

# PERFORMANCE AUDIT REPORT

Use of State-Supplied Vaccines by a Provider  
Report No. 3030

September 29, 2011

STATE AUDITOR  
ROBERT R. PETERSON



Phone (701)328-2241  
Fax (701)328-1406

STATE OF NORTH DAKOTA  
**OFFICE OF THE STATE AUDITOR**  
STATE CAPITOL  
600 E. BOULEVARD AVENUE – DEPT 117  
BISMARCK, NORTH DAKOTA 58505

September 29, 2011

Honorable Jack Dalrymple, Governor

Members of the North Dakota Legislative Assembly

We are pleased to submit this performance audit report of aspects of the use of state-supplied vaccines by a provider. This report contains the results of our review of whether state-supplied vaccines were used in compliance with agreed upon terms and conditions by the provider.

We conducted this audit under the authority granted within North Dakota Century Code Chapter 54-10. Included in the report are the objective and scope, findings and recommendations, and management responses.

We want to extend our appreciation to the immunization personnel of the Department of Health for their assistance and cooperation during this audit.

Respectfully submitted,

A handwritten signature in cursive script that reads "Bob Peterson".

Robert R. Peterson  
State Auditor

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## State-Supplied Vaccines

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### Introduction

The objective of this performance audit was to answer the following question:

“Were state-supplied vaccines used in compliance with agreed upon terms and conditions by the provider?”

Based on our review of information, we determined state-supplied vaccines were not used in compliance with agreed upon terms and conditions by a certain provider. As a result, the Department of Health should meet with the Office of the Attorney General to determine what appropriate step(s) to take. In our review, we also identified improvements the Department of Health could take to improve monitoring the use of state-supplied vaccines. Significant improvements needed are included in this chapter. Improvements of less significance were communicated in a separate letter to the Department of Health.

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### State-Supplied Vaccine Information

Free vaccines are made available to providers through the Vaccines for Children (VFC) program or through the federal Section 317 vaccine program. The VFC program is a federal entitlement program for administration of vaccines to VFC-eligible children. VFC-eligible is defined as a child who is 18 years of age or younger and meets one or more of the following criteria:

- Is an American Indian or Alaska Native
- Is eligible/enrolled in Medicaid
- Has no health insurance
- Is underinsured

Section 317 vaccines are funded through discretionary federal funds. These funds are made available through an annual federal appropriation to provide a safety net to provide vaccines to underinsured children and adolescents not served by the VFC program and, as funding permits, provide vaccines to uninsured and underinsured adults.

For a provider to receive free vaccines, the provider must annually enroll with the Department of Health in the Prevention Partnership Program. Providers must agree to 13 conditions listed on the enrollment form including to administer only VFC or state-supplied vaccines to individuals meeting established criteria and to immunize eligible individuals with VFC or state-supplied vaccines at no charge to the patient.

Providers submit orders for the free vaccines to the Department of Health. While the Department of Health submits the vaccine orders, the vaccines are shipped directly to providers free of charge. Additional information related to state-supplied vaccines is included in Chapter 2.

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## Chapter 1 State-Supplied Vaccines

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### Reviewing a Provider's Use of State-Supplied Vaccines

On June 15, 2011, the Department of Health was notified by a public health unit of potential problems related to the VFC program at a provider. Department of Health personnel reviewed vaccination data related to the provider and contacted the provider for further information. Following this, the Department of Health terminated the provider from the program, required remaining state-supplied vaccines be sent to another provider, and referred information to the Office of the Attorney General. A request was made by the Office of the Attorney General of our office to conduct an audit of the terminated provider.

When vaccines are administered, providers are required to enter vaccination information into the North Dakota Immunization Information System (NDIIS). Information entered by the provider includes demographic information of the patient as well as the vaccine lot number and whether the patient was eligible for the VFC program or not. The Department of Health provided NDIIS data related to the terminated provider and we conducted a review of the information. Based on the information within NDIIS, it is apparent the terminated provider was using state-supplied vaccines for non-eligible individuals.

We conducted an on-site visit of the terminated provider to review a selection of vaccinations administered from January 1, 2010 through June 19, 2011. For selected vaccinations, we reviewed the medical records and/or billing information to determine VFC eligibility and whether payment was received for state-supplied vaccines administered. In our review, we concluded the eligibility status entered into NDIIS was not always accurate. See Appendix A for eligibility statuses determined to be incorrectly entered into NDIIS by the terminated provider.

**State-supplied vaccines were inappropriately used by a provider. This provider was terminated from the vaccination program.**

We reviewed information to determine whether the terminated provider had used state-supplied vaccines and improperly billed for the vaccines. Based on our review of information, state-supplied vaccines were being administered by the provider and subsequently billed if the patient had insurance. The provider was in noncompliance with program requirements. Interviews with provider personnel indicated the typical process was to bill if there was insurance for any vaccination, regardless of eligibility and what vaccination was used.

We attempted to identify the benefit received by the terminated provider for the inappropriate use of state-supplied vaccines. However, we were unable to determine an approximate amount due to concerns with the inaccuracies of the eligibility status entered into NDIIS. To determine an accurate amount, all vaccinations would need to be individually reviewed and compared to medical records and/or billing information. There were over 4,000 vaccinations listed in NDIIS from January 1, 2010 through June 19, 2011 for the terminated provider. In our review of a selection of state-supplied vaccines administered (total of 125 reviewed), we identified the provider received payments totaling approximately \$5,000. Additional information related to our review is included in Appendix A.

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## Chapter 1 State-Supplied Vaccines

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Interviews with personnel of the terminated provider indicated there were insufficient private vaccines being ordered by the terminated provider. When asked why sufficient private vaccines were not being purchased, personnel identified financial concerns. Based on a limited review of vaccine ordering information of the terminated provider, it appears a sufficient supply of private vaccines was not being ordered. Due to the lack of private vaccine, when patients were at the facility and needed an immunization, the provider would use state-supplied vaccines. This was inappropriate as the state-supplied vaccines should not have been used as a replacement system.

Program requirements do allow for state-supplied vaccines to be “borrowed” to administer to non-VFC eligible individuals. However, this is to occur only in rare, unplanned situations. Lack of properly ordering a sufficient supply of private vaccines would not be an allowable “borrowing” situation.

### Recommendation 1-1

We recommend the Department of Health meet with the Office of the Attorney General to discuss concerns noted with the review of information regarding the terminated provider and determine the next appropriate step(s) to take.

### Management’s Response

The Department of Health agrees. The department will meet with the Attorney General to review legal options based on the facts presented by the audit. The department has met with their assigned assistant attorney generals to review the audit report.

Goals of any litigation or settlement will include restitution for the cost of improperly administered state supplied vaccine; sufficient consequences to address unjust enrichment and to prevent reoccurrence; and rehabilitative measures necessary for the provider to again participate in the VFC program.

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## Establishing a Monitoring Process

No review of vaccination data was performed to monitor providers’ use of state-supplied vaccines.

Providers in the state who administer vaccinations to children are required by state law to enter vaccination information into the North Dakota Immunization Information System (NDIIS). The Department of Health has entered into a contract with an outside vendor to maintain and enhance the database. The immunization records entered into NDIIS are the sole property of the Department of Health. Information within NDIIS provides the Department of Health with an opportunity to monitor providers receiving state-supplied vaccines. For example, data within NDIIS could be used to identify potential problem areas such as an inordinate amount of state-supplied vaccines being administered to non-eligible individuals. A periodic review of data would provide the Department of Health with the necessary information to identify potential problem areas. The Department of Health could then use this information to determine what actions to take to enhance the integrity of the program.

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## Chapter 1 State-Supplied Vaccines

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### Recommendation 1-2

We recommend the Department of Health periodically review vaccination data related to providers receiving state-supplied vaccines. At a minimum, the Department should:

- a) Establish parameters, data outliers, or other criteria to identify potential problem areas; and
- b) Establish policies and procedures regarding the use of such information and action to be taken by the Department.

### Management's Response

The Department of Health agrees.

- a) The immunization program sees a need and value in using the NDIIS for accountability and VFC Program compliance. The immunization program will establish criteria to identify potential problems and will develop policies and procedures regarding the use of NDIIS data to identify problems with VFC compliance and/or other immunization-related program issues.
- b) The policies and procedures will also describe the immunization program's response to the identified problems.

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## Making Changes with On-Site Visits

The Centers for Disease Control and Prevention (CDC) currently requires an on-site visit of at least 50% of enrolled and active VFC providers each year (in calendar year 2010, the requirement was 25% a year). According to Department of Health personnel, approximately 69% of providers received an on-site visit in calendar year 2010. Two public health units are contracted with to perform the site visits (total of two contracts approximately \$118,000 per year) and one Department of Health employee also performs site visits.

CDC publishes a provider site visit questionnaire which is to be completed by the reviewer while on-site at a provider. This questionnaire includes high priority questions which automatically require a corrective action be recommended when an incorrect or inappropriate response is identified. At the end of a site visit, the reviewer is to provide the Department of Health with the corrective actions recommended.

In our review of a completed site visit questionnaire conducted by one of the contractors, we identified concerns related to how certain questions were answered and how relevant information regarding the results of the review were not appropriately communicated. For example, the reviewer indicated a borrowing report was completed correctly and documented timely replacement of vaccine to the appropriate stock. In our review of this provider's records and in discussions with provider personnel, no such borrowing report existed. Concerns identified by the contractor which required corrective action be taken were not communicated to the Department of Health as required and did not appear to be communicated to the provider. In addition, other compliance concerns we identified at this provider were not identified through the on-site visits. Additional information may need to be used to complete the questionnaire and/or a review of certain areas not included in the questionnaire could be conducted.

**On-site reviews of providers need improvement to ensure compliance with program requirements.**

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## Chapter 1 State-Supplied Vaccines

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The use of contractors to perform the on-site visits may not be the most efficient and effective manner to monitor providers. CDC's technical site visit of the state's immunization program identified one of the contractors had four different people in the last four years conducting site visits. While a representative of the Department of Health went with a contractor on one on-site review to monitor performance, no additional review or monitoring of the contractor's performance is conducted.

### **Recommendation 1-3**

We recommend the Department of Health make changes to on-site reviews of providers receiving state-supplied vaccines to ensure program requirements are met and the Department is properly informed of results.

### **Management's Response**

The Department of Health agrees. The immunization program has revised VFC site visit corrective action report forms for contractors. Policies and procedures also will be revised to ensure contractors receive appropriate training and are following VFC guidelines. An algorithm for the reporting and response to high-priority issues will be developed for contract staff conducting site visits to ensure the immunization program is aware of certain VFC-related issues and to outline issues that may be corrected by contract staff.

### **Recommendation 1-4**

We recommend the Department of Health conduct a formal cost/benefit analysis of the use of separate entities to perform on-site reviews of providers receiving state-supplied vaccines. Based on the results of this cost/benefit analysis, the Department should either:

- a) Take appropriate action to obtain the necessary resources to perform the on-site visits with state personnel; or
- b) Establish a monitoring process of contractors to ensure on-site reviews are performed as required.

### **Management's Response**

The Department of Health agrees. The department will conduct a formal cost/benefit analysis of the use of separate entities or state personnel to perform on-site reviews of VFC providers. If the analysis indicates state personnel is more cost beneficial the department will realign our budget accordingly or seek any additional resources needed. Until that time the Department of Health will strengthen the contracts with the two VFC site visit contractors and will improve the monitoring process of the contractors. The department will also explore the possibility of personal service contracts with qualified individuals.

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## Chapter 1 State-Supplied Vaccines

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### Making Improvements with the Borrowing of State-Supplied Vaccines

CDC guidance states borrowing VFC vaccine to administer to a non-VFC eligible patient can occur only in rare, unplanned situations. The guidance also states VFC vaccine is not to be used as a replacement system for a provider's privately purchased vaccine system. A "borrow/return" function is included within NDIIS for providers to use to track borrowing situations. Our review of information regarding the terminated provider identified NDIIS was not used to monitor "borrowing" until June 2011 and no borrowing reports were used to track these situations. As part of this audit, we conducted a limited review of another provider who received state-supplied vaccines. This provider also appeared to not be completing borrowing reports. Department of Health personnel identified concerns with the program related to borrowing as providers may be borrowing in more instances than they should.

### Recommendation 1-5

We recommend the Department of Health make improvements related to the borrowing of state-supplied vaccines to ensure it occurs only in rare, unplanned situations. If additional training, additional requirements added to the enrollment process, and/or monitoring is unable to improve compliance with borrowing requirements, the Department should mandate no borrowing of state-supplied vaccine without prior written authorization.

### Management's Response

The Department of Health agrees. The immunization program will enhance education of providers about the borrowing and returning guidelines for the VFC Program. The program will revise borrowing and returning guidelines and make additional requirements as needed. The immunization program is exploring changes to the NDIIS to better facilitate tracking of borrowed and returned doses. If enhanced education, additional requirements, and changes to the NDIIS do not sufficiently improve compliance with borrowing and returning guidelines after a certain period of time, the immunization program will no longer allow providers to borrow and return between VFC and private vaccine supplies without prior written authorization.

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## Audit and VFC Background Information

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### Purpose and Authority of the Audit

The performance audit of aspects of the use of state-supplied vaccines by a provider was conducted by the Office of the State Auditor pursuant to authority within North Dakota Century Code Chapter 54-10.

Performance audits are defined as engagements that provide assurance or conclusions based on an evaluation of sufficient, appropriate evidence against stated criteria, such as specific requirements, measures, or defined business practices. Performance audits provide objective analysis so management and those charged with governance and oversight can use the information to improve performance and operations, reduce costs, facilitate decision making by parties with responsibility to oversee or initiate corrective action, and contribute to public accountability. The purpose of this report is to provide our analysis, findings, and recommendations regarding our limited review of whether state-supplied vaccines were used in compliance with agreed upon terms and conditions by the provider.

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### Background Information

The VFC program is a federal entitlement program for administration of vaccines to VFC-eligible children. VFC-eligible is defined as a child who is 18 years of age or younger and meets one or more of the following criteria:

- Is an American Indian or Alaska Native
- Is eligible/enrolled in Medicaid
- Has no health insurance
- Is underinsured

An underinsured child is a child who has insurance but the coverage does not include vaccines, a child whose insurance covers only selected vaccines, or a child whose insurance caps vaccine coverage at a certain amount. Once the coverage amount is reached, the child is categorized as underinsured.

Funding for the VFC program is through the Centers for Medicare and Medicaid Services to the Centers for Disease Control and Prevention (CDC). The Department of Health is the grantee for the program and free vaccines are available to providers. Vaccine orders are submitted by providers to the Department of Health and the vaccines are shipped directly to the provider. The Department of Health and the providers pay nothing for the cost of the vaccines or the shipping of the vaccines as they are made available free of charge through the VFC program to administer to VFC-eligible children. The vaccines available through the VFC program cover the vaccines recommended by the Advisory Committee on Immunization Practices.

To receive free vaccines, providers must annually enroll in the Department of Health's Prevention Partnership Program. Providers must agree to 13 conditions listed on the enrollment form including to administer only VFC or state-supplied vaccines to individuals meeting established criteria and to immunize eligible individuals with VFC or

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## Chapter 2

### Audit and VFC Background Information

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state-supplied vaccines at no charge to the patient. Providers are required to screen patients at all immunization encounters for eligibility purposes. While providers are required to ask a parent of the child such questions necessary to determine eligibility, providers are not required to independently verify the answers to such questions. While providers are not to bill for the cost of state-supplied vaccines, a vaccine administration fee may be charged for state-supplied vaccines (current maximum is \$13.90 per vaccination administered).

Providers may also receive vaccines for free through the federal Section 317 vaccine program. Section 317 vaccines are funded through discretionary federal funds. These funds are made available through an annual federal appropriation to provide a safety net to provide vaccines to underinsured children and adolescents not served by the VFC program and, as funding permits, provide vaccines to uninsured and underinsured adults. The Department of Health determines what adults are eligible and the type of vaccines which are available to administer to adults. The Department of Health updates the Vaccine Coverage Tables when changes occur to vaccinations covered and eligibility.

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#### Objective of the Audit

The objective of this performance audit is listed below:

“Were state-supplied vaccines used in compliance with agreed upon terms and conditions by the provider?”

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#### Scope and Methodology

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Audit field work was conducted from the middle of August 2011 to the end of September 2011. The audit period for which information was collected and reviewed was January 1, 2010 through August 10, 2011. Vaccination data used to review information at the terminated provider was from January 1, 2010 through June 19, 2011. This was due to a change in how certain data was entered into NDIIS by the provider in June 2011.

To determine whether state-supplied vaccines were used in compliance with agreed upon terms and conditions by the provider, we:

- Reviewed applicable federal requirements including CDC guidelines;
- Reviewed Department of Health policies and procedures;

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## Chapter 2

### Audit and VFC Background Information

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- Reviewed vaccination data within the North Dakota Immunization Information System for two providers;
- Reviewed information related to the use of state-supplied vaccines at the terminated provider (see Appendix A for information related to vaccinations reviewed);
- Reviewed information related to the use of state-supplied vaccines at one additional provider including 11 vaccinations administered; and
- Interviewed selected personnel.

While the majority of work performed in this audit related to reviewing the use of state-supplied vaccines at the terminated provider, we did conduct a limited review of another provider's use of state-supplied vaccines. This was done to gain an understanding of how another provider used state-supplied vaccines. In addition, we also reviewed information related to the Department of Health's monitoring of the use of state-supplied vaccines. This was done to gain an understanding of the program as well as to identify where improvements could be made with the program.

## Vaccination Information Reviewed

When the Department of Health was made aware of a potential problem with the Vaccines for Children (VFC) program at a provider, vaccination data related to the provider was reviewed and the provider was contacted. The Department of Health terminated the provider from the program and the provider was no longer eligible to receive state-supplied vaccines.

To review information related to the terminated provider, we were provided vaccination information from the North Dakota Information Immunization System (NDIIS). Based on this information, we identified state-supplied vaccines were being administered to non-eligible individuals. We categorized the vaccination information into various categories for review purposes and selected certain vaccinations to review. We were on-site at the terminated provider for four days and reviewed applicable medical record information, billing information, vaccination logs, vaccine ordering information, and other information regarding immunizations. We also conducted interviews with selected personnel. Based on our review of information, there were insufficient private vaccines being ordered by the terminated provider. As a result, state-supplied vaccines were being inappropriately used. The table below summarizes our review of vaccinations at the terminated provider (NDIIS data from January 1, 2010 through June 19, 2011, payment amounts identified do not include the allowable administrative fee).

NDIIS Information				Office of the State Auditor	
Vaccine Type	VFC Type	Demographic	Population	Reviewed	Observations
State	Not Eligible	18 years old and younger	1,220	58	8 vaccinations were administered to VFC eligible patients. Remaining 50 vaccinations the provider billed and received payment of \$3,497.
State	VFC Eligible	18 years old and younger	813	37	6 vaccinations were administered to non-VFC eligible. 11 vaccinations the provider billed and received payment of \$868.
State	Not Eligible	19 years old and older (vaccination may be eligible for Section 317)	296	20	10 vaccinations the provider billed and received payment of \$530.
State	Not Eligible	19 years old and older (vaccination not eligible for Section 317)	152	10	5 vaccinations the provider billed and received payment of \$121. All 152 vaccinations in this population appear to be inappropriate use of state-supplied vaccines.
Private	VFC Eligible	18 years old and younger	234	29	5 vaccinations were administered to non-VFC eligible patients.
Private	Not Eligible	All age groups	1,523	15	15 vaccinations reviewed appeared to be coded correctly.

As seen by the table above, approximately \$5,000 was received in payments by the provider when using state-supplied vaccines. These vaccines were shipped to the provider at no cost (neither the cost of the vaccine nor shipping costs are paid by the provider). No projection is made to the population as inconsistencies exist with data within NDIIS (eligibility type was identified as not being accurate in certain instances).