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June 4, 2009

Richard F. Daines M.D.  
Commissioner  
NYS Department of Health  
Corning Tower  
Empire State Plaza  
Albany, NY 12237

Re: Report 2008-F-06

Dear Dr. Daines:

Pursuant to the State Comptroller's authority as set forth in Article V, Section 1 of the State Constitution; and Article II, Section 8 of the State Finance Law, we have followed up on the actions taken by officials of the New York State Department of Health (Department) to implement the recommendations contained in our audit report, *Immunization Program* (Report 2005-S-41).

**Background, Scope and Objectives**

New York State's Public Health Law requires children to be immunized against certain communicable diseases before they can attend any public or private school, nursery school, or day-care facility. At the time of our audit, these communicable diseases included diphtheria, haemophilus influenzae type b, hepatitis B, measles, mumps, poliomyelitis (polio), rubella and varicella (chicken pox). Since that time, tetanus, pertussis (whooping cough) and the pneumococcal (pneumonia) vaccines have been added as requirements. The Department is responsible for promoting and monitoring compliance with these immunization requirements. To fulfill these responsibilities, the Department established its Immunization Program (Program). The Program is administered by the Department's Bureau of Communicable Disease Control, the Department's four regional offices, and county health departments throughout the State.

Our initial audit report, which was issued on February 28, 2007, examined the Department's activities for promoting and monitoring compliance with the immunization requirements. Our objective was to determine whether the Department's Immunization Program provides reasonable assurance children are immunized against communicable diseases in accordance with the requirements contained in the Public Health Law. We concluded that, although the Program does provide reasonable assurance that children are immunized against communicable diseases in accordance with the Public Health Law, some of these requirements were not always being met.

The objective of our follow-up was to assess the extent of implementation, as of March 12, 2009, of the eight recommendations included in our initial report.

### **Summary Conclusions and Status of Audit Recommendations**

We found Department officials have made progress in implementing the recommendations contained in our prior report. However, additional improvements can still be made. Of the eight prior audit recommendations, four recommendations have been implemented, two recommendations have been partially implemented, and two recommendations have not been implemented.

### **Follow-up Observations**

#### **Recommendation 1**

*Enforce the statutory and regulatory requirements governing evidence of immunization, and revise audit practices to include verification of information contained in cumulative health records.*

Status - Implemented

#### **Recommendation 2**

*Revise Department guidelines to conform to the specific immunization documentation requirements set forth in Department Regulations.*

Status - Implemented

Agency Action for Recommendations 1 and 2 - The Department is now enforcing the regulatory requirements governing evidence of immunization, and it has revised Department guidelines to conform to documentation requirements as set forth in Department regulations. When conducting audits the Department now requires original records be reviewed in all circumstances, even when this requires school officials to retrieve these records from storage. To convey these requirements, Regional Office officials responsible for conducting audits were provided with the May 2007 and 2008 letters described below. In addition, as discussed under Recommendation 3, the Department has increased the number of audits completed each year.

During our original audit, we found some schools maintained only cumulative health records for each student, with original documents not available to support these records. Further, there was some confusion on the part of school officials regarding the documentation they were required to maintain. Department officials provided us with a letter they sent to school officials dated May 2007 that clearly explains the Department's expectations regarding the maintenance of original immunization documentation. According to these expectations, the Department requires original documentation to be retained and available, including at the time of audit. This same letter also appeared in the instruction booklet for the 2008 school immunization survey. Further, the development and

implementation of the Department's New York State Immunization Information System (NYSIIS) will aid in the maintenance of immunization records.

### **Recommendation 3**

*Increase the number of immunization audits performed each year, and use a formal and comprehensive risk analysis process to select schools and day-care facilities for audit.*

Status - Partially Implemented

Agency Action - In our prior audit, we concluded that the Department needed to increase the number of immunization audits performed each year. During our original audit, we found that approximately 140 audits were conducted in 2005. Listings provided to us by the Department of the schools audited during school years 2006-2007 and 2007-2008 showed a total of 183 and 162 audits conducted respectively, or more than the number that were conducted in the past. However, in a number of cases the same school appears on these lists multiple times with different grade levels listed. According to the Department, each time a school is listed it represents an audit of a different grade level within the school, since each grade level has different immunization requirements for school entrance and attendance. When we re-numbered the Department's audit lists to take out any duplicate audit visits, we found the Department conducted 166 audits during the 2006-2007 school year and 157 audits during the 2007-2008 school year, still greater than in the prior period. Department officials report they have encountered significant staffing shortages that have prevented them from further increasing the number of audits conducted.

We found the Department has not developed a formal and comprehensive risk analysis process to select schools and daycare facilities for audit. Department officials provided a 2008 memo issued to regional office officials responsible for conducting audits. The memo did not provide a formal and comprehensive analysis process that was required to be followed, but was rather a listing of certain factors that needed to be taken into consideration. More importantly, they were the same criteria that were in effect during our original audit, such as the inclusion of students from a variety of listed grade levels, and selection based on factors such as: random selection, geographical representation of the region, and/or a history or report of immunization problems in a particular school or school district. A comprehensive risk analysis should outline a series of steps to be completed when choosing schools for audit, not factors to consider, in order to ensure a documented, consistent approach.

### **Recommendation 4**

*Determine whether county health departments could perform, or assist in the performance of, immunization audits.*

Status - Implemented

Agency Action - In response to our prior audit, the Department indicated that “Requiring local health department staff to absorb this activity would not positively impact public health as it would detrimentally impact the other immunization activities they perform.” During our follow-up, Department officials stated that they had determined that given the lengthy list of activities they request county health departments to undertake, there is limited opportunity to add time consuming tasks like school immunization audits. Officials also cited additional activities that have been added on to county health department responsibilities since our audit, regarding monitoring vaccine storage and handling in private physicians' offices. However, officials remain open to re-considering this issue in the future.

### **Recommendation 5**

*Develop complete written procedures for immunization audits, give schools and day-care facilities no more than two weeks advance notice of the audits, and do not give advance notice of the grade levels that are scheduled for audit.*

Status - Partially Implemented

Agency Action - We found Department officials had issued an addition to their existing written audit procedures that specifically instruct reviewers to schedule an audit by sending a letter that includes the date and time of the upcoming audit which is no more than two weeks from the date of the letter. These guidelines also instruct reviewers to not give notice of the grade level to be reviewed or of the number of records to be reviewed. However, when the Department provided us with six letters as examples of those that had been sent to schools to schedule audits, we found they did not meet the Department's updated procedures, as they did not include the date of the upcoming audit. They instead stated that someone would be contacting the school within the next few weeks to schedule the audit. Further, when we obtained the reports from each of the six audits, we found that none of the audits were initiated within two weeks of the date of the letter, as required, as they were initiated between 23 to 92 days from the date of the letter.

### **Recommendation 6**

*Require that the goals in the county health departments' annual work plans be quantified.*

Status - Not Implemented

Agency Action - We found the Department still does not require that county health departments' annual work plans be quantified. While the Department instructs counties to report the type and quantity of education and outreach efforts in their quarterly reports, they are not specifically instructed to do so in their work plans. We reviewed the work plans and quarterly reports for Erie and Steuben Counties for contract year 2007-2008. We found that while Steuben County's work plan contained quantifiable goals, Erie's did not. While Erie County's quarterly reports documented the number of visits made or educational packets distributed for the quarter, the Department could not measure this information against a set goal, as one was not set within the work plan. In contrast, Steuben County set quantifiable goals, for example educating parents of newborns regarding immunizations and having new

clients fill out questionnaires. They set a goal of 200 for the year. Each quarter when the county reported the number of visits completed, the Department could measure their progress toward achieving their goal and identify whether they were having any issues in achieving that goal.

### **Recommendation 7**

*Increase the number of Provider-Based Immunization Initiative visits made, especially in those counties where few visits are made.*

Status - Not Implemented

Agency Action - We found the number of AFIX Assessments (Assessment, Feedback, Incentives, eXchange assessments), previously known as Provider-Based Immunization Initiative visits, carried out by the counties has decreased since our prior audit. During our original audit, we found that a total of 548 visits were completed for 2004 and 2005. Based on statistics provided by the Department, the number of assessments has decreased to 480 for 2007 and 2008, or 68 fewer assessments. In addition, we noted that the number of assessments of Oneida and Niagara counties went from 9 and 18 assessments (respectively) for 2004 and 2005, to none for 2007 and 2008. Department officials stated they are currently re-examining how these visits are conducted, and are concentrating on the impact of the visits, rather than the number. However, they noted that increasing the number of visits performed remains a required element of the county work plans and quarterly reports. The Department is hoping to increase the number of assessments in 2009 by requiring providers participating in the Department's Vaccines for Children program to participate in AFIX Assessments. They are hoping this will allow them to get into some places they have been unable to get into before; as these visits have previously been voluntary on the part of the provider.

### **Recommendation 8**

*Expedite plans to provide a new registry system that is accessible through the internet.*

Status - Implemented

Agency Action - The Departments' implementation of a statewide internet-based immunization registry, the New York State Immunization Information System (NYSIIS), a secure web-based application to track immunizations began in October 2005. In response to our prior audit report, the Department indicated that it was on track to have the new registry application developed and ready for deployment prior to the January 1, 2008 implementation date required under the Public Health Law. According to Department officials, they have used a regional implementation approach for the implementation of NYIIS. They started with the Hudson-Capital District region in January/February 2008, and then targeted the other five regions in the State. The Department expects full implementation by 2010. As of December 2008, NYSIIS contains more than 1.9 million patients and 19.9 million immunizations.

In reviewing NYSIIS with Department officials, we identified several significant improvements over the Department's previous voluntary registry such as input controls to ensure the quality of data. In addition, we acknowledge the Department's efforts to include other Department programs in NYSIIS, such as lead poisoning, and encourage them to continue these efforts.

Major contributors to this report were Todd Seeberger, Vicki Wilkins, Andrew Davis and Mark Radley.

We would appreciate your response to this report within 30 days, indicating any actions planned to address the unresolved issues discussed in this report. We also thank the management and staff of the Department for the courtesies and cooperation extended to our auditors during this process.

Very truly yours,

Michael Solomon  
Audit Manager

cc: S. Abbott, Department of Health  
Thomas Lukacs, Division of the Budget