take into account provider labor, overhead and malpractice costs. Over 70% of private payers and 60% of Medicaid plans base their payments on the RBRVS system (J. Bradley, presentation at NVAC Meeting, 6/7/2007, Washington DC). The AMA has recently proposed adjustments to the Relative Value Units (RVUs) associated with vaccine administration in order to account for additional non-vaccine costs of vaccination: purchase of dedicated refrigerators and freezers with alarm systems, temperature and alarm monitoring and documentation, and entering data into immunization information systems. If approved by CMS, these changes will take effect in 2009 (J. Bradley, presentation at AHIP Vaccine Finance Roundtable, 7/15/2008, Arlington, VA).

Physicians and other clinicians providing vaccines during the course of a well-child visit can bill for a preventive service visit as well as for vaccine administration when submitting claims for reimbursement. Evaluation and management (E&M) preventive medicine codes do not include counseling for vaccines²⁸, which is included in vaccine administration codes. Clinicians can also bill for E&M office visit codes provided they have performed a separate, medically necessary service aside from vaccination.²⁹⁻³⁰ Over half (57%) of insurance plans do not reimburse for an office visit when routine vaccination is the only service provided;³¹ however, the majority of childhood vaccinations are provided during well-child visits. Maximum reimbursement can only be obtained when physicians include codes for both vaccines and vaccine administration when billing for vaccination-only visits²⁹, and submit E&M codes when appropriate.

V. Past reports on vaccine financing

Although recent vaccine recommendations have increased the perceived pressure on the vaccine financing and delivery system, concerns about vaccine financing are not new. In 1995, NVAC recognized lack of financing as a barrier to vaccination and recommended first-dollar insurance coverage for vaccination and increased enrollment of VFC providers to sustain high rates of childhood vaccination coverage.³² In 2004, the Institute of Medicine (IOM) released a report¹ commissioned by CDC to examine vaccine financing arrangements and propose strategies to relieve tensions in vaccine financing. IOM recommended a universal federal reimbursement system consisting of a federal mandate on public and private insurers to cover ACIP-recommended vaccines, which would be supplemented by federal vaccine subsidies for insurers and clinicians, and would include federal vouchers for uninsured children and adolescents to assure financing for recommended vaccines. Subsidies would be set through analyses of societal benefit.

Following the 2004 IOM report, NVAC formed a working group to examine the IOM's recommendations and held a stakeholders meeting in June 2004.³³ NVAC endorsed many of the findings in the IOM report, but suggested different action steps due to concerns about the feasibility of implementing universal federal reimbursement. These steps included expansion of the 317 program and VFC funding, promotion of first-dollar health insurance coverage for vaccinations (in which deductibles or co-pays do not apply to vaccination), and adequate reimbursement for vaccine administration.³³ Section 317 program funds for vaccine purchase have increased by 20% since 2004, compared to an increase of more than 170% in VFC allocations. Therefore, 317 program funding covers a smaller proportion of the birth cohort in 2008 than in 2004 due to the rising cost of the full recommended immunization schedule for children and adolescents.³⁴ Other recommendations from the 2004 NVAC working group remain largely unimplemented. As new and more expensive vaccines continue to be licensed and recommended for routine use, the financing stresses identified in 2004 are compounding.

In February 2007, the AMA, AAP and IDSA co-sponsored a National Vaccine Congress to begin to address the financial stresses of vaccination. This Congress convened a broad spectrum of stakeholders including physicians, public health personnel, government officials, insurers and employers, and vaccine manufacturers. Meeting participants developed consensus statements about the nature of difficulties in financing vaccination and the principles that should guide solutions to the problem; they also proposed potential solutions to continue supporting the vaccine delivery system.³⁵ The outcome of this meeting provided the groundwork for the VFWG to consider comprehensive solutions for child and adolescent vaccine financing that incorporate deliberations and input reflecting a variety of stakeholder perspectives.

VI. Literature review: the challenges facing child and adolescent vaccination

The major factor leading to stress in financing childhood and adolescent vaccinations is the dramatic increase in the cost to fully vaccinate a child or adolescent as a result of multiple new vaccines recommended for routine use by the ACIP since 2000. Added to this are expansions of existing ACIP recommendations for vaccines such as varicella, influenza, and acellular pertussis. The increased number of vaccines recommended for universal use means that the number of vaccine doses administered to a child by the second birthday increased from a maximum of 15 in 1998 to a maximum of 26 in 2008. By age 18, a child born in 2008 is recommended to receive as many as 48 vaccine doses, compared to just 19 for a child born in 1998 (Table 5).

In addition to greater numbers of recommended vaccines, the cost to purchase vaccines has risen over the past decade.³⁴ Vaccine costs at the federal contract price to fully vaccinate a child through age 18 years have risen from \$223 in 1995 to \$1,105 for males and \$1,407 for females in 2008 (Figure 1, adjusted to 2008 dollars). Newly recommended vaccines are more expensive than vaccines recommended prior to 1995.³⁶ This increased cost is due in part to the complexity of manufacturing techniques for newer vaccines, the cost and complexity of conducting increasingly larger clinical trials to more fully characterize vaccine safety and efficacy, and the cost of remaining in compliance with

regulatory requirements for licensure and continued manufacturing.¹ Increased vaccine costs may also be partly due to the small number of manufacturers producing vaccines for the U.S. market, especially in the case of vaccines produced by only one company and therefore having limited price competition.

Non-vaccine costs associated with child and adolescent vaccination (i.e., the costs of vaccine administration) have also increased with the increase in number and expense of recommended vaccines. These costs may include increased storage needs, need to purchase insurance policies against product loss, increased time required for IIS data entry, additional staff time to manage vaccine inventory, and increased vaccine counseling time. Some reimbursement systems may not have been adjusted to account for these increases or for inflation, with the result that reimbursement for vaccine administration may not cover all these costs.³⁷ The American Academy of Pediatrics recently estimated that provider costs to acquire vaccines may be 17-28% above the price of the vaccine itself.³⁷

The number of vaccine doses required to fully vaccinate children has in some cases been reduced by using combination vaccines. In addition to reducing the number of injections that a child receives, combination vaccines may save providers money by reducing inventory needs, administration costs, wastage, and staff time.³⁸ On the other hand, use of combination vaccines may increase costs if additional inventory and recordkeeping are required, or if the reimbursement for a combination vaccine is less than reimbursement would be for each of the component vaccines if administered separately.³⁸ Vaccine providers must continue to address questions and issues regarding each of the diseases prevented by these vaccines and counsel parents for each vaccine component individually. Therefore, an administration reimbursement for a combination vaccine that is equivalent to that for administering a single-antigen vaccine is unlikely to fully cover counseling costs. The AMA is currently working to develop CPT billing codes for administration of combination vaccines that account for both increases in physician labor and reduced practice expenses associated with the use of combination vaccines (see J. Bradley 6/7/2007, *supra*).

Private sector providers, who vaccinate the majority of children and adolescents (Figure 5), have expressed increasing concern that insufficient reimbursement rates for vaccination of children and adolescents are a disincentive to participate in vaccination programs or to implement new vaccines.³⁹⁻⁴⁰ These concerns relate to reimbursement from public as well as private insurance, since provider offices are the usual source of primary care for a majority of low-income and uninsured children⁴¹ and over 70% of VFC sites are private providers.⁴² Unlike other preventive services, vaccines require upfront investment of capital to purchase and maintain an adequate inventory. Once used to purchase vaccine, this money is unavailable for other needs of the medical practice (opportunity cost). If payment for vaccine is due before insurance reimbursement for vaccines administered is received, cash-flow problems may result. In addition, the expanded schedule of recommended vaccines for children and adolescents requires substantial additional staff time to carry out routine vaccination-related activities⁴³, decreasing labor available to perform other duties. The increased number of vaccine

doses required for children and adolescents has the potential to decrease provider revenue, as small marginal gains or even losses on each vaccine dose will not cover the additional costs of ordering, storing, and labor to administer more vaccines. A 2001 study showed that average provider reimbursement for vaccine administration covered variable but not fixed costs of vaccination, and that the margin earned by providers for vaccine administration had decreased noticeably since 1997.⁴⁴

State and local health departments responsible for implementing population-wide vaccination programs cannot always finance new vaccines in a uniform manner for all children and adolescents in their jurisdiction. A number of states have had to scale back programs providing vaccines to exclude certain classes of children based on their insurance status.^{23, 45-47} This scaling back is likely to continue if state budgets are reduced in reaction to the current economic climate.

Additionally, trends in the types of plans offered to and selected by persons with employer-based health insurance may affect access to vaccination. It is estimated that 11%-13% of young children^{24, 49} and 21% of adolescents (NIS 2006, unpublished) are underinsured for vaccines, meaning that they have health insurance that does not include any coverage for one or more vaccines. Children and adults covered by self-insured health plans, which cover about one-third of the privately employed, are more likely to be underinsured for vaccines.⁵⁰ National data from 2007 estimated that 17.5% of adults under age 65 were enrolled in high-deductible health plans (HDHPs), defined in the survey as deductibles of at least \$2,200 for a family.⁵¹ Adults in HDHPs were significantly more likely than those in plans with lower deductibles to spend over 10% of their income on family insurance premiums and out of pocket expenses (43%) and to report outstanding medical debt or problems paying medical bills (41%).⁵² Although it is not required, it has been estimated that over 80% of HDHPs linked with health savings accounts (HSA) provide first-dollar coverage for preventive services including vaccinations.⁵³⁻⁵⁴

Vaccinating the adolescent population presents additional challenges because physicians and other clinicians serving the pediatric population may not have the same access to teenagers as to younger children. In addition, adolescents may not have the same levels of vaccination benefits in their health insurance plans as young children, and teens – especially older teens – do not make regular visits to primary care doctors.⁴⁸ This suggests that financing solutions for adolescents seeking vaccines in alternative locations, such as schools, may be needed.

Finally, financial pressures may increase because of new vaccine recommendations anticipated in the coming years. Annual influenza vaccination of all children and adolescents was recently recommended by ACIP; other vaccines are in the development pipeline.

Despite building pressure on the current vaccination financing system, the consequences of these challenges may not yet be readily visible in the form of reduced vaccination coverage. Vaccination rates are high (>80%) for most child and adolescent vaccines

recommended for routine use prior to 2000; coverage for vaccines recommended since is suboptimal.⁵⁵⁻⁵⁶ Low rates of most vaccine-preventable diseases remove the visible reminders to parents, physicians, and policymakers of the importance of vaccines. Diseases preventable by recently recommended vaccines are either relatively rare (e.g. meningococcal disease), are not recognized as problems by the public (e.g. rotavirus), or cause delayed morbidity that obscures the impact of vaccination (e.g. human papillomavirus).⁵⁷ There is concern that given current trends, vaccination rates will be compromised for newly-recommended and future vaccines and vaccine uptake will be delayed. In addition, if financial barriers cause medical providers to stop offering vaccines, even vaccination rates for older child and adolescent vaccines could fall, resulting in disease outbreaks.² In early 2008, suboptimal vaccination coverage among children in San Diego led to a rapidly spreading outbreak of measles, despite the fact that endemic measles has been eliminated from the United States.⁵⁸

In the past, financial barriers to vaccination resulted in lower vaccination coverage. It is known that patient cost-sharing in the form of deductibles and co-pays reduces the use of recommended preventive services generally.⁵⁹⁻⁶⁰ Correspondingly, it is not surprising that higher out of pocket costs are associated with a lower likelihood of being up-to-date for recommended vaccines.⁶¹ Interruptions in public or private insurance coverage are also associated with reduced likelihood of being up-to-date on vaccinations.⁶² Taking steps to address these known barriers to child and adolescent vaccination has resulted in increased vaccination coverage. State vaccine purchasing policies that enhance the standard VFC program (i.e. universal purchase or enhanced VFC) have been shown to raise vaccination rates among the underinsured⁴⁹ and to increase access even to newer and more expensive vaccines for children without insurance.⁶³ Reducing out of pocket costs for vaccination also increases coverage with recommended vaccines.⁶⁴

To reduce underinsurance, many states have instituted state-based insurance mandates, which require health plans regulated by the state to make provision of recommended childhood and adolescent vaccines a covered service to varying degrees.⁶⁵ Insurance mandates can add to the cost of health insurance premiums;⁶⁶ premium increases vary by type of insurance plan and the baseline cost and utilization of the service covered.⁶⁷ Economic modeling studies estimate that 250,000-300,000 fewer U.S. workers are covered by employer-sponsored health insurance for every 1 percent increase in health care premium costs relative to inflation⁶⁸ or income.⁶⁹ This means that the effect of premium increases on employer-based insurance coverage depends upon the greater economy.⁷⁰ For example, from 1996-2000, the proportion of Americans under 65 with employer-based insurance increased, even though healthcare premiums also increased during this period. Conversely, from 2000-2006, increasing premiums and a weak economy resulted in a decrease in the proportion of Americans with employer-based health insurance.⁷¹ A study of hypothetical insurance benefits showed that 78% of parents would be willing pay a premium increase equivalent to 1-3% in order to guarantee insurance coverage for future vaccines for their children.⁵⁰

However, the potential for mandates to increase vaccination coverage is limited because these mandates do not apply to the approximately 50% of U.S. health insurance plans that

are self-insured, and therefore exempt from state regulation. In addition, vaccination coverage mandates in the states are not comprehensive with respect to covering ACIP recommended vaccines for all children under 18 without cost-sharing.⁶⁵ An unpublished analysis by America's Health Insurance Plans showed that states without insurance mandates had similar childhood vaccination coverage rates (within 1-3%) to states with mandates, and that coverage was most closely correlated with education levels and physician-to-population ratios in the states studied.⁷²

Although some strategies undertaken in the past have resulted in improvements in coverage rates for childhood and adolescent vaccines, the increasing cost and number of recommended vaccines has limited the ability of public and private payers to provide access to recommended vaccines to children and adolescents without financial barriers. In light of the current situation, this review of the literature strongly suggests that new strategies and efforts will be required.

VII. Stakeholder perspectives

Successfully addressing the increasing costs of child and adolescent vaccination will require determining the value of vaccines from the perspective of many different stakeholders.⁷³ Five key stakeholder groups have been identified whose perspectives are reflected in this Report: health insurers, employers and other health care purchasers; vaccine manufacturers; physicians and other clinicians; consumers (parents); and state and local governments including state immunization programs, state Medicaid directors, and state legislators and governors.

A. Health insurers, employers, and other purchasers

It is the goal of private health insurance plans, employers, and other purchasers of health care to ensure that all Americans have access to affordable health care and preventive services including vaccination. Public and private health insurance plans look for effective ways to reduce the costs associated with providing health care while continuing to provide multiple options in benefit design packages to their members.

Most health benefits purchasers and insurance plans provide coverage for the standard of care for children and adolescents, including all vaccines recommended by ACIP and the AAP.^{31, 74} In a 2005 survey, 92% of insurance plans reported following ACIP recommendations to determine covered vaccines, 16% of plans conduct cost-effectiveness analysis for new vaccines, and 40% also use other criteria (e.g. state mandates, FDA approval, or physician feedback).³¹ Of the plans that followed ACIP recommendations, the majority (60%) could act on the recommendations within 3 months; 13% could act in less than 1 month.³¹

The U.S. Chamber of Commerce, National Business Group on Health (NBGH), and AHIP, who were represented on the VFWG, strongly oppose insurance mandates. These

mandates, whether applying to plans regulated by ERISA^d or by the states, reduce the ability of employers to develop benefit designs appropriate for their work force.⁷⁵ Furthermore, mandates have not been shown to increase childhood vaccination rates⁷², possibly due to the inherent weaknesses in state-based insurance mandates noted above in Section VI. The effect of federal mandates on vaccination rates cannot be studied as no such mandates exist.

B. Vaccine manufacturers

All routinely recommended vaccines are produced in the private sector by a small number of manufacturers.⁷⁶ Vaccine manufacturers have traditionally been concerned that a universal vaccine purchaser (i.e., the federal government) would drive down vaccine prices, thereby reducing returns on investment and subsequent outlays for research and development of new vaccines. Maintenance of a robust private market for vaccines including the ability to set vaccine prices is a priority for vaccine manufacturers, as they are part of publicly traded pharmaceutical companies with expectations of profit. Furthermore, a robust vaccine industry that supplies current vaccines and invests in new vaccines depends on appropriate profit, as investment capital is available only for vaccines that will provide an appropriate return on this investment.⁷⁷ Incentives for manufacturers may be made by means other than increasing prices: for example, by providing tax relief for new or renovated facilities. Profit margins for vaccines are often lower than for other pharmaceutical products;⁷⁸ however, for newer vaccines, significantly greater profitability exists. In fact, manufacturers perceive vaccines as a “growth industry”.⁷⁹

Manufacturers evaluate market research and the policy environment in deciding which vaccine candidates to develop for licensure and marketing. Manufacturers are not required to solicit government guidance on which vaccines they will attempt to develop, although such guidance would be of interest because it affects the potential market for new vaccines through the federally-funded VFC program.

Globally, private U.S.- and European Union-based manufacturers have spearheaded development and production of most new vaccines in use. In the United States, vaccine research often involves collaboration between government, academia and industry.^{36, 80} Much of upstream vaccine discovery is performed in government, biotechnology and academic settings, and funded by the NIH, although industry also plays a role.⁸¹ The majority of the biotechnology firms that perform initial research and development for new vaccines are located in the United States. (M. Coleman, personal communication, 2/28/2008). In addition, about two-thirds of the vaccines licensed worldwide in the past 25 years were created in the United States (C. Colwell, presentation at NVAC Vaccine Financing Stakeholders Meeting, 4/30/2008, Rockville, MD). Promising vaccine candidates are further developed, produced and distributed by vaccine manufacturers,

^d ERISA is the Employee Retirement Income Security Act of 1974, which provides in part that self-insured employers are exempt from insurance regulation by state governments. A self-insured employer is one who pays health insurance claims and administration costs for employees directly using company funds, rather than contracting with an insurance plan to purchase health insurance coverage for its employees.

who have the fiscal resources to construct large manufacturing plants and to conduct the large clinical trials needed to demonstrate vaccine safety and efficacy.³⁶ Smaller companies have in some cases supported clinical trials and built vaccine manufacturing plants, but with significantly greater difficulty and financial risk. Once a vaccine has been licensed and produced, manufacturers may distribute the vaccine themselves, through a vaccine distributor, or both, depending on the manufacturer and the vaccine.

C. Physicians and other clinicians

Physicians and other clinicians serving children and adolescents try to balance providing needed care including vaccines to their patients, while earning enough profit to keep their practices in business. As noted above in Section IV, many providers encounter two different overarching financing models for procuring vaccines: a private sector model, with vaccine purchase first and reimbursement later, and a public sector model, in which vaccine is provided up front and replaced as needed. Since most vaccines purchased with both public and private funds are delivered by private providers (Figure 5), inequities in care may occur in provider offices if the private sector is able to cover new vaccines earlier than the public sector (or vice versa). Both public and private providers may face ethical dilemmas in which they must decide whether to delay implementation of a new vaccine until they are able to provide it to all of their patients, regardless of type of insurance.

Underinsured children present additional challenges. Some state vaccine financing models do not allow underinsured children to receive publicly purchased vaccines in private provider offices, which often results in referral to public health department clinics for vaccination. Referrals for vaccination outside the medical home lead to missed opportunities to vaccinate and lower vaccination rates.⁸²⁻⁸³ One success of the VFC program has been increasing the proportion of children vaccinated in the medical home by reducing referrals for vaccination outside the provider office.^{8, 84-85} In fact, VFC-eligible children vaccinated in the medical home have vaccination coverage equivalent to that of privately insured children.⁸⁶

Physicians and other clinicians also deal with multiple different systems for reimbursement of vaccine administration costs. In general, private health insurance plans pay vaccine administration fees that are higher than the average Medicaid vaccine administration fee for VFC.⁴⁴

D. Consumers and parents

Consumers, most often the parents of children and adolescents needing vaccination, must balance the desire to protect their children against disease with personal financial constraints that may be related to their children's insurance coverage or lack thereof. Parental demand for vaccines is related to provider recommendations for vaccination.⁸⁷⁻⁸⁸ Therefore, it is important that both healthcare providers and their patients understand how vaccines and vaccine administration costs will be reimbursed by private or public insurance.

For children and adolescents covered by commercial private insurance, parents have two primary worries related to financing of vaccinations when they go to the doctor. First, is the vaccination included in their health insurance benefits? As noted above, underinsurance for vaccines affects more than 1 in 10 children, and 1 in 5 adolescents. Second, what are the costs associated with vaccination that insurance will not pay for? These might include co-pays for office visits or vaccinations, co-insurance for expensive vaccines that are not completely covered by the insurer, or the need to meet a significant deductible before insurance coverage is available. Studies show that cost-sharing, particularly co-insurance and deductibles, reduces the use of preventive services.⁵⁹⁻⁶⁰ As vaccines become more expensive, parents of privately insured children whose insurance plans do not fully cover vaccines may either have to forgo recommended vaccinations or pay the entire cost out of pocket.⁸⁹

Parents whose children have public health insurance or who are without health insurance coverage for vaccinations can usually access VFC program vaccine. There are no charges to consumers for VFC vaccines, which are provided to physicians and other clinicians free of charge. Providers are permitted to seek payment for vaccine administration from VFC patients who are not Medicaid-enrolled; however, they cannot legally withhold VFC vaccine due to a patient's inability to pay an administration fee. This is a potentially difficult position in which to place parents and providers. If parents of VFC-eligible children do not understand this distinction, they may believe that their provider is intentionally or unintentionally ignoring VFC rules, or may forgo vaccination due to the provider's request for payment.

E. State and local government

Many actors at the state level influence vaccination reimbursement policies in each of the fifty states. Governors and state legislators establish state laws and budgets, including state Medicaid funding, the level of which is likely to be affected in every state by the current economic situation. State Medicaid directors are responsible for developing state Medicaid reimbursement policies within CMS rules. State Medicaid budgets must be used to cover an increasing number of services, so using state funds to increase vaccine administration fees may be difficult. In addition, the Medicaid program and the VFC program in most states are administered by two different departments, so state Medicaid agencies may have different priorities than those of VFC administrators for Medicaid funds. Immunization programs within state and local health departments have had to make financing-based decisions about which recommended vaccines to implement for underinsured and, in universal purchase states, fully-insured children.^{23, 46-47} Finally, Section 317 operations funding, which pays for non-vaccine costs of state immunization programs, has not increased to the same degree that the number of vaccine doses needing to be administered has increased.^{34, 90}

Underinsurance is the largest financing gap in the childhood vaccination program, a gap that has a dual root cause: in the private sector, some purchasers choose commercial health plans that do not cover all recommended vaccines,⁷⁴ while in the public sector, the

VFC safety net is assigned to FQHCs and RHCs rather than to health department clinics, the traditional healthcare safety net provider. FQHCs and RHCs have limited capacity and geographic reach: fewer than 10% of VFC providers are FQHCs or RHCs. In addition, as noted above, no administration fee is provided by VFC for underinsured children, so these sites have little incentive to conduct outreach to the underinsured.

Many states attempt to address the underinsured gap with a combination of Section 317 funding and state funding. However, discretionary funding is subject to the annual appropriations process and has not kept pace with purchasing needs for new vaccines.³⁴ This has led to two-tiered^e vaccine financing systems in many states. The ultimate effect of two-tiered systems is prioritization of vaccines based not on the benefits of vaccination, but on insurance status.⁴⁵ Children eligible for VFC in any setting and privately insured children with full coverage for vaccines are vaccinated as soon as their insurance coverage takes effect. Vaccination of underinsured children is *de facto* a lower priority, as these children are not vaccinated unless they visit certain types of clinics or unless there is adequate 317 and state discretionary funding to purchase vaccines for this population. As the cost of the recommended vaccine series rises, the difficulty in securing enough funds to purchase vaccines for all children increases.

This *de facto* prioritization varies by state; ergo, child and adolescent vaccination recommendations are not being implemented uniformly across the country.^{23, 45} However, there is reluctance in all states to continue implementing two-tiered vaccination systems that are not inclusive of all children and adolescents. In some states, implementation of a newly recommended vaccine is delayed until the state is able to finance vaccines for underinsured children. Other states may choose not to provide a newly recommended vaccine to underinsured children in the public sector safety net at all.²³ Both of these situations result in an ethical tension in which some children do not receive timely benefits from new vaccines.

In an attempt to avoid these tensions and provide equitable care, states have explored a variety of solutions to the problem of two-tiered vaccination financing. Some health departments can bill insurers for vaccines given at health departments to privately insured children.⁹¹ This saves 317 discretionary funds that can then be used to provide additional vaccines to the under- or uninsured.⁹² Still other states are exploring using state discretionary funds to implement universal purchase programs to replace two-tiered systems and to support physicians and other clinicians by implementing a vaccine replacement system for all children, including the privately insured.

VIII. Results of unpublished studies

Manufacturer and insurer studies

^e “Two-tiered” indicates a state vaccine financing system under which the set of publicly purchased vaccines provided to underinsured children is not the same as the set provided to other VFC-eligible children.²³

In late 2006, a series of key informant interviews relating to vaccine financing was conducted among all six manufacturers that provided pediatric vaccines in the United States. Results included three overarching themes, common to all respondents, identifying critical elements of any solution to vaccine financing problems: preservation of the current public-private sector system and avoiding erosion of the private market; assurance of an environment that keeps the vaccine field attractive to allow for innovation through research and development; and recognition that timeliness of new vaccine implementation can be improved by decreasing time to, and increasing the efficiency of, publication of ACIP recommendations and subsequent processes.

In 2007, a study was conducted among a convenience sample of 20 AHIP members; 15 (75%) responded. All participants answered a thirteen-item questionnaire and 10 completed a follow-up open-ended interview. The majority of insurers surveyed cover all recommended vaccines for children (80%) and adolescents (70%) in all insurance products and plans offered. The most important factors used to determine or adjust reimbursement rates were manufacturer's price for vaccines (80%) and physician feedback (53%). Frequency of review of reimbursement rates varied by plan from weekly to less than annually. Over half of respondents participating in the follow-up interview felt that vaccine financing was a barrier to childhood vaccination; most reasons cited related to the cost to physicians to provide vaccines. Suggested solutions included obtaining provider input on reimbursement, complying with AAP recommendations to increase reimbursement, not using the AMA relative value unit (RVU) system as a basis for payment, and instituting universal vaccine purchase by states or insurers.

Provider cost and reimbursement studies

The data in this section refer to currently unpublished studies of vaccination in pediatric medical practices, many of which were conducted at the request of CDC and AAP to inform the conclusions and recommendations presented in this Report. The results of these studies are currently being prepared for release in the peer-reviewed literature.

Costs to purchase vaccine in pediatric medical practices are highly variable. Some practices report paying less than the federal contract price for vaccines; some report paying much more. Estimates of the cost to administer vaccines to children or adolescents ranged from \$20-\$40 and differed depending on the methodology used to calculate provider costs as well as higher practice overhead in some states.

Reimbursements received for vaccine purchase and vaccine administration are also variable: some providers are reimbursed above, and some below, their product costs. Some vaccine products seem to be at least minimally reimbursed above costs for most practices; however, for newer vaccines like varicella and rotavirus, 10-20% of practices in one study were losing money on every dose purchased. For vaccine administration, physicians report a range of fee reimbursements, with an average reimbursement of \$14-\$17 per dose. In general, small practices pay more and are reimbursed less for vaccines, while practices in purchasing cooperatives pay less for vaccines and may also negotiate more favorable reimbursement terms. As a result, physicians and other clinicians in smaller practices may not be able to cover vaccine purchase and vaccine administration

with available reimbursement, and may face marginal losses. Most physicians do not cover their vaccine administration costs unless they vaccinate a child with at least three doses of vaccine in the same visit.

Public insurers (i.e., Medicaid) pay only administration fees on the assumption that VFC vaccine is used to vaccinate. Administration fees vary from state to state. In Georgia, they average \$10 for the first dose, and \$8 for additional doses administered in the same visit. Therefore, medical practices serving a large number of publicly insured patients, who receive free vaccine purchased by the government, lose out on gains from reimbursements for vaccine products and are also paid vaccine administration reimbursements that are less than their labor and overhead costs to administer vaccines.

Newly recommended vaccines may increase pressure on vaccine providers. Physicians have delayed purchase of recently recommended vaccines due to financial concerns. In addition, non-routine costs of vaccination such as ordering and inventory management have increased in the past 5 years. A small proportion of physicians has seriously considered no longer providing any vaccines to children.

Tensions resulting from changing vaccination costs, variable reimbursements, and practice expenses demonstrate a need for action on the part of all stakeholders participating in the vaccine financing and delivery system. The following section will summarize conclusions based on existing research and outline recommendations to remove financial barriers to vaccine access for all children and adolescents.

IX. NVAC Conclusions and Recommendations

Organization of conclusions and recommendations:

- A. Context
- B. General conclusions related to vaccines and vaccine financing
- C. Conclusions related to specific challenges and gaps in financing vaccine purchase and vaccine administration in the public and private sectors
- D. Recommendations related to financing vaccine purchase and vaccine administration in the public and private sectors
 - i. Public sector vaccine purchase for underinsured children in public health department clinics
 - ii. Funding vaccine administration reimbursement for all VFC-eligible children and adolescents including those not enrolled in Medicaid
 - iii. Improving vaccine administration reimbursement for VFC-eligible children and adolescents enrolled in the Medicaid program
 - iv. Supporting delivery of vaccines in the medical home by improving business practices in private provider offices
 - v. Reducing underinsurance and financial barriers to vaccination of privately insured children and adolescents through implementation of voluntary quality standards for health insurance plans
 - vi. Activities of federal agencies and offices related to financing vaccines for children and adolescents
 - vii. Activities of state agencies and offices related to financing vaccines for children and adolescents
 - viii. Strategies to support child and adolescent vaccination in complementary venues

A. Context

In 2004, NVAC convened a working group to respond to the recommendations of the 2004 IOM report, “Financing Vaccines in the 21st Century”.¹ The working group interviewed representatives of vaccine manufacturers, federal government agencies, public health agencies, provider organizations, and health insurers, and convened a stakeholders meeting to discuss the IOM’s recommendations.³³ NVAC subsequently issued a set of recommendations for stabilizing the U.S. vaccine financing system that included expanding 317 funding for infrastructure, operations, and vaccine purchase; appropriating additional 317 funds when new vaccines are recommended for universal use; expanding VFC to cover underinsured children served in public health department clinics; promotion of first-dollar insurance coverage for immunizations; promotion of prompt insurance coverage and recalculated capitation rates following new vaccine recommendations; and assurance of adequate reimbursement for vaccine administration.³³ With the exception of modest increases in 317 program funds, the 2004 NVAC recommendations were not implemented. Several of these recommendations were revisited by the VFWG in the course of formulating the most recent NVAC recommendations, outlined below.

The conclusions and recommendations presented here are based on the deliberations of the NVAC Vaccine Financing Working Group, and reflect feedback received at the April 2008 Stakeholders Meeting, as well as input from a preliminary review of recommendations by the full NVAC following its June 2008 meeting. These recommendations also include financing solutions developed by the NVAC Adolescent Working Group, which, with the exception of one recommendation having to do with mandated insurance coverage, were integrated with those proposed by the VFWG in order to produce a single set of recommendations for consideration by NVAC. The goal of the document is to present recommendations that minimize or eliminate financial barriers to accessing all vaccines routinely recommended by ACIP for children and adolescents.

Pros and cons are presented with each recommendation, along with a notation on whether the recommendation would require authorizing federal legislation to be implemented. Recommendations have been directed to specific stakeholders defined in this report as: (1) federal, state, and local governments (2) employers, payers, and health insurers (3) vaccine manufacturers (4) health care providers and their organizations (5) vaccine distributors and purchasers (6) consumers or other stakeholders. The conclusions that formed the basis for these recommendations are listed prior to the recommendations.

In the process of developing this report, the Vaccine Finance Working Group recognized that any recommendations requiring additional state or federal funding may create demands on state or federal budgets that may compete with other worthy public goods. This Report does not attempt to prioritize the NVAC vaccine financing recommendations against these other public goods, but reflects the general position that vaccinations should receive a high priority in state and federal budgets for the reasons stated in the General Conclusions below. NVAC also recognizes that it would be difficult to achieve uniform national implementation of any recommendations that require legislative or budgetary action by each state and therefore generally favors actions at the federal level, when appropriate, to achieve its goals.

The following conclusions and recommendations were adopted by unanimous vote at the September 16, 2008 meeting of the National Vaccine Advisory Committee. The National Vaccine Program Office will complete a fiscal analysis of each of the adopted recommendations, and this analysis will be presented to NVAC at its February 2009 meeting. In addition, NVAC should evaluate the impact of its recommendations for financing child and adolescent vaccination by revisiting the recommendations one year following their formal adoption. To inform this evaluation, the Committee should monitor implementation of the recommendations by requesting periodic reports from the various stakeholder groups identified in the recommendations that detail the activities undertaken by these stakeholders to implement each recommendation, as appropriate.

B. General conclusions related to vaccines and vaccine financing

1. Vaccines recommended for routine use in children and adolescents in the U.S. have demonstrated high levels of efficacy and safety. Vaccinations are different from other preventive health services in that most vaccines provide not only protection to the individual but also to the community through herd immunity. The current system of vaccine financing and delivery in the United States has led to record high immunization coverage rates and record low levels of vaccine-preventable diseases for most vaccines incorporated into the immunization schedule prior to 2000.
2. The successes of the current vaccine delivery system in reducing vaccine-preventable diseases are the result of public and private sector collaboration. The key components of this collaboration are the public sector VFC and Medicaid programs funded by federal, state and local governments and operated by state health departments and Medicaid agencies; the public and private sector vaccine providers including pediatricians, family practitioners and other clinicians working in office-based practices and clinics; the private sector vaccine manufacturers who develop and produce vaccines; the public and private sector employers and insurers who pay for the costs of providing vaccinations; and parents who present their children for care and, in some cases, directly pay for their vaccines. The public sector infrastructure in many states would not be adequate to vaccinate all children and adolescents should significant numbers of private healthcare providers cease administering vaccines. Vaccinating children and adolescents in the medical home is associated with improved vaccination rates and other health benefits.
3. The current vaccination financing system is a mixed public and private sector effort. Implementing new vaccination recommendations for children and adolescents requires decisions and fiscal appropriations by federal, state, and local governments as well as decisions by multiple independent insurers and employers to provide reimbursement for vaccine and vaccine administration. For most private insurers, the decision to provide coverage for vaccinations is voluntary.
4. Vaccine-preventable diseases are not constrained by geographic boundaries. Policies addressing vaccine financing need to be comprehensive enough to cover all parts of the country to ensure that financing barriers do not lead to localized areas of low vaccination coverage. Areas with low vaccination rates could serve as reservoirs for vaccine-preventable infections that could be transmitted to non-immune people in other areas of the country. It is in the public's best interest to maintain high vaccination coverage against communicable diseases by assuring that children and adolescents in all states have access to ACIP-recommended vaccines without financial barriers.
5. The current system of vaccine financing and delivery may not assure access for all children and adolescents without financial barriers. Since 2000, eight ACIP recommendations for adding new vaccines or additional doses of previously recommended vaccines have been incorporated into the routine U.S. child and adolescent immunization schedules. Anecdotal data suggest the current delivery system is experiencing challenges in delivering more recently recommended vaccines. Whether the current system of vaccine financing can accommodate these newly added vaccines and future vaccine recommendations is uncertain. There is a need for more data to better

define the magnitude of the problem in public and private sector vaccination financing and delivery systems in the U.S.

6. Proposed solutions must address not only the vaccine financing problem in the near term, but should also anticipate that there will continue to be changes in the recommended immunization schedule for children and adolescents over the next decade or more. The vaccination financing system should be robust enough to accommodate additions to the schedule with minimal delay between adoption of new routine vaccination recommendations and the time at which children and adolescents can receive the vaccines. Proposed solutions should also acknowledge potential changes in the healthcare delivery system over the next ten or more years.

7. If reimbursements to healthcare providers are less than the costs of providing vaccination services to children and adolescents, this may serve as a financial disincentive to offer vaccination services to patients. There needs to be a better understanding of costs associated with efficient vaccination services, including the cost of vaccines, vaccine administration, and other non-vaccine costs of vaccination. This information would be important to individual providers, public and private insurers, and policy makers in determining appropriate reimbursements for vaccines and vaccine administration.

8. The problems that the Vaccine Financing Working Group has identified are multi-factorial; therefore the solutions will also have to be multi-factorial. It is likely that a series of solutions affecting multiple stakeholder groups will be needed to comprehensively address all facets of the problem, and all stakeholders will need to participate in implementing these solutions.

C. Conclusions related to specific challenges and gaps in financing vaccine purchase and vaccine administration in the public and private sectors

Public sector

9. While the VFC program has largely been successful in providing vaccines to the three groups of children and adolescents – Medicaid eligible, uninsured, and American Indian or Alaska Native – entitled to receive vaccines at any VFC-enrolled provider, underinsured children and adolescents continue to place financial stress on public financing of vaccines. Underinsured children and adolescents are entitled to VFC vaccine only at Federally Qualified Health Centers (FQHCs) and Rural Health Centers (RHCs), but many do not have convenient access to these settings. Most underinsured children are served at private provider offices or health departments, so their vaccinations must be paid for out-of-pocket by parents or provided free of charge by the vaccine provider. About 12% of young children are underinsured, and about 15% of these underinsured children are vaccinated at public health departments. Underinsured children and adolescents who seek vaccination at health departments can receive only those vaccines that the state has chosen to purchase for them using 317 or state funds. Due to limited

funds, many public health departments have recently instituted two-tiered systems under which underinsured children are not eligible to receive newer, more expensive vaccines.

10. State and Section 317 program funds have failed to keep pace with the number of newly recommended vaccines. This has led to two-tiered vaccination programs in some states, which could result in many underinsured children and adolescents not receiving these vaccines. Currently available data do not indicate lower coverage among underinsured children for older vaccines. However, vaccines recommended after 2004 are substantially more expensive than vaccines recommended prior to 2000 and thus present a greater financial burden to patients or providers if not reimbursed by insurance. Coverage data for these more recently recommended vaccines is not yet available. However, action should be taken to assure that adequate levels of coverage with these vaccines can be attained.

11. In some cases, privately insured children and adolescents may be vaccinated in the public sector with publicly purchased vaccines. Not all states and localities have mechanisms to bill private insurance for these vaccinations. Public providers without the ability to bill insurers may nevertheless provide 317 or state-purchased vaccine to privately insured children to ensure that no child in need of vaccination is turned away from a public clinic, placing further stress on limited public funds.

12. Recommendations for legislative changes to VFC carry some risk due to the potential for current provisions of VFC to be weakened in the legislative process. At the same time, there is a need to strengthen VFC to ensure that it can continue to provide access to vaccines for children and adolescents who might otherwise remain unvaccinated. The benefits of improving VFC must be weighed against the risks of opening the VFC legislation for amendment.

13. Reimbursement for administration of VFC vaccine is only available for VFC-eligible children and adolescents who are Medicaid-eligible. This is a barrier to immunizing the uninsured, the underinsured, and American Indian/Alaska Native children and adolescents served by VFC, for whom vaccine administration is not reimbursed. Although vaccine products are supplied free of charge to VFC providers, provider offices incur additional costs related to vaccine administration and overhead. By law, VFC providers cannot refuse to vaccinate VFC-eligible non-Medicaid children who are unable to pay an administration fee.

14. CMS set state-specific maximum rates (caps) for Medicaid reimbursement for vaccine administration in 1994. These reimbursement rates have not been updated since 1994, and do not reflect all the factors that contribute to the cost of providing child and adolescent vaccinations in 2008.

15. Vaccine administration reimbursement in fee-for-service Medicaid is inadequate to cover costs of providing vaccines in most states, varying from \$2 per dose to \$18 per dose (median \$9.45) in 2008. These reimbursements are far below the CMS-established cap in most states, and are less than Medicare Part B reimbursement for vaccine

administration. Based on study data collected in 2006-2007, Medicaid reimbursement is substantially lower than private insurance reimbursement. Studies in various states including Colorado and Georgia have also shown Medicaid reimbursement to be substantially below practice costs to administer vaccines.

Public and private sector

16. The American Medical Association-sponsored system of establishing billing codes is the basis of reimbursement for vaccine administration for the majority of public and private insurers. It is not clear that this system fully assure that the components of CPT codes for vaccine administration accurately reflect all of the expenses that medical providers incur in delivering vaccinations. In addition, the CPT coding system does not recognize the increased workload or the possible cost savings from the use of combination vaccines, nor does it provide incentives to use combination vaccines.

17. Public and private employers have a wide range of benefit plan designs to choose from, including those that cover the full cost of vaccinations so that beneficiaries do not have to pay out of pocket to receive covered vaccines. No standardized method of vaccination benefit coverage exists: which vaccines are covered at what levels of cost-sharing is determined at the level of individual benefit plans.

Private sector

18. Vaccines are unique among medications in that they are purchased prior to administration by providers rather than prescribed by providers and purchased by patients. Private providers face high opportunity costs due to the time lag between purchasing expensive new vaccines and subsequently administering and being reimbursed for the administration of those vaccines. As vaccines become more expensive, providers may be less willing to purchase vaccines under the assumption that they will be reimbursed at a later time.

19. About half of private providers in one unpublished study reported delaying purchase of new vaccines due to financial concerns. It is not clear if these concerns related to up front purchase costs, levels of reimbursement, or other financial issues.

20. Some providers have raised concerns about whether vaccine administration reimbursements for privately or publicly insured children and adolescents sufficiently cover provider costs to administer vaccines, while other providers believe that reimbursement is adequate. In one unpublished study, 11% of private providers reported they had seriously considered ceasing provision of all childhood vaccines because of their belief that vaccine purchase and administration reimbursements do not fully cover their costs. A loss of 11% of vaccination providers could have a significant impact on vaccine availability for children and adolescents, leading to increased referrals for vaccination outside the medical home and, consequently, lower vaccination coverage.

21 Variability in business practices related to vaccine purchasing and variability in insurance reimbursements among private providers likely indicates sub-optimal business practices in some provider offices. Improvements in business practices in these offices could lead to increased efficiency in vaccine administration.

22. Many private health plans report that they begin coverage for vaccinations following an ACIP vote which often takes place months before MMWR publication. However, other health plans do not cover ACIP-recommended vaccines until publication of official ACIP recommendations in the MMWR.

23. Insurance coverage for vaccines is positively associated with increased receipt of vaccines by children and adolescents. State insurance mandates requiring coverage of vaccination benefits are controversial in that there is no evidence that insurance mandates positively impact immunization rates. State mandates do not affect persons covered by ERISA-exempt (self-insured) plans and are usually general in nature rather than specifying coverage levels or reimbursement amounts. Insurers, employers, and healthcare purchasers are strongly opposed to insurance mandates.

(NB: The VFWG did not agree with the conclusion of the NVAC Adolescent Working Group that insurance mandates were an important strategy and should be recommended for ERISA-exempt insurance plans. NVAC's most recent recommendation related to insurance coverage was in favor of "promotion of 'first-dollar' insurance coverage for immunization..."³³).

24. Increases in insurance premiums can lead to decreases in the number of people with employer-based insurance when the larger economy is weak. The marginal increase in insurance premiums that would result from providing coverage for all ACIP recommended vaccines for children and adolescents is unknown and is likely to vary depending on type of insurance plan and current benefits. It is important to determine how benefits coverage for all routinely recommended vaccines for children and adolescents would impact insurance premiums.

D. Recommendations related to financing vaccine purchase and vaccine administration in the public and private sectors

i. Mechanism for public sector vaccine purchase for underinsured children and adolescents served in public health department clinics

Recommendation #1. The Vaccines for Children program (VFC) should be extended to include access to VFC eligible underinsured children and adolescents receiving immunizations in public health department clinics and thus not be limited to access only at Federally Qualified Health Centers and Rural Health Clinics.

(NB: In 2004, NVAC also recommended that such an expansion be considered and did support VFC coverage for underinsured children and adolescents in all public health departments.)

Pros: provides greater access to vaccines for underinsured children and adolescents; removes vaccine cost as a barrier for underinsured children and adolescents at non-FQHC/RHC sites; could reduce state reliance on limited Section 317 funds; would decrease the pressure to increase Section 317 appropriations each time a new vaccine is recommended; would not change market share as children and adolescents covered are generally those already covered by public sector financing for older vaccines; if pursued through legislation, would solve the problem in all 50 states.

Cons: if accomplished through modification of VFC legislation, risks other modifications that could weaken the VFC program; would not cover underinsured children and adolescents in private provider offices; may cause underinsured children and adolescents to leave their medical home to receive vaccines; if not pursued through legislation, would require individual efforts by each state and FQHC that may lead to inequitable solutions across states.

Directed to: (1) Federal Government – Congress

Requires authorizing legislation: Yes

ii. Funding vaccine administration reimbursement for all VFC-eligible children and adolescents including those not enrolled in the Medicaid program

Recommendation #2. VFC should be expanded to cover vaccine administration reimbursement for all VFC-eligible children and adolescents. (Currently the vaccine administration fee is not covered by VFC.) This should include children on Medicaid as this would provide for a single system and uniform vaccine administration fee. The vaccine administration reimbursement should be sufficient to cover the costs of vaccine administration (as referenced elsewhere in these recommendations).

Pros: would provide a uniform national system of reimbursement for vaccine administration and eliminate the current state-to-state variation in Medicaid administration fees; if the federal government used the Medicare influenza vaccine administration fee or other evidence-based method as a model, would provide reimbursement that covers provider costs in many circumstances; no need for state expenditures for vaccine administration; saves state Medicaid funds which could go to other services; provides incentive for providers to serve all VFC-eligible children and adolescents regardless of reason for eligibility including the uninsured and American Indians/Alaska Natives; covers vaccine administration for underinsured children who are VFC eligible; eliminates inequities in VFC program; automatically removes major financial barriers (i.e., paying for vaccine administration) to access to vaccines recommended by ACIP for inclusion in VFC based on an ACIP vote.

Cons: requires amending VFC legislation, which risks other modifications that could weaken the VFC program; increases the federal budget; requires states to develop administration fee reimbursement mechanisms.

Directed to: (1) Federal Government - Congress

Requires authorizing legislation: Yes

iii. Improving reimbursement for vaccine administration for VFC-eligible children and adolescents enrolled in the Medicaid program

(NB: Recommendation #2 and Recommendations #3-#5 are designed to accomplish similar goals with respect to improving vaccine administration reimbursement in VFC. NVAC voted to approve both sets of recommendations understanding that the latter would not be needed if legislation were passed to cover administration fees for all VFC-eligible children through VFC, as in Recommendation #2 above.)

Recommendation #3. The Centers for Disease Control and Prevention (CDC) and the Centers for Medicare and Medicaid Services (CMS) should annually update, publish, and disseminate actual Medicaid vaccine administration reimbursement rates by state.

Pros: would bring attention to the issue which might cause states to reevaluate the adequacy of their reimbursement rates; would provide information for state-by-state advocacy to increase state-specific Medicaid reimbursement rates; doesn't require federal legislative action.

Cons: publication of information does not directly achieve change; addresses only administration fees in Medicaid and not for other groups of VFC-eligible children and adolescents.

Directed to: (1) Federal Government – CDC and CMS

Requires authorizing legislation: No

Recommendation #4. CMS should update the maximum allowable Medicaid administration reimbursement amounts for each state and include all appropriate non-vaccine related costs as determined by current studies. These efforts should be coordinated with the American Medical Association's (AMA) review of Relative Value Unit (RVU) coding (Recommendation #6).

Pros: provides federal support for states currently at the cap to increase reimbursement if desired; updated caps may be more reflective of current costs than prior caps; attention to issue might cause states to reevaluate their reimbursement levels; doesn't require federal legislative action.

Cons: updating the caps does not assure reimbursement would increase to the cap level; state budgets are limited; addresses only administration fees in Medicaid and not for other groups of VFC-eligible children and adolescents.

Directed to: (1) Federal Government - CMS

Requires authorizing legislation: No

Recommendation #5. Increase the federal match (i.e. a larger federal proportion) for vaccine administration reimbursement in Medicaid to levels for other services of public health importance (e.g. family planning services).

Pros: requires only action and funding at the federal level.

Cons: requires federal legislation; only covers VFC children and adolescents in Medicaid and not other VFC eligible persons; sets precedent to increase Federal Medical Assistance Percentage (FMAP) rates for services other than vaccination.

Directed to: (1) Federal Government - Congress

Requires authorizing legislation: Yes

iv. Supporting delivery of vaccines in the medical home by improving business practices in private provider offices

Recommendation #6. AMA's RVS Update Committee (RUC) should review its RVU coding to ensure that it accurately reflects the non-vaccine costs of vaccination including the potential costs and savings from the use of combination vaccines.

Pros: the Resource-Based Relative Value Scale (RBRVS) is the basis of reimbursement for many public and private insurers, therefore this will help make insurance reimbursement commensurate with provider costs (these include: vaccine acquisition, storage, inventory management, data entry into immunization information systems, alarm systems, backup power systems, catastrophic loss insurance, and other costs); assures no duplication of reimbursement by clarifying components of E&M and vaccine administration codes; efforts by the AMA to update vaccine administration RVUs are already underway.

Cons: may impact how RVUs for other services are calculated.

Directed to: (4) Health Care Provider Organizations – AMA

Requires authorizing legislation: No

Recommendation #7. Vaccine manufacturers and third-party vaccine distributors should work with providers on an individual basis to reduce the financial burden for initial and ongoing vaccine inventories, particularly for new vaccines. This may include extending payment periods (e.g. from 60 days to 90 or over 120 days), or until vaccine has been administered and reimbursed. It may also include options not related to payment terms for vaccine inventory.

Pros: reduces up-front costs to providers; allows provider time to obtain income from reimbursements for vaccine administration before paying for product, alleviating cash-flow concerns; several manufacturers have already undertaken such efforts.

Cons: may create cash-flow difficulties for manufacturers and distributors who have organized business systems around collections on a 30- to 60-day cycle.

Directed to: (3) Vaccine Manufacturers
(5) Vaccine Distributors and Purchasers

Requires authorizing legislation: No

Recommendation #8. Professional medical organizations should provide their members with technical assistance on efficient business practices associated with providing immunizations, such as how to contract and bill appropriately. Medical organizations should identify best business practices to assure efficient and appropriate use of ACIP recommended vaccines and appropriate use of CPT codes, including Evaluation and Management (E&M) codes, when submitting claims for vaccines and vaccine administration. These organizations may receive federal assistance from CMS or other relevant agencies.

Pros: helps improve business practices among vaccine providers; helps increase marginal profit per dose for providers who may be paying above market averages for vaccine; multiple medical professional organizations have already undertaken this type of training.

Cons: none noted, although organizations must be sure not to give the appearance of collusion or violate antitrust laws by sharing proprietary information on contract terms or vaccine purchase prices.

Directed to: (4) Health Care Providers and Organizations

Requires authorizing legislation: No

Recommendation #9. Medical providers, particularly in smaller practices, should participate in pools of vaccine purchasers to obtain volume ordering discounts. This may be done by individual providers joining or forming purchasing collaboratives, or through a regional vaccine purchasing contract held by professional medical organizations on behalf of providers.

Pros: lower purchase prices make it more likely that insurance reimbursements will cover costs of and could increase the return on provider investments in vaccine purchase; could provide incentives to private practitioners to continue providing vaccines; may allow small providers to purchase newer, more expensive vaccines that would otherwise be unaffordable; would result in lower cash outlays to purchase initial vaccine inventories; AAP already developing a list of group purchasing organizations that accept pediatricians as participants.

Cons: may lower revenues for manufacturers and distributors for vaccine sales; organizations must be sure not to give the appearance of collusion or violate antitrust laws by sharing proprietary information on contract terms or vaccine purchase prices.

Directed to: (4) Health Care Providers and Organizations

Requires authorizing legislation: No

v. Reducing underinsurance and financial barriers to vaccination of privately insured children and adolescents through implementation of voluntary quality standards for health insurance plans

Recommendation #10. CDC, professional medical organizations, and other relevant stakeholders should develop and support additional employer health education efforts. These efforts should communicate the value of good preventive care including recommended vaccinations.

Pros: gives employers an understanding of the importance of vaccines; communicates cost-effectiveness of vaccines to employers; supports educational efforts already undertaken by employer groups.

Cons: will have impact only to the extent that employers change vaccination benefits purchasing based on this education.

Directed to:

- (1) Federal Government
- (2) Employers, Payers, and Health Insurers
- (4) Health Care Providers and Organizations

Requires authorizing legislation: No

Recommendation #11. Health insurers and all private healthcare purchasers should adopt contract benefit language that is flexible enough to permit coverage and reimbursement for new or recently altered ACIP recommendations as well as vaccine price changes that occur in the middle of a contract period.

Pros: likely to decrease the time from ACIP recommendations to insurance coverage for recommended vaccines.

Cons: requires insurer-by-insurer decision-making and may lead to non-uniform implementation.

Directed to:

- (1) Federal Government & State Governments
- (2) Employers, Payers, and Health Insurers
- (4) Health Care Providers and Organizations

Requires authorizing legislation: No

Recommendation #12. All public and private health insurance plans should voluntarily provide first-dollar coverage (i.e., no deductibles or co-pays) for all ACIP-recommended vaccines and their administration for children and adolescents.

Pros: could eliminate parent out-of-pocket costs that may serve as a barrier to obtaining vaccines for their children; could assure providers receive full reimbursement since it will not have to come from parent out-of-pocket funds; could eliminate underinsurance. The Adolescent Working Group recommended mandated first-dollar coverage for ERISA-exempt plans.

Cons: no guarantee of first-dollar coverage; first dollar coverage may decrease manufacturer incentives to reduce prices to gain a greater market share since parents would not have to directly cover any of the costs; first dollar coverage may increase the cost of insurance premiums, reducing the number of people who would opt to take the coverage, which could in turn increase the number of people on public coverage or increase the number of uninsured, leading to greater public program costs at the federal, state, and local levels.

NB: To the extent that this recommendation has support from any employer or healthcare purchaser group, that support is contingent upon the voluntary nature of the proposed recommendation. Employers and healthcare purchasers represented on the workgroup strongly and uniformly objected to mandates for insurance benefits or coverage levels. The VFWG did not accept the recommendation of the Adolescent Working Group that first-dollar coverage be required for ERISA-exempt plans.

Directed to: (2) Employers, Payers, and Health Insurers

Requires authorizing legislation: No

Recommendation #13. Insurers and healthcare purchasers should develop reimbursement policies for vaccinations that are based on methodologically sound cost studies of efficient practices. These cost studies should factor in all costs associated with vaccine administration (including, for example, purchase of the vaccine, handling, storage, labor, patient or parental education, and record keeping).

Pros: adjusts reimbursement to levels needed to cover actual provider costs with a margin of profit.

Cons: no means to assure compliance.

Directed to: (2) Employers, Payers, and Health Insurers

Requires authorizing legislation: No

vi. Activities of federal agencies and offices related to financing vaccines for children and adolescents

Recommendation #14. Congress should request an annual report on the CDC's professional judgment of the size and scope of the Section 317 program appropriation needed for vaccine purchase, vaccination infrastructure, and vaccine administration. Congress should ensure that Section 317 funding is provided at levels specified in CDC's annual report to Congress.

Pros: enforces an existing Institute of Medicine recommendation from the "Calling the Shots" report⁹³ that "CDC be required to notify Congress each year of the estimated cost impact of new vaccines that have been added to the immunization schedule so that these figures can be considered in reviewing the vaccine purchase and infrastructure budgets for the Section 317 program"; allows the program to provide realistic estimates of need not filtered through the traditional budget process, which weighs program needs in the context of overall executive branch priorities for limited resources and through which budget requests to Congress may not fully cover program needs.

Cons: none identified.

Directed to: (1) Federal Government – DHHS and Congress

Requires authorizing legislation: No

Recommendation #15. CDC and CMS should continue to collect and publish data on the costs and reimbursements associated with public and private vaccine administration according to NVAC standards for vaccinating children and adolescents.⁹⁴ These costs include costs associated with the delivery of vaccines, such as purchase of the vaccine, handling, storage, labor, patient or parental education, and record keeping. These published data should be updated every five years and also include information about reimbursement by provider type, geographic region, and insurance status. State governments should use this information in determining vaccine administration reimbursements rates in Medicaid.

Pros: improve stakeholders' understanding of costs to vaccinate.

Cons: none noted.

Directed to: (1) Federal Government – CDC and CMS

Requires authorizing legislation: No

Recommendation #16. NVPO should calculate the marginal increase in insurance premiums if insurance plans were to provide coverage for all routinely ACIP-recommended vaccines.

Pros: provides a context for the cost of insurance coverage for vaccines with respect to total insurance costs.

Cons: calculation methodology may not be generalizable to all types of insurance plans.

Directed to: (1) Federal Government – NVPO

Requires authorizing legislation: No

Recommendation #17. NVAC should convene one or more expert panels representing all impacted stakeholders to consider whether tax credits could be a tool to reduce or eliminate underinsurance. The panel would determine if policy options that would be acceptable to stakeholders could be developed to address the burden of financing for private sector child and adolescent vaccinations by using tax credits as incentives for insurers, employers, and/or employees (consumers), and whether these credits would provide added value to vaccination of children and adolescents.

Pros: explores other options.

Cons: difficult to gain acceptability of all stakeholders.

Directed to: (1) Federal Government – NVAC

Requires authorizing legislation: No

Recommendation #18: CDC should substantially decrease the time from creation to official publication of ACIP recommendations in order to expedite coverage decisions by payers to cover new vaccines and new indications for vaccines currently available.

Pros: faster adoption of coverage benefits supporting new vaccine recommendations by private insurers who wait for MMWR publication to begin coverage.

Cons: none noted.

Directed to: (1) Federal Government – CDC

Requires authorizing legislation: No

Recommendation #19: Congress should expand Section 317 funding to support the additional national, state and local public health infrastructure (e.g., widespread and effective education and promotion for healthcare providers, adolescents, and their parents; coordination of complementary and alternative venues for adolescent vaccinations; record keeping and immunization information systems; vaccine safety surveillance; disease surveillance) needed for adolescent vaccination programs as well as childhood vaccination programs for new recommendations such as universal influenza vaccination.

Pros: decreases need for state discretionary funding to support adolescent vaccination infrastructure; increases number of venues at which adolescents might be vaccinated; tailors vaccine delivery to healthcare usage patterns of adolescents, which are less concentrated around regular visits to a primary care provider.

Cons: Section 317 appropriations are discretionary and determined annually, therefore funding increases would not be permanent.

Directed to: (1) Federal Government – DHHS and Congress

Requires authorizing legislation: Yes

Recommendation #20: Continue federal funding for cost-benefit studies of vaccinations targeted for children and adolescents.

Pros: improve stakeholder understanding of costs and benefits related to new child and adolescent vaccines.

Cons: none noted.

Directed to: (1) Federal Government

Requires authorizing legislation: No

vii. Activities of state agencies and offices related to financing vaccines for children and adolescents

Recommendation #21. State, local and federal governments along with professional organizations should conduct outreach to physicians and non-physician providers who currently serve VFC-eligible children and adolescents to encourage these providers to participate in VFC if they currently do not. Outreach directed at providers serving adolescents who may not have provided vaccinations in the past (e.g. obstetrician-gynecologists) is a particular priority.

Pros: adds providers to VFC who serve children and adolescents eligible for free vaccines under VFC (e.g., obstetrician-gynecologists for adolescent females) and therefore fulfills the intent of the VFC entitlement.

Cons: none noted.

Directed to: (1) Federal, State, and Local Health Departments
(4) Health Care Providers

Requires authorizing legislation: No

Recommendation #22. States and localities should develop mechanisms for billing insured children and adolescents served in the public sector. CDC should provide support to states and localities by disseminating best practices and providing technical assistance to develop these billing mechanisms. (This may require additional resources not currently in CDC's immunization program budget.) Further, NVAC urges states and localities to reinvest reimbursements from public and private payers back into immunization programs.

Pros: conserves and reinvests funds for immunization; the Association of State and Territorial Health Officials (ASTHO) is already providing support for such systems.

Cons: may require state by state legislation; states and localities may prefer insurance reimbursements to go into state or local general funds to allow flexibility in their use.

Directed to: (1) State and Local Governments – State and Local Health Departments

Requires authorizing legislation: No

viii. Strategies to support child and adolescent vaccination in complementary venues

Recommendation #23: Ensure adequate funding to cover all costs (including those incurred by schools) arising from assuring compliance with child and adolescent immunization requirements for school attendance.

Pros: encourages compliance with mandates; protects schools from financial consequences of unimmunized students; provides societal support for societal benefit (herd immunity).

Cons: does not suggest specific sources of funds or provide action steps for specific stakeholders to pursue; limited state and school district budgets may complicate efforts to ensure funding; potential duplication of effort as many students will already have private insurance coverage for mandated vaccines.

Directed to: Unclear

Requires authorizing legislation: No

Recommendation #24: Promote shared public and private sector approaches to help fund school-based and other complementary-venue child and adolescent immunization efforts.

Pros: increases number of venues at which children and adolescents might be vaccinated; provides opportunities to reach children and adolescents who do not regularly encounter the traditional healthcare system; provides societal support for societal benefit (herd immunity).

Cons: does not suggest specific sources of funds or provide action steps for specific stakeholders to pursue; limited state and school-district budgets may complicate efforts to ensure funding.

Directed to: Unclear

Requires authorizing legislation: No

APPENDIX 1: Table of recommendations adopted by NVAC

NVAC RECOMMENDATIONS
<p>Recommendation #1. The Vaccines for Children program (VFC) should be extended to include access to VFC eligible underinsured children and adolescents receiving immunizations in public health department clinics and thus not be limited to access only at Federally Qualified Health Centers and Rural Health Clinics. <i>(NB: In 2004, NVAC also recommended that such an expansion be considered and did support VFC coverage for underinsured children and adolescents in all public health departments.)</i></p>
<p>Recommendation #2. VFC should be expanded to cover vaccine administration reimbursement for all VFC-eligible children and adolescents. (Currently the vaccine administration fee is not covered by VFC.) This should include children on Medicaid as this would provide for a single system and uniform vaccine administration fee. The vaccine administration reimbursement should be sufficient to cover the costs of vaccine administration (as referenced elsewhere in these recommendations).</p> <p><i>NB: Recommendation #2 and Recommendations #3-#5 are designed to accomplish similar goals with respect to improving vaccine administration reimbursement in VFC. NVAC voted to approve both sets of recommendations understanding that the latter would not be needed if legislation were passed to cover administration fees for all VFC-eligible children through VFC, as in Recommendation #2 above.</i></p>
<p>Recommendation #3. The Centers for Disease Control and Prevention (CDC) and the Centers for Medicare and Medicaid Services (CMS) should annually update, publish, and disseminate actual Medicaid vaccine administration reimbursement rates by state.</p>
<p>Recommendation #4. CMS should update the maximum allowable Medicaid administration reimbursement amounts for each state and include all appropriate non-vaccine related costs as determined by current studies. These efforts should be coordinated with the American Medical Association's (AMA) review of Relative Value Unit (RVU) coding (Recommendation #6).</p>
<p>Recommendation #5. Increase the federal match (i.e. a larger federal proportion) for vaccine administration reimbursement in Medicaid to levels for other services of public health importance (e.g. family planning services).</p>
<p>Recommendation #6. AMA's RVS Update Committee (RUC) should review its RVU coding to ensure that it accurately reflects the non-vaccine costs of vaccination including the potential costs and savings from the use of combination vaccines.</p>
<p>Recommendation #7. Vaccine manufacturers and third-party vaccine distributors should work with providers on an individual basis to reduce the financial burden for initial and</p>

ongoing vaccine inventories, particularly for new vaccines. This may include extending payment periods (e.g. from 60 days to 90 or over 120 days), or until vaccine has been administered and reimbursed. It may also include options not related to payment terms for vaccine inventory.

Recommendation #8. Professional medical organizations should provide their members with technical assistance on efficient business practices associated with providing immunizations, such as how to contract and bill appropriately. Medical organizations should identify best business practices to assure efficient and appropriate use of ACIP recommended vaccines and appropriate use of CPT codes, including Evaluation and Management (E&M) codes, when submitting claims for vaccines and vaccine administration. These organizations may receive federal assistance from CMS or other relevant agencies.

Recommendation #9. Medical providers, particularly in smaller practices, should participate in pools of vaccine purchasers to obtain volume ordering discounts. This may be done by individual providers joining or forming purchasing collaboratives, or through a regional vaccine purchasing contract held by professional medical organizations on behalf of providers.

Recommendation #10. CDC, professional medical organizations, and other relevant stakeholders should develop and support additional employer health education efforts. These efforts should communicate the value of good preventive care including recommended vaccinations.

Recommendation #11. Health insurers and all private healthcare purchasers should adopt contract benefit language that is flexible enough to permit coverage and reimbursement for new or recently altered ACIP recommendations as well as vaccine price changes that occur in the middle of a contract period.

Recommendation #12. All public and private health insurance plans should voluntarily provide first-dollar coverage (i.e., no deductibles or co-pays) for all ACIP-recommended vaccines and their administration for children and adolescents.

Recommendation #13. Insurers and healthcare purchasers should develop reimbursement policies for vaccinations that are based on methodologically sound cost studies of efficient practices. These cost studies should factor in all costs associated with vaccine administration (including, for example, purchase of the vaccine, handling, storage, labor, patient or parental education, and record keeping).

Recommendation #14. Congress should request an annual report on the CDC's professional judgment of the size and scope of the Section 317 program appropriation needed for vaccine purchase, vaccination infrastructure, and vaccine administration. Congress should ensure that Section 317 funding is provided at levels specified in CDC's annual report to Congress.

Recommendation #15. CDC and CMS should continue to collect and publish data on the

costs and reimbursements associated with public and private vaccine administration according to NVAC standards for vaccinating children and adolescents.⁹⁴ These costs include costs associated with the delivery of vaccines, such as purchase of the vaccine, handling, storage, labor, patient or parental education, and record keeping. These published data should be updated every five years and also include information about reimbursement by provider type, geographic region, and insurance status. State governments should use this information in determining vaccine administration reimbursements rates in Medicaid.

Recommendation #16. NVPO should calculate the marginal increase in insurance premiums if insurance plans were to provide coverage for all routinely ACIP-recommended vaccines.

Recommendation #17. NVAC should convene one or more expert panels representing all impacted stakeholders to consider whether tax credits could be a tool to reduce or eliminate underinsurance. The panel would determine if policy options that would be acceptable to stakeholders could be developed to address the burden of financing for private sector child and adolescent vaccinations by using tax credits as incentives for insurers, employers, and/or employees (consumers), and whether these credits would provide added value to vaccination of children and adolescents.

Recommendation #18: CDC should substantially decrease the time from creation to official publication of ACIP recommendations in order to expedite coverage decisions by payers to cover new vaccines and new indications for vaccines currently available.

Recommendation #19: Congress should expand Section 317 funding to support the additional national, state and local public health infrastructure (e.g., widespread and effective education and promotion for healthcare providers, adolescents, and their parents; coordination of complementary and alternative venues for adolescent vaccinations; record keeping and immunization information systems; vaccine safety surveillance; disease surveillance) needed for adolescent vaccination programs as well as childhood vaccination programs for new recommendations such as universal influenza vaccination.

Recommendation #20: Continue federal funding for cost-benefit studies of vaccinations targeted for children and adolescents.

Recommendation #21. State, local and federal governments along with professional organizations should conduct outreach to physicians and non-physician providers who currently serve VFC-eligible children and adolescents to encourage these providers to participate in VFC if they currently do not. Outreach directed at providers serving adolescents who may not have provided vaccinations in the past (e.g. obstetrician-gynecologists) is a particular priority.

Recommendation #22. States and localities should develop mechanisms for billing insured children and adolescents served in the public sector. CDC should provide support to states and localities by disseminating best practices and providing technical assistance to develop these billing mechanisms. (This may require additional resources not currently in CDC's

immunization program budget.) Further, NVAC urges states and localities to reinvest reimbursements from public and private payers back into immunization programs.

Recommendation #23: Ensure adequate funding to cover all costs (including those incurred by schools) arising from assuring compliance with child and adolescent immunization requirements for school attendance.

Recommendation #24: Promote shared public and private sector approaches to help fund school-based and other complementary-venue child and adolescent immunization efforts.

APPENDIX 2: Table of proposed recommendations not presented by the VFWG for NVAC consideration, with justifications

PROPOSED RECOMMENDATIONS NOT PRESENTED TO NVAC

A. NVAC recommends expansion of appropriations of federal Section 317 funds to cover vaccine administration reimbursement for VFC-eligible non-Medicaid children and adolescents and for states to establish vaccine administration reimbursement systems.

B. NVAC recommends that the Section 317 program appropriation language be amended to call for an increase in the appropriation amount each year at least equivalent to rates of increase in the VFC program.

Justification: In general, solutions relying on 317 funds require annual efforts to increase the amount of the appropriation. These recommendations would increase the scope of 317 at a time when it is not meeting its traditional obligations and so would be very unlikely to have any impact.

C. NVAC recommends expansion of Section 317 federal program funding to support vaccine purchase for all children and adolescents who traditionally have relied on Section 317 for their vaccines. This includes support to eliminate recently implemented two-tiered systems for new ACIP recommendations and support for vaccine purchase for underinsured children and adolescents in all states. Professional judgment from the CDC on the cost to provide this level of support is detailed in the 2008 “Report to Congress on the 317 Immunization Program.”

Justification: Because they require annual appropriations, 317-based solutions are not optimal for long-term programmatic fixes, which are the priority of the VFWG. However, the VFWG recognizes the importance of the 317 program in supporting state and local vaccination delivery systems, and has made two general recommendations to increase 317 funding as needed to continue this support (see #14 and #19, above).

D. NVAC recommends expansion of VFC to include underinsured children and adolescents in any setting.

E. NVAC recommends refining the Vaccines for Children (VFC) program so that all VFC-enrolled providers are allowed to use VFC vaccine to vaccinate adolescents who are underinsured for one or more of the recommended vaccines and who cannot otherwise afford to be vaccinated.

Justification: Expanding VFC to underinsured children and adolescents in any setting would threaten the private vaccine market and could cause employers and healthcare purchasers to reduce or drop vaccination benefits coverage.

F. NVAC recommends all states reimburse for vaccine administration at the CMS established maximum allowable reimbursement amount. NVAC recommends CMS work with the states to achieve this.

G. NVAC recommends states fund state Medicaid and State Children’s Health Insurance Plan

(SCHIP) managed care plans at a level that would provide vaccine administration reimbursement at the CMS established maximum allowable Medicaid reimbursement rate. CMS should work with states to achieve this.

H. NVAC recommends state and local governments use state and local funds to cover the provision of recommended vaccines to underinsured and non-VFC eligible children and adolescents served at public health department clinics and private medical setting.

Justification: There is concern that state-by-state solutions are unlikely to significantly contribute to ameliorating a national problem, and may lead to inequity among states. In addition, most state budgets are currently unable to assume additional financial burdens.

I. NVAC recommends that CMS set minimum required reimbursement levels for Medicaid vaccine administration.

Justification: In addition to creating an additional financial burden for many states, setting a minimum reimbursement may result in states with higher reimbursement rates choosing to reimburse at the minimum rate, resulting in a loss to providers.

J. NVAC recommends that the NVAC convene one or more expert panels representing all impacted stakeholders to determine if policy options could be developed that would be acceptable to stakeholders to address the burden of financing for private sector childhood vaccinations for (1) some form of insurance mandates for first-dollar coverage of recommended vaccines and their administration and (2) some form of universal federal vaccine purchase or universal federal reimbursement for vaccines and vaccine administration.

K. NVAC recommends that Congress develop and implement national legislation to mandate first-dollar insurance coverage of ACIP-recommended vaccines (and associated vaccination costs) for children and adolescents in all health plans exempted from state mandates by ERISA and in all health plans serving federal employees.

Justification: These ideas were judged to be currently beyond the reach of a consensus agreement.

APPENDIX 3: Tables and figures

Table 1: Health and Economic Outcomes for Selected Vaccine Preventable Diseases With and Without a Vaccination Program⁴

	Without Vaccination Program				Prevented or Saved by Vaccination Program			
	No. Of Cases	No. of Deaths	Direct Costs (millions , \$)	Total Costs (millions, \$)	No. Of Cases	No. of Deaths	Direct Costs (millions , \$)	Total Costs (millions, \$)
Diphtheria	247,214	24,721	2,358	24,930	247,212	24,721	2,358	24,930
Tetanus	153	23	8	29	146	22	8	28
Pertussis	2,662,307	1,049	2,265	3,668	2,614,874	1,008	2,193	3,545
<i>Haemophilus influenzae</i> type b	17,530	663	1434	2,696	17,469	661	1,430	2,689
Poliomyelitis	60,974	723	2,084	4,890	60,974	723	2,084	4,890
Measles	3,493,722	2,795	2,646	5,875	3,433,036	2,794	2,645	5,874
Mumps	2,100,718	11	936	1,459	2,095,917	11	934	1,456
Rubella	1,786,334	14	88	381	1,784,030	14	88	380
Congenital rubella syndrome	616	68	115	173	602	66	112	169
Hepatitis B	232,001	3,427	168	1,272	207,353	3,024	149	1,121
Varicella	3,788,807	70	205	1,184	3,160,391	57	173	993
Total	14,330,376	33,564	12,307	46,557	13,622,004	33,101	12,174	45,075

* Costs are rounded and given in US dollars

Table 2: Comparison of 20th Century Annual Morbidity and Current Morbidity: Vaccine-Preventable Diseases⁵⁷

Disease	20th Century Estimated Annual Cases	2006 Reported Cases	Percent Decrease
Smallpox	29,005	0	100%
Diphtheria	21,503	0	100%
Measles	530,217	55	> 99%
Mumps	162,344	6,584	96%
Pertussis	200,752	15,632	92%
Polio (paralytic)	16,316	0	100%
Rubella	47,745	11	> 99%
Congenital Rubella Syndrome	152	1	> 99%
Tetanus	580	41	93%

Table 3: Cost-effectiveness of newer vaccines from selected studies (base case) compared to other recommended preventive services

Intervention	Author, Year	Conditions compared*	\$/outcome**	Notes
Human papillomavirus vaccination	Chesson 2008	Adding 3-dose series of HPV vaccine for 12 year-old girls to existing cervical cancer screening	\$3,906 per QALY saved	Estimate for a single cohort aged 12-99 years (females only).
Cervical cancer screening	Mandelblatt 2002	Pap tests every three years until age 65	\$11,835 per QALY saved	Estimated for a hypothetical population of women aged 18-65 years.
Colorectal cancer screening	Frazier 2000	Fecal occult blood test plus sigmoidoscopy every 10 years compared to no screening	\$21,200 per life-year saved	Estimated for a hypothetical population representative of U.S. 50 year-olds.
Hepatitis A vaccination	Rein 2007	Routine vaccination at age 1 compared to no vaccination	\$28,000 per QALY saved	Estimate for a single cohort aged 0-95 years.
Meningococcal conjugate vaccination	Shepard 2005	Routine vaccination at 11 years old vs. no vaccination	\$138,000 per QALY saved	Estimate for a single cohort aged 11-33 years.
Rotavirus vaccination	Widdowson 2007	Routine vaccination at 2, 4, and 6 months compared to no vaccination	\$197,190 per life-year saved	Estimate for a single cohort aged 0-59 months. Cost is \$3,024 per serious case averted.

* When multiple prevention strategies were analyzed, the condition that corresponds to the most current recommendation of the Advisory Committee on Immunization Practices (ACIP) or the U.S. Preventive Services Task Force is presented here.

**** Some studies calculated cost per life-year saved; others calculated cost per quality-adjusted life year (QALY) saved. QALYs are outcomes that incorporate the quality or desirability of a health state with the duration of survival.**

NOTE: All results are from a societal perspective (i.e. they include lost productivity and other indirect costs in addition to direct medical costs). Economic analyses generally contain a variety of assumptions that are varied in sensitivity analyses to produce a range of results. Estimates of cost per QALY or life-year saved may not be directly comparable as studies may use different methodology. Please see published studies and technical appendices for full results and a list of assumptions.

Sources:

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Table 4: Actual vs. allowable Medicaid administration fees paid for VFC vaccine administration, 2008.

State	State contribution	Federal contribution	Total administration fee	CMS administration fee cap
Hawaii	0.83	1.17	2.00	15.71
Connecticut	1.00	1.00	2.00	16.56
New Jersey	1.25	1.25	2.50	16.34
New Hampshire	1.50	1.50	3.00	14.51
Wisconsin	1.39	1.89	3.28	15.02
Kentucky	1.00	2.30	3.30	14.17
District of Columbia	1.20	2.80	4.00	16.55
Maine	1.83	3.17	5.00	14.37
Missouri	1.93	3.07	5.00	15.07
Texas	1.97	3.03	5.00	14.85
Iowa	2.01	3.24	5.25	14.58
Washington	2.89	3.07	5.96	15.60
Vermont	2.46	3.54	6.00	13.86
Illinois	3.20	3.20	6.40	16.79
Colorado	3.25	3.25	6.50	14.74
Michigan	2.93	4.07	7.00	16.75
Rhode Island	3.32	3.68	7.00	14.93
Alabama	2.59	5.41	8.00	14.26

Georgia	2.95	5.05	8.00	14.81
Indiana	2.98	5.02	8.00	14.47
Delaware	4.00	4.00	8.00	15.13
North Dakota	2.98	5.23	8.21	13.90
Minnesota	4.25	4.25	8.50	14.69
South Dakota	3.60	5.40	9.00	13.56
California	4.50	4.50	9.00	17.55
Louisiana	2.60	6.85	9.45	15.22
Nevada	4.48	4.97	9.45	16.13
Arkansas	2.59	6.97	9.56	13.30
Mississippi	2.37	7.63	10.00	13.92
Arizona	3.38	6.62	10.00	15.43
Ohio	3.92	6.08	10.00	15.67
Kansas	4.06	5.94	10.00	14.80
Nebraska	4.20	5.80	10.00	13.58
Florida	4.32	5.68	10.00	16.06
Pennsylvania	4.59	5.41	10.00	15.76
Maryland	5.00	5.00	10.00	15.49
Wyoming	5.00	5.00	10.00	14.31
New Mexico	3.17	7.77	10.94	14.28
Virginia	5.50	5.50	11.00	14.71
West Virginia	3.09	8.91	12.00	14.49

Utah	3.43	8.67	12.10	14.52
South Carolina	3.93	9.07	13.00	13.62
Oklahoma	4.39	8.94	13.33	13.89
Tennessee	4.97	8.73	13.70	13.70
Montana	4.45	9.68	14.13	14.13
Oregon	5.95	9.24	15.19	15.19
Massachusetts	7.89	7.89	15.78	15.78
Idaho	4.82	11.18	16.00	14.34
North Carolina	6.20	11.05	17.25	13.71
Alaska	8.34	9.20	17.54	17.54
New York*	8.93	8.93	17.85	17.85

Source: Centers for Medicare and Medicaid Services (CMS). Data for Arizona and the District of Columbia were obtained by querying immunization program managers in those states; data for Arizona represented the lowest rate paid by any Medicaid plan. Rates are for the first vaccine dose and do not reflect elevated reimbursement for combination vaccines permitted in some states.

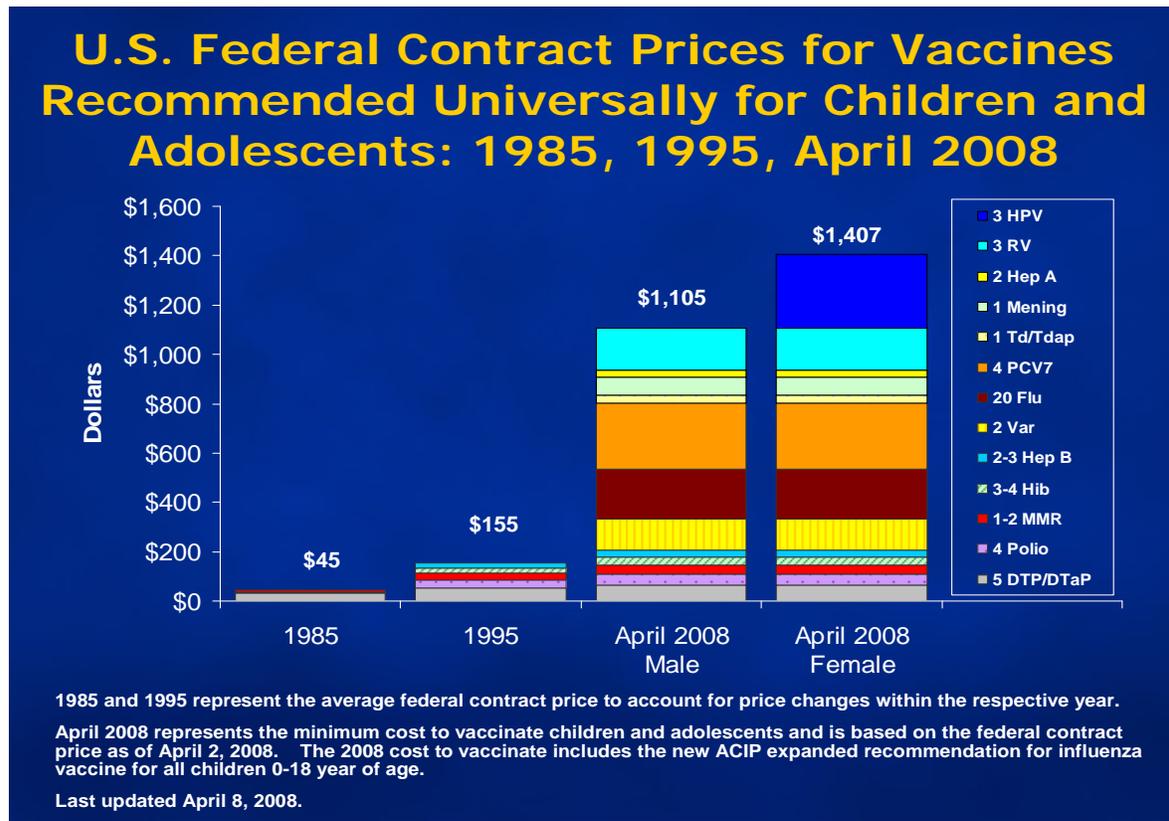
***State and federal shares sum to greater than total administration reimbursement due to rounding.**

Table 5: Diseases prevented by vaccines recommended for universal use, 1988-2008.

Vaccine-preventable diseases		
1988	1998	2008
Diphtheria	Diphtheria	Diphtheria
Tetanus	Tetanus	Tetanus
Pertussis	Pertussis	Pertussis
Measles	Measles	Measles
Mumps	Mumps	Mumps
Rubella	Rubella	Rubella
Polio	Polio	Polio
Hepatitis B	Hepatitis B	Hepatitis B
<i>Haemophilus influenzae</i> type b	<i>Haemophilus influenzae</i> type b	<i>Haemophilus influenzae</i> type b
	Varicella	Varicella
		Pneumococcal disease
		Rotavirus
		Hepatitis A
		Meningococcal disease
		Human papillomavirus
		Influenza

Source: Advisory Committee on Immunization Practices. Recommended Immunization Schedule for Persons 0-6 Years—United States, 2008 and Recommended Immunization Schedule for Persons Aged 7-18 Years—United States 2008. Available at <http://www.cdc.gov/vaccines/recs/schedules/child-schedule.htm#printable>.

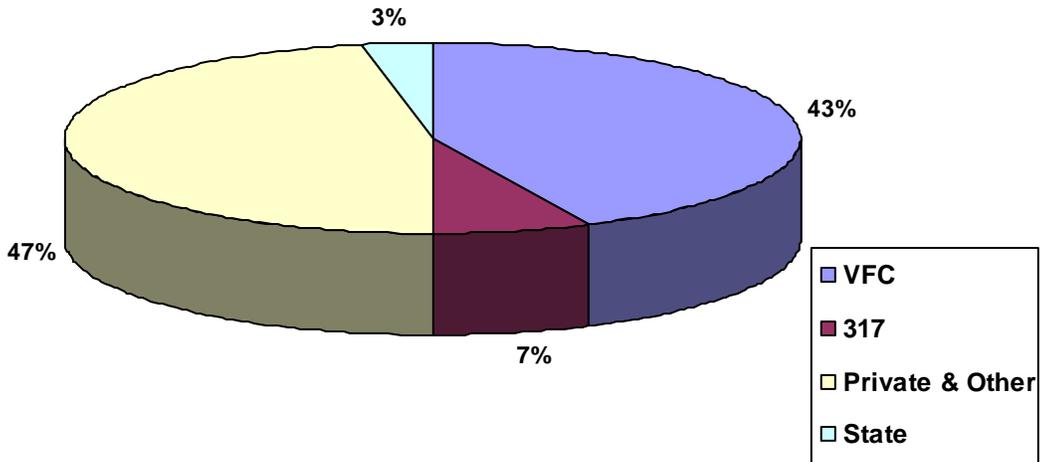
Figure 1: Cost to purchase vaccine for a child up to age 18 in 1985, 1995, and 2008.



*Source: CDC Vaccine Price List. Retrieved April 8, 2008. Current prices available at www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list.htm

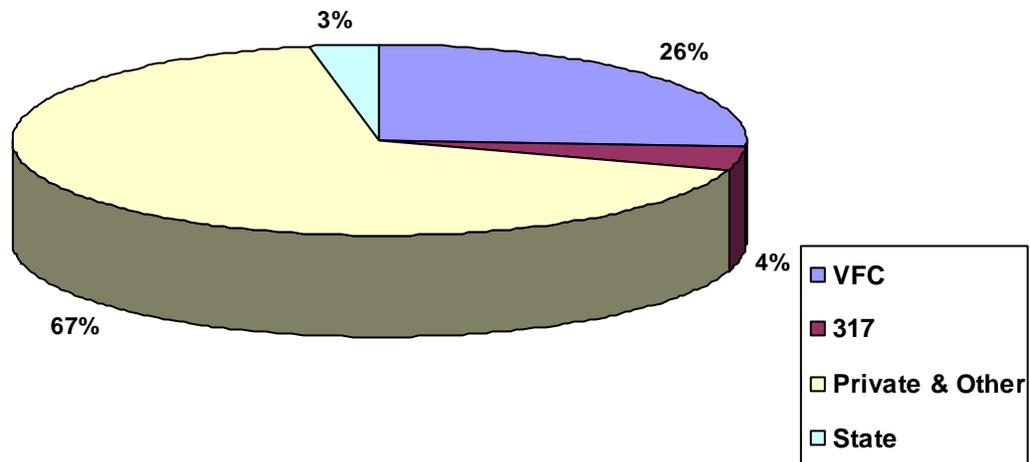
Figure 2: Pediatric and adolescent vaccine doses distributed by funding source, CY 2007

Pediatric vaccine doses (children 0-6)



***Source: Vaccine manufacturers' Biologics Surveillance Data (2007). Does not include influenza vaccine.**

Adolescent vaccine doses



***Source: Vaccine manufacturers' Biologics Surveillance Data (2007). Includes Tdap (tetanus, diphtheria, acellular pertussis), meningococcal and human papillomavirus vaccines.**

Figure 3: Comparison of vaccine funding appropriations: Section 317 (1990 – 2007) vs. Vaccines for Children Program (1995 – 2007).³⁴

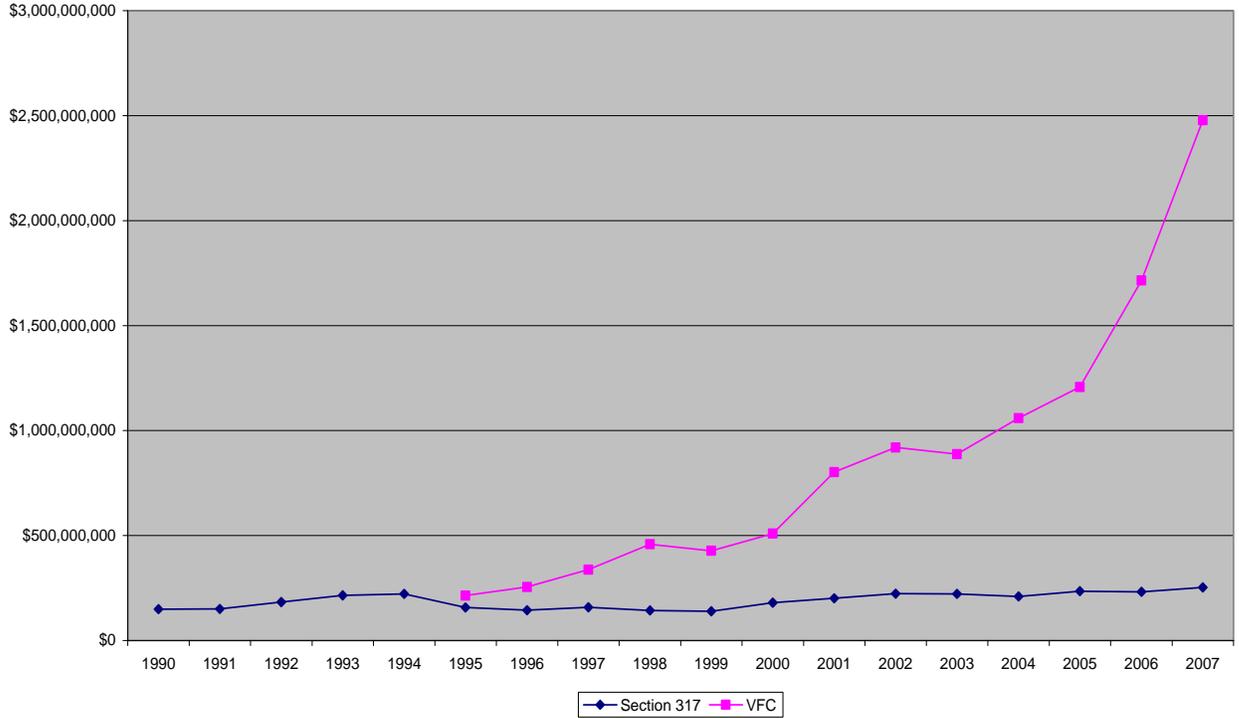


Figure 4: Children receiving VFC vaccines by eligibility category, 2006.²⁴

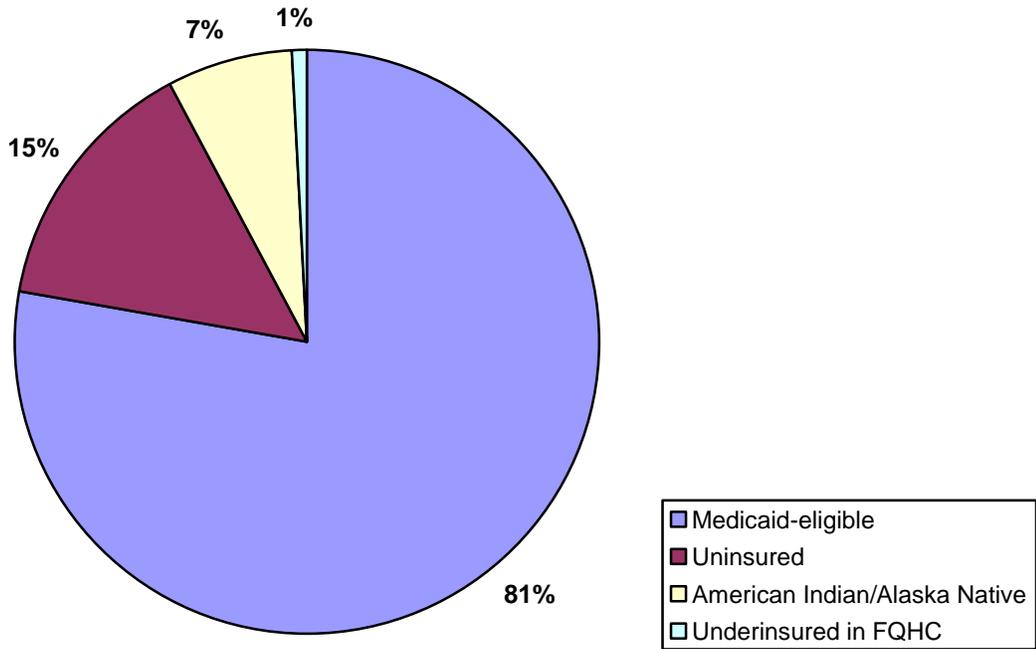
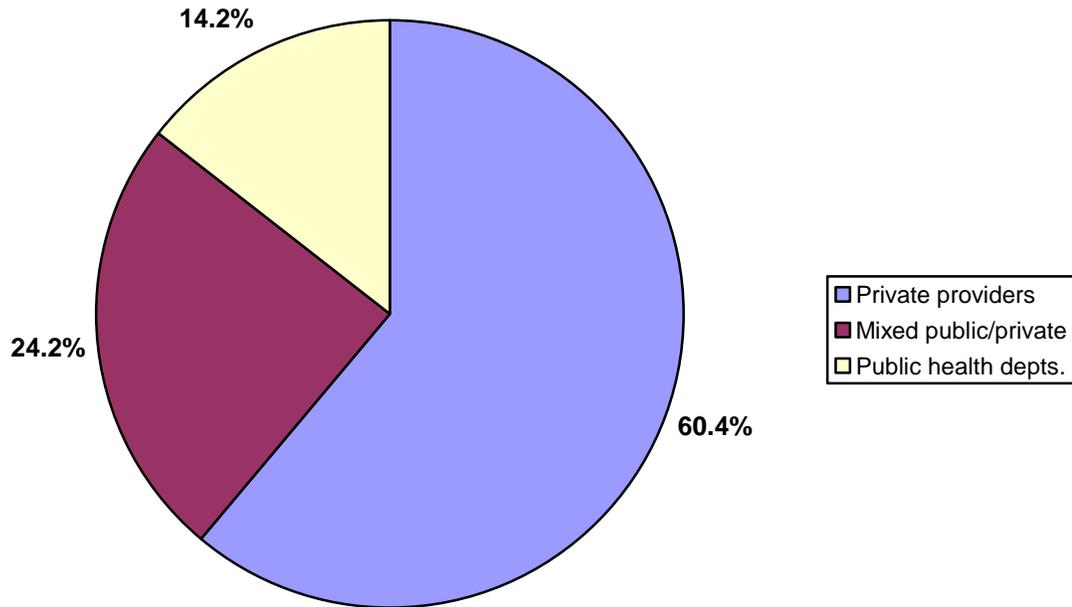


Figure 5: Pediatric immunization delivery system, 2004



Source: National Center on Health Statistics. National Immunization Survey, 2004 (unpublished data).

APPENDIX 4: Membership of the Vaccine Financing Working Group and the NVAC Adolescent Working Group

Vaccine Financing Working Group

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Department of Pediatrics, Wake Forest University School of Medicine
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Jon R. Almquist, MD
Virginia Mason Medical Center
NVAC Member

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Barbara Edwards
National Association of State Medicaid Directors

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Merck Vaccine Division, Merck & Co., Inc.
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Bruce Gellin, MD, MPH
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Lance K. Gordon, PhD
ImmunoBiologics Corp
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Elizabeth Greenbaum, MPH
National Business Group on Health

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Task Force for Child Survival and Development
NVAC Member

Calvin B. Johnson, MD, MPH
Pennsylvania Department of Health
NVAC Member

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Every Child by Two

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Centers for Disease Control and Prevention

Joy Johnson Wilson, MRP
National Conference of State Legislatures

Anthony C. Wisniewski, JD
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David R. Johnson, MD, MPH
sanofi pasteur
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Suffolk County Department of Health Services
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