PHYSICIAN PARTICIPATION IN THE VACCINES FOR CHILDREN PROGRAM
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The OIG's Office of Audit Services (OAS) provides all auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations in order to reduce waste, abuse, and mismanagement and to promote economy and efficiency throughout the Department.

The OIG's Office of Investigations (OI) conducts criminal, civil, and administrative investigations of allegations of wrongdoing in HHS programs or to HHS beneficiaries and of unjust enrichment by providers. The investigative efforts of OI lead to criminal convictions, administrative sanctions, or civil money penalties. The OI also oversees State Medicaid fraud control units which investigate and prosecute fraud and patient abuse in the Medicaid program.

The OIG's Office of Evaluation and Inspections (OEI) conducts short-term management and program evaluations (called inspections) that focus on issues of concern to the Department, the Congress, and the public. The findings and recommendations contained in these inspection reports generate rapid, accurate, and up-to-date information on the efficiency, vulnerability, and effectiveness of departmental programs.

OEI's Atlanta Regional Office prepared this report under the direction of Jesse J. Flowers, Regional Inspector General and Christopher Koehler, Deputy Regional Inspector General. Principal OEI staff included:

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For additional copies of this report, please contact the Atlanta Regional Office at 404-331-4108.
EXECUTIVE SUMMARY

PURPOSE

To identify issues affecting physician participation in the Vaccines for Children program.

BACKGROUND

The Public Health Service (PHS) launched a major initiative to help increase immunization levels for 2-year-olds. Rates for the complete vaccine series increased from about 50 percent in 1991 to 66 percent in the first quarter of 1994. However, the goal is to reach 90 percent. One part of the PHS initiative is the recently enacted Vaccines for Children program (VFC) which allows the Federal government to purchase vaccines from manufacturers and provide the vaccines free to physicians who participate in the program. Participating physicians can use the free vaccines to immunize children enrolled in Medicaid, Native American children, Alaskan Native children, and children without insurance. Children who have insurance but the insurance does not cover immunizations ("underinsured" children) are also eligible for VFC program vaccines, but only at Federally Qualified Health Centers or Rural Health Clinics.

Prior to the VFC program, 12 States were providing free vaccine to private physicians to immunize all children in their States. The States are commonly referred to as universal States. Most universal States had a 90 percent or more physician participation rate.

The Centers for Disease Control and Prevention (CDC) asked for assistance from the Office of Inspector General to identify and describe barriers to physician participation in the VFC program. We conducted this study in response to that request. To identify issues that affect physician participation in an immunization program, we surveyed 669 physicians practicing in five States that were already providing free vaccines to private physicians to immunize all children in their States. To put physician responses in context with their State policies, we surveyed immunization program officials in 11 of the 12 universal States. We then interviewed immunization program officials from 21 non-universal States. We gathered our data in August and September 1994, the two months immediately preceding the programs start-up date.

FINDINGS

_Paperwork requirements could discourage some physicians from participating in the VFC program._

Fifty-two percent (135 of 260) of the physicians we surveyed said paperwork requirements in their universal State programs were excessive. However, their
universal programs only required one form. Under the VFC program, physicians have to complete three one-page forms. Sixteen percent of the physicians we surveyed said they do not expect to enroll in the VFC program due to excessive paperwork requirements. Physicians also said two forms, Provider Profile Form and Patient Eligibility Screening Record, provide unreliable information.

**Inefficient vaccine delivery systems could discourage physician participation.**

Thirty-eight percent (38 of 101) of the physicians from States with drop points and 31 percent (49 of 159) of the physicians from States with direct delivery systems complained about the efficiency of their State delivery systems. If physicians participating in the VFC program experience similar vaccine delivery problems, they may drop out of the VFC program.

**Lack of vaccine delivery systems in some States impedes physician participation.**

According to VFC legislation, Federal funds are to finance delivery of program vaccines. However, only one vaccine manufacturer would agree to a delivery contract at the federally capped vaccine price. As a result, no Federal delivery system has been established, and CDC continues to explore other delivery options. Thirty-five States have established their own delivery systems for private providers, and at least ten of the remaining fourteen States reported they plan to do so this year. All States are delivering vaccines to the public sector.

**Newly established maximum allowable vaccine administration fees for physicians could help overcome a barrier to physician participation.**

Prior to the VFC program, the fees States allowed physicians to charge parents for administering State-purchased vaccines discouraged some physicians from participating in universal States. To illustrate, 25 percent (64 of 260) of the physicians we surveyed said the fees States allowed them to charge were inadequate. For the VFC program, the Health Care Financing Administration established significantly higher fees that physicians can charge parents for administering vaccine. The new rates are comparable to what physicians were charging parents to administer privately-purchased vaccines. Thus, the fees should not be a barrier to physician participation in the VFC program.

**RECOMMENDATIONS**

The CDC should continue to develop an efficient and reliable vaccine accountability mechanism. The CDC officials said they are presently reexamining other ways to obtain information intended to be provided by the provider profile. We encourage CDC to continue this effort, and also examine the efficacy of the Patient Eligibility Screening Record in universal States.
The CDC should continue to explore alternative delivery systems and should examine the efficiency of both drop-point and direct delivery systems. Physicians we surveyed described problems with both types of delivery systems.

AGENCY COMMENTS

The Assistant Secretary for Health commented on our draft report and concurred with our recommendations. He expressed CDC's concerns that the accountability system for the VFC program balance the need for accountability with the need for a system that encourages physician participation and reported that CDC is continuing to develop accountability systems. Further, he stated that CDC is committed to establishing a delivery system for States who do not choose to deliver vaccines themselves.

The Assistant Secretary for Health, the Health Care Financing Administrator, and the Assistant Secretary for Planning and Evaluation provided additional points of clarification and technical comments which we responded to by editing portions of the report.
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INTRODUCTION

PURPOSE

To identify issues affecting physician participation in the Vaccines for Children program.

BACKGROUND

Millions of American children are at risk of severe illness and possible death from childhood diseases such as measles, mumps, rubella, polio, diphtheria, pertussis, tetanus, hemophilus b influenza, and hepatitis B. The Advisory Committee on Immunization Practices\(^1\) and the American Academy of Pediatrics regularly issue guidelines to health care providers on scheduling childhood immunizations. They currently recommend that all children complete a schedule of vaccinations by 18 months of age that includes four doses of diphtheria, tetanus, and pertussis (DTP) vaccine; three doses of oral poliovirus (OPV) vaccine; one dose of measles, mumps, and rubella (MMR) vaccine; and a complete series of Hemophilus influenzae type b vaccine. In November 1991, the Advisory Committee also recommended three doses of hepatitis B vaccine.

Between 1989 and 1991, several major outbreaks of measles refocused Federal attention on childhood immunizations. The number of measles cases increased from approximately 3,400 cases in 1988 to 28,000 cases in 1991. In response to this concern and the need to develop a sustainable system, PHS launched the Childhood Immunization Initiative (CII). The CII is a comprehensive approach to increase immunization levels for children under the age of two. A major goal of the initiative is to increase immunization levels for two-year-old children to at least 90 percent for the most critical doses in the vaccination schedule by 1996. The initiative would achieve this goal by improving immunization delivery services, increasing community participation, educating parents, monitoring disease and vaccination coverage, improving vaccines and vaccine use, and reducing the cost of vaccines.

In 1991, the number of children two years of age who had completed the recommended immunization schedule was only about 50 percent. In 1992, this had increased to 55 percent. In 1993, the immunization level had increased to 67 percent. In the first quarter of 1994, the rate changed slightly to 66 percent. However, this is still far below the national goal of 90 percent for the complete series by the year 2000.

\(^1\)The Advisory Committee on Immunization Practices is composed of representatives from Federal and State health agencies, medical schools, and associations representing various health groups.
**Vaccines for Children Program**

To reduce the cost of vaccines to parents (one of the goals of the CII), Congress authorized the Vaccines for Children program (VFC) as part of the Omnibus Budget Reconciliation Act (OBRA) of 1993. The VFC program allows the Federal government to purchase vaccines from manufacturers at discounted prices and provide the vaccines free to physicians who participate in the program. Participating physicians can use the free vaccines to immunize children enrolled for Medicaid, Native American children, Alaskan Native American children, and children without insurance.

Children who have insurance but the insurance does not cover immunizations ("underinsured" children) are also eligible for VFC program vaccines, but only at Federally Qualified Health Centers (FQHCs) or Rural Health Clinics (RHCs). Many State officials have expressed concern that such a policy would create a barrier to underinsured children getting immunized. They are concerned that if physicians refer underinsured children to FQHCs or RHCs for immunizations, an opportunity to immunize is lost. Underinsured children will go to a private physician's office for other health care because they have insurance coverage. When this happens, the physician has an opportunity to screen the child's immunization status and immunize the child on the spot. However, if the physician refers the child to a FQHC or RHC for immunizations, the parent may not follow-through with or may delay getting their child immunized. Studies have shown that such missed opportunities contribute to why children are not adequately immunized.

The VFC program began October 1, 1994, and is administered by the Centers for Disease Control and Prevention (CDC).

**Physician Participation**

The national goal is to increase immunization levels of 2-year-olds for specific antigens to 90 percent by 1996. Widespread participation of physicians in the VFC program is considered essential to achieve that goal. However, early in the program, medical societies indicated that many physicians might not be willing to participate in the VFC program.

The CDC asked for assistance from the Office of Inspector General to identify and describe barriers to physician participation in the VFC program. We conducted this study in response to that request.

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2 Federally Qualified Health Centers and Rural Health Clinics serve medically underserved areas and rural areas that meet qualifications for receiving grants under the Public Health Service (PHS) Act. FQHCs include community, migrant, or homeless health centers receiving grants under the PHS Act.
Universal States

Prior to the VFC program, 12 States\(^3\) were providing free vaccine to private physicians to immunize all children in their States. These States are commonly referred to as universal States. Many universal States began their universal vaccine programs during the 1960s when Federal funding for State-based immunization programs began.

The Federal government provides grants to all States to purchase vaccines at the Federal discount price and funds immunization program initiatives. These grants are authorized under Section 317 of the PHS Act. With the inception of the VFC program, universal States have additional Federal funds to purchase vaccine for their Medicaid, uninsured, Alaskan Native American, and Native American children.

Universal States rely heavily on private physicians to immunize children because they have very limited public health clinics. Most physicians participate in their universal State programs. The following chart illustrates the percentage of physicians who participated in universal State programs in 1992.

**PHYSICIAN PARTICIPATION IN UNIVERSAL STATE VACCINE PROGRAMS**

![Bar Chart]

Note: Rates are estimates provided by immunization program officials. Idaho is not shown because participation rates were not available.

Washington became universal in 1990, and North Carolina in 1992. This may explain, in part, why they do not have as high physician participation rate as the other

universal States. North Carolina did, however, achieve a 70 percent participation rate within six months after the program began. North Carolina’s success is primarily due to strong support from medical societies which lobbied the State legislature to fund the program.

As of March 1995, three other States (New Mexico, Nevada, and North Dakota) have become universal.

**Non-Universal States**

Most non-universal States have public health departments and clinics. In many non-universal States, it is common for physicians to refer children to public health departments for immunizations. For example, a recent study in New York showed 50 percent of the physicians surveyed referred all or some of their patients elsewhere for vaccinations. According to the study, the primary reason for such referrals was the lack of insurance to cover the cost of immunizations.

Some non-universal States have experience with distributing free vaccines to private physicians because they were purchasing vaccine at the Federal contract price to distribute to Medicaid physicians, commonly referred to as a Medicaid Replacement Program. State health departments purchased and distributed free vaccines to Medicaid physicians, and Medicaid reimbursed the State health department. Non-universal States also distributed free vaccines to public health clinics for childhood immunizations.

**METHODS**

To identify issues affecting physician participation in the VFC program, we first surveyed physicians practicing in universal States. We believed we could learn from physician experiences in those universal State programs. We asked what problems they had previously encountered and which features of the VFC program would influence their decision to participate. We then considered how the issues identified by physicians in universal States might affect the willingness of physicians in non-universal States to participate in the VFC program. (We did not survey physicians in non-universal States because, at the time of our survey, many of these States postponed notifying physicians about the VFC program due to delays in establishing a Federal vaccine delivery system.)

We selected five universal States in which to conduct the physician survey—Washington, South Dakota, North Carolina, Massachusetts, and Connecticut. These States were chosen primarily because they represent different regions of the country. Appendix A further describes our criteria for selecting these States.

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In each of the States, we obtained a list of physicians from the American Board of Medical Specialties’ official directory of certified specialists. From the list of pediatricians, family, and general practice physicians we randomly selected 150 physicians from each State, for a sample of 750 physicians. We dropped 81 physicians from the sample because 30 did not give immunizations and 51 questionnaires were not deliverable. This reduced the sample from 750 to 669 physicians.

Our response rate was 39 percent (260 of 669). We are unable to perform a non-respondents analysis due to a lack of demographic data in our sampling frame. Thirty of the physicians we surveyed returned questionnaires indicating they did not give immunizations because they were retired, subspecialists, in academic medicine, or did not treat patients two years of age or younger. We believe a large number of physicians may not have responded for these same reasons. It is quite likely that, for physicians immunizing young children, we may have a much higher response rate. In any event, we believe our results are informative and generally representative of physicians providing immunization services.

To put physician responses in context with their State policies, we surveyed immunization program officials in 11 of the 12 universal States. One of the 12 universal States chose not to participate in our survey. We conducted site visits in seven universal States and mailed standardized questionnaires to the remaining five States.

We then interviewed immunization program officials from 21 non-universal States to obtain information on how they were implementing the VFC program and their perception of issues affecting physician participation in non-universal States. We interviewed the non-universal State officials at regional meetings sponsored by CDC. The 21 States include the District of Columbia. For the purpose of this study, we will refer to the District of Columbia as a State.

To obtain an understanding of the VFC program, we interviewed officials from the National Immunization Program and the National Vaccine Program Office. We also interviewed representatives from the American Academy of Pediatrics, American Medical Association, and the American Academy of Family Physicians. We reviewed laws and implementation guidelines for the program, and reports regarding State vaccine programs and related subjects.

We collected data between August and September 1994, the two months immediately before the program start-up date.

This report describes (1) the effect of VFC program requirements on physician participation in universal States, and (2) the potential effect of these issues on physician participation in non-universal States.

We conducted this inspection in accordance with the Quality Standards for Inspections issued by the President’s Council on Integrity and Efficiency.
reports. However, States can elect to continue requiring them. Appendix C shows an example of a vaccine usage report.

The physicians we surveyed said that it is time-consuming and cumbersome to break down doses administered by age groups as the vaccine usage reports require. Physicians said they did not take the vaccine usage reports seriously and often guessed at the reported information. Officials in some universal States reported that some physicians did not comply with this requirement.

Physicians informed us that the Provider Profile Form provides unreliable information. Physicians said they do not have a credible basis for estimating, by eligibility category, the number of children they expect to immunize. Thus, the estimates on the provider profile do not provide an accurate basis for States to apportion costs of vaccines between 317, VFC and State funds. Some State officials said they can estimate the number of children to be immunized better than physicians. For example, States can look at State Medicaid records to determine the number of Medicaid children eligible for program vaccines.

The Patient Eligibility Screening Record was cited as unreliable for two reasons. First, the law does not require that a child’s eligibility be verified. Therefore, parents could misrepresent their child’s eligibility status. Second, physicians are only required to complete the Patient Eligibility Screening Record at the time of the first immunization. However, a child’s VFC eligibility status may change after the first immunization. For example, it is not uncommon for families to frequently go on and off Medicaid during the course of a child’s immunization schedule. In addition, physicians said the Patient Eligibility Screening Record is superfluous in universal States because they provide free vaccines to all children and do not have to differentiate between which children are eligible for VFC program vaccines.

The Physician Enrollment Form should not be a problem for physicians who previously completed a similar enrollment form in their State universal program.

Non-Universal States

We expect that physicians in non-universal States will have similar concerns about paperwork as those cited by physicians in universal States. As noted earlier, fifty-two percent of the physicians in universal States said the paperwork in their State universal program was excessive (even though they were only required to complete one form for their State program).

Physicians in universal States said they cannot provide reliable estimates for the provider profile. Physicians in non-universal States may also be unable to provide reliable estimates.

Although physicians in universal States said the Patient Eligibility Screening Record was superfluous in universal States, this record could serve a purpose in non-universal
States. It could act as a deterrent for abuse, and provide physicians a means to determine if a child is eligible for VFC program vaccines.

To further illustrate the problem of excessive paperwork, we note that paperwork was one reason why States did not have success in getting physician participation in their Medicaid vaccine replacement programs. For example, when North Carolina was a non-universal State they conducted a study to determine the extent of participation in their Medicaid replacement program. The study showed that 79 percent of the physicians said they did not participate in the replacement program because of excessive paperwork.5

**INEFFICIENT VACCINE DELIVERY SYSTEMS COULD DISCOURAGE PHYSICIAN PARTICIPATION**

Delivery systems generally fall into two categories. Vaccines may be delivered to a State depot and then shipped directly to physicians, or vaccines may be delivered to a State depot and then shipped to "drop points" within a State, such as local health departments, clinics, and local hospitals. In drop-point systems, physicians must arrange to pick up vaccines from the drop points.

*Universal States*

Eight of the universal States we surveyed have direct delivery systems, three have drop-point systems. In the States where we surveyed physicians, South Dakota, North Carolina, and Massachusetts have direct delivery systems; while Washington and Connecticut have drop-point systems. Thirty-eight percent (38 of 101) of the respondents from States with drop points and 31 percent (49 of 159) of the respondents from direct delivery systems complained about the efficiency of their State delivery systems.6

Physicians identified problems applicable to both direct delivery and drop-point systems including vaccines not being delivered on time and in the correct quantities ordered. Physicians said when such problems occur, they must turn patients away and an opportunity to immunize is missed.

Physicians in States with drop-point systems cited additional problems including

- pick-up times at drop points are frequently inconvenient,
- physicians or their employees must drive long distances to drop points,

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6There is no statistically significant difference between the number of complaints in drop-point systems and the number of complaints in direct delivery systems.
• drop point employees are busy, and physicians or their employees have experienced long waits to obtain vaccines, and

• after driving long distances, and waiting for service, physicians are sometimes told that vaccines are not available.

State officials in States with direct delivery systems contend direct delivery is better because it facilitates communication between State agencies and physicians. For example, they put letters, pamphlets, and new immunization schedules in with vaccine shipments.

Non-Universal States

The delivery of vaccines to physicians in non-universal States may present a particular problem for the VFC program. If physicians perceive inordinate vaccine delivery problems, they may be less likely to participate, especially if children who are eligible for the VFC program represent a small portion of the physician’s practice. Likewise, if physicians experience vaccine delivery problems while participating, they may drop out of the program. Inefficient vaccine delivery systems not only lose the opportunity to immunize but can also hinder the relationship between the physician and patient.

LACK OF VACCINE DELIVERY SYSTEMS IN SOME STATES IMPEDES PHYSICIAN PARTICIPATION

According to VFC legislation, Federal funds are to finance delivery of program vaccines. Only one vaccine manufacturer would agree to a delivery contract at the capped vaccine price, so no Federal delivery system has been established. However, CDC continues to explore other delivery options.

All States are delivering vaccine to the public sector which accounts for about 50 percent of the nation’s immunizations. For private provider delivery, as of March 30, 1995, 35 States (including all 12 universal States) have established vaccine delivery systems using available Federal funding. Alaska also has a distribution system; however, they operate a centralized distribution system separate from the VFC program. At least 10 of the remaining 14 States reported they plan to begin delivering vaccine this year. This lack of private sector delivery has impeded private physician participation in these 14 States.

NEWLY ESTABLISHED MAXIMUM ALLOWABLE VACCINE ADMINISTRATION FEES FOR PHYSICIANS COULD HELP OVERCOME A BARRIER TO PHYSICIAN PARTICIPATION

Prior to the VFC program, physicians could charge parents a fee for administering free vaccines in universal States. Most universal States allowed physicians to charge parents from two to ten dollars per dose. Some universal States did not specify an amount, but told physicians they could charge parents a "reasonable" amount. The
allowable fees, however, discouraged some physicians from participating in State-sponsored programs. To illustrate, 25 percent (64 of 260) of the universal State physicians we surveyed said the fee their State allowed was inadequate. Twelve percent (31 of 260) of the physicians we surveyed said the amount physicians were allowed to charge parents was important to getting physician participation in the VFC program.

Under the VFC program, the Health Care Financing Administration (HCFA) established maximum allowable vaccine administration fees that physicians in each State could charge parents. The maximum allowable fees represent a cap, not a required amount. However, if universal States adopt HCFA’s maximum allowable fees, physicians in universal States will be allowed to charge parents significantly more than they were allowed to charge previously under their State program. The maximum allowable fees are comparable to what physicians charge parents to administer privately-purchased vaccines. Therefore, the newly established rates should encourage physician participation in the VFC program.

HCFA based the maximum allowable rates partly on studies done by the American Academy of Pediatrics (AAP). Under a HCFA contract, AAP conducted a survey of physicians to obtain national data on administration fees for pediatric immunizations. The survey showed that the average administration fee to private pay patients for each dose of pediatric vaccine is $15.09. The HCFA then adjusted the average rate for geographic cost differences to establish a maximum allowable physician fee for administering VFC vaccines. The maximum rates were set based on charge data rather than cost data which was required by law. HCFA plans to revise the maximum rates based on cost data. Appendix D shows, by State, the maximum fees established by HCFA.

State Medicaid agencies are not obligated to set their Medicaid VFC administration fees at the maximum level established by HCFA. However, 13 of the 21 non-universal States we surveyed said they would do so, or they would establish a slightly lower fee. To encourage physician participation in the VFC program, several non-universal States are offering additional incentives. For example, one State has offered an additional $5 to physicians for every new child they get to complete the immunization series. Another State plans to pay physicians $3 for each dose administered, to offset paperwork requirements.
RECOMMENDATIONS

Physician participation in the VFC program is essential to reach the National goal to increase immunization levels of 2-year-olds for specific antigens to 90 percent by 1996. Our study showed that unreliable, burdensome accountability requirements and inefficient vaccine delivery systems could adversely affect a physicians' decision to participate in the program. Therefore, we make two recommendations that we believe will further the goals of the VFC program.

*Continue to develop efficient and reliable vaccine accountability mechanisms.*

The CDC should explore alternative means to obtain the information intended to be provided by the provider profile. For example, States could use Medicaid records to determine how many Medicaid children are eligible for VFC program vaccines. Other records may be readily available to determine how many uninsured, underinsured, Native Alaskan American, and Native American children are eligible. States could conduct random sample surveys of physicians to confirm these projections. The CDC is already reexamining how to validate the provider profile information through implementing a usage based system. CDC is conducting a study to evaluate methods of accountability for VFC vaccines based on actual vaccine usage data. We encourage CDC to continue these efforts.

In addition, CDC should examine the efficacy of the Patient Eligibility Screening Record in universal States. These States may already have effective systems in place to accomplish what was intended by the Patient Eligibility Screening Record. The CDC has told us they are aware of this issue and are examining the legal and policy implications.

*Continue to explore alternative vaccine delivery systems.*

Obviously, the lack of vaccine delivery systems to private providers in fourteen States impedes physician participation in the VFC program as well as the ability of the program to increase childhood immunizations in those States. The CDC informed us that they are working with interested parties to establish vaccine delivery systems.

In addition, CDC should examine the efficiency of drop-point systems and direct delivery systems. Physicians we surveyed described problems with both types of delivery systems. If physicians experience vaccine delivery problems while participating, they may drop out of the program.
AGENCY COMMENTS

The Assistant Secretary for Health commented on our draft report and concurred with our recommendations. He expressed CDC's concerns that the accountability system for the VFC program balance the need for accountability with the need for a system that encourages physician participation and reported that CDC is continuing to develop accountability systems. Further, he stated that CDC is committed to establishing a delivery system for States who do not choose to deliver vaccines themselves.

The Assistant Secretary for Health, the Health Care Financing Administrator, and the Assistant Secretary for Planning and Evaluation provided additional points of clarification and technical comments which we responded to by editing portions of the report. Appendix E shows the full text of the comments.
APPENDIX A

SAMPLE OF FIVE UNIVERSAL STATES
FOR PHYSICIAN SURVEY

<table>
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<th>Sample States</th>
<th>% Pop. Urban</th>
<th>% Pop. Rural</th>
<th>Pop. Density Per Sq. Mile</th>
<th># Pediatricians</th>
<th># Family Physicians</th>
<th>Geographic Region</th>
<th>Other Universal States in Geo. Reg.</th>
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<tr>
<td>CT</td>
<td>92%</td>
<td>8%</td>
<td>768.4</td>
<td>848</td>
<td>292</td>
<td>New England</td>
<td>ME,NH, RI,VT</td>
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<tr>
<td>MA</td>
<td>95%</td>
<td>5%</td>
<td>767.6</td>
<td>1,762</td>
<td>501</td>
<td>New England</td>
<td>ME,NH, RI,VT</td>
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<td>NC</td>
<td>57%</td>
<td>43%</td>
<td>136.1</td>
<td>1,085</td>
<td>1,236</td>
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<tr>
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<td>29.5%</td>
<td>70.5%</td>
<td>9.2</td>
<td>59</td>
<td>188</td>
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<td>WA</td>
<td>82%</td>
<td>18%</td>
<td>73.1</td>
<td>781</td>
<td>1,361</td>
<td>Pacific NW</td>
<td>None</td>
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(Source: STATE YELLOW BOOK, VOL. V, No. 1, Spring 1993)

NOTES:

1. The sample reflects geographic and demographic diversity.
2. Two New England States were selected because half of the 12 universal States are in that region.
APPENDIX B

PHYSICIAN ENROLLMENT FORM

PROVIDER PROFILE FORM

PATIENT ELIGIBILITY SCREENING RECORD
Provider Enrollment
Vaccines for Children Program

Physician or Clinic
______________________________

Address
______________________________

( ) Telephone
______________________________

Fax
______________________________

Contact Name(s)
______________________________

Employer Identification Number
______________________________

Is your practice/clinic a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC)?  Yes _____ No _____

In order to participate in the Vaccines for Children (VFC) program and/or to receive other federally procured vaccine provided to me at no cost, I, on behalf of myself and any and all practitioners associated with this medical office, group practice, Health Maintenance Organization, health department, community/migrant/rural clinic, or other entity of which (you are the physician-in-chief or equivalent) agree to the following:

1. VFC program-purchased vaccine will be administered only to a child (≤18 years of age) who: (a) is on Medicaid (or qualifies through a State’s Medicaid waiver), or (b) has no health insurance, or (c) is an American Indian or Alaskan Native, or (d) has health insurance that does not pay for the vaccine (applicable only to vaccines administered by or on behalf of a FQHC or RHC).

2. I will maintain records of the authorized representative’s responses for a period of 3 years, unless State requirements call for a longer duration. Release of such records will be bound by the privacy protection of Federal Medicaid law.

3. If requested, I will make such records available to the State or the Department of Health and Human Services (DHHS).

4. I will comply with the appropriate immunization schedule, dosage, and contraindications, that is established by the DHHS Advisory Committee on Immunization Practices, unless (a) in making a medical judgment in accordance with accepted medical practice, I deem such compliance to be medically inappropriate or (b) the particular requirement is not in compliance with the law of my State, including State laws relating to religious or other exemptions.#

5. I will provide vaccine information materials and maintain records in accordance with the National Childhood Vaccine Injury Act.*

6. I will not impose a charge for the cost of the vaccine.*

7. I will not impose a charge for the administration of the vaccine in any amount higher than the maximum fee established by DHHS.

8. I will not deny administration of a federally procured vaccine to a child due to the inability of the child’s parent/guardian/individual of record to pay an administrative fee.*

9. I will comply with the State’s requirements for ordering vaccine and other requirements as outlined on the attached form(s).*

10. I or the State may terminate this agreement at any time for personal reasons or failure to comply with these requirements.*

Provider signature
______________________________

Date
______________________________

This record is to be submitted to and kept on file at the State Health Department or State Public Health Agency and must be updated in accordance with State policy.

*If a provider receives vaccine purchased off federal contracts, but is not enrolled in the VFC program, then the provider is only required to agree to these conditions.

# Note: The ACIP Immunization Schedule is compatible with the AAP recommendations.

For State use only (enter date in only one box):

Date certified for VFC: ____________________________ Date certified for vaccine purchased off Federal contracts, excluding VFC: ____________________________

Date certified for VFC and other vaccine purchased off Federal contracts: ____________________________
Provider Profile
Vaccines for Children Program

Date: ____________________________

All public and private healthcare providers approved by the State for participation in the Vaccines for Children Program (VFC) must complete this form. This document provides shipping information and helps the State determine the amount of vaccine to be supplied through the VFC program. The form also may be used to compare estimated vaccine needs with actual vaccine supply. The State or Immunization Project must keep this record on file with the "Provider Enrollment" form. The Provider Profile form must be updated annually or more frequently if: (1) estimates of children served changes, or (2) the status of the facility changes (e.g., private provider becomes an agent of a Federally Qualified Health Center). This form may be completed by one provider for the entire practice.

A. Employer Identification Number: _______________________________________

B. Facility Name: _________________________________________________________
   or
   Provider Name: ____________________________  Last Name: __________________
               First Name: __________________  MI: __________________

C. Contact Name(s): _______________________________________________________
   Last Name: __________________  First Name: __________________  MI: __________

D. Vaccine Delivery Address (no PO Boxes): _________________________________
   City: ___________________  State: _________  Zipcode: ________________
   ( ) ___________________  ( ) __________________
   Telephone: ___________  Fax: ______________

E. Type of Facility (please check only one box):
   □ 10  Public Health Department
   □ 11  Public Hospital
   □ 12  Other Public
   □ 13  Federally Qualified Health Center or Rural Health Clinic
        (check here if an agent of a FQHC or RHC for the VFC program) □
   □ 20  Private Practice (Individual or Group)
   □ 21  Private Hospital
   □ 22  Other Private

F. For the 12-month period beginning 10/1/94, estimate the numbers of children who will receive vaccinations at your practice/clinic.

<table>
<thead>
<tr>
<th></th>
<th>&lt;1 year old</th>
<th>1 through 18 years</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

G. Of the total numbers entered above, how many children are expected to be VFC eligible because they are:

   * Complete only if E -13 above is checked (either box).

Note: Do not count a child in more than one category.

<table>
<thead>
<tr>
<th></th>
<th>&lt;1 year old</th>
<th>1 through 18 years</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrolled in Medicaid</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Without health insurance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>American Indian or Alaskan Native</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Underinsured*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Complete only if E -13 above is checked (either box).
A record must be kept in the healthcare provider's office that reflects the status of all children 18 years of age or younger, who receive immunization through the VFC program. The record may be completed by the parent, guardian or individual of record, or by the healthcare provider. This same record may be used for all subsequent visits as long as the child's eligibility status has not changed. While verification of responses is not required, it is necessary to retain this or a similar record for each child receiving vaccine.

This child qualifies for vaccination through the VFC program because he/she (check only one box):

(a) is enrolled in Medicaid

(b) does not have health insurance

(c) is American Indian or Alaskan Native

(d) has health insurance that Does Not pay for vaccines

(Applicable only to children attending a Federally Qualified Health Center or Rural Health Clinic.)
VACCINE USAGE REPORT
Enter on the appropriate line designated for each vaccine, the total number of doses given of each vaccine according to age groups indicated. Please DO NOT use hash marks. Use additional copies for worksheets.

<table>
<thead>
<tr>
<th>Type of Vaccine</th>
<th>TOTAL DOSES GIVEN, BY PATIENT AGE-GROUP</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;1</td>
</tr>
<tr>
<td>DTP</td>
<td></td>
</tr>
<tr>
<td>DT (peds)</td>
<td></td>
</tr>
<tr>
<td>Td (adult)</td>
<td></td>
</tr>
<tr>
<td>HibTITER</td>
<td></td>
</tr>
<tr>
<td>PedvaxHIB</td>
<td></td>
</tr>
<tr>
<td>O.P.V.</td>
<td></td>
</tr>
<tr>
<td>I.P.V.</td>
<td></td>
</tr>
<tr>
<td>M/M/R</td>
<td></td>
</tr>
<tr>
<td>Influenza</td>
<td></td>
</tr>
<tr>
<td>Hep B (infant)</td>
<td></td>
</tr>
</tbody>
</table>

This report is authorized by law (42 USC 247b. 42CPR 51b.) and is to be submitted by the 5th working day of each quarter. Its submission is needed to provide effective program management and is a condition of immunization project grant awards.
OIG Recommendation

We recommend that the Centers for Disease Control and Prevention (CDC):

1. Continue to develop efficient and reliable vaccine accountability mechanisms.

PHS Response

We concur. Financial accountability is an essential part of the Vaccines For Children (VFC) program. The States have primary responsibility for accounting for vaccine. Given their 30 plus years of experience managing immunization programs, the States are in the best position to account for vaccines because of their knowledge of unique circumstances and provider practices.

The OIG report documents concerns that additional paperwork requirements will discourage physicians from participating in the VFC program. Because of this concern, CDC has developed an accountability system for the VFC program that balances the essential need for accountability with the mandate to encourage physicians to participate in the program. If CDC had required providers to report each immunization transaction, they would be burdened with filling out and sending in over 14 million pieces of paper a year.

The CDC is continuing to develop additional accountability mechanisms. CDC officials have met with States to review State accountability plans and to identify promising approaches to accountability. The CDC is also working with Battelle to pilot test additional accountability methods in selected States.

Recommendation

2. Continue to explore alternative vaccine delivery systems.

PHS Response

We concur. The CDC is committed to establishing a delivery system for those States which do not choose to deliver vaccines themselves. Initially, as requested by the States, CDC proposed distributing vaccine to private physicians in selected States through a national distribution center. However, the Congress preferred having the private sector carry out this vaccine distribution. Accordingly, in September 1994, CDC began negotiations with vaccine
manufacturers with anticipation of delivery to private physicians in December. On April 10, CDC had to discontinue these negotiations. Although final agreement was reached with one manufacturer, it was determined that time was not available to reach agreements with the remaining manufacturers. CDC is now holding meetings with interested parties to determine the most appropriate manner to conduct this vaccine delivery.

Despite this, it should be recognized that VFC vaccine is being delivered to tens of thousands of public and private providers. All States are delivering vaccines to public clinics, which account for about 50 percent of immunizations nationwide. In addition, as of March 30, 35 States had informed CDC that they were delivering vaccine to enrolled private providers. All of the remaining 14 States reported they plan to begin delivering vaccine to private providers this year or next year. [Alaska, which already delivers vaccines to all providers in the State, is not participating in the VFC program.]
DATE MAY 22 1995

TO June Gibbs Brown
Inspector General

FROM Bruce C. Vladeck
Administrator


We reviewed the above-referenced draft report which identifies issues affecting physician participation in the Vaccines for Children program, and recommends that the Centers for Disease Control and Prevention continue to take effective actions to improve the vaccine delivery systems. We have a few editorial comments, which are attached for your review.

Thank you for the opportunity to comment on this draft report.

Attachment
JUN 9 1995

TO: June Gibbs Brown
    Inspector General

FROM: Assistant Secretary
      for Planning and Evaluation


Thank you for providing me with a draft of the above mentioned report for review and comment. I understand that the Public Health Service and the Health Care Financing Administration are also reviewing the report and will be providing your office with specific comments. We would defer to their expertise and experience with the VFC program in addressing any concerns they might have with the report. In addition, we would suggest that a clarification be made within the Executive Summary and the body of the report emphasizing that the data was collected prior to the implementation of the VFC program on October 1, 1994. While some states may have informed their physicians about the anticipated requirements of the VFC program prior to October 1, 1994 other states may not have done so by the time data was collected.

David T. Ellwood

Prepared by Amy Nevel, OASPE