

Universal Purchasing of Childhood Vaccines in New York State: A Feasibility Assessment

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Contents

EXECUTIVE SUMMARY	i
I. Introduction	1
II. Methodology of Feasibility Assessment	2
Literature Review.....	2
Stakeholder and Expert Interviews	3
Cost Estimates.....	4
III. National Policy.....	5
The History of Childhood Immunization in the United States	5
The Vaccines for Children (VFC) Program.....	7
Immunization Rates in the United States.....	10
Costs and Cost Effectiveness of Childhood Immunizations.....	10
Vaccine Manufacturing.....	13
IV. State Vaccine Purchasing Programs	14
Background.....	14
State Supplied Vaccine Financing	15
State Vaccine Purchase and Delivery	17
Immunization Registries	17
State Immunization Rates	18
V. Current Vaccine Policy in New York State	18
Background.....	18
Immunization Registries	19
New York State Immunization Regulation.....	20
VI. A Universal Childhood Vaccine Purchasing Program in New York	21
Stakeholder Opinions about Universal Purchasing of Vaccines.....	21
Potential New York State Revenue Sources for Universal Childhood Vaccine Purchasing....	27
Costs and Benefits of a Universal Vaccine Purchasing Program in New York State	28
VII. Recommendations	36
Financing.....	37
Purchase and Delivery	39
Program Administration.....	40

Tables and Figures

Table 1: Number and Type of Interviews Conducted.....	3
Table 2: Recommended Childhood Immunization Schedule	8
Table 3: Cost Effectiveness of Recommended Immunizations	12
Table 4: State Vaccine Programs by Type.....	15
Table 5: Benefits of a Universal Vaccine Purchasing Program for Children	28
Table 6: Cost of Immunizing all Non-VFC Eligible New York State Infants/Toddlers and 11 Year Olds Under Alternative Assumptions (2009\$).....	32
Table 7: Financial Winners and Losers in a Universal Vaccine Purchasing Program in New York State.....	34
Figure 1: Number of Recommended Childhood and Adolescent Vaccines.....	6

Appendices

Appendix A: Key Informants Interviewed By Stakeholder Status
Appendix B: Interview Topics
Appendix C: Cost Estimate Calculations And Assumptions
Appendix D: Glossary of Terms

Acknowledgments

EXECUTIVE SUMMARY

Universal Purchasing of Childhood Vaccines in New York State: A Feasibility Assessment Sarah Benatar, Embry Howell, and Randall R. Bovbjerg Health Policy Center, The Urban Institute Final Report to the New York State Department of Health, September 2010

Introduction

This report assesses the administrative, fiscal, and political feasibility of implementing a universal vaccine purchase and distribution program in New York State. Universal childhood vaccine purchasing would entail state purchase and delivery of all vaccines for privately insured children and adolescents in the state free of charge to providers. The goals of universal vaccine purchasing include addressing physicians' concerns about rising costs for providing immunizations to children and adolescents, maintaining and increasing immunization rates, and supporting continuity of medical care in children's medical homes.

Six "universal" states presently purchase all recommended pediatric vaccines for privately insured children. An additional nine "universal-select" states purchase most vaccines for this group, typically excluding only the most expensive vaccines. State purchase of vaccines for privately insured children is one strategy for addressing the growing financial strain on providers who administer childhood immunizations. As additional and more expensive vaccines are included in the recommended immunization schedule, pediatricians and family practitioners are struggling to pay in advance for the vaccines they administer. Furthermore, providers frequently report inadequate reimbursements from health plans for the vaccine serum as well as the additional costs of storing and administering the vaccine.

Data and Methods

Information for this study was gathered from 57 interviews with key stakeholders and independent experts including physicians, vaccine manufacturers, health plans, regulatory officials, and staff in other states that have pursued this course. Peer reviewed literature as well as relevant reports were also consulted. In assessing universal vaccine purchasing in New York State, the costs of the program, its benefits, and the challenges of implementing and monitoring the program were considered. Feasibility was considered in light of the experience of other states, likely winners and losers in New York State under universal vaccine purchasing, an evaluation of the existing public health framework for vaccines in New York, a review of potential funding mechanisms, and the present operational capabilities of the state.

Key Findings on Costs and Benefits

New state spending needed to purchase vaccines for all children not already receiving free vaccines was estimated under three different price assumptions: the federal contract price (a 10-65 percent discount obtained by the Centers for Disease Control and Prevention (CDC) for purchasing vaccines for public provision), full list price, and a negotiated price in between. These initial estimates suggest that purchasing vaccines would cost the state approximately \$160

million at the low end of the range and \$224 million at the high end. Administrative costs at the state level would amount to approximately one percent of the cost of purchasing vaccines.

Likely benefits from universal vaccine purchasing are considerable, although only assessable in qualitative terms in a project of this type. One is to boost physicians' willingness to deliver childhood immunizations by alleviating the current burden of prepaying for vaccines. A second benefit is increased efficiency in vaccine ordering, delivery, and management, with possible side benefits for the completeness and utility of the state's vaccine registry. Third, presuming high physician participation and reduced financing and logistical burdens, the state could work to maintain or increase immunization rates in New York, a very important public health benefit.

The middle cost estimate of \$192 million constitutes about one tenth of one percent of all health spending in the state or approximately \$10 per New Yorker per year. Costs should be considered in broad perspective, as all residents benefit when immunizations reduce exposure to contagious diseases, and savings from reduced illness accrue throughout health care.

Recommendations

New York State should consider purchasing vaccines for all privately insured children in the state. This recommendation reflects our assessment that many providers are financially strained to provide vaccines to their patients, and the state is risking a possible erosion of immunization rates (especially for higher priced vaccines) that can be avoided by a modest per-person investment of public funds. In addition, such a program would likely improve the efficiency of ordering and monitoring vaccine supplies, possibly leading to reduced costs provided that a stable financing mechanism is identified that would not unduly shift the burden of costs across stakeholders.

This report cautions, however, that the state must recognize the limitations of a universal vaccine purchasing program: it will eliminate the opportunity for some providers to generate revenue from vaccine purchasing; it may not do enough to stabilize or raise immunization rates; and it will not address concerns about inadequacies in administration fee reimbursement. Furthermore, these recommendations are not yet fully implementable. State budgetary planning must re-estimate actual costs of the program once more program parameters are established. Planning for implementation should also engage all key stakeholders in order to forestall problems in design details and implementation as well as to persuade all parties to participate.

In expectation of good planning to meet the challenges identified above, we recommend that the state pursue universal vaccine purchasing in the following manner:

Financing

- Funding flows for this program should be stable, have the ability to accommodate growing vaccine costs, and have the flexibility to address changes in vaccine schedules or prices that occur out of synchronization with the state's annual budget cycle. Without reliable funding, a universal vaccine purchasing program cannot achieve its intended benefits.

- Should any form of health plan assessment be identified to finance this program, New York State should consider forming an advisory board that will engage health plans in the process of setting assessments.
- All monies collected to support universal vaccine purchasing should be placed in a trust fund or other account designated solely for this program. The fund should begin with sufficient resources to meet one-time start-up expenses, and it should accumulate and maintain a balance judged sufficient to cope with mid-year changes, such as recommendation of a new vaccine, a supply shortage, or a price increase.

Purchase and Delivery

- New York State should plan to negotiate directly with manufacturers for a reasonable price as a bulk purchaser of vaccines. It is unlikely that federal administrators will allow the state to utilize the federal contract for vaccine purchases.
- New York State should provide all authoritatively recommended vaccines to privately insured children and adolescents, as for publicly covered children. Over time, however, new vaccines should be scrutinized for cost-effectiveness to the extent that this criterion is not used by those making vaccine recommendations nationally.
- New York State should offer all vaccine brands to providers rather than restrict vaccines to those from certain manufacturers. This is the current state policy for publicly provided vaccines, encourages provider participation, and allows for consistent offerings from year to year.
- New York State should utilize the CDC's centralized delivery system for state vaccine purchases, in tandem with federally funded vaccines delivered in New York.

Program Administration

- New York State should invest in integrating the state's ordering, tracking, and monitoring system with the New York City and New York State immunization registries in order to achieve efficiencies.
- New York State should extend the CDC standards for monitoring and quality assurance to the additional vaccines supplied by the state under universal purchasing.
- New York State should consider various options for monitoring vaccine administration fees paid to providers in the interest of achieving the important public health benefits of high participation and vaccination rates.

I. Introduction

New York's 2008 budget mandated that the State Department of Health conduct a feasibility study on developing a universal vaccine purchase and distribution system in New York State.¹ Universal childhood vaccine purchasing would entail state purchase and delivery of all vaccines for privately insured children and adolescents in New York free of charge to providers. This program would make all vaccines available by wrapping around the existing federal-state Vaccines for Children (VFC) program which pays for and delivers vaccines for Medicaid, uninsured, and underinsured children.

There are three key intended benefits of a universal vaccine purchasing program. One is to boost physicians' willingness to deliver childhood immunizations by providing the financial benefit of free vaccines. Full public financing would alleviate the burden of prepaying for vaccines—well in advance of actual usage and ability to bill—felt by many pediatricians and family practitioners. Burdens arise from the increasing prices of newer vaccines and the small practice sizes within which most practitioners operate. A second goal is to increase the efficiency of vaccine ordering, tracking, delivery, and monitoring. A universal vaccine purchasing program would unify the ordering and delivery of private vaccines with the system in place for publicly provided vaccines. A unified system could also boost the completeness and utility of the state's relatively new registry for vaccine monitoring and oversight. Third, by alleviating financing and logistical burdens, the state would hope to maintain, or even increase, immunization rates in New York, a very important public health benefit.

The feasibility study on universal vaccine purchasing was unanimously supported by New York's Immunization Advisory Council, whose formation was an offshoot of an unsuccessful 1991 attempt to enact universal vaccine purchasing in the state. In September 2008

The Urban Institute was contracted by New York State to execute this feasibility assessment in time to present it to the legislature by the beginning of 2009.

This report presents the findings from that feasibility study. It describes the methods used, provides background on existing national and state vaccine policy, enumerates the likely benefits of a universal vaccine purchasing program, considers the likely reactions of stakeholders, estimates likely spending requirements, and makes recommendations with appropriate cautions about the need for careful implementation.

II. Methodology of Feasibility Assessment

In this report, we assess the administrative, fiscal, and political feasibility of implementing a universal vaccine purchasing program in New York State. The report is based on a policy analysis that provides a qualitative assessment of feasibility. The methods are designed to present recommendations within a very short time frame, and without any new data collection or analysis. Accordingly, we rely on findings from existing studies in other settings, and the opinions of key informants. For example, universal vaccine purchasing benefits are assessed by generating hypotheses from literature and key informants, and considering the face validity of their opinions in qualitative fashion.

Literature Review

We conducted a systematic scan of the peer reviewed literature written on the topics of vaccine financing, childhood immunization cost-effectiveness, and immunization policy. In addition, we reviewed other relevant publications, including those from the Centers for Disease Control and Prevention (CDC), and reports and presentations of state and federal advisory committees. (See Bibliography for a list of significant documents reviewed.)

Stakeholder and Expert Interviews

Fifty-seven independent experts and key stakeholders were interviewed for this report, including providers and representatives of provider organizations; vaccine manufacturers; health plans; independent experts; public health officials from the CDC, the New York State Department of Health, and the New York City Department of Health and Mental Hygiene; and officials in other states. We utilized an intentional “snowball” method to populate our sample of key stakeholders, asking many interviewees to identify individuals or groups that may have an informed perspective and important contribution to make. (See Table 1 for a list of types of interviews and Appendix A for a full list of those interviewed.) Topics covered in the interviews are provided in Appendix B.

Especially key for understanding the administrative feasibility of universal vaccine purchasing were interviews with representatives of existing vaccine purchasing programs in several states. Specifically, we spoke with immunization managers in New Hampshire, Rhode Island, Massachusetts, North Carolina, New Mexico, Wyoming, and Washington State, as well as the Executive Director for the Association of Immunization Managers.

Table 1: Number and Type of Interviews Conducted

Type of Interview	Number
Independent Experts	8
Health Plans	5
Manufacturer Representatives	7
New York State/New York City Health Department	13
Providers & Provider Association Representatives	10
Regulatory Officials	6
State Immunization Managers	8
Total	57

Source: Authors' Tally (Appendix A)

Cost Estimates

This report provides a reasonable estimate of the cost of universal vaccine purchase and program administration in New York State. This fiscal assessment presents the likely range of costs for purchasing the full recommended course of vaccines per child and the numbers of children affected.

We estimate the cost to the state of purchasing all recommended regularly scheduled vaccines for all privately insured children, that is, all children not already eligible for existing public vaccine purchase programs. The cost estimate is determined by multiplying the number of regularly scheduled immunizations that children should receive times the price per dose of vaccine.^{2, 3} We estimate a range of vaccine prices per scheduled vaccination to reflect uncertainty about the outcome of price negotiations—at the federal contract price, at the manufacturers' list price, and at a third price point midway between the federal and list price. The estimate does not include the cost of annual influenza vaccination or of some vaccines that are recommended only for high risk groups.

Administrative spending level estimates are based on current costs of this type reported by vaccine program managers in New York and in other states with existing universal purchase programs. These cost estimates, however, must be refined using a more detailed assessment of administrative functions before an actual budget is developed. Such an analysis was beyond the scope of this project.

III. National Policy

The History of Childhood Immunization in the United States

The public health contribution of vaccines is unique in both reach and efficacy. Childhood immunizations avert millions of preventable illnesses in the United States and around the globe. In addition to preventing disease in those to whom they are administered, immunizations have spillover effects that reach beyond individuals, especially in cases where the illness being prevented is highly contagious. Widespread immunization has virtually eliminated deaths from polio, measles, and rubella, and there has been nearly a 100 percent decline in deaths due to diphtheria, mumps, pertussis, and tetanus (Roush and Murphy, 2007).

Because of the clear public health benefit of vaccines, federal, state, and local governments have played a role in vaccine development, regulation, delivery, and financing for more than a century.⁴ Government supports basic research, regulates manufacturing and safety of vaccines, shields manufacturers of childhood vaccines from liability lawsuits,⁵ and has provided increasing amounts of funding for vaccines over time (Institute of Medicine, 2000).

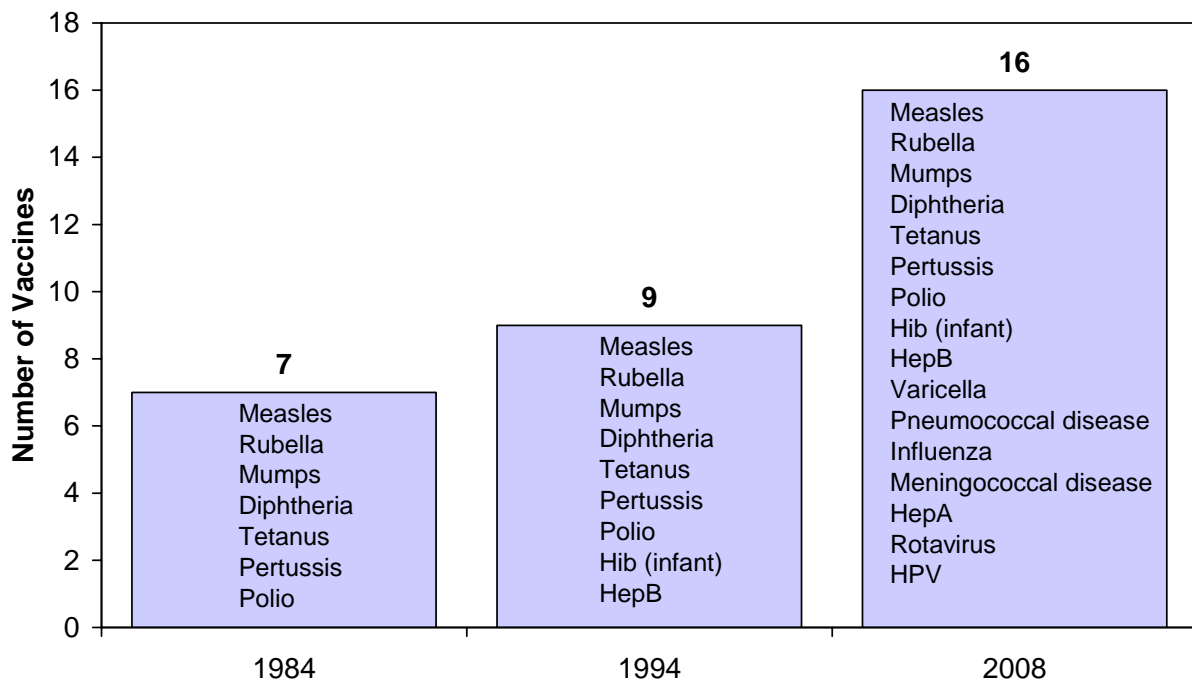
Childhood vaccinations were traditionally financed mainly through public health systems and family payments (Institute of Medicine, 2003). More recently, health insurers have played an increasing role in financing vaccine purchase and delivery through payments to contracted providers. Pioneers in emphasizing preventive services—such as immunizations—included Medicaid’s Early Periodic Screening, Diagnosis, and Treatment provisions and prepaid group practices. By the 1990s, private fee-for-service and managed care plans had both greatly expanded payment protections for childhood vaccines, as had the new federal Vaccines for Children (VFC) program. Increased coverage helped shift the typical site of vaccinations from public health sites to children’s medical homes (Szilagyi et al., 2000; Freed et al., 1999).

Nationally, nearly three-quarters of vaccines are now administered in private providers’ offices

(Institute of Medicine, 2003). New York State Department of Health officials suggest that this number may be higher in New York. These figures compare with only 50 percent of children in 1990 being vaccinated in private providers' offices (National Vaccine Advisory Committee, 1991; Santoli et al., 1999). Immunizations are administered primarily by pediatricians (70 percent) and family physicians (12 percent). A much smaller percentage of children receive vaccinations from other providers or in other settings, including public health clinics (Santoli et al., 1999).

In recent years, the number of recommended childhood vaccines has more than doubled—to 16, up from 7 in 1984 and 9 in 1994 (Figure 1).

Figure 1: Number of Recommended Childhood and Adolescent Vaccines



Source: Orenstein, W. 2008

The Vaccines for Children (VFC) Program

The federal-state Vaccines for Children (VFC) program took effect in October 1994.⁶ VFC is a federal entitlement program covering more than 35 million children ages 0-18 (Centers for Disease Control and Prevention, 2009a). Vaccines purchased under the VFC program are supplied free of charge to providers for administration to Medicaid-eligible children, Alaska Native and American Indian children, and uninsured children. The program also provides vaccines for underinsured children who are vaccinated at Federally Qualified Health Centers (FQHC) or Rural Health Clinics (RHC).

The Centers for Disease Control and Prevention (CDC) of the U.S. Department of Health and Human Services administers the VFC program. All vaccines recommended by a CDC advisory committee—the Advisory Committee on Immunization Practices (ACIP)⁷—are adopted by the VFC program. Recommendations include age for vaccine administration; number of doses and dosing intervals; and precautions and contraindications. These recommendations are science-based, and consider the burden of disease, efficacy, safety, feasibility, coordination with recommendations of other groups, and cost-benefit analyses. According to ACIP's criteria, the cost of a specific vaccine is not supposed to be a deciding factor. ACIP guidelines have been harmonized with American Academy of Pediatrics (AAP) and American Academy of Family Physicians (AAFP) recommendations.

Nationally, VFC-funded vaccines account for approximately 43 percent of all vaccine purchases. Forty-seven percent of vaccines are purchased by private providers, and the remaining 10 percent are purchased with state funds and Section 317 federal grants received by states⁸ (Centers for Disease Control and Prevention, 2007c). The Department of Health and Human Services VFC budget was \$2.9 billion in FFY 2007 (U.S. Department of Health and Human Services, 2008).

Table 2: Recommended Pediatric Immunization Schedule, 2008

<i>4:3:1:3:3:1 Series</i>	Number of Doses by 35 Months
Diphtheria, Tetanus, Pertussis	4
Inactivated Poliovirus	3
Measles, Mumps, Rubella	1
<i>Haemophilus influenzae</i> type b	3
Hepatitis B	3
Varicella	1
<i>Additional Vaccines for Infants/Toddlers</i>	Number of Doses by 35 Months
Rotavirus	3
Pneumococcal Conjugate	4
Influenza*	1 (annually)
Hepatitis A	2
<i>Vaccines for 4- to 6-Year-Olds</i>	Number of Doses by 6 Years
Diphtheria, Tetanus, Pertussis	1
Inactivated Poliovirus	1
Measles, Mumps, Rubella	1
Varicella	1
Influenza	1
<i>Vaccines for Adolescents</i>	11- to 12-Year-Olds
Human Papillomavirus (girls only)	3
Meningococcal	1
Influenza	1

* Note: flu vaccination is recommended annually for all children over the age of 6 months.

Source: Recommended Immunization Schedules for Persons Aged 0-18; approved by the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, and the American Academy of Family Physicians

CDC negotiates directly with vaccine manufacturers to establish the prices of vaccines that are purchased for the VFC program. The CDC discount ranges from 10 to 65 percent below the private sector catalog price, depending on the specific vaccine (Centers for Disease Control and Prevention, 2008a).⁹ States that purchase additional vaccines with Section 317 funds are also entitled to the CDC contract price, as are state Medicaid-based SCHIP programs. Some argue that this discount creates a cap on manufacturers' vaccine earnings, which has contributed to

shrinking the private market and may threaten future vaccine innovation (Offit, 2005). On the other hand, these contracts ensure a predictable market for manufacturers.

CDC also finances the distribution of VFC vaccines, which amounts to approximately one percent of the cost of the vaccines.¹⁰ In 2006, CDC contracted with McKesson Specialty Distribution to distribute all VFC vaccines (as well those ordered by state vaccine purchasing programs) from a central warehouse in Tennessee. According to CDC representatives, in the future more than one distributor could receive contracts. A central delivery mechanism for VFC, Section 317, and state supplied vaccines offers a streamlined (if sometimes imperfect) ordering and delivery system. CDC began transitioning to this centralized delivery system in early 2007, and is pleased with its improved ability to track the distribution of vaccines under the new system.

CDC requires that VFC grantees (i.e., states and some large cities and counties) ensure that participating providers comply with certain monitoring procedures for VFC supplied vaccines. This includes site visits to a minimum number of providers to ensure that vaccines are being stored properly, and to monitor any potential for fraud or abuse.

A major goal of the VFC program has been to encourage immunization in children's medical homes. Prior to VFC, many uninsured and Medicaid-enrolled children were immunized at public health clinics. One study done in New York State found that physicians reported referring significantly fewer patients to public health clinics for immunization following the establishment of the VFC program (Szilagyi et al., 2000a,b). Furthermore, they found that providers who did not obtain VFC vaccines were twice as likely as VFC providers to refer patients elsewhere for immunizations (Szilagyi et al., 2000a,b).

Immunization Rates in the United States

The other major goal of the VFC program has been to raise immunization rates in the United States. Efforts of the VFC program and related state and local initiatives—such as evidence-based strategies in primary care, and increasing use of immunization registries to track which children are immunized—have likely contributed to such gains (Shefer et al., 1999). Cases of vaccine preventable illnesses in the United States are at an all time low (Roush and Murphy, 2007) and immunization rates are at, or near, record highs (Centers for Disease Control and Prevention, 2008b). In 2007, less than one percent of children in the United States received no vaccinations by age 19-35 months. Immunization rates are well above 90 percent for most individual vaccines, and are nearing 80 percent for the recommended series of childhood immunizations. *Healthy People 2010* established a coverage target of 80 percent for the combined 4:3:1:3:3:1 series (see Table 2). In 2007, 77.4 percent of 19-35 month olds completed the 4:3:1:3:3:1 series, up slightly from 76.9 percent in 2006 (Centers for Disease Control and Prevention, 2008b).

Costs and Cost Effectiveness of Childhood Immunizations

While the cost of older vaccines is relatively low, many of the recently introduced vaccines have been much more expensive. With the introduction of new vaccines, the cost per fully-vaccinated child, based on the discounted federal contract price, has risen dramatically to \$1,105 for boys (0-18) and \$1,407 for girls (0-18), up from \$45 in 1985 and \$155 in 1995 (Orenstein, 2008).¹¹ To illustrate this increase, while some of the older vaccines sell for less than \$10 per dose, the average sales price per dose is \$78.80 for pneumococcal conjugate vaccine and \$93.87 for meningococcal vaccine (Centers for Medicare and Medicaid Services, 2008).¹² The steep increase in vaccine costs is the result of a revival of innovative vaccine development, in itself a

positive trend. Childhood vaccine costs will likely continue to grow as new and expensive vaccines become available (Institute of Medicine, 2003).

These increasing costs have had a substantial impact on the practice costs of physicians administering childhood vaccines. One study asserts that up to 20 percent of pediatric practice costs can be attributed to immunizations (Berman, 2008). Unlike prescription drugs, providers purchase vaccine supplies in advance of administering them to privately insured patients, and seek reimbursement after they are dispensed. In addition to the costs of the vaccine, providers incur costs associated with obtaining, storing, and administering immunizations. For example, appropriate cooling facilities are required for vaccine storage. A power outage or storage equipment malfunction could lead to significant loss of vaccines and the associated up-front investment.

Physicians report a wide range of prices for vaccines purchased, as well as varying reimbursement levels from third-party payers, resulting in a positive net yield for some practices and losses for others (Freed et al., 2008b). In addition to reimbursements for vaccines, physicians usually receive an additional “administration fee” for each vaccination. Vaccine administration fees also vary widely, with payer reimbursement per dose ranging from a low of \$0.00 to a high of \$26.55, with a mean of \$16.62.¹³ In New York Medicaid fee-for-service pays an administration fee of \$17.85, which is the federal maximum allowance last updated in 1994 (American Academy of Pediatrics, 2007).

While vaccines represent a revenue stream for some physicians, interviewees report that many others are losing money, so there is a growing risk that they could decide not to immunize children in their practices but rather to refer them elsewhere. One study found that 11 percent of providers say that they have seriously considered no longer offering immunizations for privately

insured children in their practices, and many report having to delay purchase of some vaccines because of financial concerns (Freed et al., 2008a).

The cost-effectiveness of individual vaccines varies widely, and thus some suggest that the most cost-effective vaccines should take a higher priority (Institute of Medicine, 2003). For example, some vaccines actually save money to society by preventing costly illness (and are “cost saving”), while others are estimated to be “cost-effective” (according to accepted guidelines for the cost per quality adjusted life year saved) or are cost-effective only for high risk groups. Table 3 illustrates this range.

Table 3: Cost Effectiveness of Recommended Immunizations

Vaccine	Indicated Age	Cost Effectiveness
Hepatitis B	Infants/toddlers	Cost saving
Rotavirus	Infants/toddlers	Cost effective
Diphtheria, Tetanus, Pertussis (DTaP)	Infants/toddlers	Cost saving
Haemophilus influenzae type b (Hib)	Infants/toddlers	Cost saving
Pneumococcal conjugate	Infants/toddlers	Cost effective
Influenza	Yearly 0-18	Not cost effective*
Measles, Mumps, Rubella (MMR)	Toddlers	Cost saving
Varicella	Toddlers	Cost saving
Hepatitis A	Infants/toddlers	Cost saving
Meningococcal	Adolescents*	Not cost effective*
Human Papillomavirus (HPV)	Adolescent females	Cost effective
Polio (IPV)	Infants/toddlers	Cost saving
Tetanus (TdaP)	Adolescents	Cost effective

*In non-high risk groups

SOURCE: Ortega-Sanchez et al., 2008

Another study estimates that for every dollar spent on the recommended seven vaccine routine (DTaP; Haemophilus influenzae type b (Hib); Hepatitis B; Measles, Mumps, Rubella (MMR); Polio (IPV); Tetanus (TdaP); and Varicella), \$5 is saved on direct medical expenditures

and an additional \$11 is saved to society (Zhou et al., 2005). On the other hand, another study estimates that for each dollar spent for pneumococcal conjugate vaccine (PCV), only \$0.68 is saved (Jacobs and Meyerhoff, 2001). Precise cost-effectiveness estimates vary across studies.

Vaccine Manufacturing

At present, there are four dominant vaccine manufacturers (GlaxoSmithKline, Merck, Sanofi-Pasteur, and Wyeth), down from approximately 26 in 1967, and 17 in 1980 (Offit, 2005). While vaccines account for a small, albeit growing, portion of these companies' revenues as newer expensive vaccines are introduced, the research and development costs for new vaccines are very high and the regulatory burden for vaccine approval and manufacturing licensing is significant. There is some evidence, however, that recent federal policies including higher vaccine prices have encouraged more research and development (Coleman et al., 2005).

In 2003 the Institute of Medicine (IoM) issued a report on vaccine financing that pointed to the poor financial return for vaccine manufacturers as a factor in the limited competition that exists in the vaccine market, noting that in several cases there is only a single manufacturer for a particular vaccine. The IoM report also described continuing market exit by manufacturing firms, frequent interruptions of vaccine supply and other shortages, as well as what they saw as under-investment in research and development for new vaccines (Institute of Medicine, 2003; Sloan et al., 2004).

The IoM report concluded that prices need to be sufficient to encourage vaccine development, but affordable enough to be provided, so that public health benefits are achieved. To achieve such pricing on a reliable basis, the report recommended an analysis-driven approach to setting prices that would base payment rates on vaccines' estimated benefits to society. The promise of higher rates going forward in turn would stimulate innovation and bring the social

benefits of new vaccines to new generations of Americans. The IoM committee proposed to end the VFC program, impose a federal mandate on all payers to cover childhood immunizations, and institute a federal subsidy program to guarantee reliable payment.

IV. State Vaccine Purchasing Programs

Background

State universal vaccine purchasing programs supplement VFC and Section 317 provisions by purchasing recommended childhood and adolescent vaccines for privately insured children (Institute of Medicine, 2000 and Institute of Medicine, 2003). Six states currently have universal purchasing programs that supply all ACIP-recommended childhood vaccines to providers (see Table 4). Five of these six states had universal programs prior to VFC. The number of universal states rose to 15 by 2000 (Institute of Medicine, 2003), but since then, nine states have converted to what is termed “universal select,” meaning that they cover all but selected vaccines. The most recent “universal select” states (2005 or thereafter) are Idaho, Maine, Massachusetts, North Dakota, and Vermont. The high cost of new vaccines has been a key problem in sustaining universal purchase programs, and those are the vaccines most likely to be omitted in “universal select” states. North Dakota took the further step of reverting to a VFC-only state this year due to the cost of vaccines.¹⁴ Wyoming is the only current universal purchase state that was implemented after VFC. New York and some other states go just one step beyond the VFC program to supply vaccines to private providers who immunize “under-insured” children (those with health insurance that does not cover vaccines) using a combination of Section 317 and state funds. Most of the states with enhanced VFC programs cover all ACIP recommended vaccines,

but three cover only select vaccines for the under-insured. Table 4 illustrates which states fall into each of these categories.

There is substantial satisfaction with universal vaccine purchasing programs by most stakeholders, especially providers. According to the health department immunization managers we spoke with, provider participation is close to universal.

Table 4: State Vaccine Programs by Type, 2008

Universal	Universal Select	VFC & Underinsured	VFC & Underinsured Select	VFC Only	
Alaska	Connecticut	Arizona	Illinois	Alabama	Nebraska
New Hampshire	Hawaii	Georgia	Indiana	Arkansas	New Jersey
New Mexico	Idaho	Kansas	South Carolina	California	North Dakota
Rhode Island	Maine	Kentucky		Colorado	Ohio
Washington	Massachusetts	Maryland		Delaware	Oklahoma
Wyoming	Nevada	Michigan		D.C.	Oregon
	North Carolina	Minnesota		Florida	Pennsylvania
	South Dakota	New York		Iowa	Tennessee
	Vermont	Texas		Louisiana	Virginia
		Utah		Mississippi	West Virginia
				Missouri	Wisconsin
				Montana	

Source: Clark et al., 2008

State-Supplied Vaccine Financing

States have many revenue options for funding their state vaccine purchasing programs, as for any other state spending. For example, several state programs are funded through direct annual appropriations from the state's general fund. This mechanism leaves state immunization programs vulnerable to funding shortfalls, and can require ongoing diligence on the part of health department employees to maintain continued support for funding. Moreover, as a practical matter, supplemental funding often cannot be appropriated mid-cycle, resulting in a lag between when a new vaccine is added to the list of recommended childhood immunizations, and when

states can begin supplying it to physicians. As a result, some universal purchase states have chosen to delay provision of available, newly recommended vaccines for VFC-eligible children until the state can finance the vaccine for its privately insured population as well. Insurance companies often do not reimburse providers for new vaccines in a timely manner either, and as a consequence, providers may find themselves giving a vaccine to one child and not another, depending on how the child's vaccine is covered.

Insurance-based financing for state supplied vaccines (such as that used in New Hampshire, New Mexico, and Rhode Island) can be more stable than other forms of state funding, although there are some potential pitfalls. For example, it is very important that the assessment is perceived to be fair. (See the box below for a description of the New Hampshire approach, in which a non-profit association, which includes insurance representatives, sets the assessment). In addition, if insurance assessments are funneled through the state general fund, there is no guarantee that they will be allocated for vaccine purchases each year. Furthermore, the issue of mid-cycle funding for newly approved vaccines is not addressed by annual assessments unless a surplus is built in to cover mid-cycle additions.

New Hampshire Vaccine Association (NHVA)

The NHVA plays a key role in the NH universal vaccine program. Created by the state legislature in 2002, the NHVA is a not-for-profit organization that determines the assessment rate levied on insurers annually to fund the universal vaccine purchasing program. The board meets several times a year and is composed of three insurance industry representatives (chosen based upon New Hampshire market shares), two health care provider representatives, the New Hampshire Commissioner of Health and Human Services, and the New Hampshire Commissioner of Insurance.

State Vaccine Purchase and Delivery

All current universal and universal select states utilize the CDC contract to purchase vaccines for non-VFC eligible children.¹⁵ States that use this option receive a significant discount on vaccines compared with the private market. CDC is cautious, however, about having additional states use the federal contract price out of concern that it could erode the existing discount and undermine the reach of VFC and Section 317 funds. States that fund their universal (or universal select) programs through payments from insurance companies are particularly discouraged from using the federally contracted price.¹⁶ Two small states that began using insurance company contributions to fund their programs prior to VFC (New Hampshire and Rhode Island) have been grand-fathered into the program and allowed to use the CDC discount. New Mexico, another such state, reports that they have been told they will no longer be allowed to rely on the federal contract for purchasing state supplied vaccines, and will be required to negotiate directly with manufacturers going forward.¹⁷

All state supplied vaccine programs rely on the CDC delivery infrastructure free of charge.¹⁸ We heard from state immunization program managers as well as physicians that there have been some complaints about the relatively new centralized delivery system. Some problems have included long delivery times, and lost or inaccurate orders. Others have expressed concerns about the stability of supply over time, noting that it might be risky to rely solely on one distributor for delivery of all childhood vaccines.

Immunization Registries

Most state immunization programs have implemented immunization registries, electronic systems for tracking childhood immunizations at the patient level. Potentially, immunization registries can improve the efficiency of managing vaccine supplies and monitoring provider practices, while encouraging record keeping and enabling more accurate tracking of

immunization rates. The capability of different states' registries, however, varies widely. For example, some states monitor and manage VFC and/or state inventory processes through their registries, while others are in the more rudimentary stages of developing their registry systems. The capabilities of state immunization registries are tracked by the American Immunization Registry Association, utilizing data from the CDC's Immunization Information System Annual Report.

State Immunization Rates

The impact of state purchasing programs on immunization rates is unclear. State immunization rates vary widely, and no published study has documented a direct correlation between states that have universal vaccine purchasing programs and higher immunization rates.¹⁹ For example, the immunization rate in Maryland—a state which does not have a universal purchase program—is 92.4 percent for the 4:3:1:3:3:1 series. By comparison, the rate for this series is 73.9 percent in Washington State, which has a universal program (Centers for Disease Control and Prevention, 2008b). On the other hand, there is evidence that past increases in Section 317 funding have been correlated with improvements in immunization rates (Rein et al., 2006).

V. Current Vaccine Policy in New York State

Background

In New York City, immunizations for 60 to 70 percent of children 0-2 years old are covered by VFC or Section 317 funds (New York City Bureau of Immunization, 2008a), while the proportions are closer to 40 percent VFC and 60 percent private upstate (New York State Bureau of Immunization, 2008). New York State and New York City operate their VFC/Section 317

programs separately, though the New York State Department of Health is in charge of ordering vaccines for all children in the state covered by SCHIP.

New York State VFC programs are operated with funds from two grants from the CDC, one to the New York State Department of Health and one to the New York City Department of Health and Mental Hygiene. Each department has dedicated staff operating VFC-funded activities. As required by the VFC program, the immunization staff manages policy implementation and responds to any policy changes; monitors program fraud and abuse; complies with quality assurance requirements; and generates required reports for CDC. New York State and New York City immunization staff also provide education for physicians who receive publicly supplied vaccines to ensure they understand program requirements and are able to comply with them.

The size of the existing vaccine administrative infrastructure in New York is substantial. For example, the New York State Bureau of Immunization receives \$12.4 million from the federal government and \$7.3 million from the state to administer its programs. A staff of about 70 people is funded by these grants. This staff administers a call center for vaccine ordering and customer service, and maintains a vaccine stockpile of emergency and backup vaccines.

Immunization Registries

New York City has an operational immunization registry that has required physician reporting for children under age 8 since 1997. This registry is not currently used for ordering vaccines through the VFC and Section 317 programs, but it is used to monitor the reasonableness of orders that are received by fax. For instance, if a physician orders 20 doses of a certain vaccine one month and reports having used only 5 doses the previous month, the city will follow up with the provider to understand the discrepancy between orders and reported usage. This reduces waste while encouraging providers to report to the registry.

New York State's immunization registry (covering all areas outside the city) has not been operational for as long as the registry in New York City, and the state has benefited by learning from New York City's experience. In 2008, New York State mandated provider participation in the upstate registry for immunizations administered to children less than 19 years of age, and the state has already achieved approximately 80 percent compliance among VFC providers. As with the city's registry, the New York State Immunization Information System (NYSIIS) is to be used to track immunization history, send reminder and recall notifications, generate vaccine inventory and VFC reports, and produce routine and ad hoc reports. State officials have said that they are considering utilizing the registry for vaccine ordering. Several other universal vaccine purchase states are moving or have moved in that direction.

New York State Immunization Regulation

New York, like most other states, mandates immunization for school children (National Network for Immunization Information, 2005) and imposes other requirements that touch upon vaccination. Notably, state-licensed health plans (but not self-insured employer plans) must cover recommended childhood vaccinations. New York further stipulates that coverage must be "first" dollar—that is, deductibles, coinsurance, or copayments cannot apply (Kaiser Family Foundation, 2006). The vaccine coverage requirement is part of a more general mandate to cover preventive and primary care services for children.²⁰ As for all state insurance regulation, requirements do not apply to ERISA self-insured plans.²¹

Although first-dollar coverage is required in New York, no minimum provider payment level is set by statute or implementing rule. Regulatory enforcement relies upon market forces, including the negotiating power of participating physicians, to assure adequate payment. How plans pay for vaccines and their administration, and at what level of payment, are not systematically understood. The Department of Insurance receives complaints of inadequate

payment fairly regularly, and is designing a survey with the Department of Health in order to increase their understanding of the reimbursement of vaccines and vaccine administration.

VI. A Universal Childhood Vaccine Purchasing Program in New York

There are many factors that determine whether New York State should implement a universal vaccine purchasing program. These include the political environment, financing options, and the benefits that will accrue to various stakeholders, most importantly the children themselves.

Stakeholder Opinions about Universal Purchasing of Vaccines

To assess the political ramifications of implementing a universal vaccine purchasing program for childhood vaccines in New York State, we spoke with key stakeholders about their opinions and concerns. The most important stakeholders are providers (pediatricians and family physicians), vaccine manufacturers, and health plans.

Physicians generally support universal vaccine purchasing programs, both in New York and other states. In the immediate past New York State legislative session, the American Academy of Pediatrics (AAP) supported such a program and this study of its feasibility. Family physicians also expressed support for a universal vaccine purchasing program. Family physicians would likely, however, prefer that the program be extended to include adult vaccines as well.

Vaccine financing for privately insured children faces challenges in New York State that mirror those in other states. The introduction and recommendation of new and increasingly expensive childhood vaccines is contributing to financial strain for physicians. Nearly all of the providers we spoke with in New York reported feeling strained by the capital outlay required to purchase vaccines for their privately insured patients. Most also mentioned that the third party reimbursements they receive for vaccines are inadequate. Some providers reported that they

regularly have as much as \$20,000 to \$100,000 tied up “in the refrigerator” (i.e., vaccines that have been ordered, received, and paid for, and that are being stored for future use). Several providers reported they have experienced a decline in profits associated with providing immunizations in recent years. On the other hand, two physicians—one from a solo practice and one from a large practice—told us that vaccines are one of the few remaining revenue generating activities in their practices.

Despite evidence that some providers are making money from vaccines, provider representatives from the New York State chapters of the American Academy of Pediatrics and the American Academy of Family Physicians stressed that vaccines pose a substantial strain on most practices. A survey conducted by the New York City Department of Health and Mental Hygiene found that more than half of physicians surveyed reported encountering financial barriers related to providing the HPV vaccine for their patients (New York City Bureau of Immunization, 2008b). One concern of practices having difficulty financing immunizations is the lag-time between when a new vaccine is recommended by the Advisory Committee on Immunization Practices (ACIP), and when private insurers will reimburse providers for administering that vaccine. Providers typically have to wait until a new contract is negotiated before third party payers will reimburse for a newly recommended vaccine.

In addition to the cost of and reimbursement for vaccines themselves, administration fee reimbursement quickly rose to the surface as a particularly troublesome issue for providers in New York. Administration fees must cover physicians’ costs for storing vaccines, the administration of each shot, associated costs of syringes and bandages, time spent counseling parents, and meeting standards of reporting and oversight. While the Medicaid fee-for-service vaccine administration fee—at \$17.85 (the maximum allowed by the federal government for that

service)—is perceived to be fair even though it has not been raised for many years, physicians reported receiving anywhere from \$4 and \$22 from private insurers for vaccine administration. Low administration fees coupled with high overhead costs, particularly in New York City, are said to exacerbate the financial difficulties experienced by many providers.

Most physicians will likely support a move toward universal vaccine purchasing in New York. Key physician leadership already does. This transition would represent the elimination of a significant revenue stream, however, for some practices that currently obtain discounts from manufacturers and favorable reimbursements from third party payers. Furthermore, if physicians—even after universal purchasing—still feel they are not being adequately reimbursed for administration of the vaccines, additional physician opposition might emerge.

Vaccine manufacturers have historically opposed universal purchase of vaccines. This opposition became clear in the early 1990's when the Clinton administration and public health advocates called for a fully universal childhood vaccine purchasing program (Pear 1993, Hilts 1993). Manufacturers argued that most children were already being successfully vaccinated, that price was not the main barrier to vaccination, and that replacing existing private funds, largely insurance dollars, with public ones was inefficient and undesirable. Manufacturers objected to all vaccines being purchased by one federal entity at a discounted price, arguing that it would undercut incentives for research and innovation. (At that time the federal price for all recommended vaccines was half of the private market rate.) Manufacturers successfully lobbied to scale back the proposal, resulting in the existing Vaccines for Children program (Institute of Medicine, 2000).

Some manufacturing representatives interviewed for this project indicated that they would oppose efforts by any additional state to begin purchasing vaccines at the federal contract

price. Furthermore, opposition to universal vaccine purchasing was, in certain cases, independent of the price promised to be paid for vaccines, reflecting concern that states would likely seek large discounts at some time in the future. Others indicated that, while it may not be their place to oppose movement toward state purchased vaccines, they believe that universal purchase is unwise. This group asserts that health plans ought to remain responsible for covering childhood immunizations. The Biotechnology Industry Organization's current statement on vaccine financing states that the sustainability of safety net programs that currently exist relies on "maintaining a strong private market for vaccines" (Biotechnology Industry Organization, 2008).

Other observers noted that manufacturers failed to support the 2003 Institute of Medicine committee's recommendation to use federal power to raise vaccine prices. A plausible explanation is that vaccines account for only a low-single-digit share of pharmaceutical sales, and firms are wary of setting a precedent for any public influence on the price of vaccines or drugs. Similarly, benefit-based pricing would have created another precedent to disallow coverage of drugs or devices that are efficacious but of low-value-added for the general population. Moreover, manufacturers may share a general business aversion to direct and long-term public intervention in previously private markets.

In New York State (in contrast to some other states, such as New Hampshire), **private health insurers** generally do not favor universal vaccine purchasing. Insurers with whom we spoke claim that they already pay for the bulk of immunizations administered in New York State for half of the state's children—approximately 40 percent in New York City and 60 percent elsewhere in the state—indeed they are required to do so by New York law.²² They also claim that their payments are adequate, generally exceeding the price physicians pay for the vaccine. Health plan sources also suggested that very low administration fees are not common. In

addition, insurers believe that payment issues are not the main reasons that children do not get vaccinated, and that other barriers are more important. A practical problem with universal vaccine purchasing insurers cited is that it is inefficient to have one payer responsible for purchasing vaccines (the state) and another payer responsible for administration fees (health plans). Transaction costs are lower where the private plan pays for both, as well as any other well-child services rendered at the same time.

In New York, most health plan representatives with whom we spoke oppose insurance assessments to fund a new universal vaccine purchasing program. This would add to the existing assessment which insurers already face from the state. One informant asserted that state policy makers currently use insurers as a “piggy bank” to generate funds in a low-profile way. Such assessments lack openness and accountability, in their view. This leads to rapid increases in costs to health plans (which are passed on to employers and individuals as increased premiums). Finally, they say that assessed funds promised to be earmarked for one purpose tend to be partially diverted to other uses as time passes (New York State Conference of Blue Cross and Blue Shield Plans, 2008; New York Health Plan Association, 2008a).

Discussions with informed observers within and outside of the federal government suggest that **CDC’s vaccine administrators** are ambivalent in their support of state universal vaccine purchasing programs.²³ This ambivalence derives from CDC’s dual mission. On the one hand, federal administrators are dedicated to enhancing the health of the entire American population. On the other hand, they are directed to buy vaccines only for disadvantaged Americans under the VFC amendment to Medicaid law.

In theory, administrators support expansion of access to childhood vaccines as a proven public health measure, and administrators have supported state universal vaccine purchasing

programs' ability to purchase VFC-discounted vaccines for non-VFC children. However, almost all of today's universal vaccine purchasing programs began before there were VFC prices, and the states involved are not large ones. In addition, CDC has not billed these states for bundling universal vaccine purchasing and VFC vaccines for joint delivery to providers' offices. CDC has simply used its VFC vaccine delivery contract to cover the modest additional shipping costs, estimated at one percent of vaccine purchase costs. This policy helps the universal vaccine purchasing states, and payment is made from CDC-controlled funds that would otherwise be distributed among all states. The policy also serves national interests by increasing CDC's oversight of national vaccine supplies. Covering both universal vaccine purchasing and VFC deliveries will inform CDC better about vaccine availability during any future shortage and also allow CDC to manage deliveries in the interest of national priorities.

CDC appears reluctant to support widespread universal purchase, however, because it would upset the implicit "business model" for CDC vaccine financing. The discounts obtained by VFC reduce federal funding requirements, and they are balanced by higher private sector prices—so that aggregate revenues keep manufacturers in business and actively developing new vaccines. The main fear is that the VFC price will rise to offset manufacturers' lost revenues from the private market. A higher price will then limit CDC's ability to provide vaccines for the disadvantaged, as it has no access to open-ended entitlement funding. Another concern is that states cannot adequately fund universal vaccine purchase programs over time. When shortfalls in state funding have cut vaccine access for non-VFC populations under universal vaccine purchase, some states have also delayed VFC ordering in the interest of maintaining parity. This approach hurts the federal constituency of Medicaid and other disadvantaged children.

In summary, balancing CDC’s population-wide and VFC-only perspectives, administrators articulated a rationale that is partly supportive of universal vaccine purchasing expansions. CDC has indicated that states may “piggy back” on VFC prices only where they are spending Section 317 or general fund dollars, not where they are using assessments on insurers. Thus, should they choose to become a universal purchase state, New York cannot expect to be able to utilize the federal contract to purchase state supplied vaccines without a change in CDC policy.

Potential New York State Revenue Sources for Universal Childhood Vaccine Purchasing

Perhaps the most formidable challenge which New York State faces in implementing a universal vaccine purchasing program is to develop adequate and sustainable revenue sources for such a program. While any of numerous state revenue sources could be used, as noted above, there is logic to raising funds from the health sector to pay for vaccines because that is where vaccines’ benefits accrue. New York State already raises funds through three types of health care assessments under the Health Care Reform Act (HCRA) of 1996—on hospital revenues and rates as well as on the number of “covered lives” of health plans.²⁴

An insurance assessment has been suggested as a reasonable revenue source in New York State for a universal vaccine purchasing program. Similarly, some other universal purchase states already raise funds from health plans. An assessment would be less subject to annual fluctuations than are sales or income taxes. This is a very important characteristic for any program that will be the sole source of the vaccines central to maintaining population health. It does not appear sensible to use the existing covered-lives-assessment rules to fund UVP because those assessment rates vary greatly by regions within the state—which may be logical for supporting graduate medical education, but not for universal vaccine purchasing.²⁵ Under current law,

Medicaid managed care plans are not assessed for their covered lives, but the state could plausibly assess those lives in the future.²⁶

Costs and Benefits of a Universal Vaccine Purchasing Program in New York State

In considering whether to implement a universal vaccine purchasing program, New York State should take into account the costs of the program, its benefits, and the challenges of implementing and monitoring the program. It is important to weigh both whether overall costs will go up or down (or remain unchanged), and whether there will be shifts in costs from one type of individual or organization to another.

Table 5 summarizes what we have learned are the likely important **benefits** of a universal vaccine purchasing program. While we do not have enough information about value of benefits in quantifiable terms (dollars, Quality Adjusted Life Years Saved, or other measures), we provide a qualitative assessment of the value of each benefit.

Table 5: Benefits of a Universal Vaccine Purchasing Program for Children

Benefit	Value
Incentive for physicians to establish and maintain a medical home for children	Greater continuity of care, more preventive screening, and more counseling of parents
Higher immunization coverage (less erosion in coverage)	Prevention of future illness in immunized children; "herd immunity" protection even for unvaccinated
Greater efficiency in ordering and storage of vaccines	Reduced frustration of providers; sustainable cost containment for physicians' offices
Full childhood coverage guaranteed, beyond health plans' typical year-by-year coverage	Investments in vaccines decided based on life-time benefits of immunization
Improved information for vaccine registry	Facilitated tracking of vaccine usage, enforcement of schoolchild mandates, and epidemiological studies

Research in New York and other states has demonstrated that universal purchasing programs can shift vaccination provision away from episodic care (for example, in health

departments) toward a “medical home” site where a child receives more continuous care (Szilagyi et al., 2000a,b; Clark & Freed, 1998). This encourages more consistent well child care, as well as developmental screening and early identification of potential problems that can be addressed through primary or specialty care. These benefits accrue to the child over the course of their life span, and are very difficult to quantify. There are no estimates of the cost-benefit ratio over a lifespan of having a medical home in childhood. Still, studies show that parents are more satisfied when they have such care (Chesney et al., 2005; Morgan et al., 2004).

There is also an opportunity to increase rates—particularly among more costly vaccines—through universal purchasing. Becoming a universal purchase state will not guarantee an improvement in immunization rates, but since cost barriers are the greatest for these newer more expensive vaccines, and vaccination coverage rates are lower, a potential benefit might be a boost in uptake of new, expensive vaccines. These vaccines currently pose the greatest financial burdens on physicians due to steep up front costs and reimbursement delays for new vaccines. Moreover, despite relatively high immunization rates in New York, there is room for improvement. For vaccines that are known to be “cost-saving” to society—a goal should be almost complete and timely coverage, as well as prevention of any erosion in coverage.

The third major benefit of the program is that it would improve the efficiency of ordering and storing vaccines. Currently doctors must order vaccines from multiple sources, according to their perceived needs, and store them separately. With a universal program, providers would order from a single source (the state). When combined with an immunization registry, with which officials can track ordering of vaccines and resulting immunizations, it should be possible to manage the stock of vaccines across providers more equitably in order to reduce hoarding and wastage. This in turn should reduce the frequency of shortages.²⁷

A fourth benefit could be an increase in participation in the two immunization registries (NYC and the rest of the state), presuming an increased reliance on the registry for ordering and tracking vaccines. If doctors perceive that their orders depend on an accurate recording in the registry, and that their immunization rates are being tracked, they should be more likely to enter accurate data. While this will help in administering the vaccine program, it will also allow for more tracking of other kinds of preventive care for children, as well as eliminating unnecessary repeat immunizations for children whose parents do not know their immunization status.

Going forward, careful implementation planning, a phase-in period, and adequate start-up funding are all needed to achieve the intended benefits. It is axiomatic in public policy that programs often fail or cause unintended consequences; in this case there is the possibility that vaccine wastage will rise if they are all free to providers. Difficulties in implementation or shortcomings in ongoing self-monitoring can also arise. To address such issues, part of implementation planning needs to be readiness to make mid-course corrections. Moreover, beginning a new universal vaccine purchasing program will call for rapid action to hire or reposition staff, and the health departments could face barriers to doing so in the face of hiring freezes or other limitations.

Should New York State implement a universal vaccine purchasing program, it is vital that the systems used, the staffing, and the funding be designed to build in sufficient excess capacity and fiscal reserves to cope with any disruptions that may occur with minimal impact on the delivery of immunization services. In addition, it will be necessary to set up a monitoring system for such a program to facilitate mid-course corrections and boost external credibility. Challenges like those just noted can only be briefly touched upon in a feasibility study like this one.

The state will assume new **costs** for administering a universal program. In addition, there will be some offsetting savings, since there should be efficiencies in merging vaccine ordering for publicly and privately insured children. In terms of new costs, under a universal vaccine purchasing program, the state will likely become responsible for negotiating with pharmaceutical companies for prices, integrating the ordering for privately insured children with VFC program ordering, and monitoring the distribution and use of vaccines to assure that the cost of vaccines is allocated to the appropriate payers (public vs. private). In addition, the state may need to take on new responsibilities for enrolling and educating physicians (those who are not participating in VFC). Although New York is presently unaware of how many providers there are who are not already registered with the state to provide VFC or Section 317 funded vaccines, the New York State Bureau of Immunization estimates that any costs associated with enrolling new providers would not be substantial.

In addition, some responsibilities currently being undertaken by the state are not particularly volume-dependent and should not require much, if any, increased resources. Since the immunization registry is improving the efficiency of ordering vaccines in New York City, and monitoring physicians in New York City, it may be possible to shift the responsibilities of some existing staff to accommodate new tasks associated with the universal program. This capacity has not been developed yet upstate, but with some investment the state could realize similar efficiencies. Based on conversations with other states, we estimate that administration costs would be at the most 1-2 percent of the total cost of purchasing the vaccines, and possibly less if the state could integrate the functions into its existing VFC infrastructure.

Most of the cost of a universal program comes from the cost of purchasing the vaccines themselves, and these costs are substantial. Table 6 illustrates the cost of immunizing three

cohorts of children who require immunization, making estimates under three alternative scenarios. It assumes fully immunizing 100 percent of a new birth cohort (all the ACIP recommended vaccines for infants and toddlers), fully immunizing all 4 year olds and fully immunizing all 11-year-old girls and boys. While these are not the only age groups requiring vaccination (since some children will require “catch-up” vaccines, annual flu shots, or other vaccines for high-risk groups), they are the most costly groups. The costs enumerated in Table 6 are not a refined cost-estimate for the annual cost of all vaccines for privately insured children in New York, but are rather a reasonable first estimate that illustrates the range in costs that could be incurred under alternative scenarios.

As shown, Scenario 1 assumes that the state would purchase all vaccines for privately insured children at the federal contract price. This is done in several states (mostly those with programs that predated the VFC program or were set up at the same time). The cost under this scenario is about \$160 million for fully immunizing the three age cohorts.

Table 6: Cost of Immunizing all Non-VFC Eligible New York State Infant/Toddlers, 4 Year Olds, and 11 Year Olds under Alternative Assumptions (2009\$)

Age Cohort	Population Size	Price Per Child			Total Cost (thousands)		
		Scenario 1	Scenario 2	Scenario 3	Scenario 1	Scenario 2	Scenario 3
		VFC Price	Average of VFC and List Price	List Price	VFC Price	Average of VFC and List Price	List Price
Infant/toddlers	120,395	\$792.46	\$973.39	\$1,154.31	\$95,408	\$117,191	\$138,973
4 Year Olds	128,945	\$167.48	\$208.57	\$249.66	\$21,596	\$26,894	\$32,192
11 Year Old							
Boys	78,963	\$121.35	\$134.37	\$146.84	\$9,582	\$10,610	\$11,595
11 Year Old							
Girls	78,963	\$423.12	\$473.19	\$523.26	\$33,411	\$37,365	\$41,318
Total					\$159,997	\$192,060	\$224,078

SOURCE: Authors' estimates. Population estimates come from the Centers for Disease Control and Prevention for non-VFC eligible children. Cost estimates come from Appendix C.

At the other extreme (Scenario 3), the state would purchase all vaccines at the list price.

In such a scenario, pharmaceutical companies would likely receive more revenue, on average,

than they do without a universal purchasing program, since few physicians currently pay the full list price. The total cost of that scenario is \$224 million (a difference of \$64 million over the VFC prices).

An in-between scenario (Scenario 2) is that the state would pay an average of the VFC price and the market price. This is a reasonable assumption, since most providers we interviewed purchase their vaccines at a discounted price, and as a high-volume purchaser, it is reasonable to assume that New York State would be able to negotiate a substantial discount. At the same time, manufacturers could expect to achieve some administrative savings from not having to deal with individual orders. The cost for Scenario 2 is \$192 million (a difference of \$32 million over the VFC price estimate). Obviously, other scenarios with lower or higher purchase prices could be assumed, with corresponding changes down or up in the overall cost of the program.

Importantly, each of these price points is likely to increase in the coming years as new and more expensive vaccines are approved and recommended for children and adolescents. (As already noted, good revenue sources will be needed to maintain universality.)

To put this total dollar estimate in context, the annual cost of vaccines in Scenario 2, the mostly likely scenario, is about \$10 per New Yorker or \$18 per privately insured person, about one tenth of one percent of total health care spending in New York State. Moreover, current spending on vaccines in the private sector would be reduced by a similar amount, which should translate into reduced upward pressure on private health spending.

While the total cost of vaccines for privately insured children might not change under a universal purchasing program, there would be a shift in who bears the cost of the vaccines (see Table 7).

Table 7: Financial Winners and Losers in a Universal Vaccine Purchasing Program in New York State

Winners	Losers
Physicians who are not currently being fully reimbursed for the cost of the vaccines they are purchasing (including the additional costs of ordering and storing vaccines from different sources)	Physicians who are making some profit on vaccines that they purchase for a lower cost than that for which they are reimbursed by health plans
Insurance plans (and their subscribers) that are assessed a lower amount under the program than they currently pay	Insurance plans (and their subscribers) that would be assessed more than they are currently paying
Parents who currently pay for the full or a portion of the vaccine cost directly	
	Pharmaceutical companies whose total reimbursement for vaccines could go down under the program

The main financial “winners” (i.e., the cost would shift away from these individuals and organizations) are: (1) physicians who are not currently reimbursed by plans for the full cost of the vaccines they purchase; (2) parents who are responsible for a portion of the cost of the vaccine; and (3) insurance plans who might pay less than they currently pay. In the case of the latter group, since the plans pass on the cost of care to their subscribers in the form of premiums, it is actually subscribers (employers and individuals) who could experience a potential drop in premiums.

On the other hand there are three potential financial “losers”. The first category of potential losers is those physicians who are currently making a profit by purchasing vaccines for a lower price than the reimbursement they receive from health plans. A recent national survey of physicians found that, on average, physicians have a “net yield” of vaccines from \$3 to \$25 per dose, depending on the vaccine/brand (Freed et al., 2008b). Physicians report that they use this profit to offset the generally-too-low “administration” fee they receive from payers. Without an adjustment to the administration fee, physicians would lose this cross-subsidy.

The second category of potential losers is insurance plans that might be assessed more than they are currently paying providers. Since the approach to raising revenue has not yet been determined, it is not possible to estimate how many plans this may be. For example, if private plans are assessed, it would be necessary to have very detailed information on the number of vaccines provided by each insurer to determine the appropriate assessment for each plan. (Over time this data should be available from the registries). Otherwise, some plans likely would be assessed more than they currently pay (and some less).

The third category of potential losers is the pharmaceutical companies, should they generate less revenue on average than they are currently (as in Scenario 1 and possibly Scenario 2).²⁸ Given that the prices paid under a universal program may be discounted, pharmaceutical companies could potentially experience some loss in revenues, though volume increases may offset these losses.

In summary, the total cost of vaccines for children in New York State could stay constant, go up, or go down. The driving factor in whether costs rise or fall is the price that the state pays for vaccines. Two other important offsetting factors that could raise cost some include increased administration cost at the state (a minor factor compared to the cost of the vaccines) and the potential for costs to rise due to increased immunization rates for more expensive vaccines. If rates go up for the recommended series, their increased costs will be offset by reduced medical expenditures over time, except possibly in the case of some recently added vaccines.²⁹ Further savings could result if the state can negotiate a discounted price for vaccines. Careful attention should be paid to the balance between “winners” and “losers,” however, in order to minimize the degree to which a universal vaccine purchasing program unduly

disadvantages specific groups. Such shifts in the burden of financing vaccines could have unexpected consequences if not carefully considered and addressed.

VII. Recommendations

Based on all the evidence collected during the course of this limited study, we recommend that New York State consider purchasing vaccines for all privately insured children in the state. This recommendation reflects our assessment that providers are financially strained to provide vaccines to their patients, and the state is risking a possible erosion of immunization rates (especially for higher priced vaccines) (Freed et al., 2008a; Sander, 2008). In addition, such a program would likely improve the efficiency of ordering and monitoring vaccine supplies, possibly leading to reduced costs provided that a stable financing mechanism is identified that would not unduly shift the burden of costs across stakeholders.

Our recommendation reflects our observations of current vaccine payment programs. Many other states have successfully operated universal vaccine purchasing for many years, albeit with funding challenges. As in other states, New York State already performs many administrative functions for VFC that can be readily adapted to accommodate a universal vaccine purchasing program. Indeed, the state already goes beyond VFC through funding and operational support for vaccine deliveries to private physician offices for under-insured beneficiaries, and administers purchasing for SCHIP enrollees as well. These observations show that universal vaccine purchasing is feasible, though they do not assure successful operations.

It is important, however, that the state recognize the limitations of a universal vaccine purchasing program. For example, universal vaccine purchasing will eliminate the opportunity for providers to generate revenue from vaccine purchasing; it may not result in higher

immunization rates; and it will not address concerns about inadequate vaccine administration fees. Accordingly, part of what needs to be decided in discussions with stakeholders is what ancillary efforts should be undertaken in concert with universal vaccine purchasing, including other efforts to boost immunization rates and private physician participation. The evolving immunization registries have good potential to further such interventions.

While this report offers a general recommendation to move forward with a universal purchasing program, considerable uncertainty remains with regard to implementation. Many of these details will require ongoing focused discussions between the state and key stakeholders, especially health plans, manufacturers, and the CDC. Those discussions need to focus on the final design issues and planning to meet the implementation challenges noted above that go beyond the scope of this study.

Finally, these recommendations are not fully implementable as currently stated. Thus the state must undertake some estimation of the actual costs of the program as well as engage all key stakeholders in order to persuade them to participate.

In expectation of good planning to meet the challenges identified above, we recommend that the state pursue universal vaccine purchase in the following manner:

Financing

Funding sources for this program should be stable, have the ability to accommodate growing vaccine costs, and have the flexibility to cope with changes in vaccine schedules or prices that occur out of synchronization with the state's annual budget cycle. While there are other revenues sources that might meet these specifications, one feasible source of funding that would meet these criteria is a health plan assessment, which we accordingly discuss in more detail.

1. Health Plan Assessment

New York State could assess health insurance plans in order to finance the purchase of routinely recommended vaccines for privately insured children and adolescents. If done properly, this should be budget neutral or slightly cost-saving as a result of increased efficiencies, when compared with health plans' existing expenditures on vaccines. A health plan assessment would also rise in tandem with prevailing health costs and thus align with likely needs to increase vaccine purchase prices.

As one possible approach, this assessment could be levied periodically through a "covered lives" assessment, which would broadly reach all plans, including self insured ones. There are rationales for basing any assessment either on a plan's number of children or on all enrollees; both groups will benefit from maintaining or improving vaccination rates. These calculations should be readjusted annually.

2. Establishment of an "Assessment Advisory Board"

Any revenue-assessment system needs to be both fair and accepted. Accordingly, we recommend that New York State form an advisory board akin to the New Hampshire Vaccine Association (see text box on Page 16). This will engage health plans in the process of setting the assessment, and help to relieve fears that the assessment will grow uncontrollably and unjustifiably shift the cost burden to health plans. The group that meets to set the assessment should be composed of provider representatives, health plan representatives, health department representatives, and state insurance department representatives. Should the state decide to address fees for vaccine administration along with universal vaccine purchasing, this board could provide good input on those issues as well.

3. Designating Funds Collected to Purchase Vaccines

The money collected from the assessment should be placed in a trust fund or other account designated solely for the purchase of vaccines. This will help to ensure that adequate financing is available for the purchase of vaccines and will acknowledge health plan concerns that the assessments they pay should not be used for other state expenses. The fund should begin with sufficient resources to meet one-time start-up expenses, and it should accumulate and maintain a balance judged sufficient to cope with mid-year changes, such as recommendation of a new vaccine, a supply shortage, or a price increase. Such issues will certainly arise, but are unpredictable in their timing, so funding must have a built-in reserve. The reserve needs to be continually adjusted in light of information about vaccines “in the pipeline” for final ACIP approval.

Purchase and Delivery

4. Vaccine Purchase Price

New York State should negotiate directly with manufacturers for a reasonable price as a bulk purchaser of vaccines. We anticipate this should result in a sensible and not excessive discount on the “list” price that may well be higher than the federal contract price.

5. Recommended Vaccine Provisions

A universal vaccine purchasing program in New York should provide all vaccines currently recommended by ACIP to privately insured children and adolescents. Over time, however, we recommend that new vaccines be scrutinized for cost-effectiveness. If ACIP moves in that direction nationally, as the 2003 IoM report recommended, this shift will occur automatically. If not, then the state will have to weigh the trade-off between spending its funds cost effectively, and maintaining parity between VFC and non-VFC children.

6. Brand Inclusion

The state should offer all vaccine brands to providers rather than restrict vaccine purchases to certain manufacturers. This was the choice made by VFC in the early 1990s. Though the state might benefit from a deeper discount from utilizing an exclusive contract, the state will incur a greater risk of shortages. Moreover, brand exclusions could complicate vaccine regimens if availability of vaccines varies from year to year, and brand inclusion is an attractive feature for providers.

7. Vaccine Delivery

New York State should utilize the CDC centralized delivery system for state supplied vaccine purchases. This will streamline ordering and delivery in the state. Furthermore, utilizing the CDC's delivery system will eliminate the need to keep childhood vaccine supplies separate in a physician's office, and can be done at no cost to the state for the time being, pending any change in current CDC policy. The potential to achieve efficiencies as a result of this streamlining is great, but would benefit from additional infrastructure investment. Investment seems especially appropriate to assure smooth operations, as difficulties will be magnified relative to the current less centralized system, and will affect all New Yorkers.

Program Administration

8. Vaccine Ordering Coordinated through the Registry

New York State and New York City should invest in integrating ordering, tracking, and monitoring with the two immunization registries in order to achieve efficiencies. Use of the registry has important public health implications that can be encouraged by tying use of the registry to receipt of free vaccines. This will encourage providers to utilize the registry and will reduce waste by integrating reports of usage with requests for vaccine. Beyond wastage, tracking vaccine usage and ordering through the registry will help in the detection of any unusual fraud or abuse.

9. Vaccine Monitoring (Best Practices, Fraud, and Abuse)

New York State should extend the CDC standards for monitoring and quality assurance to additional state supplied vaccines. This will harmonize the processes in place and prevent duplication of efforts as well as confusion among the provider community. Increased use of the immunization registry will also help with education and monitoring.

10. Administration Fee Reimbursement

Universal vaccine purchasing based on the model utilized by other states will not address concerns about the adequacy of vaccine administration fees; payments that are too low have the potential for large fiscal impact on providers and their willingness to provide vaccinations that might exceed the benefit of free vaccines. Absent policy action, many providers may well continue to feel they are not being adequately covered for the costs associated with administering vaccines. The state should consider various options for increasing reimbursements to providers for vaccine administration fee along with the state supplied vaccine program.

Endnotes

¹ The provision provides, “The commissioner [of health] shall, on or before January first, two thousand nine, conduct a study on the feasibility and cost-effectiveness of a program to make vaccines universally available for children and adolescents up to age nineteen, without charge to the patient or to local health departments, licensed physicians, hospitals, clinics and such other licensed health care providers, as determined by the commissioner. Such study shall include consultation with stakeholders on potential financing mechanisms and implementation options.” NY Public Health Law, Article 6, Title 2, Section 613(7) (2008).

² Some children get “catch up” immunizations, but these total no more than the missed vaccinations on the regular schedule. Non-scheduled vaccinations are recommended for certain high-risk older children. These are not accounted for in our estimates, but are likely to be relatively small in number.

³ Cost estimates are based on a cohort of 0-2 year olds, 4-6 year olds and 11 year old boys and girls in 2009. This is the largest group, but only a subset, of those who would be immunized in a given year given catch-up immunization and annual flu vaccination recommendations.

⁴ The foundation of public health authority is a 1905 Supreme Court decision on mandatory smallpox vaccination in Massachusetts. [*Jacobson v. Massachusetts*, 197 U.S. 11 (1905)]

⁵ The National Childhood Vaccine Injury Act of 1986 created a new federal compensation program to pay for vaccination-caused injuries. See Title III of Public Law 99-660, codified at 42 U.S. Code, sects. 300aa-1 and following.

⁶ Enabling legislation for the VFC program was passed as part of the Omnibus Budget Reconciliation Act (OBRA) of 1993, Public Law 103-66. States must help administer VFC as a condition of state participation in Medicaid, under section 1902(a) (62) of the Social Security Act, and states pay vaccine administration fees through Medicaid, with full federal matching support.

⁷ ACIP is composed of 15 experts in fields associated with immunization who have been selected by the Secretary of the U. S. Department of Health and Human Services to provide advice and guidance to the Secretary, the Assistant Secretary for Health and the Centers for Disease Control and Prevention (CDC) on the control of vaccine-preventable diseases. The Committee develops written recommendations for the routine administration of vaccines to children and adults in the civilian population.

⁸ Section 317 of the Public Health Services Act, the Immunization Grants Program, was established by the Vaccination Assistance Act of 1962. It provides Direct Assistance to states, for the purchase of vaccines, and Financial Assistance, for states’ programmatic activities. Section 317 funding has grown unevenly over the past decade, now accounting for a smaller share of states’ discretionary spending on vaccines. USDHHS 2008, p.44.

⁹ Interviews and published survey evidence suggests that private purchasers can also obtain discounts (Freed et al. 2008b).

¹⁰ CDC utilizes Section 317 funds to finance distribution of publicly purchased vaccines. This federal spending results in a slightly decreased pool of money available for Section 317 categorical grants to states.

¹¹ Prior to the 2006 approval of Gardasil vaccine for HPV, there was no difference in immunization recommendations for boys and girls.

¹² Federal price caps were established in 1994 for older vaccines, holding price increases to no more than the rate of inflation. Few vaccines are currently affected by these pricing caps, as new formulations have been developed, or the specific vaccine antigen has been combined with others in new combination vaccine products.

¹³ Administration fees are not paid by VFC or existing state supplied vaccine programs; Medicaid and SCHIP do pay administration fees, and providers participating in VFC may not refuse to vaccinate a child because of inability to pay the provider’s full fee.

¹⁴ Since North Dakota became a VFC-only state, two of the state’s local health clinics no longer provide vaccines for non-VFC eligible children.

¹⁵ The VFC statute provides that “Each State, at the option of the State, shall be permitted to obtain additional quantities of pediatric vaccines ... at the applicable price negotiated by the Secretary” see 42 U.S.C. sec. 1396s, subsection 4(B).

¹⁶ CDC informants report that this is perceived as using private funds to purchase at discounts set for public programs.

¹⁷ This feasibility assessment simply observes the likely negative administrative reaction to any future state's seeking "optional use" of the federal price through a new UVP program funded by assessments on health plans. We do not consider the legal rationale for states' access to the federal contract price, nor interpret the statutory language of the VFC enabling act, 42 U.S.C. 1396s(d)(4)(B).

¹⁸ As noted above, CDC funds delivery by reducing Section 317 grants to states generally.

¹⁹ A University of Baltimore report (McGrath 2008) found that there was no correlation between being a universal purchase state and higher immunization rates.

²⁰ New York Insurance Law, sects. 3216(i)(17), 3221(l)(8), and 4303(j) (2008); NY Dept. of Insurance, "Coverage for Preventive and Primary Care Services," Circular Letter No. 13 (2006), May 10, 2006 http://www.ins.state.ny.us/circltr/2006/cl06_13.htm.

²¹ ERISA is the Employee Retirement and Income Security Act of 1974, a federal statute that regulates workplace based pension and health plans and bars, or pre-empts, certain forms of state regulation (Borzi 2008).

²² Fully insured plans face the mandate; ERISA-protected self-insured plans do not. Data are lacking to assess the extent of vaccination insurance coverage in New York. Nationally, the IOM committee estimated that "13.8 percent of children" under five "have private insurance that does not include immunization benefits." "Insurance coverage and cost sharing are among the important factors influencing rates of immunization," they found, and "It cannot be assumed that private insurers will continue to share responsibility for vaccine purchase." (Institute of Medicine 2003).

²³ One set of CDC authors referred to the agency's "dual roles" Coleman et al., 2005, p. 641.

²⁴ The New York State Health Care Reform Act (HCRA) webpage of the Department of Health includes statutory and other materials on the law. <http://www.health.state.ny.us/nysdoh/hcra/hcrahome.htm>. See also the discussion in Bovbjerg et al., 2006. Unlike the first two HCRA revenue streams or conventional premium taxes on insurers, the covered-lives assessment is related only to the number of enrollees in health plans, not to the amount of their claims spending or premiums. Self-insured health plans must pay the assessments along with fully insured ones, and the U.S. Supreme Court supported New York these assessment practices against ERISA challenge in two landmark cases.

²⁵ The assessment varies from a high of \$164.61 per life in New York City to a low of \$6.74 for Utica/Watertown. 2009 GME Surcharges / Assessments http://www.health.state.ny.us/nysdoh/hcra/gme/docs/surcharges_and_assessments_2009.pdf.

²⁶ One precedent is that Medicaid managed care plans evidently must already contribute through HCRA's other two assessment mechanisms.

²⁷ In a study in Maryland, about 45 percent of doctors interviewed had experienced supply problems with Hepatitis A vaccine and about 25 percent with varicella vaccine (McGrath 2008).

²⁸ The use of vaccines could climb with the program, increasing the volume of purchases. If pharmaceutical companies are reimbursed for the full market price and volume increases they could stand to gain.

²⁹ While studies do not show the newer vaccinations to be cost-saving (meningococcal, pneumococcal, HPV, rotavirus, and flu), they are generally cost-effective (in QALYS) according to generally-accepted standards for other health interventions (Shepard, Ortega-Sanchez, Scott, Rosenstein & the ABC's Team, 2005); (Widdowson et al., 2007); (Ortega-Sanchez et al., 2008)

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APPENDIX A

KEY INFORMANTS INTERVIEWED BY STAKEHOLDER STATUS

APPENDIX A: Key Informants Interviewed, by Stakeholder Status

New York State Department of Health

Guthrie S. Birkhead, MD, Deputy Commissioner; Chair of National Vaccine Advisory Committee of the Centers for Disease Control and Prevention (CDC)

Debra S. Blog, MD, Medical Director, Bureau of Immunization

David R. Lynch, Assistant Bureau Director, Bureau of Immunization

Dale L. Morse, MD, Director, Office of Science and Public Health; Chair of CDC's Advisory Committee on Immunization Practices (ACIP)

Maria Reardon, Immunization Program Administrator

Gary Rinaldi, VFC Coordinator, Bureau of Immunization

Loretta A. Santilli, Project Manager, New York State Immunization Information System (NYSIIS, the state's Registry)

New York City Department of Health and Mental Hygiene

Marie B. Casalino, MD, Assistant Commissioner, Bureau of Early Intervention

David B. Eagle, MD, Director, Childhood and Adolescent Immunization

Dennis King, Deputy Director, Bureau of Immunization

Amy Metroka, Director, New York Citywide Immunization Registry (CIR)

Sheila Palevsky, MD, Provider Liaison & Chief, Professional Education Unit, Bureau of Immunization

Jane R. Zucker, MD, Assistant Commissioner, Bureau of Immunization

Other State Immunization Programs

Janna Bardi, Immunization Program Manager, Washington State Department of Health

Marcela Bobinsky, Immunization Program Manager, New Hampshire Department of Health

Robert Grenwelge, CDC Public Health Advisor, Immunization Program, Wyoming Community and Public Health Division

Claire Hannan, Executive Director, Association of Immunization Managers

Gayle Kenny, Immunization Program Manager, New Mexico Department of Health

Susan M. Lett, MD, Medical Director, Immunization Program, Massachusetts Department of Public Health

Patricia Raymond, Chief, Office of Immunization, Rhode Island Department of Health

Beth Rowe-West, Head, North Carolina Immunization Branch, Division of Public Health, NC Department of Health and Human Services

Other Regulatory Officials

K. Gloria Dee, Supervising Actuary, Health Bureau, NY State Department of Insurance

Deberal Denson, Public Health Advisor, CDC

Thomas Fusco, Associate Insurance Attorney, Health Bureau, NY State Department of Insurance

Kevin Malone, Office of the General Counsel, CDC

Lance Rodewald, MD, Director, Immunization Services Division, National Center for Immunization and Respiratory Diseases, CDC

Jeanne M. Santoli, MD, Deputy Director, Immunization Services Division, National Center for Immunization and Respiratory Diseases, CDC

Vaccine Manufacturers

Elizabeth Blowers-Nyman, Senior Director of Health Policy and External Affairs, Merck Vaccines and Infectious Diseases

Isabel Claxton, Director, Policy Advocacy, Public Policy Development, GlaxoSmithKline

Mark Feinberg, MD, Vice President, Medical Affairs and Policy, Merck Vaccines and Infectious Diseases

Judy Fisher, Sanofi-Pasteur (vaccines division of the Sanofi-Aventis Group)

Sanford Kaufman, Director, State Government Affairs, Sanofi-Pasteur

Robert Luria, Executive Manager, State Government Affairs, GlaxoSmithKline

Julie Tardino, Management Associate, Sanofi-Pasteur

Physicians & Physician Representatives

Anne Burrowes, MD, Medical Director, Pediatric Outpatient Practice, Bronx Lebanon Hospital

Robert M. Corwin, MD, Elmwood Pediatric Group, LLP, Rochester, NY; Chair of the Immunization Advisory Council of the State of New York; former member, AAP Board of Directors

George Dunkel, Executive Director, American Academy of Pediatrics, District II

Vito Grasso, Executive Vice President, NY Academy of Family Physicians

Philip Kaplan, MD, Fairgrounds Family Physicians, PLLC, Manlius, NY

Marc Lashley, MD, Valley Stream Pediatrics, Valley Stream, NY; Chair, Physician's Education Committee, Department of Health Immunization Task Force

Kevin B. Norowitz, MD, FAAP Pediatrics & Adolescent Medicine, Brooklyn, NY

Vicki A. Papadeas, MD, LaGuardia Place Pediatrics, New York, NY

Marcy Savage, Weingarten, Reid & McNally, Albany, NY; government affairs consultant to NYSAFP

Elie Ward, Director of Policy & Advocacy, American Academy of Pediatrics, District II

Health Plans & Insurers

David Audie, Pharmacy Manager, WellCare of NY, Inc.

Sean E. Doolan, Co-Chair of Government Relations Department, Hinman Straub, P.C., Albany, NY; Counsel to the New York State Conference of Blue Cross and Blue Shield plans

Paul Macielak, President & CEO, NYS Health Plan Association

Ronald B. Menzin, MD, Medical Director, WellCare of NY, Inc.

Arthur Tomases, MD, Medical Director, Group Health Insurance, EmblemHealth

Independent Experts

Rosemary Chalk, Senior Program Officer; Director, Board on Children, Youth, and Families, Institute of Medicine; Study Director of the 2003 IoM Committee

Dack Dalrymple, Dalrymple and Associates, LLC, Washington, DC

Gary L. Freed, MD, Percy and Mary Murphy Professor of Pediatrics and Child Health Delivery, the Director of the Division of General Pediatrics in the School of Medicine, and Professor of Health Management and Policy in the School of Public Health, University of Michigan; former chair of National Vaccine Advisory Committee

Walter A. Orenstein, MD, Director of Emory University's Program for Vaccine Policy and Development; consultant to the Bill & Melinda Gates Foundation; former Director of the National Immunization Program at the Centers for Disease Control and Prevention (CDC)

Mark V. Pauly, Bendheim Professor; Professor of Health Care Systems, Public Policy and Management, Insurance and Risk Management, and Economics, The Wharton School of the University of Pennsylvania; member of the 2003 IoM Committee on the Evaluation of Vaccine Purchase Financing in the United States

Frank A. Sloan, J. Alexander McMahon Professor of Health Policy and Management and Professor of Economics, Duke University, NC, Chair of the 2003 IoM Committee

Peter Szilagyi, MD, Professor of General Pediatrics, University of Rochester, NY; also, consultant to this project

Cole Werble, Editor-in-Chief, *The RPM Report*, Washington, DC

APPENDIX B

INTERVIEW TOPICS

APPENDIX B: Interview Topics

Academic Researchers:

- Relevant research on vaccines and universal vaccine programs
- Policy issues concerning vaccine programs

Physician Representative:

- Information on NYS Vaccine Project
- Physicians' concerns with vaccines
- Cost issues

Regulatory Officials:

- Role of your agency
- Issues with VFC programs
- Universal vaccine programs in states

State Informants:

- Your state's universal vaccine program
- Your role with the program
- Enactment and initial implementation of the program
- Operational issues of the program
- Cost and budgetary issues
- Experience with existing programs

Pharmaceutical Representatives:

- Your involvement with state universal or universal select programs
- How these programs operate (from your company's perspective).
- What are some of the problems/issues you face?
- How do they affect your company's vaccine revenues?
- If NYS were to decide to purchase all vaccines for children in the state how would pricing work?
- How are prices set in the private market?

APPENDIX C

COST ESTIMATE CALCULATIONS AND ASSUMPTIONS

APPENDIX C: Cost Estimate Calculations and Assumptions

Cost Estimates of Vaccine Purchases for Privately Insured Children (0-2 and 4-6) and adolescents (11) in New York State								
Recommended Vaccines			Prices					
0-2 year olds			VFC Price ^a		Midway between VFC and List		List Price	
Name*	Antigen	Number of Doses	Price	Total	Price	Total	Price	Total
<i>Infanrix</i>	DTap	4	\$13.75	\$55.00	\$17.60	\$70.38	\$ 21.44	\$ 85.76
<i>IPOL</i>	e-IPV	3	\$11.48	\$34.44	\$18.91	\$56.73	\$ 26.34	\$ 79.02
<i>VAQTA</i>	Hepatitis A-Pediatric	2	\$12.75	\$25.50	\$21.56	\$43.12	\$ 30.37	\$ 60.74
<i>RECOMBIVAX HB</i>	Hepatitis B-Ped/Adol	3	\$9.75	\$29.25	\$16.48	\$49.43	\$ 23.20	\$ 69.60
<i>PedvaxHIB</i>	Hib	3	\$11.26	\$33.78	\$17.02	\$51.05	\$ 22.77	\$ 68.31
<i>MMRII</i>	Measles, Mumps, Rubella	1	\$80.75	\$80.75	\$102.56	\$102.56	\$124.37	\$124.37
<i>Pprevnar</i>	Pneumococcal	3	\$66.44	\$199.32	\$75.16	\$225.48	\$ 83.88	\$ 251.64
<i>Rotarix</i>	Rotavirus	3	\$82.25	\$246.75	\$92.38	\$277.13	\$102.50	\$ 307.50
<i>Varivax</i>	Varicella	1	\$61.50	\$61.50	\$69.51	\$69.51	\$ 77.51	\$ 77.51
<i>Fluzone</i>	Influenza	2	\$13.09	\$26.17	\$14.01	\$28.02	\$ 14.93	\$ 29.86
Total**				\$792.46		\$973.39		\$1,154.31
4-6 year olds								
Name	Antigen	Number of Doses	Price	Total	Price	Total	Price	Total
<i>Infanrix</i>	DTap	1	\$13.75	\$13.75	\$17.60	\$17.60	\$ 21.44	\$ 21.44
<i>IPOL</i>	e-IPV	1	\$11.48	\$11.48	\$18.91	\$18.91	\$ 26.34	\$ 26.34
<i>MMRII</i>	Measles, Mumps, Rubella	1	\$80.75	\$80.75	\$102.56	\$102.56	\$124.37	\$124.37
<i>Varivax</i>	Varicella	1	\$61.50	\$61.50	\$69.51	\$69.51	\$ 77.51	\$ 77.51
Total***				\$167.48		\$208.57		\$ 249.66
11 year old girls								
Name	Antigen	Number of Doses	Price	Total	Price	Total	Price	Total
<i>Gardasil</i>	HPV	3	\$100.59	\$301.77	\$112.94	\$338.82	\$125.29	\$ 375.87
<i>Meningococcal</i>	Menactra	1	\$76.35	\$76.35	\$85.11	\$85.11	\$ 93.87	\$ 93.87
<i>Adacel</i>	Tetanus, Diptheria, Pertussis	1	\$30.75	\$30.75	\$34.09	\$34.09	\$ 37.43	\$ 37.43
<i>Fluzone</i>	Influenza	1	\$14.25	\$14.25	\$15.17	\$15.17	\$ 16.09	\$ 16.09
Total****				\$423.12		\$473.19		\$ 523.26
11 year old boys								
Name	Antigen	Number of Doses	Price	Total	Price	Total	Price	Total
<i>Meningococcal</i>	Menactra	1	\$76.35	\$76.35	\$85.11	\$85.11	\$ 93.87	\$ 93.87
<i>Adacel</i>	Tetanus, Diptheria, Pertussis	1	\$30.75	\$30.75	\$34.09	\$34.09	\$ 37.43	\$ 37.43
<i>Fluzone</i>	Influenza	1	\$14.25	\$14.25	\$15.17	\$15.17	\$ 16.09	\$ 15.54
Total*****				\$121.35		\$134.37		\$ 146.84

* For simplicity, we chose only single antigen vaccines for this cost calculation, though we understand that combination vaccines are being widely used. If there was a brand choice and a price difference, we chose the more expensive brand so as not to underestimate the costs. For influenza, we chose a preservative free formulation for all age groups.

** This estimates the cost of fully immunizing a low-risk child with recommended vaccines by the age of 2.

*** This represents the additional cost of immunizing a low-risk child as recommended by the age of 6 (presuming he/she has received the recommended infant/toddler vaccinations).

**** This represents the additional cost of immunizing a low-risk 11 year old girl as recommended (presuming she has received the recommended vaccinations through age 6).

***** This is the estimated additional cost of immunizing a low-risk 11 year old boy as recommended (presuming he has received the recommended vaccinations through age 6).

a. Based on the VFC Vaccine Price List with Contract end date 3/31/2009

SOURCE: Centers for Disease Control and Prevention. 2008a. CDC Vaccine Price List reviewed/updated August 26, 2008; downloaded October 20, 2008.

APPENDIX D

GLOSSARY OF TERMS

APPENDIX D: GLOSSARY OF TERMS

4:3:1:3:3:1 Vaccine Series. A basic immunization series consisting of 4 doses of Diphtheria, Tetanus & Acellular Pertussis (DTaP), 3 doses of Inactivated Polio Virus (IPV), one dose of Measles, Mumps and Rubella vaccine (MMR), 3 doses of Haemophilus influenza type b vaccine (Hib), 3 doses of Hepatitis B vaccine (Hep B), and 1 dose of Varicella vaccine.

Administration Fee. A fee which a medical professional charges in order to cover the costs of providing a vaccine. Administration fees can include costs for the administration of the shot, cost of syringes and bandages, time spent to inventory vaccines or report to a state immunization registry, or time spent counseling parents. The administration fee is separate from any fee charged to cover the cost of the vaccine itself.

Advisory Committee on Immunization Practices (ACIP). A committee of 15 experts in fields associated with immunization who have been selected by the Secretary of the U.S. Department of Health and Human Services to provide advice and guidance to the Secretary, the Assistant Secretary for Health, and the Centers for Disease Control and Prevention (CDC) on the control of vaccine-preventable diseases. The Committee develops written recommendations for the routine administration of vaccines to children and adults in the civilian population and recommends vaccines for inclusion in the Vaccines for Children (VFC) program.

Catch-up Vaccines. Vaccines administered to a child on a special schedule when the child has started the vaccine late or is late in receiving a recommended dose.

Diphtheria, Tetanus & Acellular Pertussis (DTaP). A combination vaccine that is recommended for young children and immunizes against diphtheria, tetanus, and pertussis (also known as whooping cough). All three are potentially fatal illnesses that are caused by bacteria. DTaP is safer than the older DTP vaccine, because DTaP includes the newer “acellular” version of the pertussis antigen, which does not contain whole cells.

Diphtheria, Tetanus, Pertussis (DTP). An older vaccine that immunizes against the same diseases as DTaP, but does not include the newer “acellular” version of the pertussis antigen. DTP is no longer used in the United States.

Federal Contract Price. The price for vaccines purchased on CDC contracts that are established for the purchase of vaccines by immunization programs that receive CDC immunization grant funds (i.e., state health departments, certain large city immunization projects, and certain current and former U.S. territories). This is the price at which vaccines for the Vaccines for Children program are purchased.

Federally Qualified Health Center (FQHC). A nonprofit health center that provides care to the underserved and uninsured. FQHCs include community health centers, public health programs, and programs serving migrants and the homeless. They are funded by federal and state/local contributions.

***Haemophilus influenzae* type b (Hib).** A bacterial disease that causes meningitis, pneumonia, and other diseases. Also denotes the vaccine that protects against it.

Healthy People 2010. A comprehensive health promotion and disease prevention agenda launched by the Department of Health and Human Services in January 2000. Healthy People 2010 includes national health objectives for the first decade of the 21st century.

Hepatitis A (Hep A). One type of a viral infection of the liver, caused by the hepatitis A virus. Hep A is often used to indicate the vaccine that protects against it.

Hepatitis B (Hep B). One type of a viral infection of the liver, caused by the hepatitis B virus. Hep B and HBV are often used to indicate the vaccine that protects against it.

Human papillomavirus (HPV). A sexually transmitted infection that can cause genital warts and cervical cancer. The HPV vaccine can protect against the four types of the infection which cause most genital warts and cervical cancers.

Immunization Registry. A centralized information system that can be used to track immunization records of individual children as well as immunization activities of medical providers. In some states, providers may use a registry to order vaccines and report to the state on how many vaccine doses are used.

Inactivated Poliovirus vaccine (IPV). The currently recommended vaccine against polio, a viral disease that attacks the nervous system and can cause paralysis and death.

Measles, Mumps, Rubella (MMR). A combination vaccine that immunizes against measles, a respiratory virus that causes a skin rash, fever, cough, and runny nose; mumps, a viral disease that causes fever, headache, muscle aches, tiredness, loss of appetite, and swelling of salivary glands; and rubella, a mild rash that can cause problems for an unborn child of a pregnant woman with the virus, also known as German measles.

Meningococcal vaccine (MCV). A vaccine that protects against a bacterial infection that infects the fluid surrounding the brain and spinal cord. The illness is the leading cause of bacterial meningitis in children.

National Immunization Survey (NIS). A survey of children between the ages of 19 and 35 months living in the United States at the time of the interview, sponsored by the National Center for Immunizations and Respiratory Diseases (NCIRD) and conducted jointly by NCIRD and the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention.

National Vaccine Advisory Committee (NVAC). A committee that meets three times a year in Washington, DC, to advise and make recommendations to the Director of the National Vaccine Program. The 17 members and chair of NVAC are appointed by the Director of the National Vaccine Program (NVP) in consultation with the National Academy of Sciences. Individuals on the committee represent parties who are engaged in vaccine research or vaccine manufacturing,

physicians, members of parent organizations concerned with immunizations, or representatives of state or local health agencies or public health organizations.

National Vaccine Program (NVP). Refers to the CDC's activities to coordinate vaccine ordering, immunization registries, and programs such as Vaccines for Children.

Pneumococcal conjugate vaccine (PCV). A vaccine given to young children to protect against *streptococcus pneumoniae* bacteria, which causes bacterial meningitis and pneumonia.

Public Health Clinic. An umbrella term that includes any publicly funded health clinic, such as community health centers, rural health centers, local health department clinics, and federally qualified health centers.

Quality Adjusted Life Year (QALY). A quality-of-life measure commonly used in cost-effectiveness analysis. The QALY value is weighted to account for the decreased quality of life experienced during a year of decreased health. For example, a year in perfect health has a QALY value of 1, while death has a QALY value of 0. A year lived in less than perfect health (e.g. due to illness or injury such as kidney disease, blindness, or loss of a limb) has a QALY value between 0 and 1.

Rotavirus. A virus that causes severe diarrhea and dehydration. The rotavirus vaccine protects children against this illness.

Rural Health Clinic (RHC). A health clinic that has been designated by the U.S. Center for Medicare and Medicaid Services to provide access to outpatient primary care in communities that are rural and medically underserved.

Section 317. Section 317 of the Public Health Services Act, enacted in 1963 by the CDC. This program provides federal funding to states for the purchase of vaccines and for program operations.

Tetanus-diphtheria (Td). A combination vaccine that protects against tetanus and diphtheria.

Tetanus, Diphtheria, and Acellular Pertussis (Tdap). A combination vaccine that is recommended for certain adolescents and adults to immunize against tetanus, diphtheria, and pertussis (also known as whooping cough). The vaccine includes the newer "acellular" version of the pertussis antigen, which does not contain whole cells.

Underinsured. Refers to children who are enrolled in a private health plan which does not cover the cost of some or all of their vaccinations.

Universal Purchase. A program in which the government purchases all recommended vaccines for all or most of the population, including those with private insurance. The government distributes the vaccines to health care providers free of charge.

Universal Select. Refers to a government purchasing program in which one or more vaccines is excluded (e.g., pneumococcal conjugate vaccine). This type of vaccine purchasing program exists in nine states.

Vaccines for Children (VFC). A federal entitlement program that provides recommended vaccines at no cost to children between the ages of 0 and 18 who are Medicaid-eligible, uninsured, Native American, Alaska Native, or receiving vaccination at a federally qualified health center or rural health clinic. VFC was created by the Omnibus Budget Reconciliation Act of 1993 and implemented in October 1994.

Varicella. The virus that causes chickenpox. Also refers to the varicella vaccine, which prevents chickenpox.

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