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**Missouri State Auditor**


# HEALTH AND SENIOR SERVICES

# School Children Immunization Compliance Requirements

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Missouri State Auditor

# YELLOW SHEET

## Better Procedures Needed to Ensure School Children Meet Immunization Requirements

The Department of Health and Senior Services (DHSS) is responsible for ensuring Missouri school children are appropriately immunized against vaccine preventable diseases. Superintendents of public and private schools are required to prepare and submit to DHSS a school summary report stating the immunization status of every child enrolled in or attending school in the superintendent's jurisdiction and a student exception report stating the names of any noncompliant students. Additionally, it is unlawful for any student to attend school unless the student has been properly immunized and can provide satisfactory evidence of such immunization, or unless the student has received appropriate approval for a medical exemption, religious exemption, or immunization in progress. Our audit concluded DHSS needs to do more to ensure students are properly immunized and schools report immunization information to DHSS.

### Some schools did not submit school summary reports or submitted inaccurate reports

At least 169 schools did not submit the 2006-07 school summary report to DHSS as of November 13, 2006. For the 2007-08 school year, 172 of the 1,234 (13.9 percent) schools had not submitted school summary reports as of January 15, 2008, three months after the report due date. In addition, of 118 school summary reports tested for kindergartners during the 2007-08 school year, 16 (13.6 percent) were inaccurate. DHSS officials said there are no written policies for (1) when and how often a school is to be contacted to obtain delinquent school summary reports, and (2) the documentation required to support the follow-up performed with the school and the record retention period for such documentation.

### DHSS did not ensure schools submitted accurate student exception reports

Reviews to ensure complete and accurate student exception reports are obtained from the schools were not initiated timely in the 2007-08 school year and were not completed in the 2006-07 school year. At the time of our review on February 19, 2008, 106 of 118 schools tested submitted 2007-08 school summary reports indicating they had kindergartners who were not in compliance with immunization requirements. As of May 6, 2008, 100 of the 106 schools had submitted a student exception report; however, 24 of the schools had submitted exception reports that were not complete and/or accurate. A DHSS official said there is no formal tracking performed to identify the schools that did not submit the required student exception report(s) to DHSS nor any documented policies for reviews.

### Better regulations needed to protect non-immunized students during an outbreak

State regulations do not require schools to maintain a list of exempt students. Additionally, state regulations do not require exempt students to be excluded from school during outbreaks of vaccine preventable diseases. Changes are needed to ensure appropriate steps are taken in the event of an outbreak or epidemic.

### DHSS not requiring compliance with federal recommendations

State law requires immunizations and their manner and frequency to comply with recognized standards of the medical practice. However, state regulations do not require the meningococcal vaccine or the human papillomavirus (HPV) vaccine and DHSS' immunization notifications sent to schools do not include requirements for school children to be vaccinated

with the second dose of varicella, as federally recommended. In addition, DHSS' recommended administration of the tetanus, diphtheria, and pertussis (Tdap) booster for adolescents did not comply with federal recommendations. State regulations also do not require parents or guardians to be notified of any deviations from federal recommendations. The U.S. Department of Health and Human Services, Centers for Disease Control and Prevention guidance allows grantees 2 years to adjust assessment practices to reflect changes in Federal Advisory Committee on Immunization Practices (ACIP) recommendations. A DHSS official said the ACIP recommended the meningococcal and Tdap booster in 2005, and the HPV and second dose of varicella in 2006.

## DHSS needs to make improvements in other areas

Further improvements are needed to (1) better validate the state's immunization rate reported to the federal government, (2) increase the functionality and reliability of the school children immunization database, (3) ensure compliance with legal provisions concerning appointments to the Advisory Committee on Childhood Immunization, (4) establish a standard immunization record requiring a physician or health care administrator's statement verifying the vaccine was administered, (5) establish regulations for the retention of immunization records, (6) improve the effectiveness of DHSS' immunization registry, (7) perform analyses to identify populations at risk for vaccine preventable diseases, and (8) report immunization information to more stakeholders.

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## Abbreviations

| | |
|---|---|
| ACIP | Advisory Committee on Immunization Practices |
| CDC | U. S. Department of Health and Human Services, Center for Disease Control and Prevention |
| CSR | Code of State Regulations |
| DESE | Department of Elementary and Secondary Education |
| DHSS | Department of Health and Senior Services |
| DSS | Division of Social Services |
| HPV | Human Papillomavirus |
| RSMo | Missouri Revised Statutes |
| SAO | State Auditor's Office |
| Tdap | Tetanus, diphtheria, and pertussis booster |

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**Missouri State Auditor**

Honorable Matt Blunt, Governor
and
Members of the General Assembly
and
Jane Drummond, Director
Department of Health and Senior Services
Jefferson City, MO

The Department of Health and Senior Services (DHSS), Division of Community and Public Health, Section for Disease Control and Environmental Epidemiology, Bureau of Immunization Assessment and Assurance Unit is responsible for promulgating rules and regulations for school children immunizations and tracks immunizations mandatory for school children. Our audit objectives included (1) evaluating state and school procedures to ensure students are properly immunized, (2) evaluating established controls to ensure the integrity and reliability of immunization data, and (3) analyzing state laws and regulations and any potential changes needed.

Our audit concluded DHSS needs to do more to ensure students are properly immunized and that all schools report immunization information to DHSS. Further improvements are needed to (1) comply with federal recommendations regarding specific immunizations and dosages and (2) require schools to comply with regulations requiring a statement from a physician or health care administrator stating the vaccine was administered.

We conducted our audit in accordance with the standards applicable to performance audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States. Those standards require that we plan and perform our audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides such a basis. This report was prepared under the direction of John Luetkemeyer. Key contributors to this report included Amanda Locke, Edward Morgan and Darrell Wolken.

Susan Montee, CPA
State Auditor

# Introduction

The Missouri Department of Health and Senior Services (DHSS), Division of Community and Public Health, Section for Disease Control and Environmental Epidemiology, Bureau of Immunization Assessment and Assurance Unit is responsible for ensuring Missouri school children are appropriately immunized against vaccine preventable diseases. DHSS services include surveying public and private schools to determine the immunization rates for school children, performing validation assessments of the immunization rates received from the schools, and reporting the results to the U. S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC).

The federal Advisory Committee on Immunization Practices (ACIP) provides advice and guidance to the CDC on the control of vaccine preventable diseases by developing written recommendations for the routine administration of vaccines to children and adults in the civilian population. These recommendations include age for vaccine administration, number of doses and dosing interval, and precautions and contraindications. The ACIP is the only entity in the federal government that makes such recommendations.

Missouri's Advisory Committee on Childhood Immunization is required by state law[1] to develop plans to increase the immunization rate in the state, identify comprehensive immunization monitoring systems, determine how to analyze and communicate immunization information to stakeholders and determine how demographic and immunization data for children under the age of five shall be obtained and entered into the computer system.

## Relevant Legal Requirements

The compulsory attendance state law[2] requires all children who are between the ages of seven and sixteen and students enrolled in a public school between the ages of five and seven to attend an academic program on a regular basis. Another state law[3] and/or regulation[4] requires school children to be immunized against diphtheria, tetanus, pertussis, polio, measles, mumps, rubella, hepatitis B, and varicella. In addition, state law allows DHSS, by regulation, to modify the immunizations required of children to conform to recognized standards of medical practice. This law and/or regulation states it is unlawful for any student to attend school unless the student has been properly immunized and can provide satisfactory evidence of such immunization, or unless the student has received appropriate

[1] Section 192.630, RSMo
[2] Section 167.031, RSMo
[3] Section 167.181, RSMo
[4] 19 CSR 20-28.010

approval for a medical exemption, religious exemption, or immunization in progress.[5]

Superintendents of public and private schools are required to prepare a record stating the immunization status of every child enrolled in or attending school in the superintendent's jurisdiction. DHSS regulations and procedures require the school superintendent to submit a "Summary Report of Immunization Status of Missouri Public, Private, and Parochial School Children" (school summary report), to DHSS no later than October 15th of each school year identifying the status of each student by grade and vaccine. School superintendents are also required to report the name of any parent or guardian who neglects or refuses to immunize a nonexempt student as well as the name of the noncompliant student to DHSS on the "Report of Students in Noncompliance with Missouri School Immunization Law" (student exception report), by October 15th. DHSS procedures require each school superintendent with a nonexempt student to provide a follow-up status for each noncompliant student to DHSS within 30 days.

According to Department of Elementary and Secondary Education (DESE) and/or Department of Social Services (DSS) officials, any parent or guardian who does not comply with the compulsory attendance law is in violation and could be reported to (1) DSS Children's Division[6] for an investigation or family assessment of educational neglect, (2) the local juvenile authority or (3) the prosecuting attorney for enforcement of criminal penalties.[7]

## Childhood Immunization Funding

DHSS received federal funding for childhood immunization activities under the CDC Section 317 Operations Program grant. In calendar year 2007, the Section 317 grant funded DHSS $3.2 million[8] towards the state's

[5] State regulations allow a student whose immunization is in progress to attend school as long as an immunization series has started and satisfactory progress is being accomplished. Failure to meet the next scheduled appointment constitutes noncompliance with the school immunization law and exclusion should be initiated immediately.

[6] The Children's Division receives reports on child abuse and neglect via a telephone hotline from mandated reporters, including school personnel. If an investigation is performed and a preponderance of evidence finding related to educational neglect is reported, the parent or guardian will be included on the Child Abuse and Neglect Central Registry, or the list of persons who have a substantiated report of child abuse and neglect.

[7] Section 167.061, RSMo

[8] The Section 317 Operations Program is a federal grant under Catalog Federal Domestic Assistance 93.268 Immunization Grants. The $3.2 million funded to DHSS by the 317 grant does not include any other federal funds received to support the vaccines reimbursed to DHSS by the Section 317 funds nor any of the funding for the Vaccines for Children program.

immunization activities. DHSS officials informally estimated activities related to school children immunization would compromise about 10 percent of the grant funds received.

### Federal reporting requirement

Each grantee of the Section 317 federal grant is required to submit immunization population assessment data to the CDC annually. The purpose of the annual report is to estimate program-wide immunization coverage and exemption rates for kindergartners and middle school children. DHSS performs validation assessments of selected schools for kindergarten and seventh grade students to ensure the accuracy of immunization data reported by schools to DHSS. For the 2006-07 school year, DHSS performed validation assessments of 2,655 kindergarten students in 71 schools and 2,491 seventh grade students in 67 schools by reviewing the immunization records maintained by the school. The data from the validation assessments are then used to monitor progress towards the CDC's 2010 Healthy People Goals. These goals include (1) 95 percent of the students in kindergarten be vaccinated against diphtheria/tetanus/acellular/pertussis, measles/mumps/rubella, polio, hepatitis B, and varicella; and (2) 90 percent of the adolescents aged 13 to 15 years be vaccinated against hepatitis B, measles/mumps/rubella, tetanus/diphtheria booster, and varicella. However, we are not confident Missouri is meeting the Healthy People goals because schools do not submit complete and accurate reports and DHSS' validation assessment procedures are inadequate. The CDC also requests each grantee to submit information about the grantee's immunization law and policies for school children.

## Scope and Methodology

To evaluate whether state policies and procedures ensure school children are properly immunized, we interviewed officials and staff at DHSS, DSS, DESE, and the CDC. We also reviewed available policies, procedures, state law, regulations and other applicable information.

To evaluate whether controls to ensure the state's Advisory Committee on Childhood Immunization appointment processes and procedures are adequate to meet state requirements, we requested and reviewed the listing of appointed members, their terms, and their respective credentials.

To evaluate the immunization policies and procedures established by schools, we selected 55 schools from DHSS' list of schools as of January 15, 2008. Of the 55 schools, 25 were selected because school summary reports had not been submitted as of January 15, 2008. We were able to contact 45 school officials and obtained the schools' immunization policies and procedures. We compared the schools' policies and procedures to those established by state law, regulations, or DHSS procedures to ensure

compliance. For 12 of the 45 schools contacted, we specifically inquired whether the schools allowed noncompliant students to attend school.

To determine schools that did not submit required reports, we obtained DHSS' listing of schools for the 2006-07 and 2007-08 school years that had not submitted required reports as of November 13, 2006 and January 15, 2008, respectively.

To determine whether DHSS' listing of schools operating in Missouri was complete, we performed Internet searches and obtained listings of public and private schools from DESE. We compared our results to the January 15, 2008, report obtained from DHSS listing the schools for the 2007-08 school year. We provided the results to a DHSS official for review and analysis in March 2008.

We judgmentally selected 25 schools from each of the 2006-07 and 2007-08 school years from DHSS' list of schools that did not submit the Summary Report for those years. We obtained documentation from DHSS and evaluated whether adequate follow-up was performed by DHSS and whether adequate documentation had been maintained to support the follow-up for 49 schools, as we subsequently determined one of the schools was closed.

We obtained the school summary reports received by DHSS for the 2007-08 school year to identify the total noncompliant kindergartners. We reviewed 118 school summary reports and obtained the respective student exception reports from DHSS. We evaluated whether complete and accurate student exception reports had been submitted, and if not, whether adequate follow-up was performed by DHSS.

To determine whether adequate documentation had been maintained to support school validation assessments, we obtained a list of the validation assessments performed in the 2006-07 school year and judgmentally selected and reviewed 25 validation assessments.

To evaluate Missouri's state law, regulations and procedures, we reviewed state law and regulations and compared them to the law and regulations in 8 surrounding states (Arkansas, Illinois, Iowa, Kansas, Kentucky, Nebraska, Oklahoma, and Tennessee). We contacted health and/or education officials in each of these states to determine certain immunization processes and procedures.

# Ineffective Procedures to Ensure School Children are Immunized

DHSS needs to do more to ensure students are properly immunized and that all schools report immunization information to DHSS. Further improvements are needed to (1) protect non-immunized students from exposure during an outbreak, (2) comply with federal recommendations regarding specific immunizations and dosages, (3) better validate the state's immunization rate reported to the federal government, (4) increase the functionality and reliability of the school children immunization database, and (5) ensure compliance with legal provisions concerning appointments to the Advisory Committee on Childhood Immunization.

## Procedures to Ensure Students are Properly Immunized are Ineffective

DHSS has not performed adequate oversight to ensure (1) schools submit complete and accurate school summary reports, (2) schools submit complete and accurate student exception reports when applicable, (3) noncompliant students do not attend school, and (4) noncompliant schools are formally notified of legal requirements. Additionally, state law has not established any penalties for schools that do not comply with state law or regulations.

DHSS officials said staffing limitations, prioritizing staff for other responsibilities, and limited funding have prevented DHSS from obtaining required reports and performing adequate reviews of the reports. Another DHSS official said state law does not require DHSS to perform any procedures to ensure reports are obtained for each public and private school nor to ensure completeness or accuracy of the information submitted.

### Some schools did not submit school summary reports or submitted inaccurate reports

At least 169 schools did not submit the 2006-07 school summary report to DHSS as of November 13, 2006. For the 2007-08 school year, 172 of the 1,234 (13.9 percent) schools had not submitted school summary reports as of January 15, 2008, three months after the report due date. In addition, of 118 school summary reports tested for kindergartners during the 2007-08 school year, 16 (13.6 percent) were inaccurate.

DHSS officials said there are no written policies for (1) when and how often a school is to be contacted to obtain delinquent school summary reports, and (2) the documentation required to support the follow-up performed with the school and the record retention period for such documentation.

We tested 49 schools that had not submitted school summary reports by the October 15th deadline for the 2006-07 and 2007-08 school years to determine whether DHSS adequately performed follow-up procedures to obtain the delinquent school summary reports. Table 2.1 shows the results of our testwork.

**Table 2.1: Analysis of Reviews Performed by DHSS to Obtain Delinquent School Summary Reports**

| Number of schools | No | Yes | Total |
|---|---|---|---|
| Adequate documentation to support DHSS contacted the school to obtain delinquent report as of March 3, 2008 | 39 | 10 | 49 |
| Delinquent report subsequently submitted by school as of April 25, 2008 | 30 | 19 | 49 |

Source: SAO analysis based on information obtained from DHSS.

### School summary reports not compared to student enrollment

According to DHSS officials, procedures have not been established to compare the enrollment reported per the school summary reports to the enrollment reported by DESE for public schools to ensure immunization statuses are reported for all enrolled students. For example, we identified one school whose enrollment totals for kindergartners and 7th graders per the 2007-08 school summary reports were 2,102 and 1,810 while the enrollment data according to DESE's website were 2,564 and 2,549 students, a difference of 462 and 739 students, respectively.

### Additional Internet searches needed to identify schools not reporting

DHSS staff reviews certain websites, such as DESE's, to search for schools that do not report student immunization information. As of January 2008, DHSS had identified 639 private schools; however, our Internet searches identified at least 9 (1.4 percent) additional private schools for the 2007-08 school year that were not on the list and had not submitted required immunization reports. We provided the results to a DHSS official for follow-up with the schools. DHSS officials stated these schools were not previously identified because there is no comprehensive listing of private schools in Missouri and state law does not require DHSS to perform any searches.

## DHSS did not ensure schools submitted accurate student exception reports

Reviews to ensure complete and accurate student exception reports are obtained from the schools were not initiated timely in the 2007-08 school year and were not completed in the 2006-07 school year. At the time of our review on February 19, 2008, 106 of 118 schools tested submitted 2007-08 school summary reports indicating they had kindergartners who were not in compliance with immunization requirements. To determine whether DHSS performed adequate procedures to obtain the corresponding student exception reports, we (1) determined whether the student exception report had been submitted to DHSS, (2) determined whether DHSS contacted schools to obtain delinquent student exception reports, and (3) compared the total noncompliant kindergartners reported per the student exception reports to those reported per the school summary reports to ensure all kindergartners were accounted for properly. Table 2.2 shows schools did not submit reports timely and DHSS did not perform adequate or timely procedures to obtain the student exception reports.

**Table 2.2: Analysis of Reviews Performed by DHSS to Obtain Delinquent Student Exception Reports**

| Number of schools | No | Yes | Total |
|---|---|---|---|
| Did the school submit student exception report(s) by February 18, 2008 | 67 | 39 | 106 |
| Did DHSS contact the school between February 19 and March 28, 2008 | 18 | 49 | 67 |

Source: SAO analysis based on information obtained from DHSS.

As of May 6, 2008, 100 of the 106 schools had submitted a student exception report; however, 24 of the schools had submitted exception reports that were not complete and/or accurate. A DHSS official said there is no formal tracking performed to identify the schools that did not submit the required student exception report(s) to DHSS nor any documented policies for reviews.

## Some schools allowed noncompliant students to attend school

Of the 12 schools contacted, we identified two schools that allowed noncompliant students to attend school. In addition, a DHSS official told us of two other schools that allowed noncompliant students to attend school. DHSS procedures require schools to submit a follow-up status update for the noncompliant students within 30 days of the original student exception report. However, some schools simply note the updated status for noncompliant students as "no change." A DHSS official said DHSS attempts to follow-up with these schools as staff time permits.

Currently, DHSS regulations do not require schools to report (1) regular status updates for noncompliant students, (2) whether noncompliant students continue attending school, (3) reasons why a student remains noncompliant, and (4) procedures performed by the school to bring students into compliance.

### Additional guidance needed for students in the process of being immunized

State regulations do not specify the amount of time a student can remain in school before the student becomes compliant with immunization requirements, or the responsibility of schools to ensure these students are progressing towards compliance. Arkansas, Iowa, Kentucky, and Nebraska have state laws or regulations specifying the maximum periods for the in progress or provisional enrollment to be valid. Arkansas regulations specifically state it is the responsibility of the school to assure the student completes the required doses on schedule.

A DHSS official said the intent of the regulations is that the schools should be obtaining satisfactory evidence to support the immunization was administered and adequate tracking should be in place by the schools to ensure students in the process of meeting requirements comply with the next scheduled appointment.

## Penalties for noncompliant schools needed

State law[9] does not contain provisions to penalize schools that (1) do not submit the required immunization reports to DHSS, (2) allow non-immunized students to attend school and (3) do not enforce the compulsory attendance state law.[10] Additionally, state regulations do not require DHSS to formally notify schools not in compliance with these state laws.

DHSS officials said DHSS attempts to notify noncompliant schools of the requirements and/or gain an understanding of school procedures; however, this follow-up is not consistently performed. DHSS officials also said DHSS does not have the authority to require schools to comply with state law nor are there any penalties in the law for noncompliant schools. The Illinois administrative code allows a reduction in a school's state aid payments if school officials do not submit required immunization reports.

# Best Practices Would Better Protect Non-immunized Students During an Outbreak

State regulations do not require schools to maintain a list of exempt students. Additionally, state regulations do not allow schools to exclude exempt students from school during outbreaks of vaccine preventable diseases. Further, of 45 schools contacted, 37 had immunization policies but only 7 had policies specifying the exclusion of exempt students in the event of an outbreak.

Arkansas regulations require a list of all exempt students to be maintained by the school and these students to be excluded from the school if the Health Department determines that an outbreak of the related disease exists in the local community. Arkansas state law indicates the tracking of students with exemptions is performed to ensure appropriate steps are taken in the event of an outbreak or epidemic. An Oklahoma official said state regulations require exemptions to be approved by the Oklahoma Department of Health to ensure exempt students are identified in the event of an outbreak. Iowa state regulation requires religious exemptions to be null and void during times of emergency.

DHSS officials stated the communicable disease state law and regulation[11] provide DHSS with the authority to exclude non-immunized students during an outbreak. The religious and medical exemption form completed by the parent, guardian or physician also states non-immunized students are subject to exclusion from school when outbreaks of vaccine preventable diseases occur. However, a current listing of exempt students is needed to ensure

[9] Section 167.181, RSMo
[10] Section 167.031, RSMo
[11] Section 192.020, RSMo and 19 CSR 20-20.040

school and health personnel are able to take quick action to protect these students in the event of an outbreak.

## DHSS Not Requiring Compliance with Federal ACIP Recommendations

State law requires immunizations and their manner and frequency to comply with recognized standards of the medical practice. However, state regulations[12] do not require the meningococcal[13] vaccine or the human papillomavirus (HPV) vaccine and DHSS' immunization notifications sent to schools do not include requirements for school children to be vaccinated with the second dose of varicella, as recommended by the ACIP. In addition, DHSS' recommended administration of the tetanus, diphtheria, and pertussis (Tdap) booster for adolescents did not comply with ACIP recommendations. State regulations also do not require parents or guardians to be notified of any deviations from ACIP recommendations. CDC guidance allows grantees 2 years to adjust assessment practices to reflect changes in ACIP recommendations. A DHSS official said the ACIP recommended the meningococcal and Tdap booster in 2005, and the HPV and second dose of varicella in 2006.

A DHSS official said the state's Advisory Committee on Childhood Immunization recommended the Tdap and second dose of varicella be required per regulations. However, this official said legislation introduced in the 2008 session delayed changes to the regulations. Also, another DHSS official stated the HPV and meningococcal immunizations were not added to DHSS' regulations because there was not adequate funding to support the cost of the vaccine for uninsured students.

In February 2008, the ACIP recommended school children be vaccinated annually with the influenza vaccine. DHSS officials should consider this vaccine when revising state regulations.

According to the CDC website,[14] immunizing children protects the health of children and the emotional and financial well being of their families and communities as well as protects the health of children who cannot be vaccinated due to medical reasons, such as a weakened immune system due to chemotherapy. A child who is not immunized against vaccine preventable

[12] 19 CSR 20-28

[13] According to the CDC website, meningococcal conjugate vaccine helps prevent against bacterial meningitis; HPV helps prevent against sexually transmitted diseases, including cervical cancer and genital warts; Tdap helps prevents against lockjaw, diphtheria, and whooping cough; varicella helps prevent chicken pox.

[14] "ABCs of Childhood Vaccines," *Center for Disease Control and Prevention*, <http://www.cdc.gov/vaccines/vac-gen/ABCs/downloads/2-ABCs-Risks.ppt#2>, accessed April 22, 2008.

diseases is at risk of a serious illness or even death. According to a DHSS official, in 2007 there were 79 confirmed or probable cases of pertussis, 10 confirmed or probable cases of meningococcal, and 895 confirmed or probable cases of varicella for children 18 years of age and younger in Missouri.

## Procedures to Report and Validate Immunization Rates Need Improvement

DHSS is required to submit immunization rates to the CDC annually. The source of the information reported is obtained from the results of DHSS' validation assessments of selected schools for kindergarten and seventh grade students. DHSS did not ensure validation assessments included an adequate representation of private schools, and did not ensure that the work of staff was properly performed, documented and retained.

### Sampling methods and procedures may not comply with CDC recommendations

DHSS does not select the schools or students to be assessed using a random sampling method. However, DHSS inaccurately reported it uses a random selection to the CDC. DHSS excludes public schools with an enrollment size of less than 25 students. Private schools are also excluded except in special circumstances. The method of selection for students is based on class enrollment size and students in smaller classes have a greater chance of being selected. A CDC official said the CDC recommends a random sample as it provides each school or student an equal probability of being selected. By excluding certain schools and students based on enrollment size, each school or student is not provided an equal probability of being selected.

According to CDC guidance and a CDC official, the CDC provides services to states that request the CDC's assistance in selecting a random sample. Kansas and Kentucky officials said the CDC assists their states in establishing samples. A DHSS official said DHSS was aware the CDC provided services to states; however, DHSS believed CDC's assistance was unnecessary because current procedures were adequate. A DHSS official said DHSS will use the CDC's assistance during the 2008-09 school year validation assessment cycle.

### School validation assessments not adequately documented

DHSS did not ensure the work of staff conducting validation assessments or evidence of supervisory review was properly documented. DHSS was not able to provide documentation identifying the names of each student reviewed, the student's date of birth, or vaccination dates for the 25 validation assessments we reviewed. In addition, a DHSS official said staff are not required to submit this data for supervisory review.

Best practices require the work of staff to be properly documented and reviewed. A DHSS official said the CDC nor state law requires validation documentation to be maintained; however, the official said if new

requirements are issued by the CDC then DHSS will adjust their procedures to meet CDC's requirements.

## School Children Immunization Database Requires Improvement

DHSS uses a database to document (1) the schools required to submit school summary and student exception reports, (2) the schools that submitted school summary reports, and (3) the immunization rates by grade and vaccine from the school summary reports. A DHSS official said the database is old and does not completely support the business needs of the department.

DHSS officials said there is no funding available to support a new database nor is there any information technology support for this database. These officials said there are options to accommodate some of the business needs. The Section for Healthy Families and Youth uses a web application to obtain data from schools and it is possible the immunization rates for school children could be calculated by this application as well. The immunization registry may also be an option if the registry is modified. During our review, we found improvements are needed in the following areas:

- Application accessibility
- Edit checks
- Tracking of noncompliant students
- Reporting
- Record retention

### Database is not accessible

The immunization database is not accessible to public or private schools. As a result, DHSS manually enters immunization information from school summary reports for over 1,200 schools. A DHSS official said a web application would better support the needs of the department and reduce time required of DHSS staff for data entry. Illinois and Oklahoma officials indicated schools are able to submit immunization results using an online application. A Kentucky official said an online database is being established for schools to submit immunization data.

## Immunization database lacks key edit checks

The immunization database lacks key edit checks[15] to effectively identify inaccurate, incomplete, or invalid information, as recommended by accepted standards. According to accepted standards,[16] data entered for processing by users should be subject to a variety of controls to check for accuracy, completeness and validity. A DHSS official agreed the immunization database does not have edit checks to identify:

- Inaccurate student totals
- Inaccurate exemption totals
- Omitted data in key fields

Without edit checks in place to enforce the controls necessary to meet business requirements, management is unable to accurately confirm the data entered has been checked for accuracy, completeness, or validity, as required by accepted standards.

## Tracking of noncompliant students needed

The immunization database does not contain fields to identify the number of noncompliant students by grade or vaccine, or the names of the noncompliant students. A DHSS official said the immunization database does not have the capability to maintain this information.

During the 2005-06 school year, DHSS maintained a separate database to track the number of noncompliant students by grade. However, the database did not identify the number of noncompliant students by vaccine or the names of the noncompliant students. No formal tracking was performed of the noncompliant students for the 2006-07 and 2007-08 school years. A DHSS official said the number of noncompliant students was not recorded in a separate database beginning with the 2006-07 school year because the noncompliant information reported to the CDC was based on the validation assessments rather than the results from the schools.

To determine the estimated number of noncompliant students each year, DHSS has to perform manual calculations based on the results from the immunization database. The accuracy of these calculations is questionable due to the accuracy concerns of the database.

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[15] An edit, also known as a data validity check, is program code that tests the input for correct and reasonable conditions, such as account numbers falling within a range, numeric data being all digits, dates having a valid month, day, and year, etc.

[16] We based our evaluation on accepted standards and best practices from IT Governance Institute. COBIT 4.0: *Control Objectives, Management Guidelines, Maturity Models*. Rolling Meadows, IL: IT Governance Institute, 2005.

## Immunization database lacks reports

The immunization database lacks reporting capabilities. Currently, the immunization database only generates immunization status reports for the state, region and county by grade and vaccine or summary by vaccine. Examples of reports not generated include (1) comprehensive immunization status reports by school, county, region or zip code and (2) status reports for each school by grade and vaccine or summary by vaccine. As a result of the database not generating adequate immunization status reports, management is unable to compare immunization rates by school to determine populations with low immunization rates or identify schools with significant fluctuations.

## Immunization data not adequately retained

The immunization database is not capable of maintaining immunization data for more than one school year. DHSS officials said only the physical reports produced from the database can be maintained after the school year is complete as the electronic data produced from the database is not in a usable format. Without data being maintained from the prior years, DHSS is unable to perform efficient comparisons of the immunization rates from one year to the next at the appropriate levels, such as by school, to determine if there were any significant fluctuations.

DHSS does not maintain all physical reports produced from the immunization database. A DHSS official said the listing of schools required to submit an immunization report was not available for the 2006-07 school year data nor could the reports be reproduced since the data was purged from the immunization database. A listing of schools that did not submit the school summary reports was not maintained after November 2006.

# Improvements to the Appointment Process for the Advisory Committee on Childhood Immunization Needed

Two committee appointees did not possess necessary credentials required by state law. One of the appointees was not licensed in the required medical field and the other appointee was not serving in the particular position at DHSS as required by state law. At least one appointment is currently vacant. In addition, DHSS has not maintained key documents to support compliance with state law, including a comprehensive list of the appointed members, the appointment terms for each member, or the credentials of the appointed members. As a result, DHSS is unable to validate whether the committee members' terms has expired, or whether members possess the required credentials.

State law[17] established the Advisory Committee on Childhood Immunization comprised of 14 members from both DHSS and private

[17] Section 192.630, RSMo

practice who meet various conditions prescribed by state law. The members are appointed by the Director of DHSS.

## Conclusions

DHSS officials did not ensure complete and accurate immunization reports were obtained from schools. Additional procedures are needed to ensure students are immunized, and noncompliant schools are notified of legal requirements. In addition, state law does not contain penalty provisions for schools that fail to comply with state laws relating to immunization.

State regulations do not require schools to maintain a list of exempt students, or allow schools to exclude exempt students from school in the event of an outbreak.

DHSS does not require students to be immunized against all federally recommended vaccine preventable diseases or with the recommended dosages.

DHSS procedures to validate the immunization rate reported to CDC do not comply with CDC recommendations. Additionally, validation assessments and evidence of review are not properly documented.

The immunization database lacks functionality and does not adequately ensure the integrity and reliability of the immunization data.

DHSS has not complied with legal provisions related to appointments to the Advisory Committee on Childhood Immunization, and key appointment documents have not been maintained.

## Recommendations

We recommend the Director of the Department of Health and Senior Services:

2.1 Improve procedures to ensure schools report complete and accurate immunization reports.

2.2 Establish regulations, in consultation with DESE, to require schools to report the status of noncompliant students, whether those students continue attending school, reasons why a student remains noncompliant, and actions taken by the school to ensure students become compliant.

2.3 Establish regulations, in consultation with DESE, to specify the amount of time a student can remain in school before a student becomes compliant with immunization requirements and to clarify

that schools are responsible for ensuring students progress towards compliance.

2.4 Pursue legislation to establish penalty provisions for schools that do not comply with state law or regulations relating to immunization.

2.5 Formally notify noncompliant schools of state laws and regulations regarding immunization requirements.

2.6 Establish regulations, in consultation with DESE, to require schools to maintain a list of exempt students, to clarify that schools may exclude exempt students from attending school in the event of an outbreak, and to implement procedures to validate the schools maintain this list during the validation assessments.

2.7 Revise state regulations, in consultation with DESE, to comply with ACIP recommended immunizations, and/or notify parents or guardians of any deviations from federal recommendations.

2.8 Ensure procedures to validate immunization information comply with CDC requirements, and ensure validation assessments and supervisory review are adequately documented.

2.9 Improve the functionality and reliability of information contained in the school children immunization database.

2.10 Comply with legal provisions and maintain documentation regarding appointments to the Advisory Committee on Childhood Immunization.

## Agency Comments

*2.1 DHSS concurs with this recommendation. Section 167.181.4, RSMo, charges each school superintendent to prepare ". . . a record showing the immunization status of every child enrolled in or attending a school under his jurisdiction." DHSS will work with the DESE to establish policies and procedures to ensure school reports are complete and will validate the accuracy of these records as defined by CDC. Instructions included with the immunization status reports sent to schools will be revised to emphasize the importance of accurately completing the reports. DHSS will collaborate with DESE to develop procedures to document and follow-up with non-compliant schools.*

*2.2 DHSS concurs with this recommendation. Section 167.181.4, RSMo, requires schools to report the immunization status of non-exempted*

*children to DHSS. In June 2008, the DHSS Bureau of Immunization Assessment and Assurance (BIAA) enhanced the reporting mechanism for schools that report noncompliant students in order to provide guidance for appropriate follow-up and documentation. DHSS will collaborate with DESE to explore establishing regulations, policies, and procedures for follow-up with schools that continue to have noncompliant students.*

*2.3 DHSS concurs with this recommendation. DHSS will confer with DESE on establishing regulations to specify the amount of time a student may remain in school before a student becomes compliant with immunization requirements. DHSS will also confer with DESE regarding the responsibility of schools to ensure students progress towards compliance. Pending the outcome of those discussions, regulations, policies, and procedures will be established as appropriate to clarify the school's responsibility with regard to noncompliant students.*

*2.4 DHSS does not concur with this recommendation. While the department strongly supports efforts to ensure school children are immunized, DHSS feels it is inappropriate for the department to pursue legislation that could negatively impact state funding for public schools. Public school funding falls under the purview of DESE, so if penalties as recommended by the State Auditor are to be pursued, DHSS believes DESE is the appropriate department to lead such efforts.*

**SAO Comment:**

Any penalties established should only impact schools that are notified of noncompliance and still choose not to comply with state immunization laws and regulations.

*2.5 Implemented – DHSS complies with this recommendation by annually mailing an information packet to all Missouri public, private, and parochial schools. The packets contain a copy of state regulation 19 CSR 20-28.010 (immunization requirements for school children).*

**SAO Comment:**

Our recommendation is specifically directed towards DHSS formally notifying those schools not in compliance with state immunization laws and regulations. An annual mailing of information packets to all schools does not accomplish the objective of our recommendation.

2.6 *DHSS concurs with this recommendation. The requirement for schools to maintain all exemptions for school children on file is found in 19 CSR 20-28.010. BIAA will collaborate with the DHSS Bureau of Communicable Disease Control and Prevention, along with DESE, to review regulations and procedures regarding exclusion of non-immunized students in the event of an outbreak and establish procedures for educating schools during validation assessments.*

2.7 *DHSS concurs with this recommendation. The purpose of state regulation 19 CSR 20-28.010 is to establish the minimum immunization requirements for school children. A revised version of this regulation has been forwarded to the Missouri Secretary of State's Office for publication in the Missouri Register as a proposed rule. The revision will add more ACIP-recommended immunizations, including a second varicella dose and Tdap booster.*

*It is important to understand that while DHSS **recommends** all ACIP-approved immunizations, it does not **require** all such immunizations for school attendance. The reasons for this differ by vaccine, but include not requiring immunizations for diseases that should not be transmitted in a school setting and/or are very expensive. For example, human papillomavirus is transmitted through sexual contact, which should not be occurring at schools—and is over $100 per dose. The only funding available to DHSS to provide immunizations for children is through the federally funded Vaccines For Children program. Because the amount available is insufficient to cover all under-insured children for all ACIP recommended vaccines, DHSS must determine how best to use limited resources. DHSS also does not require vaccines for school attendance that are only recommended for children younger than those entering school. For example, rotavirus vaccine is recommended by ACIP—but only for infants. Protection from rotavirus is no longer necessary by the time children are old enough to enter kindergarten. Once the current proposed rule is adopted, all ACIP-recommended immunizations applicable to children at the age of entry into kindergarten will be required by DHSS.*

2.8 *DHSS concurs with this recommendation. DHSS has collaborated with CDC to establish validation procedures and assistance in selecting a random sample of schools for validation assessments for the 2008-09 school year. BIAA is establishing policies and procedures to ensure validation assessments and supervisory review are adequately documented.*

2.9 *DHSS concurs with this recommendation. Funding has been secured to develop a web-based immunization registry. This web-based application will significantly improve the functionality and reliability of this database.*

2.10 *DHSS concurs with this recommendation. All future appointees to the Advisory Committee on Childhood Immunization (ACCI) will be required to complete an extensive application before being considered. A current resume will have to be submitted with the application. Checks will be completed to ensure all credentials claimed by applicants are current and correct. Letters sent to persons selected to serve on the ACCI will include the following information to ensure accuracy and compliance with state law:*

- *Full, legal name of the appointee;*
- *Address of the appointee;*
- *Term of the appointee; and*
- *Full name of the ACCI member being replaced.*

*DHSS will maintain a comprehensive list of ACCI appointees including the beginning and end dates for each appointee's term on the ACCI and the particular slot to which each person is appointed.*

# Management of Immunization Information Needed

DHSS has not required schools to comply with regulations requiring a physician's or health care administrator's statement verifying the vaccine was administered. In addition, DHSS has not established regulations for the retention of immunization records, DHSS' immunization registry is not effective, DHSS has not performed analyses to identify populations at risk for vaccine preventable diseases, and DHSS has not reported immunization information to most stakeholders.

## Immunization Records are Not Adequate

Immunization records to support a vaccine was administered to a student are inadequate because (1) DHSS allows schools to accept either a verbal confirmation from the physician or immunization records that do not have a physician's signature, and (2) DHSS has not established a regulation identifying the record retention requirement for schools' immunization records. Additionally, DHSS has created an immunization registry to maintain immunization information; however, this information is not complete or accurate.

### Standard immunization record that is signed by the provider is not required

Although DHSS regulations require a statement from a physician or health care administrator stating the vaccine had been administered, DHSS allows schools to accept either a verbal confirmation from the physician or immunization records that do not contain the physician's statement. In addition, DHSS has distributed example forms that do not provide for a physician's signature. A CDC official said the CDC recommends an immunization record signed by the person administering the vaccine and a CDC recommended vaccine form includes the signature or initials of the vaccinator.

According to a 2004 CDC survey, 31 (54.4 percent) of the 57 states/entities reporting require a standard certificate or document be presented to the school/facility to document the vaccination status. According to a school year 2005-06 CDC survey, 31 (63 percent) of the 49 states/entities reporting require the provider's signature on the immunization record.

### No record retention period for immunization records specified

State law[18] and DHSS regulations do not specify the record retention period for the immunization records of school children. Of 45 schools contacted, 37 had immunization policies, but for 31 schools the policies did not specifically identify the record retention period for immunization records. The Secretary of State has established a record retention period for immunization records for public schools; however, the retention period for private schools is not documented. A Secretary of State staff said public schools are required to maintain immunization records and religious

[18] Section 167.181, RSMo

exemptions permanently, medical exemptions until graduation or leaving the district, and immunizations in progress until the next dose is due. A DHSS official said DHSS' informal guidance is for schools to maintain student immunization records until the student is 21 years of age or three years after graduation, which does not agree to the Secretary of State's requirements.

Arkansas regulations require a copy of the immunization record be maintained in the student's permanent file. Oklahoma regulations require schools to maintain immunization records on each student. Iowa requires schools to maintain the immunization record for three years, commencing upon transfer or graduation from the school, unless the record is provided to the student upon graduation or requested by the parent. Kentucky requires an immunization record be maintained for a child enrolled in a public or private school and available for inspection by the Cabinet for Health Services.

## DHSS' immunization registry is outdated and ineffective

DHSS allows schools to use the immunization records obtained from DHSS' immunization registry[19] to support student immunization requirements; however, DHSS officials said the records contained in the registry are not complete or accurate. As of February 2008, only 55,270 (29 percent) of the 190,372 total children in the immunization registry with birthdays between June 2002 and June 2004 had complete immunization records, according to DHSS records. DHSS officials said the records in the immunization registry are not complete and accurate because (1) state law does not require the physician or other recognized health facility or personnel to update the registry when a vaccine is administered, (2) the current immunization registry is not accessible through a web application nor are records able to be electronically uploaded by users or shared with other systems, which makes it more time consuming for providers and schools to update or view immunization records and (3) duplicate or inaccurate records are entered into the immunization registry by providers.

Federal goals of the immunization registry include being able to maintain information relating to a particular individual in a single accurate immunization record.

[19] Immunization registries are recommended by the CDC to increase and sustain high vaccination coverage by consolidating vaccination records of children from multiple providers, generating reminder and recall vaccination notices for each child, and providing official immunization records and vaccination coverage assessments.

According to CDC websites,[20] the immunization registry will help ensure a child is not over-immunized or under-immunized, ensure a child has received the required vaccines for school entry, and identify populations at high risk for vaccine preventable diseases. Without complete and accurate records in the registry, there is a greater risk children are being under or over-immunized and the ability to identify populations at high risk for vaccine preventable diseases are reduced. An improved registry with appropriate controls would potentially lessen the record keeping burden of the immunization records for school attendance.

A DHSS official said the current immunization registry had been created over 12 years ago and DHSS officials said this registry does not completely support the business needs of the department and/or meet all minimum federal recommendations. DHSS has taken steps to identify solutions or alternatives to meet the business needs. For example, DHSS hired a consultant to perform a system analysis and needs assessment. Based on the analysis completed as of May 2008, a DHSS official said the costs required to modify the current immunization registry is estimated to be approximately $1.5 million over an 18 to 24 month period. DHSS official(s) said the CDC does provide some grant funding to support the immunization registry and certain departmental funds are available to dedicate to modifying the existing registry. Previously, the state legislature approved funds totaling $500,000 towards a new immunization registry in fiscal years 2007 and 2008. A DHSS official said less than $100,000 of the funds were utilized in fiscal year 2008 to pay the cost of the consultant and the state legislature approved the use of the remaining $400,000 towards the registry in fiscal year 2009. However this official said available funding is not sufficient to completely develop and implement the modified registry.

## Reviews to Identify Populations with Low Immunization Rates are Not Performed

DHSS has not established policies and procedures to identify populations with low immunization rates or significant immunization rate fluctuations for school children. A DHSS official said DHSS has not established any manual procedures to identify populations by school or county with low immunization rates or with significant fluctuations from one year to the next. A DHSS official said DHSS has not been instructed to perform these reviews nor does DHSS have the funding or resources to perform these reviews. Additionally, the immunization database does not generate

[20] "IIS: Frequently Asked Questions" *Centers for Disease Control and Prevention*, <http://cdc.gov/vaccines/programs/iis/faq.htm>, accessed January 22, 2008.
"Vaccine Records: Finding, Interpreting and Recording," *Centers for Disease Control and Prevention*, <http://www.cdc.gov/vaccines/recs/immuniz-records.htm>, accessed May 21, 2008.

comprehensive immunization reports by county or school to identify populations with low immunization rates or significant fluctuations. Implementation of a complete immunization registry could also assist DHSS in performing fluctuation reviews.

### Retrospective analysis recommended federally

DHSS does not perform any retrospective analysis to determine the immunization history of school children when they were younger to assist in explaining the current immunization rates. CDC officials stated the retrospective analysis is recommended by the CDC to perform population assessments. A CDC official also said the retrospective analysis could help identify populations with under-immunized children or determine why outbreaks occurred. Kansas and Illinois perform retrospective analysis to evaluate the immunization coverage rates of kindergartners when they were two years old. The Advisory Committee on Childhood Immunization is responsible for developing plans for increasing the rate of childhood immunization in Missouri. The retrospective analysis would be a tool to assist the committee in its planning. A DHSS official said lack of funding has prevented DHSS from performing the analysis and another official said the analysis has not been a high priority since the analysis is time consuming and is primarily focused on past data.

## Reports Not Provided to Stakeholders

DHSS currently provides immunization reports to county health officials. Other stakeholders, such as parents of school children, public officials, DESE, or schools are not provided information regarding immunization rates. Pursuant to state law, the Advisory Committee on Childhood Immunization is responsible for determining, in conjunction with DHSS, how the data collected on immunizations shall be analyzed and communicated to parents, health care providers, and public officials.

We identified other states that provide regular reports to stakeholders as follows:

- According to a 2004 CDC survey, 18 (43.9 percent) of the 41 states/entities responding reported immunization data to the state's Department of Education and 23 (56.1 percent) reported immunization data to individual schools.
- Arkansas regulations require the geographical patterns of exemptions and vaccination rates be reported to public officials every six months.
- Illinois has an online immunization status report available for the public to view to determine the immunization rates by the state, school, or vaccine and Iowa has an online status report by county.

A DHSS official said DHSS would consider making immunization reports available to the public; however, limited reports are currently available due to the immunization database lacking reporting capabilities.

## Conclusions

DHSS allows schools to accept either a verbal confirmation from the physician or immunization records that do not have a physician's or health professional's signature. DHSS has not established a regulation specifying the record retention period for immunization records; however, the Secretary of State's Office has a record retention policy for public schools related to immunization records. State law does not require providers to record immunization records in the immunization registry nor does the registry contain complete and accurate records. DHSS has not established procedures to identify populations at high risk for vaccine preventable diseases. DHSS does not provide immunization reports to stakeholders, such as parents, DESE, schools, or public officials.

## Recommendations

We recommend the Director of the Department of Health and Senior Services:

3.1 Establish by regulation a standard immunization record which requires the signature or initials of the physician or health professional who administered the vaccine.

3.2 Establish a record retention period for student immunization records to be maintained by schools and work with the Secretary of State's Office to revise their record retention schedule if necessary.

3.3 Improve the effectiveness and completeness of the immunization registry and pursue legislation to require health professionals to record immunizations in the registry.

3.4 Perform fluctuation and retrospective analyses to identify populations at risk for vaccine preventable diseases.

3.5 Periodically report immunization information to the general public.

## Agency Comments

*3.1 DHSS does not concur with this recommendation. The federal standard of care does not require a signature on an immunization record by a physician or health professional that administered a vaccine. Also, no federal or state law, rule or regulation requires a physician's signature on a statement, certificate, or record of immunization. CDC requires each state to have an immunization registry. The Missouri immunization registry allows immunization*

*data to be entered by physicians, local public health agencies, clinics, etc. This reduces the administrative burden on DHSS staff for record entry and, most important, makes the information available to schools more rapidly. DHSS relies on school nurses to verify the legitimacy of immunization documentation in the event that questions arise. DHSS is not aware of any evidence suggesting the department's reliance on school nurses is unfounded. If the State Auditor's Office is concerned that persons may be fraudulently entering initials on immunization cards, the department respectfully notes that anyone willing to take such action could also forge a signature. Thus, the involvement of school nurses would still be required for validation efforts. So while it does not appear that requiring a signature would result in beneficial effects, it could create a significant burden on schools, health professionals and parents in obtaining the necessary documentation for children to attend school.*

**SAO Comment:**

The control weakness of allowing immunization records to be accepted without the signature of the physician or health professional who administered the vaccine results in less assurance students were properly immunized. Requiring the provider's signature will also assist school nurses when validating immunization records. A reliable immunization registry will require appropriate access and security measures be taken to ensure immunization information was obtained from the physician or health professional who administered the vaccine.

*3.2 DHSS concurs with this recommendation. DHSS will collaborate with DESE and the Secretary of State to establish school procedures for student immunization record retention. Workgroups have already been established to discuss these procedures.*

*3.3 DHSS concurs with this recommendation. Funding has been secured to initiate construction of a web-based immunization registry. The initiatives to be included in the DHSS legislative package for the upcoming session will be determined after consultation with the next administration.*

*3.4 DHSS concurs with this recommendation. The new immunization registry will include functionality to perform fluctuation and retrospective analyses to identify populations at risk for vaccine preventable diseases.*

3.5 *DHSS concurs with this recommendation. DHSS annually mails a packet of information to all Missouri public, private, and parochial schools that lists the prior year's reported immunization rates of school children. DHSS updates and maintains an immunization website that includes several links to immunization information. This website will be updated to include additional information and links to immunization rates listed on the CDC's National Immunization Survey website. Also, the reporting capabilities of the new, web-based immunization registry should significantly enhance DHSS' ability to provide immunization information.*