

**Assuring Vaccination without Financial Barriers - A DRAFT White Paper of the  
NVAC Vaccine Financing Working Group (VFWG)**

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**Assuring Vaccination without Financial Barriers**  
**A “White Paper” Report of the NVAC Vaccine Financing Working Group (VFWG)**

I. 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 individual protection but also provides protection to other children and adults in society.<sup>1-2</sup> 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 which 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.<sup>3</sup> The greater the proportion of people in the population who are 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. Unvaccinated persons are at risk of exposure, infection, and disease if vaccination coverage is not maintained at optimal levels.<sup>2</sup> 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 (Figure 1).<sup>4</sup> For these reasons, vaccines are a unique public good and warrant the most vigorous efforts by society to remove barriers to vaccination and to achieve the highest possible levels of coverage. Mandates that children be vaccinated to attend school are an example of how society recognizes this unique role of vaccination.

In the 20<sup>th</sup> century, vaccines have reduced deaths from vaccine-preventable diseases to record lows (Table 1). Vaccines for children and adolescents recommended prior to 2000 are cost-saving: for every dollar spent on vaccinating children, more than \$1 is saved in medical or societal costs (e.g. lost productivity). More specifically, over the lifetime of each birth cohort in the United States, these vaccines save society \$43 billion including \$10 billion in direct medical costs, and prevent 14 million cases of vaccine-preventable disease (VPD) and 33,000 VPD deaths (Figure 1).<sup>4</sup> The vaccines introduced for routine use in children and adolescents in 2000 and thereafter are cost-effective<sup>1</sup> with respect to other routinely recommended preventive services, but unlike previously recommended vaccines, are not cost-saving (Table 2). Vaccination of children and adolescents can save employers money by reducing lost workdays for parents who stay home to care for ill children.<sup>5</sup> Providing recommended vaccines is also beneficial for health care payers, as each fully vaccinated child reduces the likelihood that the payer will later incur costs to treat that person for many vaccine-preventable diseases.

Because vaccines are effective and are often cost-saving, vaccination is a top-ranked clinical preventive service in the U.S. In 2006, Partnership for Prevention rankings of 25

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<sup>1</sup> 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.<sup>6</sup>

widely recommended clinical preventive services give childhood vaccination a perfect score, based on clinically preventive burden and cost-effectiveness.<sup>7</sup> 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.<sup>8</sup> Underimmunization is a marker for delay in other 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.<sup>9</sup> 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.<sup>10</sup>

Access to a stable supply of recommended vaccines from vaccine manufacturers is one important part of assuring high levels of vaccination coverage for children and adolescents. Although the worldwide vaccine market of \$9 billion in sales is only a small fraction of the \$550 billion in global pharmaceutical sales, the vaccine segment is growing at a rapid rate (ref). Between 1999 and 2004, the vaccine segment increased 26% and is expected to more than triple by 2010 to over \$20 billion (ref). This growth has been attributed to several factors; one important factor is the potential for “blockbuster” billion dollar revenue products. Prevnar®, which entered the market in 2000, was the first of these products; estimates for Prevnar® sales reached \$2.4 billion in 2007 (ref). Merck’s Gardasil® vaccine doubled Merck’s vaccine sales in 2005, reaching \$1.5 billion in sales in addition to Merck’s \$1.5 billion in sales of other vaccines in 2005. Vaccine sales at sanofi pasteur and GlaxoSmithKline, two other major manufacturers of vaccine licensed in the U.S., increased by over \$1 billion between 2005 and 2007. This growth has increased and strengthened manufacturing infrastructure and international production capacity, and fostered innovative approaches to new vaccine technologies. 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 make it into the routine vaccination schedule for children and adolescents in the next ten years.<sup>12</sup> 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 from licensure and recommendations.

Since 1999 there have been 7 new vaccines recommended for routine administration by children and adolescents in the U.S.: pneumococcal conjugate, rotavirus, meningococcal conjugate, hepatitis A, tetanus-diphtheria-acellular pertussis, human papillomavirus, and annual influenza vaccines. Many of these vaccines are the most expensive ever to go on the market. The vaccine costs at the federal contract price for fully vaccinating a child up through age 18 years have risen from \$205 in 1995 to \$893.60 for males and \$1181.60 for females in 2006, an increase of 336% and 476%, respectively (Figure 2, data adjusted to 2006 dollars). Costs in the private sector may be higher in many cases. The costs of administering vaccines have also risen over this time with the number of vaccines and

vaccine doses that need to be managed and new costs such as those related to vaccine storage and management, and cost of entering vaccination data into immunization registries. 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.

## II. Purposes of this report

In 2006, the National Vaccine Advisory Committee (NVAC) formed a Vaccine Financing Working Group (VFWG) to examine the current state of financing vaccinations for children and adolescents in the United States, to define any financial barriers to effective delivery of vaccinations, and to explore policy options to address these barriers. This draft Report contains the Working Group's findings, conclusions and proposed policy options, for stakeholder review. Following receipt of public comments and stakeholder feedback, the revised draft Report will be presented to the full NVAC for consideration and eventual adoption. The goal of the Working Group's efforts 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 are widespread but often anecdotal, and there is a need to better define the root causes and the magnitude of the problem in the current public and private sector vaccination financing system in the U.S. Questions of interest include:

- 1) What does it cost physicians and other clinicians to vaccinate children and adolescents?
  - a) How much do physicians and other clinicians pay to purchase vaccines?
  - b) What types and amounts of expenses are associated with the vaccination process (beyond vaccine purchase) in pediatric and adolescent medical practices?
- 2) What do physicians and other clinicians currently earn for vaccinating children and adolescents?
  - a) How much are physicians and other clinicians reimbursed by public and private payers for vaccines and vaccine administration?
  - b) How much time is spent by various members of the health care team in providing immunization services?
  - c) What evaluation and management (E&M) codes can be billed for visits during which vaccine administration occurs?
  - d) What is the marginal gain<sup>2</sup> earned by a provider for giving a vaccine?
- 3) Based on these costs and earnings, is the current business case for the physicians and other clinicians delivering pediatric and adolescent vaccination favorable or unfavorable?
  - a) How has the business case changed in light of newly recommended vaccines?

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<sup>2</sup> In this case, "marginal gain" means "excess of revenue over expenses". Throughout the paper, we will refer to this as the "marginal gain". Greater total expenses than revenue generated will be referred to as "marginal loss."

- b) How does the business case vary by provider characteristics?
- c) Is the concern that physicians and other clinicians will cease to administer vaccines justified?
- 4) What factors are most important in determining the costs associated with vaccines and their administration?
  - a) Which of these can be positively influenced by physicians and other clinicians and which cannot?
  - b) What opportunities exist to improve the operation of physician practices, including vaccine ordering, billing, and recordkeeping?

Given the current state of the vaccine market and delivery system, and the limited amount of data to address the questions above, the purposes of this Report are twofold. The first purpose is to describe current challenges in child and adolescent vaccine financing and delivery in the public and private sectors. These challenges are viewed from the perspective of key stakeholders: physicians and other clinicians; vaccine manufacturers and distributors; insurers, employers, and other 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 and financing system was necessary to answer these questions. The second purpose of this Report is to identify potential solutions and suggest policy options for future action to address the challenges identified.

These policy options may be directed to any of the stakeholders: policy makers in government, professional organizations, and industry groups, to ensure access to vaccines recommended for universal use for children and adolescents without financing barriers. These policy options should be consistent with a policy environment that promotes both continued investment in innovation of new vaccines and new vaccine technology, as well as continued access to affordable health insurance for all children and adolescents and coverage of vaccination insurance benefits as defined in health insurance plan contracts and paid by health insurers. These policy options should also serve to end what has become an ad hoc prioritization of childhood vaccines that is taking place throughout the U.S., described in further detail below.<sup>13</sup>

### III. Vaccine Financing Working Group Process and Methods

The charge from NVAC to the VFWG was to explore all options with regard to vaccine financing, and to recommend potentially viable 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 present findings and policy options to the full NVAC for discussion and recommendations.

To carry out its charge, the VFWG carried out a number of activities. First, it conducted a literature review of the current vaccine financing system in the United States and challenges to financing vaccine delivery to children and adolescents (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. To this end, Centers for Disease Control and Prevention (CDC)-financed studies of the cost to provide childhood and adolescent vaccinations are underway; at least one additional study is underway at the request of the American Academy of Pediatrics (AAP). Preliminary data from these studies was made available to the VFWG, are summarized in this paper, and will be presented at the NVAC Stakeholders Meeting held in Rockville, Maryland on April 29 and 30, 2008. 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 2006 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), conducted a survey and interview of 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 its deliberations, the VFWG has sought to fully explore and define a range of policy options and their pros and cons. This Report summarizes the range of these options. In some cases, the VFWG recognizes that the options presented for consideration and public comment may be contradictory or overlapping. This is intentional and consistent with the Working Group's purpose of exploring all potential options. Where possible, the VFWG will strive to achieve consensus in the final set of policy options that will be forwarded to NVAC for consideration, but this has not been the group's primary goal. Rather, the range of options, and their pros and cons, will be presented to the full NVAC for its consideration and eventual adoption.

As mentioned above, NVAC will hold a key stakeholders meeting on April 29 and 30, 2008 to obtain stakeholder input and to discuss conclusions, solutions, recommendations, and guidelines. The Stakeholders Meeting was announced in the Federal Register in March 2008. The Federal Registry announcement also invited written comments from interested parties and the general public. The VFWG will review the input received at the Stakeholders Meeting and contained in written comments. In addition, comments received in response to a set of draft financing recommendations developed by a separate NVAC Adolescent Working Group will be reviewed. The VFWG will review this input and present a revised version of this report to NVAC at its June 2008 meeting. NVAC will adopt a final Report with recommendations after a full discussion of the issues.

#### 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 (317 program), and state funds (Figure 3). 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<sup>3</sup> 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 following endorsement of the Committee's recommendation by the U.S. Department of Health and Human Services (HHS). VFC providers receive shipments of vaccine for eligible patients, and incur no cost for this vaccine. Approximately 48% of each birth cohort is covered by the VFC program.

All states use the 317 program to cover non-VFC eligible and adolescents – usually those who go to public health department clinics 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 new vaccine recommendations.<sup>14</sup> The 317 program budget for vaccine purchase is currently 1/10<sup>th</sup> the size of VFC (Figure 4), and Section 317 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% of total federal funds for vaccine purchase in FY2007.

State funds have also been used to purchase vaccines for children 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 (called “universal purchase” states) although recently, the number of states that exercise this option has been decreasing because of the increasing costs of vaccines.<sup>15</sup> If current economic circumstances reduce state discretionary funds available for immunization programs, the implementation of universal vaccine purchase policies may continue to decline.

Private sector vaccine purchase accounts for about 45%-50% of the vaccines sold annually in the U.S. (Figure 3), 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 distributors or manufacturers and reimbursement

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<sup>3</sup> Underinsured children are defined as those children who have health insurance but the coverage does not include vaccines. Children whose insurance covers only selected vaccines (and are therefore VFC-eligible for non-covered vaccines only), or children whose insurance caps vaccine coverage at a certain amount -- once that coverage amount is reached, these children are categorized as underinsured.

with health insurers, and 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, for example pharmacies or retail clinics, may also utilize other business approaches.

#### *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 57% of VFC vaccine recipients in 2000 (Figure 5). In the fee-for-service Medicaid program, vaccine administration reimbursement rates are set by state Medicaid agencies. The federal government will match state expenditure up to a federally established maximum vaccine administration rate (cap). The current Medicaid vaccine administration reimbursement caps were set by the federal Centers for Medicare and Medicaid Services (CMS) in 1994 and have not been modified since that time. Current state-specific vaccine administration reimbursement amounts (state plus federal share) vary from a low of \$2 in some states to over \$18 per vaccination in others (Table 3). Most states do not contribute enough state funds to draw the maximum federal matching contribution allowable (based on the federal medical assistance percentage, or FMAP<sup>4</sup>) for vaccine administration (Table 3). 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), but the negotiated reimbursement amount cannot exceed the federal cap. Many children and adolescents receiving vaccine in public sector settings are under- or uninsured, and privately insured children may also receive vaccine at public health departments;<sup>16</sup> 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, vaccine providers and insurers negotiate reimbursement terms that are mutually acceptable. Vaccine administration may be reimbursed by fee-for-service payments based on the AMA's Current Procedural Technology (CPT) billing codes or may be included in a standard office visit rate as it is for capitated insurance plans, or both. CPT codes for vaccine administration cover a wide range of costs associated with vaccine delivery

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<sup>4</sup> The Federal Medical Assistance Percentages (FMAPs) are used in determining the amount of Federal matching funds for State expenditures for 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.

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.<sup>17</sup>

Reimbursements made based on Medicare's Resource-Based Relative Value Scale (RBRVS) also take into account labor, overhead and malpractice costs. It is not clear how non-vaccine costs of vaccination such as purchasing and managing the vaccine inventory (including items like freezer and refrigerator temperature alarm systems, insurance policies against catastrophic loss, etc.), and entering data into immunization information systems are accounted for in these labor and overhead values.

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 include obtaining vaccine history and ordering needed vaccines<sup>17</sup>, but do not include counseling for vaccines<sup>18</sup>, 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.<sup>19,20</sup> About 57% of insurance plans do not reimburse for an office visit when routine vaccination is the only service provided.<sup>21</sup> Maximum reimbursement can only be obtained when physicians include codes for both vaccines and vaccine administration when billing for vaccination-only visits<sup>19</sup>, and submit additional 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. The Institute of Medicine (IOM) released a report in 2004<sup>1</sup>, 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 financing working group to examine the recommendations of the report, including a stakeholder's meeting in June 2004.<sup>22</sup> 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 (i.e., deductibles or co-pays would not apply to vaccination), and adequate reimbursement for vaccine administration.<sup>22</sup> Section 317 program funds for vaccine purchase have increased by 20% since 2004; however, 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 childhood and adolescent vaccination schedule.<sup>23</sup> Other NVAC recommendations from the 2004 NVAC

working group remain largely unimplemented. As new and more expensive vaccines continue to be licensed and recommended, the financing stresses noted in 2004 are being compounded.

#### VI. Literature review: the challenges facing childhood and adolescent vaccination

The section summarizes the conclusions of the recent papers in the scientific literature related to vaccine financing that were reviewed by the VFWG. The major factor identified in the literature leading to stress in the financing of childhood and adolescent vaccinations is the dramatic increase in costs to fully vaccinate a child or adolescent as a result of new and often expensive vaccines recommended for routine use by the ACIP (particularly vaccines recommended since 2000). Added to these costs are those associated with the expansion of existing ACIP recommendations for vaccines like varicella and acellular pertussis vaccines. In addition, gaps are identified in the financing of vaccinations for some children and adolescents, particularly those who are underinsured. 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 doses of vaccine, compared to just 19 for a child born in 1998 (Table 4).

In addition to greater numbers of recommended vaccines, the costs to purchase vaccines have risen over the past decade.<sup>23</sup> Newly recommended vaccines are more expensive than vaccines recommended prior to 1995.<sup>24</sup> The vaccine costs at the federal VFC contract price for fully vaccinating a child up to age 19 years have risen from \$205 in 1995 to \$893.60 for males and \$1181.60 for females in 2007 (Figure 2, adjusted to 2006 dollars). This increased cost is due in part to 1) the complexity of the manufacturing techniques for the newer vaccines, 2) the cost and complexity of conducting large clinical trials to more fully characterize safety and efficacy and 3) the cost of remaining in compliance with regulatory requirements for licensure and continued manufacturing.<sup>1</sup> Increased vaccine costs may also be a reaction by vaccine developers and manufacturers to perceived under-pricing of older vaccines, or may be due to the small number of manufacturers producing vaccines for the U.S., especially for vaccines that are produced by only one company and therefore have limited price competition in the market.

Non-vaccine costs associated with child and adolescent vaccination (i.e. costs of vaccine administration) have also increased with the increase in number and expense of the vaccines involved. These costs may include increased storage needs, the need to purchase insurance policies against product loss, requirement for data entry into immunization information systems, additional staff time to manage vaccine inventory, and increased counseling time. Some reimbursement systems may not have been adjusted to account for these costs or for inflation with the result that reimbursement for vaccine administration may not cover all of these costs. This may be an issue particularly for children who are served by the VFC program.

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 doses of vaccine that a child receives, combination vaccines may save providers money by reducing inventory needs, administration costs, wastage, and staff time.<sup>25</sup> On the other hand, use of combination vaccines may increase costs if additional inventory and recordkeeping are required, or if the reimbursement for combination vaccines is less than the reimbursement for each of the vaccines administered separately.<sup>25</sup> In addition, vaccine providers need to continue to address questions and issues regarding each of the diseases that are prevented by vaccines and counsel parents for each vaccine component individually. Therefore, a single administration fee reimbursement for a combination vaccine that is equivalent to that for a single-antigen vaccine is unlikely to fully cover counseling costs for the greater number of diseases addressed. The AAP is currently working to assure that CPT billing codes for administration of combination vaccines account for both increases in physician labor and reduced practice expenses associated with the use of combination vaccines.<sup>17</sup>

Private providers, who vaccinate the majority of children and adolescents (Figure 6), have expressed increasing concern that insufficient reimbursement rates for vaccination of children and adolescents is a disincentive to participate in vaccination programs or to implement new vaccines.<sup>26-27</sup> Unlike other preventive services, vaccines require upfront investment of capital to purchase these pharmaceutical products 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.

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. Furthermore, state and local health departments that are 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.<sup>13, 15</sup> This scaling back is likely to continue if state budgets are reduced in reaction to the current economic climate.

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 coverage in their health insurance plans as young children, and teens – especially older teens – do not make regular visits to primary care doctors.<sup>28</sup> This suggests that vaccination financing for adolescents seeking vaccines in alternative locations, such as schools, may be needed.

Finally, financial pressures may increase because of anticipated new vaccine recommendations 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 vaccine financing system, the consequences of these challenges may not yet be readily visible in terms of reduced vaccination rates with the newer vaccines. Vaccination rates are high (>80%) for most vaccines recommended for routine use in children and adolescents prior to 2000; coverage for vaccines recommended since is suboptimal.<sup>29-30</sup> 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).<sup>31</sup> 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 childhood and adolescent vaccines could fall, resulting in disease outbreaks.<sup>2</sup> In early 2008, suboptimal vaccination coverage among community 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.<sup>59</sup>

In the past, financial barriers to vaccination have 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.<sup>32-33</sup> 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.<sup>34</sup> Interruptions in public or private insurance coverage are also associated with reduced likelihood of up-to-date vaccination.<sup>35</sup>

Taking steps to address these known financial 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 underinsured<sup>36</sup> and to increase access even to newer and more expensive vaccines for children without insurance (Davis 2003).<sup>37</sup> Reducing out of pocket costs for vaccination increases coverage with recommended vaccines.<sup>38</sup> Many states have instituted state-based insurance mandates, which require health insurance plans regulated by the state to make provision of recommended childhood and adolescent vaccines a covered service to varying degrees<sup>39</sup> The impact of such mandates to increase coverage may be limited because these mandates do not cover the approximately 50% of U.S. health insurance plans that are self-insured, and therefore exempt from state regulation. 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.<sup>40</sup>

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 have 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.<sup>11</sup> Five key stakeholder groups have been identified whose perspectives are reflected in this Report: health insurers, employers and other healthcare purchasers, vaccine manufacturers; medical providers; 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 allow options in benefit design packages.

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.<sup>21, 41</sup> 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).<sup>21</sup> 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.<sup>21</sup>

The U.S. Chamber of Commerce and AHIP strongly oppose insurance mandates. These mandates, whether applying to plans regulated by ERISA<sup>5</sup> or by the states, reduce the ability of employers to develop benefit designs appropriate for their work force<sup>60</sup> and have not been shown to increase vaccination rates<sup>40</sup>. A report commissioned by AHIP from PricewaterhouseCoopers noted that state and federal mandates add to the cost of health insurance premiums.<sup>62</sup> It is calculated that every 1 percent increase in health care premiums results in 300,000 fewer U.S. workers accepting employer-sponsored health insurance.<sup>42</sup>

### *B. Vaccine manufacturers*

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<sup>5</sup> 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.

All routinely recommended vaccines are produced in the private sector, by a small number of manufacturers.<sup>43</sup> Vaccine manufacturers have been traditionally concerned that a single 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. Profit margins for vaccines are often lower than other pharmaceutical products.<sup>44</sup> However, on the newer vaccines, significant greater profitability exists. Manufacturers perceive vaccines as a “growth industry”.<sup>45</sup>

Manufacturers evaluate the market research and the policy environment in deciding on 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 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.<sup>24, 46</sup> Much of upstream vaccine discovery is performed in government, biotechnology and academic settings, and funded by the NIH although industry plays a role.<sup>47</sup> The majority of the biotechnology firms that perform initial research and development for new vaccines are located in the United States. (Coleman, unpublished). Promising vaccine candidates are further developed, produced and distributed by vaccine manufacturers, who have the fiscal resources to construct large manufacturing plants and conduct the large clinical trials needed.<sup>24</sup> Smaller companies have in some cases supported clinical trials and built vaccine manufacturing plants, but with significantly greater difficulty and risk. Once a vaccine has been licensed and produced, manufacturers work with vaccine distributors to varying degrees, depending on the manufacturer or the vaccine.

### *C. Physicians and other clinicians serving children and adolescents*

As noted above, many medical care providers serving children and adolescents have to deal with two 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 physicians and other clinicians (Figure 6), 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, both public and private.

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.<sup>48-49</sup> 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 physician office.<sup>8, 50-51</sup> In fact, VFC-eligible children vaccinated in the medical home have vaccination coverage equivalent to that of privately insured children.<sup>52</sup>

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 and less variable than the average Medicaid administration fee for VFC.

#### *D. Consumers and parents*

Parental demand for vaccines is related to provider recommendations for vaccination.<sup>53-54</sup> 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? 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 reduces the use of preventive services<sup>32-33</sup>, particularly co-insurance and deductibles.<sup>33</sup> Although use of high-deductible health plans (HDHPs) may be increasing, it has been estimated that over 80% of HDHPs linked with health savings accounts (HSA) provide first-dollar coverage for preventive services including vaccinations.<sup>55-56</sup> As vaccines become more expensive, parents of privately insured children whose insurance plans do not fully cover vaccines may have to forgo recommended vaccinations or pay the entire cost out of pocket.<sup>57</sup>

Children with public health insurance or without health insurance coverage for vaccinations can usually access VFC program vaccine, although this may vary by setting and state (see Section IV). 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. This is a potentially difficult position to place parents and providers in. 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 physicians and other clinicians' requests 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 increasing vaccine administration fees using state funds 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 for Medicaid funds than those of VFC administrators. State and local immunization programs within state health departments have had to make financing-based decisions about which of the recommended vaccines to implement for underinsured and, in universal purchase states, fully-insured children.<sup>11, 15</sup> 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 administered has increased.<sup>23,61</sup>

Underinsurance is the largest financing gap in the childhood vaccination program. This gap has a dual root cause. First, in the private sector, some purchasers choose commercial health plans that do not cover all recommended vaccines.<sup>41</sup> Second, 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. FQHC and RHCs have limited capacity and geographic reach: fewer than 10% of VFC providers are FQHC 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 discretionary funding. However, discretionary funding is subject to the annual appropriations process and has not kept pace with purchasing needs for new vaccines.<sup>23</sup> This has led to two-tiered<sup>6</sup> vaccine financing systems in many states. The ultimate effect of two-tiered systems is a prioritization of vaccines based not on vaccine benefits but on insurance status.<sup>13</sup> Children eligible for VFC in any setting and commercially-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.

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<sup>6</sup> “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. (Lee 2007)

This *de facto* prioritization varies by state; ergo, childhood vaccine recommendations are not being implemented uniformly across the country.<sup>13, 15</sup> 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.<sup>15</sup> Both of these situations result in an ethical tension in which some children do not receive timely benefit 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 financing. Some state health departments have initiated systems that bill insurers for vaccines given at health departments to privately insured children. This saves discretionary funds that can then be used to provide additional vaccines to the under- or uninsured using 317 funds.<sup>58</sup> Still other states are exploring the use of state discretionary funds to implement universal purchase to overcome 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 VFWG-suggested studies

##### *Manufacturer and insurer studies*

In late 2006, a series of key informant interviews about vaccine financing was conducted with all six manufacturers that provide pediatric vaccines in the United States. Results included three overarching themes common to all respondents about critical elements required in any solution to vaccine financing problems: preservation of the current public-private sector system and avoiding erosion of the private sector 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, 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 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 relative value units (RVUs, a system designed by AMA) 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, the results of which are currently being refined and prepared for public release. This section will be modified to include specific references and results following finalization of results and approval by the principal investigators of the studies in question.

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. With regard to non-vaccine costs of the vaccination process (including but not limited to labor and overhead), estimates average between \$20-\$40 for administration of vaccines to children or adolescents.

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 generally be at least minimally reimbursed above costs while others (e.g. rotavirus and varicella) are money losers, with 10-20% of practices losing money on every dose purchased. For vaccine administration, physicians report a range of fee reimbursements, with an average reimbursement of \$14-\$17 per product. Most physicians do not cover administrative costs unless they vaccinate a child with at least three products with the product and administrative reimbursements from private insurance. Public insurers (i.e., Medicaid) pay only administrative fees on the assumption that VFC vaccine is used to vaccinate. In Georgia these administrative fees average \$10 for the first dose, and \$8 for additional doses concurrently administered. Therefore, medical practices serving a large number of publicly insured patients lose out on small gains from products and are paid administrative reimbursements that are less than their costs to administer vaccines.

In some cases, overall vaccine payment exceeds vaccine price, but some practices lose money on vaccine product alone. As the number of vaccine doses given per visit rises, marginal gain increases with additional administrative reimbursements and potential gains from product reimbursements. These marginal gains/losses vary based on practice characteristics: 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 face marginal losses.

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 like ordering and inventory management have increased in the past 5 years. A small proportion of physicians has seriously considered no longer providing 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 propose potential recommended activities to remove financial barriers to vaccine access for children and adolescents.

*DRAFT for Comment*

IX. NVAC VFWG Draft Conclusions and Proposed Policy Options for NVAC Consideration

**Organization of Draft Conclusions and Policy options for Discussion:**

- A. Context
- B. General Conclusions
- C. Public Sector Financing for Vaccine Purchase and Vaccine Administration Reimbursement
  - i. Conclusions Related to Public Sector Vaccine Purchase and Vaccine Administration
  - ii. Proposed Policy options Related to Public Sector Vaccine Purchase and Vaccine Administration
- D. Private Sector Financing for Vaccine Purchase and Vaccine Administration Reimbursement
  - i. Conclusions Related to Private Sector Vaccine Purchase
  - ii. Proposed Policy options Related to Private Sector Vaccine Purchase
- E. APPENDIX: Table of Proposed Policy Options for the National Vaccine Advisory Committee (NVAC) Consideration Regarding Vaccine Purchase and Vaccine Administration Reimbursement (formatted in the form of recommendations)
  - i. Public Sector
  - ii. Private Sector

A. Context

The draft conclusions and policy options presented here are based on the deliberations of the National Vaccine Advisory Committee Vaccine Financing Working Group (NVAC VFWG). The goal of the document is to present potential policy options that may help to assure that any financial barriers to accessing all vaccines routinely recommended for children and adolescents by the Advisory Committee on Immunization Practices (ACIP) are either minimized or eliminated.

The draft conclusions and potential policy options are presented for the purpose of discussion and to elicit additional input. Pros and cons are presented with each consideration may not be comprehensive. Because there may be multiple ways to assure adequate financing of vaccines and vaccination, multiple approaches have been presented as options. As a result, some draft considerations may not be consistent with each other. Further, the numbering of the policy options and the conclusions are not intended to match directly. In cases where multiple options on the same issue are presented to elicit input, it is likely that only a limited number of options, compatible with each other, would ultimately go forward from NVAC.

In addition to the pros and cons listed with each policy option there is a rating of the potential impact of implementing each policy option as “minor,” “moderate,” or “major” in terms of impact of eliminating financial barriers to access to vaccines if implemented. Further, there is a notation on whether or not the policy option requires authorizing federal legislation. Policy options have been directed to specific stakeholders defined in

this report as: (1) Federal, State, and Local Health Departments (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 Vaccine Finance Working Group recognizes that any policy options to improve vaccine financing that would require additional state or federal funding could create demands on state or federal budgets that may compete with other worthy public goods. The Working Group did not attempt to prioritize their vaccine financing policy options against these other public goods, but believes in general that vaccinations should receive a high priority in state and federal budgets for the reasons stated in the General Conclusions (below), particularly number 3.

The Working Group also recognizes that it would be difficult to achieve uniform, universal national implementation of any policy options in the U.S. that require legislative or budgetary action by each state or locality and so, in general, would favor actions, when appropriate, at the federal level to achieve such implementation.

In a separate process, the NVAC Adolescent Working Group has developed a set of recommendations for vaccine finance (enclosure). These have been previously shared with stakeholders for comment. The adolescent financing recommendations are being included again in this mailing in order to consolidate the process of getting input on both documents. NVAC will work to make both sets of recommendations the same following receipt of public comment.

The draft conclusions and policy options in the white paper and from the NVAC Adolescent Working Group are presented here for the purpose of discussion and to elicit comments. Pros and cons are presented with each consideration. Because there may be multiple ways to assure adequate financing of vaccines and vaccination, multiple approaches have been presented as options. Some draft considerations may not be consistent with each other. In cases where multiple options on the same issue are presented to elicit input, it is likely that only a limited number of options, compatible with each other, would ultimately go forward to NVAC.

No final determinations on the policy options have been made at this point. Following the receipt of public comments in writing and from the April 29-30, 2008 Stakeholders Meeting, the VFWG will present a set of conclusions and policy options to the full NVAC at its June 2008 meeting for consideration. Based on the discussion at the NVAC meeting, a revised set of conclusions and policy options will be developed by the VFWG and sent to interested stakeholders for comment after the June meeting. It is anticipated that NVAC will adopt final childhood and adolescent vaccine financing conclusions and recommendations at its September 16, 17 2008 meeting in Washington, D.C

#### B. General Conclusions

- (1) The current system of vaccine financing in the United States (U.S.) 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, when newer more expensive vaccines, beginning with pneumococcal conjugate 7-valent vaccine (PCV7), came onto the immunization schedule. Vaccines recommended for widespread use in children and adolescents have demonstrated high levels of efficacy and safety and provide substantial benefits to children, adolescents, and society in general. Prior to 2000 the existing system had the capacity to deliver ACIP recommended vaccines to children and adolescents. The current system is experiencing challenges in delivering vaccines recently recommended by the ACIP for universal vaccination of children and adolescents. Whether the current delivery system can accommodate vaccines that will be recommended in the future is in question.

- (2) The successes of the current vaccine financing system in reducing vaccine-preventable diseases are the result of public and private sector collaboration, reinforced by the VFC program. The public sector infrastructure in many states would not be adequate to vaccinate all children and adolescents should significant numbers of private sector health care providers stop providing vaccinations. Providing vaccines to children and adolescents in their medical homes has been associated with improved vaccination rates and other health benefits.
- (3) Vaccinations are different from other preventive health services in that most vaccines provide not only protection to the individual from vaccine-preventable diseases but also protection to the community through herd immunity. For example, widespread use of pneumococcal conjugate vaccine in young children has been associated with marked reductions in invasive pneumococcal disease in older children and adults. Children and adolescents are required by state laws to obtain many vaccines for school entry to protect both themselves and their communities. It is in the public's best interest to maintain high vaccination coverage against communicable diseases by assuring that all children and adolescents have access to vaccines without financial barriers.
- (4) The current system of financing does not assure access for all children and adolescents without financial barriers. Since 2000, eight new ACIP recommendations to incorporate new vaccines into the routine immunization schedule or increase the number of doses needed of vaccines already in the schedule (pneumococcal conjugate, meningococcal, acellular pertussis boosters for adolescents, rotavirus, HPV, hepatitis A, second dose varicella and annual influenza vaccination) has led to the identification of significant problems in the vaccine financing and delivery system. The system is challenged to deliver recently recommended vaccines and to implement future new vaccine recommendations. There is a need to better define the magnitude of the

problem in the current public and private sector vaccination financing and delivery systems in the U.S.

- (5) Proposed vaccination financing solutions should anticipate that there will continue to be changes in the recommended vaccination schedule such as future vaccines being added in the next ten or more years. The vaccination financing system should be robust enough to accommodate these new vaccines with minimum delay between the adoption of new routine vaccination recommendations for children and adolescents and the time at which children and adolescents can receive the vaccines. Proposed solutions should also take into account potential changes in health care delivery over the next ten or more years.
- (6) Vaccine-preventable diseases are not constrained by geographic boundaries, therefore policy options for addressing vaccine financing need to be comprehensive enough to cover all states and all parts of the country to ensure that financing barriers do not lead to localized areas of low vaccination rates in some locations. Areas with low vaccination rates could serve as reservoirs for maintaining circulation of vaccine-preventable infections and children living in these areas could transmit those organisms to persons residing in other states who cannot be vaccinated (i.e., with contraindications), have compromised immune systems and thus cannot mount a protective immune response, or are the few persons for whom a vaccine is not effective.
- (7) The current vaccination financing system is a mixed public and private sector effort. A decision to implement new routine vaccination recommendations for children and adolescents requires budgetary appropriations by federal, state, and local governments as well as decisions by multiple independent insurers and employers to assure reimbursement of medical care providers for vaccines and the costs of vaccine administration.
- (8) Medical providers should be reimbursed for provision of efficient vaccination services for children and adolescents to cover costs of vaccine purchase, vaccine administration, and other non-vaccine costs of vaccination. Reimbursement should be structured to provide an incentive for medical providers to offer vaccination services.
- (9) 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 other costs of vaccination.

- (10) Since the vaccination financing problems that the Vaccine Financing Working Group has identified are multi-factorial, it is likely that the solutions will also have to be multi-factorial. No single policy option or action affecting one stakeholder group or sector is likely to have a large impact. It is likely that a series of solutions will be needed, affecting multiple sectors and stakeholder groups to address all facets of the problem in a comprehensive manner. All stakeholder sectors will need to participate in this effort.

*DRAFT for Comment*

C. Public Sector Financing for Vaccine Purchase and Vaccine Administration Reimbursement

**i. Conclusions Related to Public Sector Vaccine Purchase and Vaccine Administration**

Vaccine Purchase

1. The Vaccines for Children (VFC) program has largely been successful in providing vaccines to the three groups of children and adolescents, Medicaid eligible, uninsured, American Indian or Alaska Native, entitled to receive those vaccines at any VFC-enrolled provider. However, VFC has not been as fully successful in serving a fourth group of entitled children and adolescents, the underinsured.

2. Underinsured children and adolescents continue to place financial stress on public financing of vaccines. Underinsured children and adolescents are only entitled to receive VFC-purchased vaccines in Federally Qualified Health Centers (FQHCs) and Rural Health Centers (RHCs). Since many underinsured children and adolescents do not have access to these settings, their vaccinations must be reimbursed through parental out-of-pocket payment. State health departments may choose to use their allotment of Section 317 in-kind doses of vaccines or state-funded doses to such patients.

3. Failure of state funds and the Section 317 program appropriations to keep pace with the newly recommended vaccines has resulted in many underinsured children and adolescents remaining under-vaccinated.

4. Many public health department clinics have instituted two-tiered systems for vaccinations: one tier for VFC eligible children and adolescents and a second tier for non-VFC eligible children and adolescents. Children and adolescents covered by VFC at the health departments can receive all recommended vaccines. Children and adolescents who are underinsured and who are not entitled to VFC vaccine at the health departments may be turned away without being vaccinated due to inadequate public sector funds to purchase new vaccines.

5. Some privately insured children and adolescents are also served in the public sector. Because states and localities often do not have mechanisms to bill private insurers, they must find additional resources to ensure that no child in need of vaccination is turned away from a public clinic.

6. There is concern about recommending legislative changes to VFC because of the potential that current provisions of VFC could be weakened in the legislative process.

Vaccine Administration

7. There is only reimbursement for vaccine administration available for one category of VFC eligible children and adolescents, those participating in Medicaid. This is a barrier to immunizing the uninsured, the underinsured, and American Indian/Alaska Native children and adolescents served by VFC and not covered by Medicaid.

8. 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 \$8.36). These rates are far below the CMS-established cap in most states, and is less than Medicare Part B reimbursement for vaccine administration (i.e. for influenza vaccine, in 2007, the average geographically unadjusted Medicare reimbursement rate was \$19.33).

9. CMS set State-specific caps to Medicaid reimbursement for vaccine administration reimbursement in 1994. These reimbursement rates are out of date and do not reflect all the factors that contribute to costs of providing childhood vaccinations in 2008. This is a barrier to immunizing children and adolescents, particularly in Medicaid fee-for-service programs.

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

11. There is a wide range of reimbursement mechanisms and amounts for vaccine administration in Medicaid and State Child Health Insurance Programs (SCHIP) and managed care programs. Although some reimbursement for vaccine administration may be included in capitation payments, office visit rates, bonuses, under Medicaid, it is not likely that these reimbursements are adequate to cover provider costs and allow a reasonable return on investment.

12. It is not clear to the VFWG that the current American Medical Association (AMA)-sponsored system of establishing billing codes for vaccine administration fully assures that the components of immunization administration CPT codes accurately reflect all of the tasks that medical providers perform in delivering vaccinations including ordering and storing vaccines, managing inventories, entering data into immunization information systems, counseling patients etc. It is also not clear that the CPT coding system fully recognizes the increased workload as well as possible cost savings, nor does the system provide incentives, for use of combination vaccines.

13. Some medical providers need assistance in utilizing appropriate billing mechanisms for vaccine administration including use of co-called evaluation and management (E&M) codes.

## **ii. Proposed Policy Options Related to Public Sector Vaccine Purchase and Vaccine Administration**

The following proposed policy options are for NVAC consideration regarding vaccine purchase and vaccine administration reimbursement and are formatted in the form of recommendations.

### **Regarding Section 317:**

1. NVAC recommends expansion of federal Section 317 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 2-tiered systems for new ACIP recommendations and support for vaccine purchase for underinsured children and adolescents in all states. Professional judgment from the Centers for Disease Control and Prevention (CDC) on the cost to provide this level of support is detailed in the recently released<sup>61</sup> 2008 “Report to Congress on the 317 Immunization Program.”

Pros: decreases need for state discretionary funding to cover the underinsured; maintains government support for children and adolescents who would otherwise not be vaccinated; paying for vaccinations reduces other costs.

Cons: has the potential to erode the private vaccine market if children and adolescents currently served with vaccines purchased with private funds now receive vaccines purchased through the federal contract; may provide economic incentives for employers and insurers to drop coverage for vaccine reimbursement since the federal government could assure vaccines would be available for those children and adolescents, thus, a mechanism would be needed to ensure maintenance of effort by employers and insurers to cover existing and new vaccines in insurance policies; Congressional action is required to increase the Section 317 appropriation whenever a new vaccine is recommended for routine use, so solving current problems does not assure future problems will be addressed; does not support development of a system to assure all ACIP-recommended vaccines for children and adolescents are automatically financed.

Impact: Major

Policy option directed to: (1) Federal Government – DHHS and Congress

Requires authorizing legislation: No

2. 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.

Pros: Section 317 program appropriations language already allows states to use funding for vaccine administration (although it is not generally used as a clinical administration

fee); would encourage FQHCs and RHCs to accept referrals for vaccination of underinsured children and adolescents who may otherwise be turned away as such centers would otherwise lose money on the costs of vaccine administration;

Cons: states would be required to develop a reimbursement system; Congressional action is required to increase the federal Section 317 program appropriation whenever a new vaccine is recommended, so relying on these funds for reimbursement for vaccine administration may not support development of a system to automatically remove financial barriers to all ACIP-recommended vaccines for children and adolescents. Federal Section 317 operations funds provided to states are not required to be used for administration fees and may go to other priorities such as surveillance and education.

Impact: Major

Policy option directed to: (1) Federal Government – DHHS and Congress

Requires authorizing legislation: No

3. NVAC recommends Congress 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 report “Calling the Shots” that “recommends 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 true need not filtered through the traditional budget process which weighs program needs in the context of overall executive branch priorities for limited resources and may not fully cover program needs in budget requests to the Congress.

Cons: none identified.

Impact: Minor

Policy option directed to: (1) Federal Government – DHHS and Congress

Requires authorizing legislation: No

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

Pros: removes the barriers to seeking additional 317 funding through the traditional appropriations process with each new vaccine policy option; that process has been problematic in recent years.

Cons: no assurances this would occur annually

Impact: Major

Policy option directed to: (1) Federal Government – DHHS and Congress

Requires authorizing legislation: No

**Regarding the VFC Program:**

5. NVAC recommends the VFC program be extended to include access to VFC eligible underinsured children and adolescent to receive immunizations in public health clinics and thus not be limited to access only at Federally Qualified Health Centers and Rural Health Clinics.

*(In 2004, NVAC 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 who now must receive them at FQHCs and RHCs; removes vaccine cost as a barrier for underinsured children and adolescents; would somewhat reduce state reliance on limited Section 317 funds; increases number of sites for underinsured to seek immunizations, would decrease the pressure to increase appropriations for 317 each time a new vaccine is recommended; would not change market share since children covered are generally those already including in public sector financing for older vaccines. If pursued through legislation, would solve the problem in all 50 states.

Cons: if this were to be accomplished through modification of VFC legislation, it would risk having other modifications made that could weaken the VFC program; would still 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 each FQHC that may lead to uneven solutions.

Impact: Major

Policy option directed to: (1) Federal Government - Congress

Requires authorizing legislation: Maybe

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

Pros: eliminates the problem of underinsurance; encourages vaccination in medical home.

Cons: has the potential to erode the private vaccine market if children and adolescents currently served with vaccines purchased with private funds now receive vaccines purchased through the Federal contract; provides economic incentives for employers and insurers to drop coverage for vaccine reimbursement since the federal government could assure vaccines would be available for those children and adolescents. Thus, a mechanism would be needed to ensure maintenance of effort by employers and insurers to cover existing and new vaccines in insurance policies.

Impact: Major

Policy option directed to: (1) Federal Government - Congress

Requires authorizing legislation: Yes

7. NVAC recommends expansion of VFC to cover vaccine administration reimbursement for all eligible children and adolescents. This should include children on Medicaid as this would provide for a single system and uniform vaccine administration fee.

Pros:, would provide uniform reimbursement for vaccine administration and eliminate the current marked variation in Medicaid administration fees in different states; if the Federal government used the Medicare influenza vaccine administration fee as a model, would provide reimbursement that should cover provider costs in most circumstances; no need for state expenditures for vaccine administration; saves states funds which currently go to Medicaid reimbursement for vaccine administration and now could go to other services; incentive for providers to serve all VFC-eligible children and adolescents regardless of reason for eligibility; eliminates inequities in VFC program; automatically removes major financial barriers (i.e., paying for vaccine administration) to access to vaccines recommended by the ACIP, based on the vote of the committee.

Cons: requires amending VFC and may jeopardize the current program; increases the federal budget; requires states to develop administration fee reimbursement mechanisms.

Impact: Major

Policy option directed to: (1) Federal Government - Congress

Requires authorizing legislation: Yes

**Regarding Medicaid Reimbursement for Vaccine Administration:**

8. 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.

Pros: increases reimbursement to levels needed to cover actual provider costs with reasonable return on investment; addresses the fact that many states are not covering the costs of vaccine administration; the increases would not be solely in state funds since a substantial proportion would come out of the Federal match; provides incentives for providers to serve Medicaid-enrolled children and adolescents.

Cons: requires state-by-state determination that this issue is important and subsequent action; would increase state Medicaid expenditures and if budgets are fixed, would require states to divert funds from other covered services.

Impact: Major

Policy option directed to: (1) Federal and State Governments

Requires authorizing legislation: No

9. 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 amount. CMS should work with states to achieve this.

Pros: increases reimbursement to levels needed to cover actual provider costs with a reasonable return on investment; uniform reimbursement at state level, provides incentives for providers to serve Medicaid-enrolled children and adolescents.

Cons: federal mandate on the states; may require legislation; increases state expenditures.

Impact: Major

Policy option directed to: (1) Federal Government – CMS; and State Government

Requires authorizing legislation: No

10. NVAC recommends CDC and CMS annually update, publish, and disseminate actual Medicaid vaccine administration reimbursement rates by state.

Pros: attention to issue might cause states to reevaluate the adequacy of their state's reimbursement rates; doesn't require federal legislative action.

Cons: publication of information does not directly achieve change.

Impact: Moderate

Policy option directed to: (1) Federal Government – CDC and CMS

Requires authorizing legislation: No

11. NVAC recommends CMS update the maximum allowable Medicaid administration reimbursement amounts for each state and include all appropriate non-vaccine related costs as determined by currently on-going studies. These efforts should be coordinated with AMA's review of RVU coding (policy option 18, below).

Pros: allows states currently at the cap to potentially increase reimbursement; caps may be more reflective of current costs than prior caps; attention to issue might cause states to reevaluate their state 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.

Impact: Major

Policy option directed to: (1) Federal Government - CMS

Requires authorizing legislation: No

12. NVAC recommends increasing 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: only covers VFC children and adolescents in Medicaid (unless #2 above adopted); sets precedent to increase Federal Medical Assistance Percentages (FMAP) rates.

Impact: Major

Policy option directed to: (1) Federal Government - Congress

Requires authorizing legislation: Yes

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

Pros: requires action only at the federal level; would ensure a minimum reimbursement for vaccine administration nationally.

Cons: new federal mandate on state Medicaid programs; doesn't cover non-Medicaid eligible VFC children and adolescents; any increase in Medicaid reimbursements for vaccine administration would likely have to be compensated for by decreases in reimbursement of other services under Medicaid; May be opposed by states who would construe this as price setting.

Impact: Major

Policy option directed to: (1) Federal Government - DHHS

Requires authorizing legislation: Yes

**Regarding State and Local Governments:**

14. NVAC recommends that state, local and federal governments along with professional organizations outreach to medical providers who currently serve VFC-eligible children and adolescents to encourage these providers to participate in VFC. 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 into VFC who serve children and adolescents eligible for free vaccines under VFC (e.g., obstetricians/gynecologists for adolescent females); fulfills the intent of VFC entitlement.

Cons: None identified.

Impact: Moderate

Policy option directed to: (1) Federal, State, and Local Health Departments  
(4) Health Care Providers

Requires authorizing legislation: No

15. 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.

Pros: provides financial coverage for more children and adolescents; lowers state healthcare costs for treating disease.

Cons: it may be difficult to increase state budgets in these tight budget times; has the potential to erode the private vaccine market if children and adolescents currently served with vaccines purchased with private funds now receive vaccines purchased through the federal contract; may provide incentives for employers and insurers to drop coverage for vaccine reimbursement since the federal government could assure vaccines would be available for those children and adolescents thus, a mechanism would be needed to ensure maintenance of effort by employers and insurers to cover existing and new vaccines in insurance policies; state and local government commitment is required to increase the funds whenever a new vaccine is recommended for routine use, so solving current problems does not assure future problems will be solved; does not support

development of a system to assure all ACIP-recommended vaccines for children and adolescents are automatically financed; requires state by state efforts and is unlikely to lead to uniform coverage in all 50 states leaving financial barriers in some states.

Impact: Moderate

Policy option directed to: (1) State and Local Health Departments

Requires authorizing legislation: No

**Regarding Business Practices in Public Sector Clinics:**

16. NVAC recommends states and localities develop mechanisms for billing insured children and adolescents served in the public sector. NVAC recommends CDC provide support to states and localities by disseminating best practices and providing technical assistance to develop these billing mechanisms. This may require additional resources that currently are not in CDC's immunization program budget. Further, NVAC recommends reimbursements from insurance (both public and private) received by states and localities be utilized to enhance their immunization program and devolve back into the immunization program (versus enhancing a general fund).

Pros: conserves and reinvests funds for immunization

Cons: would likely require state by state legislation; states and localities may not agree and may prefer any reimbursements from insurance go into general state or locality revenues to allow flexibility in their use.

Impact: Minor

Policy option directed to: (1) State and Local Health Departments

Requires authorizing legislation: No

17. NVAC recommends CDC and CMS continue to collect and publish data on the costs associated with public and private vaccine administration. Costs include costs associated with the delivery of vaccines including such activities as inputting data into immunization registries and maintenance of appropriate storage requirements for vaccines. NVAC recommends that these published data be updated every five years and also include information about the current state of reimbursement by provider type, geographic region, and insurance status.\*\*

*\*\*This policy option is recommended for both the public and private sectors though is stated only once.*

Pros: improved stakeholders understanding of cost.

Cons: none noted.

Impact: Moderate

Policy option directed to: (1) Federal Government – CDC and CMS

Requires authorizing legislation: No

18. NVAC recommends the American Medical Association's (AMA) RVS Update Committee (RUC) should review its Relative Value Unit (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) system is the basis of reimbursement for many insurers; therefore, this will help make insurance reimbursement commensurate with costs for many providers; these costs include: vaccine acquisition, storage, inventory management, data entry into immunization information systems, alarm systems, backup power systems, catastrophic loss insurance, and other costs.

Cons: may have a ripple effect on how other RVUs are calculated and make the process for evaluating these costs extremely complicated and burdensome.

Note: requires evaluation of components of E&M codes to ensure that any components of vaccine administration reimbursed through E&M codes are not also included in the calculation of reimbursements obtained through vaccine administration codes, as this would constitute duplicate reimbursement for such components.

Impact: Major

Policy option directed to: (4) AMA

Requires authorizing legislation: No

D. Private Sector Financing for Vaccine Purchase and Vaccine Administration Reimbursement

**i. Conclusions Related to Private Sector Vaccine Purchase and Vaccine Administration**

- (1) Most private health plans report covering all ACIP recommended vaccines upon publication of ACIP policy options in the MMWR. Many health plans report that they begin coverage following an ACIP vote which often takes place months before MMWR publication.
- (2) 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 costs. A standardized method of coverage of vaccination does not exist. Which vaccinations are covered at what levels of cost-sharing is determined at the level of individual plans.
- (3) Private providers face high opportunity costs based on the time lag between purchasing expensive new vaccines and subsequently administering and being reimbursed for the administration of those vaccines. Further, some providers have raised concerns about whether reimbursements for vaccine administration for insured children and adolescents sufficiently cover provider costs. As vaccines become more expensive, private providers may be less willing to purchase vaccines under the assumption that they will be reimbursed at a later time.
- (4) Some private providers (11% in one unpublished study – Freed, 2008) have seriously considered ceasing to provide all childhood immunizations because of their belief that vaccine purchase and administration reimbursements do not fully cover their costs. A loss of 11% of vaccine providers could have a significant impact on making vaccines available to children and adolescents leading to increased referrals for vaccination outside the medical home and, consequently, lower vaccine coverage levels.
- (5) About half of private providers in one unpublished study (Freed, 2008) reported they delayed purchasing new vaccines out of financial concerns.
- (6) Variability among private providers with respect to business practices related to vaccine purchasing and variability in vaccine administration reimbursements may indicate sub-optimal business practices in some provider offices. Improvements in business practices in such offices could lead to increased efficiency in vaccine administration.
- (7) Insurance coverage for vaccines is positively associated with increased receipt of vaccines by children and adolescents. State mandates that require all plans in a state to cover immunization are controversial in that:

- a. State mandates do not affect persons covered by ERISA-exempt (self-insured) plans;
  - b. Research indicating the effectiveness of state mandates is limited; and,
  - c. State mandates are usually general in nature (e.g. “require coverage for ACIP-recommended vaccines”) and do not specify coverage levels or provider reimbursement amounts.
- (8) It is important to determine how coverage of all immunizations recommended by the ACIP for routine administration to children and adolescents impact insurance premiums.
- (9) The marginal increase to total insurance premiums to include all ACIP recommended vaccines for children and adolescents is not known by the work group.

DRAFT for Comment

**ii. Proposed Policy options Related to Private Sector Vaccine Purchase and Vaccine Administration**

The following proposed policy options are for NVAC consideration regarding vaccine purchase and vaccine administration reimbursement and are formatted in the form of recommendations. The numbering of policy options is continued from the above public sector section III.B.

**Regarding Technical Assistance Related to Business Practices:**

19. NVAC recommends vaccine manufacturers and third party distributors of vaccine work on an individual basis with providers 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 to 90 days to 120 days or more), and/or until vaccine has been administered and reimbursed.

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.

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

Impact: Minor

Policy option directed to: (3) Vaccine Manufacturers  
(5) Vaccine Distributors and Purchasers

Requires authorizing legislation: No

20. NVAC recommends professional medical organizations provide their members with technical assistance on efficient business practices associated with providing immunizations such as how to contract and bill appropriately. Medical societies 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.

Cons: none noted.

Impact: Moderate

Policy option directed to: (4) Health Care Provider Organizations

Requires authorizing legislation: No

21. NVAC recommends 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 the costs and could increase the return on provider investments to purchase vaccines.; 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 inventories of vaccines.

Cons: may lower revenues for manufacturers and distributors for vaccine sales.

Impact: Moderate

Policy option directed to: (4) Health Care Providers and their organizations

Requires authorizing legislation: No

**Regarding Purchasers of Health Care:**

22. NVAC recommends CDC, professional medical organizations, and other relevant stakeholders develop and support additional employer health education efforts. These efforts should communicate the value of good preventive care including appropriate vaccinations.

Pros: gives employers an understanding of the importance of vaccines;  
communicates cost-effectiveness of vaccines to employers.

Cons: will have impact only to the extent that employers adopt the standard.

Impact: Minor

Policy option directed to: (1) Federal Government  
(2) Employers, Payers, and Health Insurers  
(4) Health Care Providers

Requires authorizing legislation: No

23. NVAC recommends health insurers and all private payers of health care coverage 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 payor coverage.

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

Impact: Minor

Policy option directed to: (1) Federal Government & State Governments  
(2) Employers, Payers, and Health Insurers  
(3) Health Care Providers

24. NVAC recommends supporting incentives for the receipt of immunizations by recommending to health insurers and purchasers of health care to eliminate co-pays and deductibles for vaccination for all routinely recommended ACIP vaccines in their plans.

Pros: could eliminate parent out of pocket costs which could serve as a barrier to obtaining vaccines for their children and adolescents; could assure providers receive full reimbursement since it will not have to come from parent out-of-pocket funds.

Cons: no means to assure compliance; health insurers and plans may be unwilling to reveal contract terms; may be viewed as anti-competitive or as undermining the free market; (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. This may increase the number of people on public coverage or increase the number of uninsured, increasing local, state and federal public program costs.

Impact: Major

Policy option directed to: (2) Employers, Payers, and Health Insurers

25. NVAC recommends that health insurers and purchasers of health care should assure reimbursement for vaccinations in their plans are based on methodologically sound cost studies of efficient practices.

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

Con: no means to assure compliance.

Impact: Major

Policy option directed to: (2) Employers, Payers, and Health Insurers

Requires authorizing legislation: No

**Regarding other:**

26. NVAC recommends NVPO calculate the marginal increase to insurance premiums to insurance plans of including all routine-ACIP recommended vaccines.

Pro: provides a context for the cost of this preventive service.

Con: calculation methodology may not be generalizable.

Impact: Minor

Policy option directed to: (1) Federal Government – DHHS/NVPO

Requires authorizing legislation: No

27. 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. Topics for discussion could include:

- (a) Some form of tax credits as incentives for insurers, employers, and/or employees/consumers in eliminating underinsurance and whether these credits would provide added value for getting children and adolescents immunized;
- (b) Some form of insurance mandates for first-dollar coverage of recommended vaccines and their administration;
- (c) Some form of universal federal vaccine purchase or universal federal reimbursement for vaccines and vaccine administration.

Pros: explores other options.

Cons: difficult to gain acceptability of all stakeholders.

Impact: Major

Policy option directed to: (1) Federal Government

APPENDIX 1: Table of Proposed Policy Options for the National Vaccine Advisory Committee (NVAC) Consideration Regarding Vaccine Purchase and Vaccine Administration Reimbursement (formatted in the form of recommendations)

<b>Proposed Policy Options for the National Vaccine Advisory Committee (NVAC) Consideration Regarding Vaccine Purchase and Vaccine Administration Reimbursement (formatted in the form of recommendations)</b>	<b>Vaccine Purchase or Vaccine Administration</b>
<b>Public Sector</b>	
<b><u>Regarding Section 317:</u></b>	
<p>1. NVAC recommends expansion of federal Section 317 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 2-tiered systems for new ACIP recommendations and support for vaccine purchase for underinsured children and adolescents in all states. Professional judgment from the Centers for Disease Control and Prevention (CDC) on the cost to provide this level of support is detailed in the recently released<sup>61</sup> 2008 “Report to Congress on the 317 Immunization Program.”</p>	Vaccine Purchase
<p>2. 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.</p>	Vaccine Reimbursement
<p>3. NVAC recommends Congress 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.</p>	Vaccine Purchase
<p>4. NVAC recommends that the Section 317 program appropriation language be amended to call for an increase in the appropriation amount each year by at least equivalent rates of increase to the VFC program.</p>	Vaccine Purchase
<b><u>Regarding the VFC Program:</u></b>	
<p>5. NVAC recommends the VFC program be extended to include access to VFC eligible underinsured children and adolescent to receive immunizations in public health clinics and thus not be limited to access only at Federally Qualified Health Centers and Rural Health Clinics.</p>	Vaccine Purchase
<p><i>(In 2004, NVAC recommended that such an expansion be considered and did support VFC coverage for underinsured children and</i></p>	

<i>adolescents in all public health departments.)</i>	
6. NVAC recommends expansion of VFC to include underinsured children and adolescents in any setting.	Vaccine Administration
7. NVAC recommends expansion of VFC to cover vaccine administration reimbursement for all eligible children and adolescents. This should include children on Medicaid as this would provide for a single system and uniform vaccine administration fee.	Vaccine Administration
<b><u>Regarding Medicaid Reimbursement for Vaccine Administration:</u></b>	
8. 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.	Vaccine Administration
9. 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 amount. CMS should work with states to achieve this.	Vaccine Administration
10. NVAC recommends CDC and CMS annually update, publish, and disseminate actual Medicaid vaccine administration reimbursement rates by state.	Vaccine Administration
11. NVAC recommends CMS update the maximum allowable Medicaid administration reimbursement amounts for each state and include all appropriate non-vaccine related costs as determined by currently on-going studies. These efforts should be coordinated with AMA’s review of RVU coding (policy option 18, below).	Vaccine Administration
12. NVAC recommends increasing 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).	Vaccine Administration
13. NVAC recommends that CMS set a minimum required reimbursement levels for Medicaid vaccine administration.	Vaccine Administration
<b><u>Regarding State and Local Governments:</u></b>	
14. NVAC recommends that state, local and federal governments along with professional organizations outreach to medical	Vaccine Purchase

<p>providers who currently serve VFC-eligible children and adolescents to encourage these providers to participate in VFC. Outreach directed at providers serving adolescents who may not have provided vaccinations in the past (e.g. obstetrician gynecologists) is a particular priority.</p> <p>15. 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.</p>	<p>Vaccine Purchase</p>
<p><b><u>Regarding Business Practices in Public Sector Clinics:</u></b></p>	
<p>16. NVAC recommends states and localities develop mechanisms for billing insured children and adolescents served in the public sector. NVAC recommends CDC provide support to states and localities by disseminating best practices and providing technical assistance to develop these billing mechanisms. This may require additional resources that currently are not in CDC's immunization program budget. Further, NVAC recommends reimbursements from insurance (both public and private) received by states and localities be utilized to enhance their immunization program and devolve back into the immunization program (versus enhancing a general fund).</p>	<p>Technical Assistance on Process</p>
<p>17. NVAC recommends CDC and CMS continue to collect and publish data on the costs associated with public and private vaccine administration. Costs include costs associated with the delivery of vaccines including such activities as inputting data into immunization registries and maintenance of appropriate storage requirements for vaccines. NVAC recommends that these published data be updated every five years and also include information about the current state of reimbursement by provider type, geographic region, and insurance status.**</p> <p><i>**This policy option is recommended for both the public and private sectors though is stated only once.</i></p>	<p>Vaccine Administration</p>
<p>18. NVAC recommends the American Medical Association's (AMA) RVS Update Committee (RUC) should review its Relative Value Unit (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>Vaccine Administration</p>

<b>Private Sector</b>	
<b><u>Regarding Technical Assistance Related to Business Practices:</u></b>	
19. NVAC recommends vaccine manufacturers and third party distributors of vaccine work on an individual basis with providers 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 to 90 days to 120 days or more), and/or until vaccine has been administered and reimbursed.	Vaccine Purchase
20. NVAC recommends professional medical organizations provide their members with technical assistance on efficient business practices associated with providing immunizations such as how to contract and bill appropriately. Medical societies 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.	Technical Assistance on Process Related to Vaccine Purchase and Administration
21. NVAC recommends 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.	Technical Assistance on Process Related to Vaccine Purchase
<b><u>Regarding Purchasers of Health Care:</u></b>	
22. NVAC recommends CDC, professional medical organizations, and other relevant stakeholders develop and support additional employer health education efforts. These efforts should communicate the value of good preventive care including appropriate vaccinations.	Vaccine Purchase and Administration
23. NVAC recommends health insurers and all private payers of health care coverage 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.	Vaccine Purchase and Administration
24. NVAC recommends supporting incentives for the receipt of immunizations by recommending to health insurers and purchasers of health care to eliminate co-pays and deductibles for vaccination for all routinely recommended ACIP vaccines in their	Vaccine Purchase and Administration

<p>plans.</p> <p>25. NVAC recommends that health insurers and purchasers of health care should assure reimbursement for vaccinations in their plans are based on methodologically sound cost studies of efficient practices.</p>	<p>Vaccine Purchase and Administration</p>
<p><b><u>Regarding other:</u></b></p>	
<p>26. NVAC recommends NVPO calculate the marginal increase to insurance premiums to insurance plans of including all routine-ACIP recommended vaccines.</p>	<p>Vaccine Purchase and Administration</p>
<p>27. 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. Topics for discussion could include:</p> <ul style="list-style-type: none"> <li>(d) Some form of tax credits as incentives for insurers, employers, and/or employees/consumers in eliminating underinsurance and whether these credits would provide added value for getting children and adolescents immunized;</li> <li>(e) Some form of insurance mandates for first-dollar coverage of recommended vaccines and their administration;</li> <li>(f) Some form of universal federal vaccine purchase or universal federal reimbursement for vaccines and vaccine administration</li> </ul>	<p>Vaccine Purchase and Administration</p>

APPENDIX 2: Tables and Figures

Figure 1: Disease cases and deaths averted for each birth cohort through routine childhood immunization series

**Table 4. Health and Economic Outcomes for Selected Vaccine-Preventable Diseases With and Without a Vaccination Program\***

	Without Vaccination Program				Prevented or Saved by Vaccination Program			
	Cases, No.	Deaths, No.	Direct Costs (Million), \$	Total Costs (Million), \$	Cases, No.	Deaths, No.	Direct Costs (Million), \$	Total Costs (Million), \$
Diphtheria	247 214	24721	2358	24 930	247 212	24721	2358	24 930
Tetanus	153	23	8	29	146	22	8	28
Pertussis	2 662 307	1049	2265	3668	2 614 874	1008	2193	3545
Hib	17 530	663	1434	2696	17 469	661	1430	2689
Poliomyelitis	60 974	723	2084	4890	60 974	723	2084	4890
Measles	3 433 722	2795	2646	5875	3 433 036	2794	2645	5874
Mumps	2 100 718	11	936	1459	2 095 917	11	934	1456
Rubella	1 786 334	14	88	381	1 784 030	14	88	380
Congenital rubella syndrome	616	68	115	173	602	66	112	169
HB	232 001	3427	168	1272	207 353	3024	149	1121
Varicella	3 788 807	70	205	1184	3 160 391	57	173	993
<b>Total</b>	<b>14 330 376</b>	<b>33 564</b>	<b>12 307</b>	<b>46 557</b>	<b>13 622 004</b>	<b>33 101</b>	<b>12 174</b>	<b>46 075</b>

Abbreviations: HB, hepatitis B; Hib, *Haemophilus influenzae* type b.  
\*Costs are rounded and given in US dollars.

Source: Zhou F et al. *Arch Pediatr Adolesc Med* 2005;159:1136-1144.

Table 1: Comparison of 20th Century Annual Morbidity and Current Morbidity: Vaccine-Preventable Diseases

Disease	20 <sup>th</sup> Century Annual Morbidity <sup>†</sup>	2005 Morbidity <sup>††</sup>	Percent Decrease
<b>Smallpox</b>	<b>48,164</b>	<b>0</b>	<b>100%</b>
<b>Diphtheria</b>	<b>175,885</b>	<b>0</b>	<b>100%</b>
<b>Measles</b>	<b>503,282</b>	<b>66</b>	<b>&gt; 99%</b>
<b>Mumps</b>	<b>152,209</b>	<b>314</b>	<b>&gt; 99%</b>
Pertussis	147,271	25,616	83%
<b>Polio (paralytic)</b>	<b>16,316</b>	<b>1*</b>	<b>&gt; 99%</b>
<b>Rubella</b>	<b>47,745</b>	<b>11</b>	<b>&gt; 99%</b>
<b>Congenital Rubella Syndrome</b>	<b>823</b>	<b>1</b>	<b>&gt; 99%</b>
<b>Tetanus</b>	<b>1,314</b>	<b>27</b>	<b>98%</b>
<b><i>Haemophilus influenzae</i></b>	<b>20,000</b>	<b>226**</b>	<b>99%</b>

Numbers in **bold** indicate at or near record lows in 2005.

<sup>†</sup> Source: CDC. *MMWR* April 2, 1999. 48: 242-264; <sup>††</sup> Source: CDC. *MMWR*. August 18, 2006 / 55(32):880-893

\* Imported vaccine-associated paralytic polio (VAPP); \*\* Type b and unknown (< 5 years of age)

Table 2: 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. 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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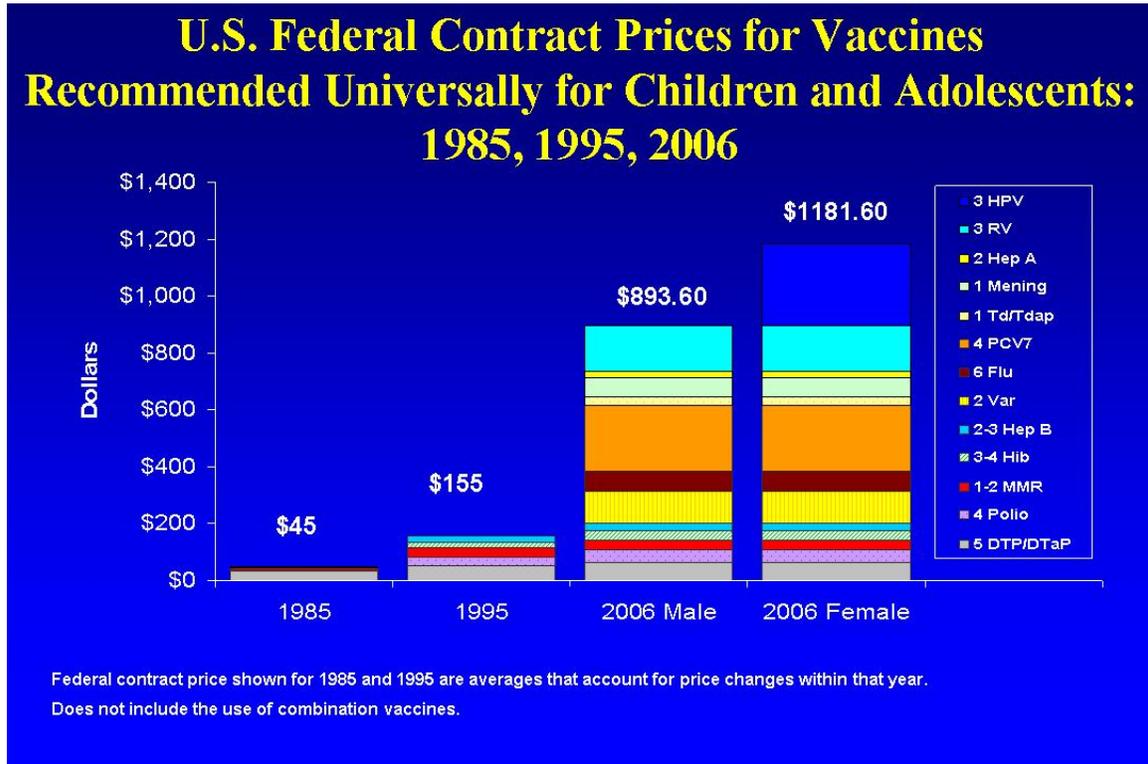
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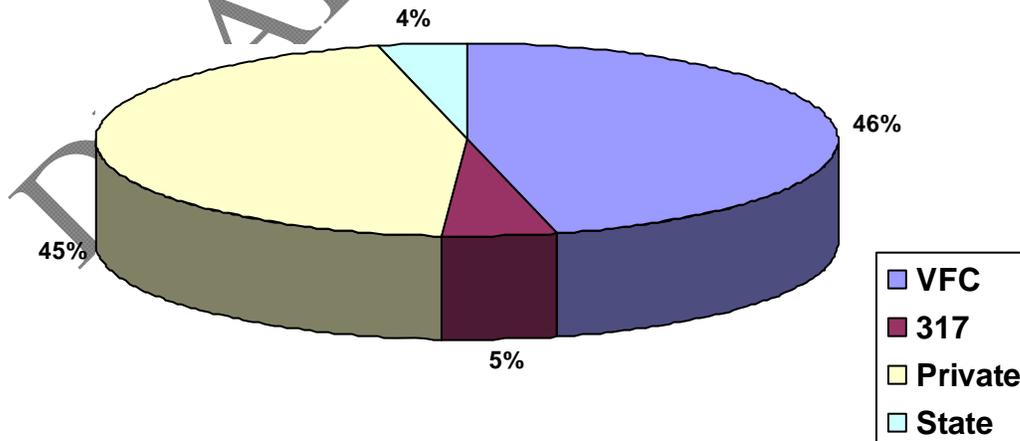
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Figure 2: Cost to purchase vaccine for a child to age 18 in 1985, 1995, and 2006.



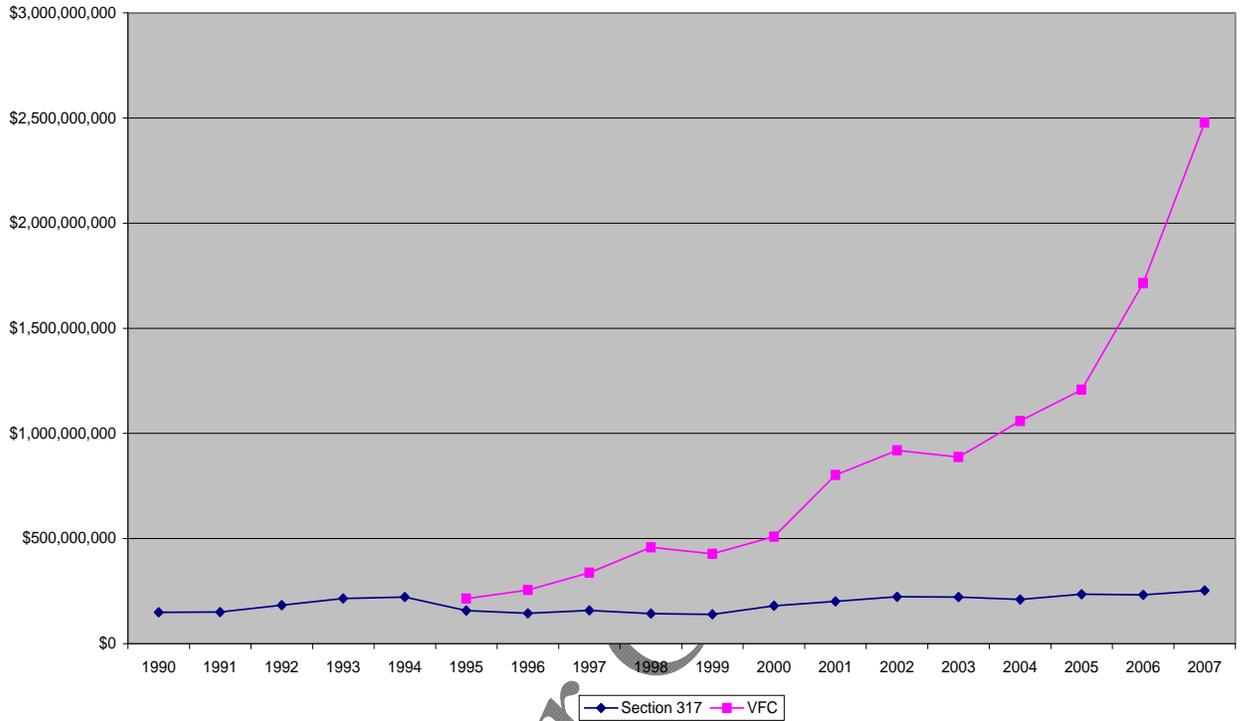
\*Source: CDC Vaccine Price List 2006. Current prices available at [www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list.htm](http://www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list.htm)

Figure 3: Pediatric and adolescent vaccine doses distributed by funding source, CY 2006



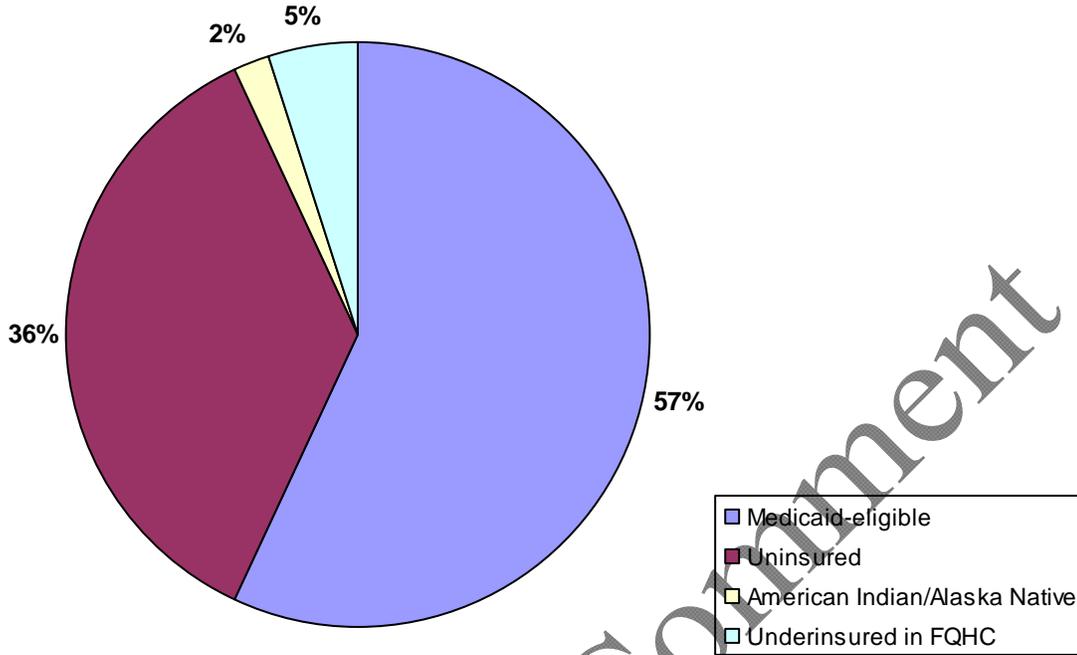
\*Source: Vaccine manufacturers' Biologics Surveillance Data (2006). Does not include influenza vaccine.

Figure 4: Comparison of vaccine funding appropriations: Section 317 (1990 – 2007) vs. Vaccines for Children Program (1995 – 2007).



Source: Centers for Disease Control and Prevention, House and Senate Appropriations Committee Report on the Status of the 317 Program. Atlanta, GA. 2007.

Figure 5: Children receiving VFC vaccines by eligibility category, CY 2000 (estimated)



Source: Institute of Medicine (IOM). Calling the shots: immunization finance policies and practices. National Academies Press: Washington, DC. 2000.

Table 3: Actual vs. allowable Medicaid administration fees paid for VFC vaccine administration, CY 2005.

State	State contribution	Federal contribution	Total administration fee	CMS administration fee cap
Hawaii	0.83	1.17	2.00	15.71
Colorado	1.00	1.00	2.00	14.74
Connecticut	1.00	1.00	2.00	16.56
New Hampshire	1.00	1.00	2.00	14.51
New Jersey	1.25	1.25	2.50	16.34
Texas	1.17	1.83	3.00	14.85
Wisconsin	1.25	1.75	3.00	15.02
Kentucky	1.00	2.30	3.30	14.17
Maine	1.76	3.24	5.00	14.37
Missouri	1.94	3.06	5.00	15.07
Ohio	2.02	2.98	5.00	15.67
Pennsylvania	2.31	2.69	5.00	15.76
Washington	2.53	2.53	5.06	15.60
Iowa	1.86	3.24	5.10	14.58
Vermont	2.39	3.61	6.00	13.86
Illinois	3.20	3.20	6.40	16.79
South Dakota	2.38	4.62	7.00	13.56
Michigan	3.03	3.97	7.00	16.75
Rhode Island	3.12	3.88	7.00	14.93
Alabama	2.33	5.67	8.00	14.26
Indiana	2.98	5.02	8.00	14.47
Georgia	3.16	4.84	8.00	14.81
Alaska	3.39	4.61	8.00	17.54
North Dakota	1.87	6.34	8.21	13.90
Minnesota	4.25	4.25	8.50	14.69
Arkansas	2.19	6.50	8.69	13.30
Nevada	3.87	4.90	8.77	16.13
California	4.50	4.50	9.00	17.55
Nebraska	3.73	5.52	9.25	13.58
Louisiana	2.74	6.71	9.45	15.22
Montana	2.67	6.83	9.50	14.13
Mississippi	2.29	7.71	10.00	13.92
New Mexico	2.57	7.43	10.00	14.28
South Carolina	3.01	6.99	10.00	13.62
Kansas	3.90	6.10	10.00	14.80
Florida	4.11	5.89	10.00	16.06
Wyoming	4.21	5.79	10.00	14.31
Maryland	5.00	5.00	10.00	15.49
Utah	2.93	7.57	10.50	14.52
Virginia	5.50	5.50	11.00	14.71
West Virginia	3.04	8.96	12.00	14.49
Arizona	3.91	8.09	12.00	15.43
Oklahoma	3.97	9.33	13.30	13.89
North Carolina	3.49	10.22	13.71	13.71
Oregon	5.91	9.28	15.19	15.19
Massachusetts	7.89	7.89	15.78	15.78
Idaho	4.70	11.30	16.00	14.34
New York	8.93	8.93	17.86	17.85

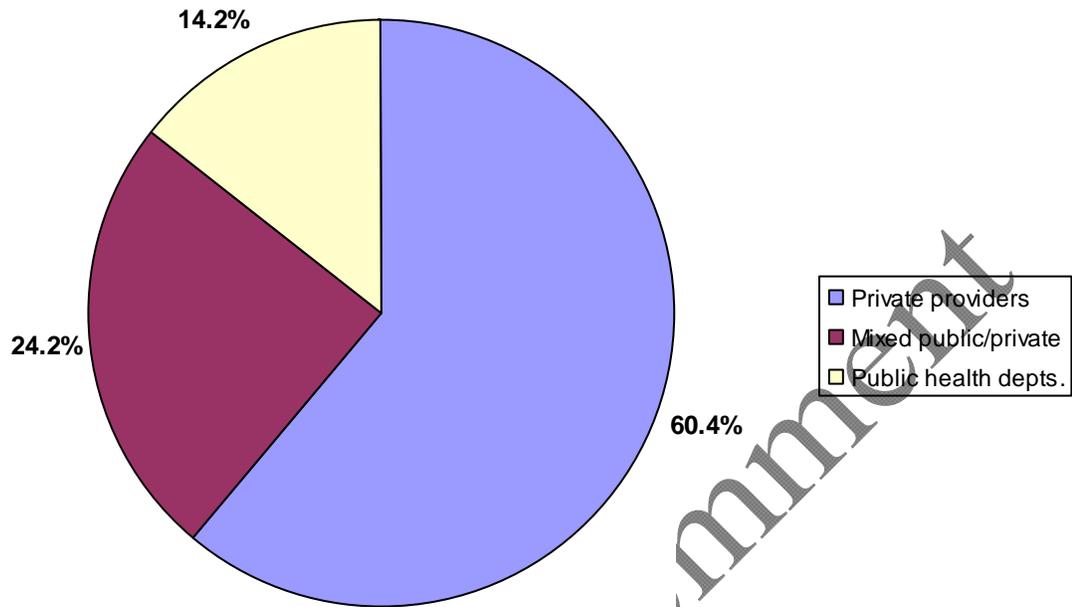
Source: Centers for Medicare and Medicaid Services (CMS) data. No data available for Delaware, the District of Columbia, or Tennessee.

Table 4: Diseases prevented by vaccines recommended for universal use, 1988-2008.

<b>Vaccine-preventable diseases</b>		
<b>1988</b>	<b>1998</b>	<b>2008</b>
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 6: Pediatric immunization delivery system, 2004



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

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