

**STATE-LEVEL PERSPECTIVES ON VACCINE
PURCHASE FINANCING**

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Introduction

This report presents the findings from structured interviews with state immunization program managers and their staff through which we sought to elicit information regarding state policies and experiences regarding the financing of vaccine purchase. Our work focused on gaining an understanding of state budgetary histories (1997-2001) for vaccine purchase, state policies and practices that influence vaccine purchases, and other factors affecting state vaccine purchase decisions. The interview protocol is found in Appendix A. Our interview questions focused mainly on state experiences within the past five years. Vaccine purchase issues prior to and just after implementation of the Vaccines for Children (VFC) program in 1994 are discussed in our November 1999 report for the Institute of Medicine's *Calling the Shots* report.¹ ***Please note that the interview questions were based on topics of interest to the IOM committee and do not necessarily reflect all issues that may be important for understanding the US vaccine purchase system and influences on state practices.*** In addition, this study did not examine state policies and practices regarding funding of immunization program infrastructure.

This report is based on information collected from 48 state immunization programs (including the District of Columbia). Findings are grouped into the following sections:

- I. Background
- II. Current State Vaccine Purchase Issues
- III. Private Provider Issues
- IV. Public Provider Issues
- V. Outside Influences
- VI. Top Concerns of State Immunization Programs

Each section describes the current situations across the states and highlights important recent trends from the perspectives of state immunization program officials.²

¹ Freed, G.L., Clark, S.J., and Cowan, A.E. *State-Level Perspectives on Immunization Policies, Practices, and Program Financing*. Report to the IOM Committee on Immunization Finance Policies and Practices. November 1999.

² Particular state observations are provided as examples throughout the document. Please note that these are not direct quotes, but rather paraphrased quotes taken from our notes.

I. Background

This section provides a brief overview of: (1) the funding sources available for state vaccine purchase, (2) state vaccine purchase financing systems, and (3) communication between state immunization programs and the National Immunization Program at the Centers for Disease Control and Prevention (CDC).

I.A Funding Sources for Vaccine Purchase

The purchase of vaccines is a major component of all state immunization programs. The primary funding sources available to state immunization programs for vaccine purchase are federal VFC program funds, federal Section 317 grants, and state funds. Each funding source is briefly described below:

- ◆ **VFC funds:** The VFC program was established by a 1993 amendment to the Social Security Act as an entitlement program to provide federal funds for the purchase of vaccines for children up to 18 years of age who are Medicaid enrolled, uninsured, Native American or Alaskan Native. VFC funds also are available to purchase vaccine for children whose health insurance does not cover immunizations (i.e., underinsured children), but only if they receive their vaccine at Federally Qualified Health Centers (FQHCs). In 2001, VFC funds accounted for over 50% of total federal vaccine purchase funding in all but one state, and more than 75% in most states.

- ◆ **Section 317 grants:** The Section 317 program is based on Section 317 of the Public Health Service Act and was initially established in 1963. The Section 317 program provides discretionary grants for vaccine purchase and infrastructure support through two types of funding:
 - § Direct assistance (DA) funds, which make up the majority of 317 funds that immunization programs receive for vaccine purchase; and
 - § Financial assistance (FA) funds, which typically support program infrastructure, but since 1999 have also included support for the purchase of vaccines for which there is no federal contract, such as tetanus and diphtheria vaccines (Td and DT).³

The proportion of total federal vaccine purchase funding that comes from 317 funds has generally decreased over the past five years. This decline is mainly due to the decreased demand for vaccines in the public sector and improved state population estimates. Factors influencing decreased demand in the public sector include increased participation of private providers in the VFC program and the

³ The federal government negotiates contracts with vaccine manufacturers for most childhood vaccines (a.k.a. the federal contract). The price for vaccines on the federal contract is 20-40% lower than the average wholesale price (AWP).

movement toward serving children in their medical home, such as through Medicaid managed care and separate Children's Health Insurance Programs (S-CHIP).

- ◆ **State funds:** Direct state funding to immunization programs for vaccine purchase is variable. Few states receive no direct state funding for vaccine purchase. In many states that do have state funding for vaccine purchase, the funds are earmarked for adult vaccines or special programs (e.g., to support a new Hepatitis B school law). State funds are typically legislatively appropriated general revenue funds, but may also come through an ongoing mechanism to generate funds through a specific tax or surcharge, or insurer contribution. Though not a focus of this report, state Medicaid and SCHIP programs also provide funds for vaccine purchase. Medicaid reimburses providers for the purchase of vaccines for persons that are Medicaid enrolled but not VFC eligible (e.g., over 18 years of age). Vaccine purchases for children served under separate SCHIP programs must be made with state funds. According to information provided by state immunization programs, 31 states have or are starting separate SCHIP programs. In about half of these states, vaccines for SCHIP enrollees are purchased through the state immunization program. Additional funding sources available in a few states are federal block grant funds (e.g., Maternal and Child Health (MCH) block grant or US Public Health Service (PHS) block grant) for vaccine purchase. Though federal funds, the funds must be appropriated through state legislatures, and so are often thought of as state funds.

Appendix B presents state-specific vaccine purchase data for 1997-2001 by funding source.

I.B State Vaccine Purchase Financing Systems

The foundation of an individual state's vaccine purchase policies is its vaccine purchase financing system – that is, for which children and through which providers the state supplies vaccine. State vaccine purchase financing systems can be classified as four types: VFC Only, Enhanced VFC, Universal Purchase, and Limited Universal Purchase. Each of these four systems is described briefly below. State vaccine purchase financing systems are shown in Table 1.

- ◆ **VFC Only:** In VFC Only states, federal VFC funds are used to purchase vaccine for VFC-eligible children in the public and private sector. For non-VFC eligible children who are seen in the public sector, vaccine purchases are made primarily with 317 funds. Nineteen states currently have VFC Only systems.

Table 1. State Vaccine Purchase Financing Systems

VFC Only	Enhanced VFC	Limited Universal Purchase	Universal Purchase
Alabama	Florida*	Connecticut**	Alaska
Arkansas	Georgia	Nevada**	Idaho
California	Illinois [§]	North Carolina**	Maine
Colorado	Kentucky*	North Dakota**	Massachusetts
Delaware	Maryland	South Dakota**	New Hampshire
District of Columbia	Michigan*	Vermont**	New Mexico
Hawaii	Minnesota		Rhode Island
Indiana	Montana ^{*,^,§}		Washington
Iowa	Nebraska ^{^^,§}		
Louisiana	New York		
Mississippi	Oklahoma ^{*,§}		
Missouri	South Carolina		
Ohio	Texas [§]		
Oregon	Utah*		
Pennsylvania	Wyoming		
Tennessee			
Virginia			
West Virginia			
Wisconsin			

* Moved from VFC Only to Enhanced VFC system since 1999.

** Moved from UP system to Limited UP system since 1999.

^ In process of changing back to VFC Only system.

^^ Private providers can choose to receive some state-purchased vaccines for non-VFC-eligible children.

§ PCV7 (and varicella in IL) available only for VFC-eligible children.

- ◆ **Enhanced VFC:** In Enhanced VFC states, VFC funds are used to purchase vaccine for VFC-eligible children in the public and private sector. For non-VFC eligible and underinsured children who are seen in the public sector, vaccine purchases are made with 317 and possibly state funds. In addition, state funds are used to purchase vaccines for underinsured children in private provider offices. Fifteen states currently have Enhanced VFC systems. However, five of these states do not have sufficient funds to purchase the recently recommended pneumococcal conjugate vaccine (PCV7) for the underinsured, so it is available only for VFC-eligible children. One of these states also provides varicella only for VFC-eligible children. In addition, one of these states is in the process of changing to a VFC Only system. Finally, one state has a partial Enhanced VFC system – private providers can elect to receive some state-purchased vaccines for non-VFC-eligible children in their practices.

- ◆ **Universal Purchase (UP):** UP states purchase all ACIP-recommended vaccines and make them available to all providers for administration to all children, regardless of insurance status. VFC funds are used to purchase vaccine for VFC-eligible children and typically some combination of 317 and state funds are used to purchase vaccine for non-VFC eligible children, including underinsured and fully insured children, seen in the public and private sectors. Most UP states have a larger proportion of state funds, relative to 317 funds, for vaccine purchase. Eight states currently have UP systems.

- ◆ **Limited UP:** As with UP states, Limited UP states use VFC funds to purchase vaccine for VFC-eligible children and some combination of 317 and state funds to purchase vaccine for non-VFC eligible children, including underinsured and fully insured children, seen in the public and private sectors. However, Limited UP states do not have sufficient funds to provide all ACIP-recommended vaccines in this manner. Six states are considered Limited UP systems.

As shown in Table 1, there have been a few changes in state vaccine purchasing systems since our 1999 report to the IOM. Six states that had VFC Only systems in 1999 now have Enhanced VFC systems (one of these states is in the process of changing back to a VFC Only system). Six states that had UP systems in 1999 now have Limited UP systems.

I.C Communication with CDC

As noted previously, the information in this report is provided by state immunization programs and as such is based on their perspective and interpretation of CDC policy. These perspectives vary and may differ in part due to various interfaces that each program has with the CDC. One formal route of communication with the CDC that has been established is through VFC program consultants. There are three VFC program consultants, each with responsibility for certain regions of the country. These consultants provide technical assistance to state immunization programs with respect to regulation interpretation, oversight and compliance with the VFC and 317 programs. Another interface with CDC may be facilitated by public health advisors (PHAs). PHAs are employees of CDC that are assigned to some state immunization programs. Because PHAs may have worked at the federal level on immunization issues, they may bring to the state a broader understanding of CDC policies.

II. Current State Vaccine Purchase Issues

States purchase vaccine through many sources including the federal government, manufacturers, distributors and wholesalers. However, the vast majority of state-purchased vaccine is purchased through the federal government using VFC or 317 funds.

II. A Vaccine Purchase Through the Federal Government

All states purchase vaccines through the CDC. To facilitate an appropriate allocation of federal funds to each state for the VFC program, each state is required by the CDC to prepare an annual estimate of the population aged 0-18, stratified by specific demographic and insurance information. The states prepare their population estimates in February/March for the upcoming calendar year.⁴ Then in August/September, each state must submit its grant application to apply for VFC and 317 funding.

Typically states receive notice of their initial award of VFC and 317 funds in late December/early January. States do not receive their full allotment of VFC and 317 DA funds but rather receive periodic installments throughout the year. States also may inform the CDC when they are running low on federal funds and request emergency funding to meet specific pressing needs.

VFC and 317 DA funding works as a line of credit. The CDC posts the funding awards to each state's account. Orders placed with VFC and 317 DA funding must go through the federal vaccine contract. When a state purchases vaccine via the CDC's electronic ordering system, VACMAN, the state's account is debited for that purchase amount. Once an order is placed, funds in that state's account are encumbered for the purchase, regardless of when the vaccine is actually delivered. Once a state has expended all of the funds in its account, it cannot order additional vaccine until more funds are placed in the account. If a state places an order when it is out of funds, typically a CDC representative will call the state to ask whether the state would like to transfer the order to a different funding source, if available; otherwise the order will be cancelled.

States receive the full amount of 317 FA (not 317 DA) funding at the beginning of the calendar year as a lump sum. States typically must go through their state purchase order system to use these funds to make vaccine purchases.

Three areas of concern regarding state purchase of vaccine from the federal government that were discussed with state immunization programs are summarized below: (1) accuracy and utility of the annual population estimates, (2) process of funding distribution, and (3) running out of federal funds.

⁴ The fiscal year for federal vaccine funding to states is the calendar year, January-December.

II.A.1. Population Estimates

States expressed a wide range of opinion regarding the usefulness of the population estimates and the role they play in their eventual federal award for vaccine purchase. Although they understood the rationale for the estimates, many state officials commented that the estimates were quite cumbersome and resource intensive to gather. Some felt that although they were helpful in creating broad estimates for VFC, 317 and state funding needs, they were not very useful in estimating need in the state for each category. The CDC provides suggested sources and websites to obtain some of the information required to complete the estimates. However, the perceived usefulness of the resources was not uniform. One program director openly stated:

[We] do not believe the CDC numbers are reliable. The CDC refers states to a Children's Defense Fund report for underinsurance numbers. (We) don't know what the formulas are.

Another commented that:

(We) just use state specific numbers to prepare estimates, not any of the sources or websites the CDC suggests.

According to some program administrators, using recent purchase and distribution information would be more useful and accurate. It is important to note that at least a few states felt that the estimates were very helpful and reflected reality very well.

One criticism of the methods used expressed by several states was that the figures are based on the 0-18 year population while it is the youngest of children that utilize the most vaccine during the primary immunization series. Some states expressed concern that the proportion of children who are VFC-eligible is not equal across the entire age distribution. This was of special concern for states with higher rates of birth and immigration.

A point frequently made by many states was the difficulty in estimating the uninsured population. Requests for greater guidance and technical assistance in this area from the CDC were requested frequently.

Some states expressed frustration that they had gone to all of the trouble to complete the population estimates, yet were not given all of the funding needed to purchase the vaccine for their population. Many remarked that they were frequently asked throughout the year if they really needed the funds requested and approved. It is unclear to the states how the CDC takes the population estimates and translates them into funding allotments. The process was described as a "black box" by one of the larger states. Others were critical about the fact that the CDC does not seem to use the estimates in determining

either the recommended or actual awards. Some questioned how the CDC transitions from the population estimate to funding percentages. As one program manager stated:

Since CDC does not appear to use them, it makes you think they don't put stock in them. In a perfect world, (we) would get what the estimates show.....a problem is that the CDC underestimated impact of new vaccines like Prevnar so couldn't afford to give to states what the estimates show.

II.A.2 Process of Funding Distribution

States receive their VFC and 317 DA funding in multiple awards over the course of a fiscal year, ranging from 1 to 2 awards per year up to 7 to 8 awards per year. Many states reported feeling that there was no discernable pattern to the number or amount of each award they received. Some reported that the number of awards changed every year. Most states reported receiving their first award in late December/early January. A frequent complaint was that the states are never told the overall amount of funds they will receive, with many reporting they are only told an initial allocation amount. This results in difficulty in program planning and vaccine ordering. Some states noted that the awards are intended to be quarterly, which additional awards for special situations. For example, some states reported receiving interim awards for emerging issues such as the release of PCV7.

There was a wide range of experiences and satisfaction reported by states regarding the funding distribution. One state reported:

(we are) often told (when) to expect additional funds, but typically don't receive them even within the approximate time frame. Helpful to have solid, firm dates for when to expect vaccine funding. Had to push to get projection of funds for the whole year; typically do not find out projection for entire year or estimate of number of awards.

At the opposite end of the spectrum one state reported that they are:

contacted by the program consultant and told the total amount of federal funding to expect for the entire year (vaccine purchase and infrastructure), which is usually close to the amount received.

II.A.3 Running Out of Federal Funds

Many states expressed frustration at the lack of a formal mechanism in place to inform them about balances and deposits to their VFC account. This resulted in them not knowing the exact amount of funds in their account at any given time. Even those who attempted to keep their own records of credits and expenditures were, almost without exception, unable to reconcile their figures with the CDC.

Running out of federal funds and being unable to order additional vaccines at a specific time was noted by 29 states. Although some states reported running out of funds at the same time each year, this was not uniform. Several reported running out of federal funds multiple times during the year while others only experienced the problem in relation to special circumstances such as the use of PCV7.

A few states volunteered that they ran out of VFC funds because of mistakes they had made when ordering vaccine. This was usually reported from states with recent turnover in some aspect of the leadership of their immunization program. At least one other disclosed that they ran out of funds in the past when they attempted to stockpile vaccine. However, this is no longer possible with the controls the CDC has placed on order volume.

III.A.4 Suggestions for Improvement from States

It was clear that some of the above issues raised were due to inexperience with, or lack of understanding of, the system for federal vaccine purchase. There is a degree of turnover in the ranks of immunization program managers and others in positions of administrative leadership at the state level. As such, one relatively new program manager noted:

There is not a written procedure manual for state immunization programs, like the VFC operations guide, and there should be so that new personnel know what to expect.

II.B Vaccine Purchase from Non-federal Sources

Although all states purchase almost all of their vaccine through the federal government via the federal contract, there are times when some states purchase some vaccines from other sources. Usually, these purchases make up less than 5% of their overall vaccine supply but they represent an important caveat to the nation's vaccine supply system.

II.B.1 Why Purchase from Non-federal Sources?

Some vaccines must be purchased from non-federal sources because there is no federal contract for them (e.g., viral influenza vaccine, Td). States may use 317 FA funds or state funds for these purchases.

For vaccines on the federal contract, almost all states purchase their entire vaccine inventory via the federal government. However, though uncommon, at least 12 states informed us that they have, on at least on occasion, purchased a vaccine available on the federal contract from a non-federal source. In some instances, a state might be able to negotiate a price below the federal contract price with a specific manufacturer. As one state immunization director reported:

Sometimes our state contract is more attractive than the federal contract. For example, DTaP was \$9.25 on state contract and \$11.25 on the federal contract. So, we can purchase more with state funds and cover more kids with less money. The CDC does not believe the state can get cheaper prices than the federal contract.

States may also attempt to purchase vaccine directly from a manufacturer, wholesaler or distributor, rather than through the federal contract, in times of shortage. If a vaccine is not available from one source (e.g., the federal government), states may try other sources to procure vaccine for their population.

Purchases that do not go through the federal contract, when there is a federal contract for that vaccine, can be made only with state funds. States that have no state funds from their legislature or other sources (as opposed to federal funds) for vaccine purchase are unable to purchase federally contracted vaccine from non-federal sources.

II.B.2 Minnesota Multi-state Contracting Alliance for Pharmacy (MMCAP)

One of the more commonly used mechanisms for the state purchase of vaccine is through the MMCAP. This is a consortium of states that have joined together for volume purchases to negotiate better prices from manufacturers for a variety of biological products. Vaccines are only one of several products available for purchase via the MMCAP. At least 30 states or their local health departments (LHDs) have purchased some of their vaccines from this source. Other states, however, feel they can get better prices at times purchasing directly from the manufacturer.

For some LHDs that provide care to children with insurance, the MMCAP is an important source of vaccine to serve this population. In some states, this is estimated to be as high as 20% of the children served in local health departments.

II.B.3 Borrowing/Trading Vaccine between States

Occasionally, states may have a defined amount of vaccine stock that is nearing its expiration date, have an urgent need for vaccine during outbreak situations, or have ordered more of specific vaccine than needed. In these instances, states may trade or purchase small amounts of vaccine (~10,000 doses or less) from each other. Over half of states reported that they had engaged in this type of trading, but none did it frequently. Fewer than 5 states reported they traded on average more than once per year. Often the CDC facilitates these trades via direct contact with states or through its electronic communication system for immunization program managers. In most cases, the transactions are dose-for-dose trades or a trade of

different vaccines of an amount of comparable value. Very rarely are these transactions outright purchases.

III. Private Provider Issues

One of the goals of the VFC program is to increase the proportion of children who receive vaccine in their medical home. Over the past several years, the proportion of children receiving publicly purchased vaccine in the offices of private physicians has increased markedly. In most states, private providers administer over 50% of publicly purchased vaccine, and several states expect this proportion to increase even further in the next few years. Table 2 provides state immunization program estimates of the proportion of publicly purchased vaccine given in the private sector.

Table 2. Proportion of Publicly Purchased Vaccine Administered in Private Sector

≤60%	60-70%	70-80%	80-90%	>90%
Alaska	Alabama	Colorado	California	Connecticut
Arkansas	Florida	Georgia	Delaware	Hawaii
District of Columbia	Idaho	New Mexico	Massachusetts	Maryland
Illinois	Indiana	North Carolina	Minnesota	New Hampshire
Kentucky	Iowa	South Carolina	Oregon	New York*
Louisiana	Michigan	Utah	Rhode Island	Pennsylvania
Montana	Mississippi	Wyoming	Virginia	Vermont
Nevada	North Dakota			Washington
Oklahoma	Ohio			
Tennessee	South Dakota			
Texas	West Virginia			
Wisconsin				

Based on estimates provided by state immunization program officials. Estimates not available for Maine and Nebraska.

* Does not include New York City.

Thus, private practices now play an important role in the administration of government purchased vaccine. A symbiotic relationship has arisen in which physicians are dependent on government-purchased vaccine for many of their patients and state governments rely on private providers to administer the bulk of government-purchased vaccine. Thus, vaccine purchase and reimbursement policies of the states can, and do, have significant impact on providers. This section of the report contains information on state variation in four areas (1) provider choice of vaccine brand (“provider choice”), (2) method of vaccine distribution to private providers, (3) state immunization program reimbursement for the use of privately purchased vaccine, and (4) Medicaid reimbursement for the use of privately purchased vaccine. Please note that these four topics do not reflect all private provider issues that may be

important for understanding the US vaccine purchase system and influences on state practices, but rather were areas specifically asked about as part of the interview protocol.

III.A Provider Choice

For many years, the federal government and the states did not allow providers to request specific brands of government purchased vaccines for use in their practices. They received and accepted whichever brands were purchased by the government. A relatively recent phenomenon has been the concept of allowing individual public and private providers to choose from competing vaccine products for their government purchased vaccines. Not all states allow choice of vaccine brand. Table 3 shows the state-by-state variation in this practice.

Table 3. Provider Choice Policies for Government Purchased Vaccine

State Chooses Vaccine Brand	Private Providers Choose All Their Vaccines	All Providers Choose All Their Vaccines	Providers Choose Some Vaccines
Alaska	Alabama	California	Kentucky
Connecticut	Arkansas	Colorado	Montana
Georgia	Louisiana	Delaware	Nevada
Hawaii	Mississippi	District of Columbia	West Virginia
Idaho	Nebraska	Florida	
Maine	Pennsylvania	Illinois	
Massachusetts	South Carolina	Indiana	
New Hampshire	Virginia	Iowa	
North Carolina	Wisconsin	Maryland	
North Dakota		Michigan	
Rhode Island		Minnesota	
South Dakota		Missouri	
Texas		New Mexico	
Vermont		New York*	
Washington		Ohio	
Wyoming		Oklahoma	
		Oregon	
		Tennessee	
		Utah	

* New York City responsible for its own public providers.

Currently, 32 states allow some type of provider choice. In some states, provider choice is restricted based on price differential. For example, in a few states there is a legislative requirement allowing provider choice only for products that are within 10% of the lowest price for that specific vaccine. Another state requires that any vaccines eligible for choice be within \$0.15 of the lowest price for that specific vaccine. Other states limit choice to only specific vaccines. Many states have embraced choice believing it will entice private practices to provide public vaccine. Some also have the philosophic belief that all vaccines available to private pay children should be available to those receiving public vaccine. However, other state program directors believe choice costs their state significant unnecessary expense. For example, combined vaccines, such as the combined hepatitis B/Hemophilus influenzae, type b vaccine, are often expensive. One state program director remarked:

Comvax (the combined vaccine) would cost our program \$500,000 more than single antigens.

However, other program directors believe if they do not provide the combination vaccines that providers will quit the program. Thus, they are willing to absorb the extra cost they entail.

Several states felt that providing choice created more complexity and a greater administrative burden for them. In some states, the immunization programs did not want to provide choice but felt that manufacturers lobbied their legislatures to make it happen.

Not all providers take advantage of the choice offered. One state immunization program director revealed that a recent survey of providers found that only approximately 50% utilize choice. The others will use whatever vaccine the state provides. In another state, the majority of responses from a recent provider satisfaction survey indicated providers did not care if vaccine choice was provided or not.

III.B Method of Vaccine Distribution

States purchase vaccine in large quantities. As such, when they take delivery of a large shipment, several logistical issues are involved in the vaccine reaching both public and private providers. The vaccine must be stored in an appropriate facility that provides adequate temperature controls and other storage requirements. The vaccine must then be delivered to multiple providers around the state. Some states distribute vaccine directly to providers while others send large amounts of vaccine to regional depots for providers to pick up themselves. Again, both the transportation mechanism and the depots must meet the requirements for the safe storage of the vaccine. These requirements and the administrative burden and cost required for storage and delivery have resulted in many states contracting with private distributors to undertake these functions. Some states have done so because they believe this will save money; others have done so in attempts to provide better service and delivery options to the providers in their state. State distribution systems are shown in Table 4.

Table 4. State Distribution Systems (as of July 2002)

Public Distributor (i.e., State)	Private Distributor	Both Public and Private Distributors
Alabama	Colorado	California
Alaska	Delaware	Hawaii
Arkansas	District of Columbia	New York
Connecticut	Idaho	Oregon
Florida	Indiana	Pennsylvania
Georgia	Kentucky	Tennessee
Illinois	Maryland	Virginia
Iowa	Minnesota	
Louisiana	Missouri	
Maine*	Montana	
Massachusetts	Nebraska	
Michigan	Nevada	
Mississippi	North Carolina	
New Hampshire	Texas	
New Mexico	Utah	
North Dakota	Wyoming	
Ohio		
Oklahoma		
Rhode Island		
South Carolina		
South Dakota		
Vermont		
Washington		
West Virginia		
Wisconsin		

* Changing to a private distributor in 2003.

III.C Immunization Program Reimbursement of Private Providers

In states that are not Universal Purchase systems, private providers who participate in VFC must maintain two separate stocks of vaccines for their patients, one for children eligible for state purchased vaccines, and one for the patients for whom they purchase vaccines in the private marketplace. Because of shortages and other issues, private providers may run out of either the public or private stock of vaccine.

No state will provide a cash reimbursement to providers who use their stock of privately purchased vaccine for a child eligible for a state or federal government vaccine program. However, at least 14 states allow trading of vaccine stock to replenish any privately purchased vaccine used in place of publicly purchased (or vice versa). Some have a defined system that requires significant documentation; others have a more informal system. Many reported more trading associated with the PCV7 shortage than they had ever experienced previously. However, others reported that because the PCV7 shortage was so severe, they stopped allowing trades because it was too difficult to document. Regardless, these states believe whichever system they use to be preferable to missed opportunities. Other states expressly discourage trading of vaccine stock.

III.D Medicaid Reimbursement of Private Providers⁵

State Medicaid programs are obligated to provide a new vaccine to eligible children within 90 days of licensure by the Food and Drug Administration. This requirement is mandatory regardless of the status of negotiations for a federal contract price. This is in distinction to the overall VFC program, where vaccines need only be provided once a federal contract price is negotiated. Further, there are some vaccines administered to Medicaid-enrolled children for which there is no federal contract.

For vaccines included in the VFC program, only a few state Medicaid programs will reimburse private providers for the use of private purchased vaccine that is available on the federal contract, even in the case of shortages when publicly purchased vaccine may not be available. However, most Medicaid programs will reimburse providers for needed vaccine for which no federal contract price exists (e.g., Td, PPV23, meningococcal) while others will not.

⁵ This project did not involve interviews with officials in state Medicaid offices. As such, the information presented in this section is derived from interviews with immunization program officials and may or may not accurately reflect Medicaid policy in each state. Communication channels and levels of cooperation between immunization and Medicaid programs vary from state to state.

IV. Public Provider Issues

Despite the increase in the proportion of vaccines given in the private sector, public clinics remain an important part of the national immunization effort and provide vaccine to a significant number of children. Because of the role they play and the manner of their funding and organization, different vaccine financing and purchase issues and policies affect their operations. This section of the report contains information on state policy variation in three areas: (1) restrictions on which children can receive vaccine in public clinics, (2) collection of vaccine administrative fees in public clinics, and (3) adult immunization. Please note that these three topics do not reflect all public provider issues that may be important for understanding the US vaccine purchase system and influences on state practices, but rather were areas specifically asked about as part of the interview protocol.

Overall, one of the more interesting findings in the area of public clinic operation was that state immunization programs often do not have jurisdiction to enforce uniform methods of the implementation of policies and procedures. Depending on the state's public health infrastructure, LHDs may have significant amounts of freedom in how they operationalize state policy.

IV.A Restrictions on Which Children Can Receive Vaccine in Public Clinics

For years, public health clinics were uniformly thought to be an impenetrable safety net where all children, regardless of insurance status or ability to pay, could be immunized free of charge. In many states this is still the case. As one immunization program director stated:

(There is) no means testing in public clinics. You can be Donald Trump and still get vaccine...

However, due to increased enforcement of regulations regarding who may receive certain government supplied vaccine, state budget problems and efforts to maintain a medical home for children, this is no longer universally the case. For many states, policies are currently in flux and more changes are expected in the near future. Few public clinics have the administrative structure in place to bill third-party insurers for vaccine.

At least 21 states place some restrictions on which children can receive free vaccine in public clinics. These restrictions take several forms. For some states that provide no state funds for vaccine purchase, only VFC eligible children may receive free vaccine in the public clinics. Such screening has placed an added administrative burden on public health clinic staff. Another state reported they had a "school rule" whereby any child K-12 that needs a vaccine required for school entry can receive it regardless of insurance status. These vaccines are paid for with 317 and state funding. However, if the vaccine is not for school entry, only VFC-eligible children may receive it at health departments.

Seven states that previously provided all recommended vaccines to any child presenting to a public health clinic, have now adopted restrictions relative to newer, and more expensive, vaccines. For example, in those states, the PCV7 vaccine is not available to children who are not VFC eligible.

In a several states, public clinics may immunize an insured patient on one occasion but then refer them to a private provider for the rest of their vaccines. In a few states, public health clinics maintain a supply of public and private stock of vaccine. Public stock has been purchased using VFC, 317, or state funding. Private stock is purchased with local county funding if available. Children who meet VFC or other state specific criteria receive vaccine from the public stock. In those counties able to purchase private stock, it is used to immunize fully insured children who choose to get their well child care at public clinics, either for convenience, lack of private providers in a given area, or historic patterns of care delivery.

Billing private providers is a local issue in which state immunization programs are not typically involved. However, the local health departments have limited experience and expertise in billing policies and procedures. In counties where there is no private stock, fully insured children are referred to their private provider for immunizations.

Some states have also classified their public health clinics as Federally Qualified Health Centers (FQHCs). This allows them to use VFC purchased vaccine for underinsured children.

IV.B Vaccine Administration Fees in Public Clinics

Although vaccine serum may be provided free of charge to most children in public clinics, in some states, clinics can charge patients for the administration of those vaccines. Each state has distinct maximum allowable amounts for administration fees for different groups of children set by the VFC and Medicaid programs as well as the state itself. These may be quite different. For example, in one state, the administration fee charged to 317/VFC eligible children is \$15 per dose, but only \$2 for Medicaid enrolled children. However, not all states use the maximum amount, nor have such significant disparities between the two charges.

At least 35 states have public health clinics that charge a fee to patients for vaccine administration. However, most of these states made clear that no patient would be refused vaccine for their inability to pay the fee. Many states refer to the payment as a “donation” rather than a fee. Even within a given state, some public health clinics charge administration fees while others do not. State immunization programs do not necessarily control this practice, nor even know which clinics do and which do not charge within a given state. In most states where administration fees are collected, the fees do not go to the immunization program but rather stay with the local health departments or revert to the state general fund.

Some clinics will bill their own state Medicaid programs for administration fees provided to Medicaid-enrolled children. Other clinics have arrangements with local health maintenance organizations to be reimbursed for an administration fee. Such efforts can vary from county to county within a given state. There is sentiment from a few program directors that such systems work better in smaller counties.

IV.C Estimation of Immunization Needs for Adult Population

As described in Section II.A.1, states expend a lot of effort in estimating the immunization needs of children. However, there is much greater variability in the efforts of states in estimating the needs of their adult populations.

Very few states systematically estimate demand for adult vaccine. Those that do, usually use the previous year's actual usage. One state reported that they do estimate the need for adults when they perform their forecasting for child immunization programs. They include adults as part of the CDC forecasting tool with some "adjustments" to the methodology. For almost all states, adult immunization is an unfunded or under-funded program activity. As one program director commented:

(We) do occasionally put together figures if requested. Nice to know but can't do anything with it due to lack of funds

In some states, the counties have responsibility for adult immunization. Influenza vaccine is purchased by the LHDs with local or county funds. In a very few other states, LHDs directly receive general revenue funding for adult vaccination that bypasses the state immunization program.

The most common vaccine provided to adults is the viral influenza vaccine, followed by Hepatitis A and B and then the 23-valent meningococcal vaccine. As the population of the US ages, many states are expecting increased demand for influenza and meningococcal vaccines from this population. Any changes in the ACIP recommendations for viral influenza vaccine will have a significant impact on adult immunization budgets. Many states also provide a significant amount of tetanus vaccine to the adult population.

Some states are experiencing a significant increase in the use of Hepatitis A and B with new programs targeting specific at-risk populations. Others with large numbers of migrants also believe they will see an increase in demand for adult immunization services. The recent downturn of the economy will also likely result in fewer adults having health insurance and seeking care (including immunizations) at public clinics.

V. Outside Influences

Three influences on state vaccine purchase practices that were discussed in our interviews with state immunization programs were: (1) state mandates for insurers to provide immunizations as a covered benefit, (2) new national vaccine recommendations, and (3) state political climate. Please note that these three topics do not reflect all outside influences that may be important for understanding the US vaccine purchase system.

V.A Insurance Mandates

The existence of state mandates for insurers to cover immunizations potentially affects the size of a state’s population considered underinsured and fully insured for immunizations, which in turn affects the funding source that is used, if available, for the purchase of vaccines for that population. As shown in Table 5, 27 states do have insurance coverage mandates. From the perspective of state immunization programs, the impact of these mandates varies, depending on the proportion of children insured through out-of-state plans or plans that fall under ERISA exemptions. In the majority of states without insurance mandates for immunization coverage, there is no active effort to pass such a mandate. Several states mentioned that they are hoping for action on this issue at the federal level.

Table 5. State Mandates for Insurance Coverage of Immunizations

No Mandate		Mandate	
Alabama	Tennessee	Arkansas	Montana
Alaska	Utah	California	Nebraska
Idaho	Vermont	Colorado	New Mexico
Illinois	Washington	Connecticut	New York
Indiana	Wyoming	Delaware	Ohio
Kentucky		District of Columbia	Oklahoma
Maine		Florida	Pennsylvania
Michigan		Georgia	Texas
Nevada		Hawaii	Virginia
New Hampshire		Iowa	West Virginia
North Carolina		Louisiana	Wisconsin
North Dakota		Maryland	
Oregon		Massachusetts	
Rhode Island		Minnesota	
South Carolina		Mississippi	
South Dakota		Missouri	

V.B New Vaccine Recommendations

National policy on immunization recommendations is established by the Advisory Committee on Immunization Practices (ACIP). After the ACIP issues a new vaccine recommendation and the federal contract for that vaccine is negotiated, states must begin providing the vaccine through the VFC program. States with Enhanced VFC, Limited Universal Purchase (UP), and UP systems feel pressured to (and want to) provide the newly recommended vaccine to the non-VFC eligible children for whom they provide other recommended vaccines. This is becoming increasingly difficult, however, due to the high prices of recently recommended vaccines. In particular, one recently recommended new vaccine (PCV7) cost as much as all of the other recommended vaccines together, effectively doubling states' vaccine budgets. As noted in Section I, some states are no longer able to implement their vaccine purchase financing system for newly recommended vaccines. States are concerned that ACIP recommendations are made without regard to their financial implications. Thus, given the recent trend toward higher prices for new vaccines, the number of vaccines for which states cannot implement their current vaccine purchase financing system will likely increase in the future.

The issuance of new recommendations can be particularly difficult financially if the recommendation is released (and federal contract negotiated) after the federal and/or state funding decisions have already been made. Even for recommendations that are anticipated before funding decisions are made, these funding decisions are based on projected need and uptake, which may not be accurate. Several states noted that the annual federal funding decisions did not adequately account for the rapid uptake of PCV7 by providers in its funding awards to states.

New combination vaccines can be problematic both financially and logistically, particularly for states that offer providers choice of vaccine brand. Combination vaccines tend to cost at least as much as all of the single antigens combined, and often are priced at a premium. In addition, these vaccines are often very popular with providers, so uptake can be rapid.

V.C Political Climate

While many states noted that their legislature and governor are generally supportive of immunizations, a few others noted that immunizations are not "on the radar screen" of their political leaders. Even those states where the legislature and governor view immunization issues positively, state immunization programs noted that this does not necessarily translate into funding support. This is particularly true in the current economic climate, with many states running budget deficits and experiencing economic downturns. The majority of states said that requests for new or additional funding to purchase vaccines would be very difficult to get through under current economic conditions. Several states, particularly those with universal purchase systems, are concerned that they will be unable to

maintain their current vaccine purchase financing system, as state legislatures lose patience with or are otherwise unable to keep pace with continuing cost increases (and related funding requests).

Another issue for immunization programs related to the political climate is that it is always changing due to term limits for legislators and governors. Thus, state immunization programs have less certainty whether the support (or lack thereof) that they have been experiencing will continue from one election to the next. Term limits also require state immunization programs to spend more time keeping elected officials informed about the functions of the immunization program and the importance of government support for their efforts.

VI. Top Concerns of State Immunization Programs

At the conclusion of our interviews, we specifically asked states to summarize their top three concerns related to vaccine purchase for their immunization program. Based on the 48 interviews conducted, the following four concerns related to vaccine purchase were most commonly cited by state immunization programs:

- ◆ **Supply:** One of the top issues for almost all state immunization programs (~40 states) is the stabilization of vaccine supply. Recent shortages of multiple vaccines on the recommended childhood immunization schedule have been very difficult for state immunization programs to manage. Specific state concerns related to vaccine supply that were frequently mentioned include:
 - § Missed opportunities and the effect they may have on immunization rates
 - § The ability, both financially and logistically, to provide “catch-up” vaccines to those children whose doses were deferred during the shortages
 - § The erosion of confidence of providers in the stable supply of publicly purchased vaccine (even though shortages usually also impacted private stock)
 - § The impact of having a sole source (i.e., one manufacturer) for many vaccines on vulnerability of vaccine supply in the future

- ◆ **Funding:** Approximately 29 states listed some aspect of vaccine purchase funding as one of their main concerns. To make program planning easier and to minimize the chance of running out of federal funds, several states would like to receive their federal funding at regular and predictable intervals. A few states noted that it would be helpful to receive their federal funds all at once at the beginning of the calendar year, but were cognizant that OMB would not likely allow this to happen. Others were concerned that federal and/or state funding be adequate to maintain their current vaccine purchase financing system or wished to expand their financing system to cover more subgroups of children.

- ◆ **Vaccine prices:** For 20 states, the price of vaccines is a major issue. Due to their relatively higher price, the impact of recently recommended vaccines (i.e., varicella and especially PCV7) on state immunization program budgets has been substantial. States are concerned that if these pricing trends continue, and funding (federal and/or state) does not keep pace, they will increasingly have to restrict access to certain vaccines. While this concern mainly has to do with new and combination vaccines, a few states mentioned that increasing prices of existing vaccines (e.g., Td) also contribute to their concern.

- ◆ Adult immunizations: Ten states mentioned adult immunization as a top concern. Specifically, these programs want to put more focus on improving adult immunization rates, but are concerned that there is no funding available to do so.

APPENDIX A:

Sample of Interview Protocol

IOM STUDY ON VACCINE PURCHASE FINANCING
QUESTIONS FOR STATE IMMUNIZATION PROGRAMS

Vaccine Purchase Funding

1. The accompanying spreadsheet summarizes the funds from VFC, 317, state and any other resources used for vaccine purchase from 1997-2001 in your state (based on data from CDC). Are there any significant funding amounts not reflected here? If so, how much and for which vaccines? What has influenced any major changes in vaccine purchase funding levels that have occurred in your state?
2. For each funding source (VFC, 317, state and other), I would like to walk through the typical funding process from budgeting through actual vaccine purchase.
 - a. When and how is the budget/estimate of need for this funding source determined relative to the year in which purchases will actually be made?
 - b. How and when do you actually receive the funds?
 - c. How are the funds disbursed for vaccine purchases?
 - d. Have you ever run out of these funds? If so: How often has this occurred? Why do you think this happened? How long until more funds became available? What do you do when this occurs? Can you still place orders?
3. Are you considering any changes to your current system of vaccine financing or any new vaccine financing strategies?
4. Is the use of vaccine given at public clinics restricted in any way? How are underinsured and insured children that come to public clinics for their immunizations handled?

Estimates of Future Demand

5. Each year, you provide the CDC with estimates of the population of children 18 and under in the state, both overall and by vaccine purchase funding source. How helpful have these estimates been for your own program planning/budgeting? How well would you say these estimates reflect reality? Are there children for whom you purchase vaccine that are not reflected in these estimates?
6. What have been the trends in recent years in your state with respect to numbers and age distribution of children for which you provide vaccine? Has the distribution of children served under different programs (e.g., VFC, SCHIP) changed? What are the reasons behind the trends you just described?
7. Though I know it is difficult to predict, what trends in the number and distribution of children served by your immunization program do you expect in the next 2 years? Would you be comfortable making predictions for the next 5 years? 10 years? 20 years? How wide a *range* of possibilities would you suggest for each of those predictions? On what assumptions do you base your predictions?
8. Do you estimate the annual needs for public sector purchase of vaccine for adult populations? What have been the trends in recent years in your state with respect to numbers and age distribution of adults for which you provide vaccine? What trends would you predict over the next several years?

Vaccine Purchase Procedures

9. What is the process by which you order vaccine from the federal contract (e.g., how determine numbers of doses to order, how often place orders)? Does it differ by vaccine or vaccine manufacturer?
10. For vaccines for which there is a federal contract, do you ever buy vaccine from manufacturers or distributors that are not part of the federal contract? If so: How often does this occur? How and why does this occur? For which vaccines? Do you pay more or less than the federal contract price?
11. Do you / have you ever purchased vaccine through a purchasing alliance or consortium, such as the Minnesota Multi-state Contracting Alliance for Pharmacy (MMCAP)? If so: How often do you purchase vaccines through the consortium? How and why does this occur? For which vaccines? Do you pay more or less than the federal contract price? Do you know whether local governments have participated in any purchasing alliances?
12. Have you ever borrowed, traded or purchased vaccine from other states? If so: How often does this occur? For which vaccines? What is the process by which this takes place? How do you establish a price for the vaccine?
13. Do you ever attempt to purchase more vaccine than you need at a specific time (i.e., stockpile) to guard against future shortages in your state? Have recent shortages had an impact on your current thinking or actions in this regard? Are there particular months with higher demand for which you place larger orders?

Program Administration

14. Over the past five years, what has been the annual proportion of publicly-purchased vaccines administered in the public vs. private clinical setting? Do you anticipate any changes in this proportion in the next five years? If so, why?
15. If you offer provider choice of vaccine brand, when was this policy established and why? Has this impacted vaccine supply or utilization in your state? If you do not offer provider choice of vaccine brand, why not? Are there any changes anticipated in this policy in the near future?
16. How do you distribute publicly purchased vaccines to private providers? Do you ever reimburse private providers for vaccine (e.g., if used private stock for public vaccine-eligible patients)?
17. Are vaccine administration fees collected in public clinics? If so: How much? How is it collected?
18. Is your state Medicaid program considering reimbursing providers to use private purchase vaccine for Medicaid patients when there is no publicly purchased vaccine available?

Outside Influences

19. Does your state mandate insurance coverage of immunizations? Is there new activity around this issue?

20. How would you describe the recent attitudes and actions of your state's legislature regarding immunization? Regarding funding in particular? Do you expect changes in these attitudes and actions in the future?
21. How would you describe the receptiveness of your state's governor regarding immunization? Regarding funding in particular? Do you expect changes in these attitudes and actions in the future?
22. What interest groups are active in your state regarding immunization issues? Have they been effective in changing the legislature's/governor's response to vaccine-relevant legislation? Do you expect changes in their effectiveness in the future?

Vaccine Purchase Concerns

23. What are the top three (3) issues for your state immunization program right now with respect to vaccine purchase?

APPENDIX B:

State-by-State Vaccine Purchase Data for 1997-2001

APPENDIX B
State-by-State Vaccine Purchase Data for 1997-2001

The following pages present state-by-state vaccine purchase data for the 48 states with which we conducted interviews. The data are presented in dollars by vaccine and funding source for the years 1997-2001. These data were provided to us by the Centers for Disease Control and Prevention (CDC) and were pulled from its electronic vaccine ordering system, VACMAN. Prior to our interviews with state immunization programs, we asked them to review the tables and discuss any significant vaccine purchases that were not reflected, as well as the influences on any major changes in funding levels. Because the data were pulled from VACMAN, the tables we provided to states contained only purchases that went through the federal contract. Purchases that were not reflected in the tables include:

- Purchases made with 317 FA funding, which the CDC has awarded to states since 1999 for the purchase of vaccines that do not have a federal contract, such as the tetanus and diphtheria booster (Td).
- Purchases made with state funds through the Minnesota Multi-state Contracting Alliance for Pharmacy (MMCAP) or direct contracts with vaccine manufacturers.
- Other vaccines that some state programs purchase, such as the meningococcal vaccine or yellow fever vaccine.
- Purchases made independently by local health departments with their own funding sources.

In general, the magnitude of these purchases is minimal relative to the overall amount of state vaccine purchases that go through the federal contract. State-specific comments and caveats related to the data in the tables are noted. For example, when available, states estimated the annual amount of 317 FA funding. In general, states were never able to exactly match the numbers provided by CDC. One reason for slight discrepancies is the idiosyncrasies in how and when end-of-year ordering gets recorded (e.g., may appear in following year). Also, states often look at budgets on a state fiscal year basis (usually July-June), which is different than the vaccine funding fiscal year (January-December).