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**OFFICE OF THE STATE COMPTROLLER**

June 5, 2007

Richard F. Daines, M.D.  
Commissioner  
Department of Health  
1495 Corning Tower  
Empire State Plaza  
Albany, NY 12237

Re: Maintaining Information on Adverse  
Patient Incidents at Hospitals and Clinics  
Follow-up Report 2006-F-52

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 Department of Health (Department) to implement the recommendations contained in our audit report, *Maintaining Information on Adverse Patient Incidents at Hospitals and Clinics* (Report 2003-S-27).

**Background, Scope and Objective**

The Department is responsible for maintaining the New York State Patient Occurrence Reporting and Tracking System (NYPORTS), an automated system containing information about certain incidents, called occurrences, at hospitals and clinics. An occurrence is defined as an unintended adverse and undesirable development in an individual patient's condition, such as death or impairment of bodily functions in circumstances other than those related to the natural course of illness, disease or proper treatment. Occurrences, which must be reported by a total of 263 hospitals and approximately 1,350 clinics, are classified by the Department as most serious or less serious. All occurrences classified as most serious must be investigated by the medical facility, and an investigation report identifying the cause of the occurrence must be submitted by the facility and entered onto the NYPORTS database.

According to State law and regulations, occurrences are to be reported within certain timeframes such as one business day for the most serious occurrences. In addition, all occurrences classified as most serious must be investigated and completed within 30 to 45 days. Medical facilities can access their own occurrence data on the NYPORTS database, and the facilities are expected to use the information in internal efforts to improve patient care and reduce medical error.

The Department developed NYPORTS to simplify and improve occurrence reporting, and to facilitate the creation of a statewide database that could be used by the participating medical facilities and the Department to improve the quality and safety of patient care. The facilities are expected by the Department to use the information in the database to assist in internal quality initiatives and medical error prevention. The Department also analyzes occurrence information on the NYPORTS database as part of its efforts to improve the quality and safety of patient care. Facility reporting and investigation practices are overseen by the Department's Bureau of Hospital and Primary Care Services (Bureau). The Bureau delegates much of its day-to-day oversight responsibility to seven field offices.

Our initial audit report, which was issued on September 28, 2004, examined the Department's oversight of NYPORTS for the period January 1, 2001 through May 21, 2003. Our initial report found that the information on NYPORTS is not complete and often is not reported in a timely manner. We also found that while the controls established to protect the validity and confidentiality of NYPORTS information are generally adequate, certain improvements are needed in these controls. The objective of our follow-up, which was conducted in accordance with generally accepted government auditing standards, was to assess the extent of implementation as of March 5, 2007, of the 18 recommendations included in our initial report.

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

We found that Department officials have made significant progress in implementing the recommendations contained in our initial audit report. Of the 18 audit recommendations, 17 recommendations have been implemented and 1 recommendation has been partially implemented.

### **Follow-up Observations**

#### **Recommendation 1**

*Expand the Department's efforts to identify unreported occurrences so that additional types of occurrences, and in particular most-serious occurrences, are subject to systematic analysis. Consider using a formal risk assessment process when determining which types of occurrences, and which individual hospitals, are to be selected for this systematic analysis.*

Status - Implemented

Agency Action - The Department expanded its efforts to identify unreported occurrences. Department staff completed a systematic review of 600 cases at a cost of \$200 per case but found only 30 unreported occurrences. In addition, the Department attempted to match NYPORTS data with other databases. However, this match did not work well because of the incompatibility of the data systems. Specifically, occurrence codes on one system did not match the other, making it difficult to identify unreported occurrences. Finally, Department management determined it was too time-consuming and not cost effective to develop a formal risk assessment for identifying unreported occurrences. However, the Department will continue to use its contractor, Island Peer Review Organization (IPRO), to identify potentially reportable NYPORTS events from retrospective reviews of Medicaid utilization data. Any cases determined to be reportable will be referred to the regional offices on a quarterly basis.

### **Recommendation 2**

*Develop written guidelines governing the enforcement of NYPORTS reporting requirements, and issue the guidelines to the field offices. The guidelines should specify the steps to be taken by a field office when a reporting violation is detected (including the enforcement information that is to be recorded on NYPORTS), and should include specific criteria for determining whether a facility should be sanctioned.*

Status - Implemented

Agency Action - The Department issued a Policy Directive on June 1, 2004 which included actions to be taken when a reporting violation is detected and specific criteria for determining whether a facility should be sanctioned. The policy calls for the regional office NYPORTS coordinators to generate a monthly report that lists occurrences that were not reported within the required timeframes. These occurrences are then grouped and a Statement of Deficiencies is issued to the non-compliant facility. The facility must then submit a Plan of Correction to address the deficiencies noted. The Department can accept or reject the Plan.

### **Recommendation 3**

*Monitor field office compliance with the guidelines governing the enforcement of NYPORTS reporting requirements, and take any corrective actions needed to improve field office compliance with the guidelines.*

Status - Implemented

Agency Action - The regional office NYPORTS coordinators have frequent contacts with Bureau staff regarding matters of code interpretation, system issues and policy. In addition, each regional office NYPORTS coordinator provides the Bureau with a quarterly Activity Summary Report, which provides data relating to compliance with NYPORTS reporting requirements. Further, in order to improve field office compliance with the guidelines, the Bureau has assigned a staff person to analyze NYPORTS reporting data and provide quality assurance feedback to both the Bureau and the regional offices.

### **Recommendation 4**

*Develop a process for initiating enforcement action (i.e., a citation or a sanction) when unreported occurrences are identified during Department-sponsored analyses of NYPORTS data.*

Status - Implemented

Agency Action - The Department implemented a revised process on November 1, 2004 for initiating enforcement action. The regional office NYPORTS coordinators receive lists of non-reported occurrences on a quarterly basis from IPRO, as well as annually from the School of Public Health. The Department then issues a citation or sanction in the form of a Statement of Deficiency to the facility, listing all non-reported occurrences. The facility is required to submit a Plan of Correction describing the corrective action to be taken.

### **Recommendation 5**

*Direct the Buffalo, Hudson Valley and Long Island field offices to enter onto NYPORTS all occurrence information reported by clinics since the implementation of NYPORTS, and to enter current information as it is reported.*

Status - Implemented

Agency Action - The Department has updated NYPORTS to give all clinics the ability to enter occurrence data directly onto NYPORTS. The Department also provided training to clinics on the use of NYPORTS. With this change, all field offices including the Buffalo, Hudson Valley and Long Island offices no longer have to enter the clinics' occurrence data onto NYPORTS.

### **Recommendation 6**

*Follow up promptly on overdue facility investigation reports to reduce delays in obtaining required investigation information.*

Status - Implemented

Agency Action - Regional office NYPORTS coordinators generate Past Due Reports on a monthly basis to monitor the timeliness of investigation reports. Under current NYPORTS policy, facilities can receive a citation for late reporting of their investigation reports at the 24-hour submission, 30-day extension request and 60-day submission timeframes.

### **Recommendation 7**

*Follow up on the missing investigation reports identified by our audit and determine whether investigations were ever performed by the medical facilities. If the investigations were not performed, take appropriate action to improve quality control practices at the noncompliant facilities.*

Status - Implemented

Agency Action - We reviewed 27 of the 264 files that were identified in the prior audit as missing the required investigation reports. We determined that investigation reports for all 27 of these cases are now complete and documented on NYPORTS. Further, as stated in the Agency Action section for Recommendation 3, the Department has assigned a person to analyze NYPORTS data and perform quality assurance reviews. This will minimize the potential for missing information on NYPORTS.

### **Recommendation 8**

*Add a data field to NYPORTS to indicate whether the investigation report submitted by the medical facility is considered complete by the facility.*

Status - Implemented

Agency Action - The Department added a data field to NYPORTS. When a facility enters a date

into this field, this represents the date in which the facility believes the investigation is complete and all outstanding information has been entered.

### **Recommendation 9**

*Develop written procedures to guide the field offices in their review of facility investigation reports and their documentation of this review, and periodically review the documentation relating to selected investigation reports to determine whether the reports were reviewed in accordance with expectations.*

Status - Implemented

Agency Action - As part of their efforts to provide guidance to field office officials who are responsible for reviewing facility investigation reports, the Department developed written procedures on November 1, 2004 directing field offices to use the Root Cause Analysis Evaluation tool. This tool is used to evaluate the credibility and thoroughness of each investigation report against established criteria. If deemed credible and thorough, the regional office NYPORTS coordinators check a box on the NYPORTS' review screen. In addition, each Regional Office Hospital Program Director reviews a sample of investigation report every quarter to determine whether the reports were reviewed in accordance with Bureau expectations. This review is also documented on NYPORTS.

### **Recommendation 10**

*Direct the field offices to use NYPORTS to document their review of facility investigation reports, monitor NYPORTS to determine whether the reviews are documented, and take corrective action when reviews are not documented.*

Status - Implemented

Agency Action - A Policy Directive, implemented June 1, 2004, directs regional office NYPORTS coordinators to use the NYPORTS review screen to document their review of facility investigation reports. A field was added to the review screen to be checked off after the regional office NYPORTS coordinator deems the investigation report to be through and credible. As part of its NYPORTS quality assurance review, the Department monitors review screen documentation for the most serious events for non-compliance with documentation expectations. In addition, responsible Department officials will notify the regional office NYPORTS coordinators on a periodic basis of any issues identified through their quality assurance activities.

### **Recommendation 11**

*Revise all existing written requirements (New York Codes, Rules and Regulations and the NYPORTS Users Manual) governing the timeliness of occurrence reporting so that they are consistent with the Department's expectations. Issue the new requirements to the field offices and the medical facilities. Modify NYPORTS so that the dates recorded on NYPORTS are consistent with the dates specified in the reporting requirements.*

Status - Partially Implemented

Agency Action - The Department revised the NYPORTS Users Manual in calendar year 2005 to address the timeliness of occurrence reporting and issued it to the field offices. The Department also revised the applicable New York Codes, Rules and Regulations. However, as of March 5, 2007, the revised regulations were still awaiting final approval and have not been formally adopted. NYPORTS has been modified so that the date a facility becomes aware of an incident is the starting point for calculating the reporting and investigation timeliness.

### **Recommendation 12**

*Develop written procedures for the enforcement of reporting timeframes, and monitor field office compliance with these procedures. The procedures should include guidelines for issuing citations or taking other actions when facilities repeatedly fail to report their occurrences on time.*

Status - Implemented

Agency Action - As stated in the Agency Action section for Recommendation 2, the Department developed a NYPORTS Policy Directive that guides regional offices in the determination of non-compliance with reporting requirements, citations and enforcement referrals. Also, the Department monitors field office compliance with these procedures.

### **Recommendation 13**

*Develop an exception reporting system to identify medical facilities that repeatedly fail to report their occurrences within the required timeframes. Use this system to monitor the actions taken by the field offices to correct the reporting practices of these facilities.*

Status - Implemented

Agency Action - Regional office NYPORTS coordinators now have the ability to generate a report that lists occurrences that were cited as part of a Statement of Deficiencies for a specified timeframe. Regional office staff use this report to track reporting requirements for specific facilities. As part of the Bureau's quality assurance activities, facility compliance is monitored. Regional offices are provided with periodic assessments of facility reporting compliance. Those facilities that have repetitive issues concerning late reporting or non-reporting may be subject to enforcement action and additional education to meet reporting requirements.

### **Recommendation 14**

*Modify the Department's written policy so that facility investigation time is measured from the date a medical facility becomes aware of an occurrence, and require the facilities to report this date on NYPORTS.*

Status - Implemented

Agency Action - On July 9, 2004, the Department added a field to NYPORTS to capture the date a facility became aware of an occurrence. Further, monitoring reports were modified to utilize this date field as a starting point in calculating the reporting and investigation timeliness.

The policy has also been updated to reinforce that the date of awareness is the starting point for monitoring reporting timeframes.

### **Recommendation 15**

*Add a data field to NYPORTS indicating whether extensions were approved for hospital investigations, and direct the field offices to complete this data field. Incorporate this data in the generation of the Past Due Report for hospital investigations. Further enhance the Past Due Report by using the date the investigation was considered complete by the facility.*

Status - Implemented

Agency Action - The Department added a data field to NYPORTS in March 2005 to allow for the documentation of extensions for investigations. The regional office NYPORTS coordinators then record the date in this field when an extension is approved. NYPORTS automatically incorporates this data to generate the Past Due Report for hospital investigations using the date of awareness as the starting point and the date that an extension is requested as its ending point. This extension should not be more than 30 days.

### **Recommendation 16**

*Develop automated controls for checking the validity of the critical dates entered on NYPORTS.*

Status - Implemented

Agency Action - In July 2004, the Department implemented several controls on NYPORTS to address the validity of critical dates and the accuracy of other data. We physically observed Department officials entering dates into critical fields and found that the controls worked as intended.

### **Recommendation 17**

*Strengthen controls over medical facilities' deletions of most-serious occurrences from NYPORTS.*

Status - Implemented

Agency Action - The Department has taken steps to strengthen controls for deletion of most serious occurrences from NYPORT. The revised policy, which went into effect June, 1 2004, now requires facilities to contact their regional office NYPORTS coordinator prior to deleting a most serious occurrence. The regional office NYPORTS coordinator will consult with the facility to determine whether the deletion is justified. If so, the regional office personnel will delete the occurrence. In addition, deletion requests are retained to document the justification for and the date of deletion. Our testing of the controls confirmed that a facility cannot delete a most serious occurrence.

**Recommendation 18**

*Process all changes in NYPORTS user access rights in accordance with Department procedures.*

Status - Implemented

Agency Action - The Bureau developed a form that the regional offices must use when submitting requests for changes in user access rights to NYPORTS.

Major contributors to this report were Ed Durocher, Brian Krawiecki and Thierry Demoly.

We would appreciate your response to this report within 30 days, indicating any actions planned to address the unresolved issue 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,

Albert Kee  
Audit Manager

cc: Lisa Ng, Division of Budget