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ANTONIA C. NOVELLO, M.D., M.P.H., Dr. P.H.
Commissioner

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December 29, 2004

Hon. Lynn Canton
Deputy Comptroller
Office of the State Comptroller
110 State Street
Albany, NY 12236

Dear Ms. Canton:

Pursuant to the provisions of Section 170 of the Executive Law, I hereby transmit to you a copy of the Health Department's comments related to the Office of the State Comptroller's final audit report (2003-S-27) entitled "Maintaining Information on Adverse Patient Incidents at Hospitals and Clinics."

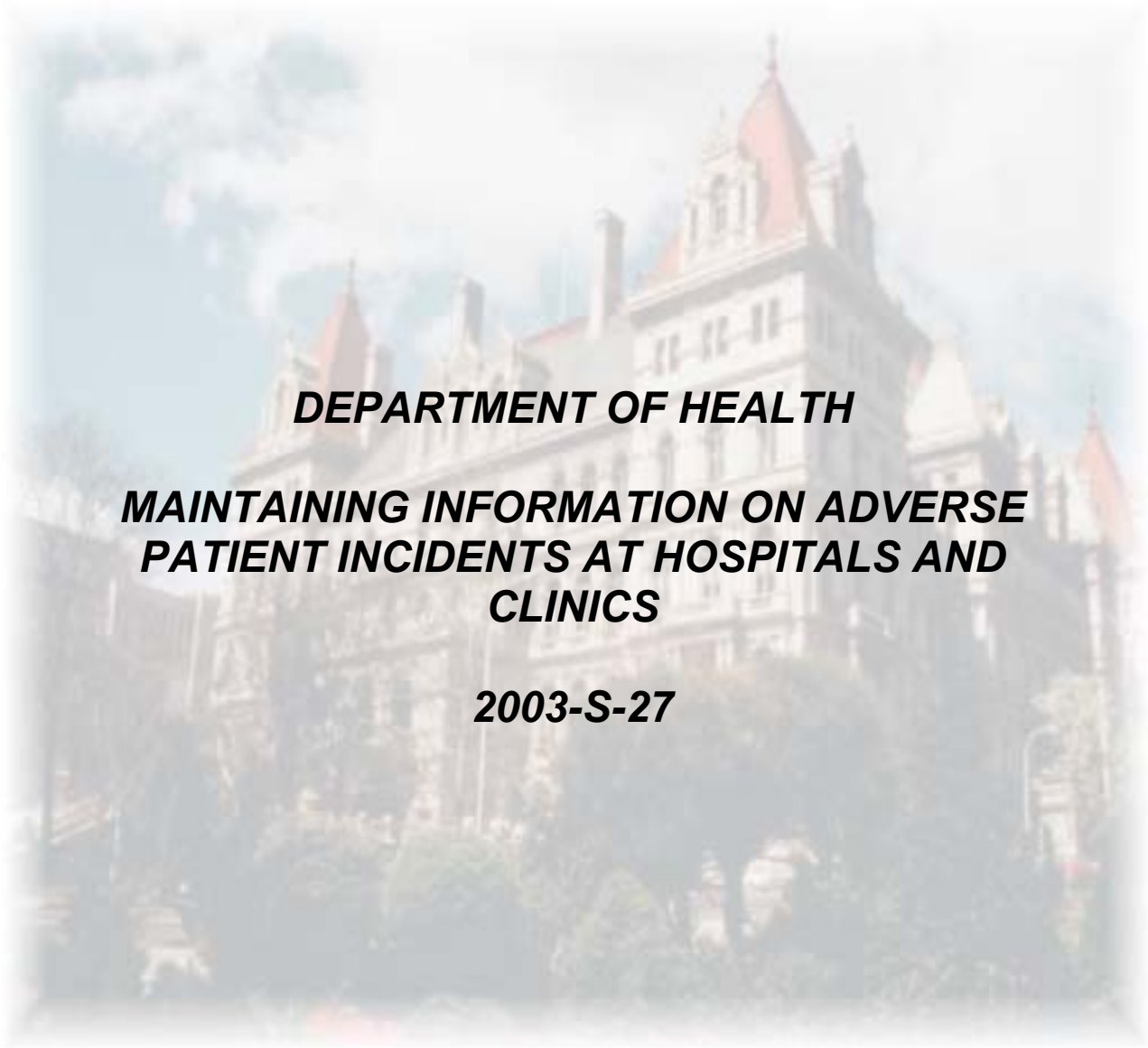
Sincerely,

Antonia C. Novello, M.D., M.P.H., Dr.P.H.
Commissioner of Health

Enclosure

A REPORT BY THE NEW YORK STATE OFFICE OF THE STATE COMPTROLLER

Alan G. Hevesi
COMPTROLLER



DEPARTMENT OF HEALTH

MAINTAINING INFORMATION ON ADVERSE PATIENT INCIDENTS AT HOSPITALS AND CLINICS

2003-S-27

DIVISION OF STATE SERVICES

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Alan G. Hevesi
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Report 2003-S-27

Antonia C. Novello, M.D., M.P.H., Dr. P.H.
Commissioner
Department of Health
Corning Tower
Empire State Plaza
Albany, NY 12237

Dear Dr. Novello:

The following is our report on the Department of Health's oversight of the New York State Patient Occurrence Reporting and Tracking System (NYPORTS), an automated system containing information about adverse patient incidents at hospitals and clinics.

This audit was performed 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 list major contributors to this report in Appendix A.

Office of the State Comptroller
Division of State Services

September 28, 2004

EXECUTIVE SUMMARY

DEPARTMENT OF HEALTH

MAINTAINING INFORMATION ON ADVERSE PATIENT INCIDENTS AT HOSPITALS AND CLINICS

SCOPE OF AUDIT

The Department of Health (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.

The information on the NYPORTS database can be accessed by medical facilities, and the facilities are expected to use the information in internal efforts to improve patient care and reduce medical error. The Department also uses the NYPORTS database in statewide efforts to improve patient care and reduce medical error. During our audit period of nearly 29 months, a total of 65,822 occurrences were recorded on NYPORTS, 2,610 of which were classified as most serious and 63,212 of which were classified as less serious. Almost all of the recorded occurrences (99.4 percent) were reported by hospitals. Our audit addressed the following question about the Department's oversight of NYPORTS for the period January 1, 2001 through May 21, 2003:

- Does the Department's oversight provide reasonable assurance that the information on NYPORTS is complete, timely, valid and adequately protected against unauthorized disclosure?

AUDIT OBSERVATIONS AND CONCLUSIONS

We found that, while the Department has taken action to improve compliance with NYPORTS reporting requirements, the information on NYPORTS is not complete and often is not reported in a timely manner. As a result, the NYPORTS database may not be as useful as it could be when it is analyzed during efforts that are intended to improve the quality of patient care. We also found that, while the automated data processing controls established to protect the validity and confidentiality of NYPORTS information are generally adequate, certain improvements are needed in these controls.

While medical facilities are required to report all occurrences to the Department, Department officials recognize the facilities may not always comply with the requirement. The Department has taken action to improve facility reporting practices, and between 1999 and 2001, the number of incidents reported annually per 100,000 discharges increased by nearly 62 percent. For example, Department officials noted this trend for one serious occurrence that they analyzed, but noted that they would like to see the variation decrease even further. While the Department seeks to identify unreported occurrences and correct noncompliant reporting practices, we examined these efforts, such as the Department's procedures for analyzing unreported occurrences and enforcing reporting requirements, and determined that they could be more effective if certain improvements were made. (See pp. 15-16)

For example, the Department recognizes 54 different types of occurrences, 19 of which are classified as most serious and 35 of which are classified as less serious. Only five types of less-serious occurrences are systematically analyzed to identify unreported occurrences. As a result, relatively few unreported occurrences could be identified by the Department and very few would be classified as most serious. We recommend that additional types of occurrences, and in particular most serious occurrences, be subject to systematic analysis to identify unreported occurrences. We further recommend that a formal risk assessment process be used to determine which types of occurrences, and which individual medical facilities, are most at risk of underreporting, and thus, most appropriate for analysis. (See pp. 16-26)

When noncompliant reporting practices are identified, the Department may require the noncompliant facility to develop a written plan of corrective action and may even publicly sanction the facility. However, we found that these actions are rarely taken by the Department. Also, written internal procedures for enforcing NYPORTS reporting requirements have not been developed by the Department. We recommend that such procedures be developed, and be applied in a consistent and systematic manner. (See pp. 18-27)

We further determined that, in many instances, the occurrences reported by clinics were not recorded on NYPORTS, and in some instances, information

about facility investigations into most-serious incidents either was not recorded, or was not fully recorded, on NYPORTS. In addition, even though occurrence and investigation information is to be reported within certain statutory timeframes, the information often is not reported within these timeframes and may be reported significantly later than required. We make several recommendations for improving the completeness and timeliness of the information on the NYPORTS database. (See pp. 29-35)

If the information on NYPORTS is to be reliable, data entry errors must be minimized and changes to information recorded on the system must be authorized. If NYPORTS information is to remain confidential, as is required by law, access to NYPORTS must be restricted to authorized users. We examined the controls that have been established by the Department to protect the validity and confidentiality of NYPORTS information. We found that these controls are generally adequate, but need to be enhanced in certain ways. For example, while certain procedures are to be followed when a change is made in the NYPORTS access granted to Department employees, these procedures were not always followed. We recommend that certain improvements be made in the data processing controls for NYPORTS. (See pp. 37-39)

COMMENTS OF DEPARTMENT OFFICIALS

While Department officials did not agree with some of our conclusions, they generally agreed with the report's recommendations and indicated actions taken or planned to implement them. A complete copy of the Department's response is included as Appendix B. Appendix C contains State Comptroller's Notes, which address comments contained in the Department's response.

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INTRODUCTION

Background

According to State law and regulations (Section 2805-l of the Public Health Law and Sections 405.8 and 751.10 of Title 10 of the New York Codes, Rules and Regulations), medical facilities in the State must report to the Department of Health (Department) certain types of adverse events, which are referred to as occurrences. 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. The law and regulations, which have been in effect since 1985, apply to a total of 1,613 medical facilities: 263 hospitals and approximately 1,350 diagnostic and treatment centers (clinics). If a facility fails to comply with these reporting requirements, it can be fined up to $2,000 per reporting violation.

Occurrences were initially reported on paper, and later through e-mail. In 1998, the Department implemented a new internet-based reporting system: the New York State Patient Occurrence Reporting and Tracking System (NYPORTS). NYPORTS is located on the Department's Health Provider Network, a statewide computer network used by various government offices and hospitals. Hospitals directly enter their occurrence information onto NYPORTS; clinics, which do not have access to the Health Provider Network, report their occurrence information to Department field offices and the field offices enter the data onto NYPORTS.

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. For example, a facility can aggregate and analyze its occurrence data to identify any areas (e.g., post-surgical wounds) in which a greater than expected rate of occurrence indicates that facility practices may need to be improved. Hospitals are able to query a specially

created comparative database that enables them to compare their experience with reported events to statewide, regional or peer group experiences. To encourage hospitals to make use of the NYPORTS database, the Department has created the Hospital Patient Safety Award Program, in which it awards grants of up to $200,000 to hospitals for their accomplishments in promoting patient safety and reducing medical errors. The first of these grants were awarded in 2002.

The Department also analyzes occurrence information on the NYPORTS database as part of its efforts to improve the quality and safety of patient care. Generally, the Department focuses its analyses on the most significant types of occurrences. For example, it analyzed the occurrence coded 912 (incorrect invasive treatment), identified certain recurring "root causes" for this type of error, developed practices that could be adopted by the facilities to prevent this type of error, and shared its findings with the facilities. Similarly, the Department has assembled a special panel of medical experts to analyze NYPORTS information relating to the occurrence coded 915 (unexpected death not directly related to the natural course of illness or underlying condition). It should be noted that, while the Department's NYPORTS analyses are an important part of its efforts to promote safe patient care, these efforts also include other critical activities such as complaint investigations and ongoing inspections, reviews and surveys performed in conjunction with facility accreditation, and licensing.

Occurrences are classified by the Department as most serious or less serious. Examples of most-serious occurrences include unexpected patient deaths and equipment malfunctions resulting in patient harm. Examples of less-serious occurrences include second and third degree patient burns and patient falls resulting in fractures. During our audit period (January 1, 2001 through May 21, 2003), a total of 65,822 occurrences were reported on NYPORTS, and as is shown by the following table, almost all of these occurrences were reported by hospitals:

Type of Occurrence	Reported by Hospitals	Reported by Clinics	Total
Most-Serious	2,577	33	2,610
Less-Serious	62,840	372	63,212
Total	65,417	405	65,822

According to State law and regulations, occurrences are to be reported within certain timeframes (e.g., most-serious occurrences are to be reported by the medical facility within 24 hours or one business day). In addition, all occurrences classified as most serious must be investigated by the medical facility. Such investigations are to be completed within 30 to 45 days, are to identify the cause of the occurrence, and are to meet certain other requirements for thoroughness. An investigation report prepared in a standard question and answer format is to be submitted to the Department by the facility, and this report becomes part of the NYPORTS database (investigation reports from hospitals are submitted in electronic format, and investigation reports from clinics are converted to electronic format by Department field offices). Thus, the information in the investigation reports, and in particular, the reported causes of all most-serious occurrences, should be available for analysis by users of NYPORTS.

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: Buffalo, Hudson Valley, Long Island, New York City, Rochester, Syracuse and Troy. These seven field offices also receive the occurrence information reported by clinics, and are to enter the information onto NYPORTS.

According to State law and regulations, all information stored on NYPORTS is confidential. Thus, the Department and other NYPORTS users are required by law to protect the confidentiality of this information.

Audit Scope, Objective and Methodology

Our audit examined the Department's oversight of NYPORTS for the period January 1, 2001 through May 21, 2003. The objective of our performance audit was to determine whether this oversight provides reasonable assurance that the information on NYPORTS is complete, timely, valid and adequately protected against unauthorized disclosure. To accomplish our objective, we reviewed applicable laws, rules, regulations, policies, procedures and the NYPORTS Users Manual. We also interviewed Department officials and officials of two Department contractors that use NYPORTS to perform various analyses for the Department. We visited six of the

seven field offices; we did not visit the Buffalo office because, according to Department officials, the Buffalo office has the same policies and procedures as the Rochester office.

We reviewed various records maintained by the Bureau and the six field offices we visited, including occurrence information recorded on NYPORTS. We selected a random sample of 43 most-serious occurrences and reviewed the facility investigation reports on file at the six field offices to determine whether the reports were prepared in accordance with Department requirements for thoroughness. We also used computer-assisted audit techniques to analyze the completeness and timeliness of occurrences reported on NYPORTS, and to analyze the validity of the dates recorded for occurrences.

To assess the adequacy of the security over NYPORTS data, we reviewed the general and application controls at the Bureau and the six field offices we visited. For example, we reviewed the controls at the Bureau and field offices for providing and changing user access to NYPORTS, backing-up and restoring NYPORTS data, providing security training to staff, and protecting user passwords. In addition, during our visits to the six field offices, we reviewed the records relating to all 176 most-serious occurrences deleted from NYPORTS during our audit period by medical facilities overseen by these six field offices, to determine whether the deletions had been properly approved by the field offices.

We conducted our audit in accordance with generally accepted government auditing standards. Such standards require that we plan and perform our audit to adequately assess the Department operations included in our audit scope. Further, these standards require that we understand the Department's internal control structure and its compliance with those laws, rules, and regulations that are relevant to the operations included in our audit scope. An audit includes examining, on a test basis, evidence-supporting transactions recorded in the accounting and operating records and applying any other auditing procedures we consider necessary in the circumstances. An audit also includes assessing the estimates, judgments and decisions made by agency management. We believe our audit provides a reasonable basis for our findings, conclusions and recommendations.

In addition to being the State Auditor, the Comptroller performs certain other constitutionally and statutorily mandated duties as the chief fiscal officer of New York State, several of which are performed by the Division of State Services. These include operating the State's accounting system; preparing the State's financial statements; and approving State contracts, refunds, and other payments. In addition, the Comptroller appoints members to certain boards, commissions and public authorities, some of who have minority voting rights. These duties may be considered management functions for purposes of evaluating organizational independence under Generally Accepted Government Auditing Standards. In our opinion, these management functions do not affect our ability to conduct independent audits of program performance.

Response of Department Officials to Audit

A draft copy of this report was provided to Department officials for their review and comment. Their comments were considered in preparing this report and are included as Appendix B. While Department officials did not agree with some of our conclusions, they generally agreed with the report's recommendations and indicated actions taken or planned to implement them. Appendix C contains State Comptroller's Notes, which address comments contained in the Department's response.

In addition to the matters discussed in this report, we have reported separately to the Department about a number of other audit issues. While these issues are of lesser significance than the issues included in our report, Department officials should implement our recommendations related to these issues to improve their oversight of NYPORTS.

Within 90 days of the final release of this report, as required by Section 170 of the Executive Law, the Commissioner of the Department of Health shall report to the Governor, the State Comptroller, and the leaders of the Legislature and fiscal committees, advising what steps were taken to implement the recommendations contained herein, and where recommendations were not implemented, the reasons therefor.

COMPLETENESS OF INFORMATION

If the information on NYPORTS is to be complete, all adverse patient incidents must be reported by hospitals and clinics. The Department recognizes that these incidents may not always be reported and takes certain steps to identify incidents that were not reported. While some unreported incidents are identified by the Department, the number is relatively small and consists almost entirely of incidents classified by the Department as less-serious. We determined that additional unreported incidents, including incidents classified as most serious, could be identified if certain improvements were made in the practices used by the Department when it attempts to identify unreported incidents.

We also found that, while the Department sometimes seeks to correct medical facilities' reporting practices when it determines that adverse incidents were not reported, its efforts would be more effective if they were applied in a more consistent and systematic manner. We further determined that the adverse incidents reported by clinics were not recorded on NYPORTS by certain field offices, and in some instances, information about facility investigations into most-serious incidents either was not recorded, or was not fully recorded, on NYPORTS. We make several recommendations for improving the completeness of NYPORTS. If the database can be made more complete, it can be more useful to the Department and medical facilities in their efforts to improve patient care and reduce medical error.

Unreported Occurrences

Hospitals and clinics have been required to report occurrences to the Department since 1985. Department officials recognize that medical facilities may not always comply with this requirement. In February 2000, the Commissioner of the Department notified hospitals, in a letter, that while the Department is ready to assist hospitals in meeting reporting requirements, it also "stands ready to enforce requirements, and will publicly sanction those facilities that fail to promptly and accurately report incidents." The Commissioner further directed the hospitals to conduct internal reviews to identify any

unreported incidents from 1999 and 2000 and to report such incidents to the Department within 60 days.

According to Department officials, the Commissioner's actions helped to prompt an improvement in occurrence reporting, as the total number of occurrences reported by medical facilities increased from 16,939 in 1999 (a rate of 716 reported incidents per 100,000 discharges), to 24,368 in 2000 (a rate of 1,004 reported incidents per 100,000 discharges), and to 28,689 in 2001 (a rate of 1,159 reported incidents per 100,000 discharges). Thus, between 1999 and 2001, the number of incidents reported per 100,000 discharges increased by nearly 62 percent.

In its NYPORTS Annual Report for 2000-2001, the Department acknowledges "it is clear that there are still a large number of cases that go unreported," based on the Department's analysis of one occurrence code: "death following specific procedure." According to Department officials, the number of unreported occurrences for this code decreased in 2001, compared to 1999 and 2000. While Department officials view this improvement as a positive trend, it would like to see a further decrease. Department officials stated that the monitoring of incident reporting will continue to be a high priority for them.

If significant numbers of occurrences are not included on the NYPORTS database, the database will be incomplete and thus less useful to the Department and medical facilities in their efforts to improve patient care and reduce medical error. It is therefore important that the Department encourages full compliance with reporting requirements, and make an effort to identify and correct noncompliance. While the Department has taken action to encourage compliance with reporting requirements, and does seek to identify and correct noncompliance, we determined that improvements can be made in these efforts, as follows.

Department Efforts to Identify Unreported Occurrences

To identify noncompliance with NYPORTS reporting requirements, the Department relies on analyses performed by two contractors and complaint investigations performed by the seven field offices. The two contractors are the State University at Albany's School of Public Health (SUNY) and the Island Peer Review Organization (IPRO). SUNY compares NYPORTS data

to the patient data on another Department reporting system: the Statewide Planning and Research Cooperative System (SPARCS). SPARCS, which was established in 1979, contains comprehensive information about inpatients and outpatients treated by medical facilities in New York State (e.g., diagnosis, type of treatment, discharge date, and much more). SUNY annually compares SPARCS data to NYPORTS data to identify occurrences that were reported on SPARCS but were not reported on NYPORTS.

IPRO performs a similar annual review to determine whether certain occurrences, which were reported on SPARCS, were also reported on NYPORTS. IPRO also conducts annual quality reviews of about 20,000 hospital Medicaid cases involving mortality, medical complications or the subsequent readmission of the patient, and during these reviews, attempts to determine whether any occurrences were not reported on NYPORTS.

We found that, while a certain number of unreported occurrences are identified by SUNY and IPRO, the number identified may be understated because the number of occurrences reviewed is relatively small. For example, only 301 unreported occurrences were identified by the two contractors over a two-year period (2001 and 2002). Moreover, the unreported occurrences identified by the two contractors are classified by the Department as less serious, because the contractors focus their analyses on five types of less-serious occurrences (the Department recognizes 54 different types of occurrences, 19 of which are classified as most-serious and 35 of which are classified as less-serious). Since none of the most-serious occurrences and only a small portion of the less-serious occurrences would be systematically analyzed to identify unreported incidents, the coverage provided by the two contractors could be very limited. While IPRO's annual review of about 20,000 Medicaid hospital cases is not restricted to the five types of less-serious occurrences, the additional coverage provided by these Medicaid reviews is small, as the reviews address a very small portion of the total number of inpatient cases in New York State (a total of about 2.5 million inpatients are discharged each year in New York).

IPRO's annual analysis of occurrences is directed at four types of less-serious occurrences, while SUNY's annual analysis of occurrences is directed at a fifth type of less-serious occurrence. IPRO focuses its analysis on four types of less-

serious occurrences, because these four types have the highest rate of occurrence statewide. Since IPRO analyzes occurrences at a sample of only 14 of the State's 263 hospitals, it focuses on the most common types of occurrences. SUNY focuses its analysis on the fifth type of less-serious occurrence, because this particular occurrence is easily identified on SPARCS. Additional analysis of the comprehensive patient information on SPARCS would have to be performed to identify other types of occurrences.

We recommend that Department-sponsored efforts to identify unreported occurrences be expanded so that additional types of occurrences, and in particular most-serious occurrences, are subject to systematic analysis to identify unreported occurrences. We also recommend that consideration be given to using a formal risk assessment process when determining which types of occurrences, and which individual hospitals, are to be selected for analysis. In such a process, the individual hospitals considered most at risk of not fully reporting occurrences and the particular occurrences considered most at risk of not being reported would receive the most intensive analysis.

In addition, Bureau officials expect that the field offices will sometimes identify unreported occurrences when they investigate complaints made by patients or patients' families. According to Bureau officials, about 2,000 such complaints are received each year by the field offices. However, we determined that the field offices usually do not identify unreported occurrences when they investigate these complaints. For example, during our audit period of nearly 29 months, the six field offices we visited identified only 20 unreported occurrences while investigating complaints. We therefore conclude that, while complaint investigations need to be performed and serve an important purpose, they cannot be expected to identify many unreported NYPORTS occurrences and add little to the Department's coverage in this area.

Department Enforcement of Reporting Requirements

To enforce NYPORTS reporting requirements, the Department may sanction a noncompliant facility by fining the facility up to $2,000 for each reporting violation and publicizing the penalty. The Department may also take less severe action and issue a citation for noncompliance. Facilities receiving a citation must submit a written plan of correction to the appropriate field office

within a specified timeframe. Bureau officials told us that the field offices are expected to issue a citation for every identified instance of noncompliance with NYPORTS reporting requirements, and are expected to record certain information about each citation on NYPORTS (e.g., the date the citation was issued, the date the plan of correction was due from the facility, and the date the plan of correction was actually received from the facility). Bureau officials stated that formal criteria have not been developed for determining when facilities should be sanctioned; rather, the field offices are expected to use their judgment and recommend that facilities be sanctioned when violations are persistent or especially serious.

To determine whether the field offices issue citations for all NYPORTS reporting violations and record all citations on NYPORTS, we interviewed officials from all seven field offices. We found that, contrary to the expectations of Bureau officials, four field offices (Buffalo, Rochester, Syracuse and Troy) do not always issue a citation for a reporting violation and five field offices (Buffalo, Hudson Valley, Long Island, New York City and Troy) do not record all citations on NYPORTS.

We also found that the expectations of Bureau officials have not been formalized as written procedures, and officials in some field offices were not aware that they were expected to issue citations for all reporting violations and record all enforcement actions on NYPORTS. We further determined that citations are not issued and facilities are not sanctioned when unreported occurrences are identified during the analyses performed by SUNY and IPRO. Rather, Bureau officials stated that they informally work with the noncompliant facilities to improve their reporting practices.

It is therefore not surprising that only a small number of medical facilities have been sanctioned and a small number of citations have been issued. According to Department records, during our audit period of nearly 29 months, only two medical facilities were sanctioned for their failure to report occurrences on NYPORTS, and a total of only 20 citations were issued to facilities for such violations. In addition, according to officials at the five field offices that do not record all citations on NYPORTS, an additional 17 citations were issued during this period for such violations, but were not recorded on NYPORTS. In light of the significant noncompliance with NYPORTS reporting requirements we question whether the Department's

low level of enforcement activity is sufficient. The low number of citations issued and facilities sanctioned does not appear to be consistent with the Commissioner's statement that the Department "stands ready to enforce requirements, and will publicly sanction those facilities that fail to promptly and accurately report incidents."

Department officials stated that they prefer to maintain a positive working relationship with medical facilities, and would rather work with a facility to improve its NYPORTS reporting practices instead of publicly sanctioning the facility for its failure to report adverse patient incidents. However, we question the extent to which such improvement can be realized when citations are not issued for any of the reporting violations identified by SUNY and IPRO, citations are issued for only some of the reporting violations identified by Department field offices, and most types of occurrences are not subject to systematic analysis to identify unreported patient incidents. If a citation is not issued for a reporting violation, a corrective action plan will not be required, and as a result, the inappropriate reporting practices are less likely to be corrected. If most types of occurrences are not subject to systematic analysis to identify unreported patient incidents, many reporting deficiencies may never even be identified, and as a result, will not be able to be corrected.

We therefore recommend the Department develop written guidelines governing the enforcement of NYPORTS reporting requirements, issue the guidelines to the field offices, monitor field office compliance with the guidelines, and take any corrective actions needed to improve field office compliance with the guidelines. The guidelines should specify the steps to be taken by a field office when a reporting violation is detected, and should include specific criteria for determining whether a facility should be sanctioned. We further recommend that a process be developed for initiating enforcement action (i.e., a citation or a sanction) when unreported occurrences are identified during Department-sponsored analyses of NYPORTS data. In the absence of a more systematic effort to identify and correct noncompliant NYPORTS reporting practices, further improvement in facility reporting practices may be difficult to obtain; and, if the facilities continue to underreport adverse patient incidents, the NYPORTS database will continue to be incomplete, and thus not as useful as intended.

In response to our preliminary audit findings, Department officials stated that they would provide a written directive to the field offices regarding the Department's policy for responding to NYPORTS reporting violations and recording enforcement actions on NYPORTS. The officials also indicated that they would confer with SUNY and IPRO officials and explore additional ways to identify unreported occurrences.

Reported Occurrences Not Recorded on NYPORTS

Since clinics do not have access to the Health Provider Network, they cannot enter their occurrence information onto NYPORTS. Instead, they are to report their occurrence information to the appropriate Department field office, and the field office is to enter the information onto NYPORTS. However, officials at three of the seven field offices (Buffalo, Hudson Valley and Long Island) told us that they have not entered this information onto NYPORTS, because they either do not have enough staff to perform this function or NYPORTS has not been programmed to include data on certain clinics.

As a result, the NYPORTS database does not include a significant portion of the reported information relating to adverse patient incidents at clinics. For example, during our visit to the Hudson Valley field office, officials showed us a report indicating that a total of 68 adverse patient incidents had been reported during the past year by clinics in that region, but none of these occurrences had been recorded on NYPORTS. In the absence of such information, NYPORTS is less likely to be of use in any efforts that are made to improve patient care at clinics. We recommend that that all clinic occurrence information reported to the three field offices since the implementation of NYPORTS be recorded on NYPORTS, and current information be recorded as it is reported.

In response to our preliminary audit findings, Department officials stated that they would provide a written directive to the field offices to clarify the policy for reporting clinic occurrences.

Missing and Incomplete Investigation Information

All most-serious occurrences must be investigated by the medical facility. In addition, an investigation report must be prepared by the facility in a standard question and answer

format that is designed to ensure the root cause of the occurrence is properly identified by the facility and the investigation is sufficiently thorough in certain other respects. The completed investigation report must be submitted to the Department and entered onto NYPORTS.

The information in the facility investigation report is a critical part of the NYPORTS database, particularly the information about the root cause of an adverse incident. If the database is to be useful in preventing future such incidents, the causes of past incidents need to be known. The rest of the information in the investigation report can also help NYPORTS users in their efforts to understand why certain errors occurred and how such errors can be prevented in the future.

To determine whether facility investigation reports were entered on NYPORTS as required, we examined the NYPORTS database. The submission of the investigation report is recorded on the database, and during our audit period of January 1, 2001 through May 21, 2003, a total of 2,505 investigation reports should have been submitted. (A total of 2,610 most-serious occurrences were reported on NYPORTS during this period, but the investigation reports for 105 of these occurrences did not have to be submitted during the period, because they were due after May 21, 2003.)

We found that, according to the NYPORTS database, only 2,241 of the 2,505 required investigation reports had been submitted. There was no indication that an investigation report had been submitted for the remaining 264 (11 percent) most-serious occurrences. These 264 missing investigation reports were overdue, as follows:

- 32 investigation reports were less than 30 days overdue,
- 26 investigation reports were between 30 and 90 days overdue,
- 30 investigation reports were between 90 and 180 days overdue,
- 48 investigation reports were between 180 and 365 days overdue, and
- 128 investigation reports were more than one year overdue.

Thus the NYPORTS database was missing required investigation information for a significant number of most-

serious occurrences, and some of this missing information was significantly overdue. Such significant gaps in investigation information could compromise the usefulness of the database. We recommend the Department follow up promptly on overdue investigation reports to reduce the delays in obtaining required investigation information. As is discussed in the following section of this report, while the Department monitors the timeliness of facility investigations of most-serious occurrences, many investigations are delayed and not completed within the required timeframes.

In addition, some investigation reports may be missing because investigations were never performed by the medical facilities. If so, the quality of care at these facilities may need to be reviewed by the Department. We recommend the Department follow up on the missing investigation reports and determine whether investigations were ever performed. If not, the Department should take appropriate action to improve quality control practices at the noncompliant facilities.

We also note that, while some investigation reports had not been submitted as required, some of the reports that were submitted may not have been complete. NYPORTS records the submission of an investigation report, but it does not record whether the report is complete. In some instances, incomplete reports are submitted. The information needed to complete the report (such as the results of an autopsy that has yet to be performed) may be submitted at a later date, but if this information is not submitted, the incompleteness of the report will not be noted by NYPORTS. We recommend that a data field be added to NYPORTS to indicate that an investigation report is in fact complete. In the absence of such a data field, Department officials cannot readily determine whether submitted investigation reports are complete.

In response to our preliminary audit findings, Department officials stated they would re-iterate expectations for investigations to medical facilities, add more useful data fields to NYPORTS and require medical facilities to report the date an investigation is completed.

For an investigation report to be considered sufficiently thorough by the Department, the report must meet certain requirements specified in Department regulations and guidelines. For example, the report must include a determination of the

proximate cause of the adverse patient incident, a detailed timeline of the patient's care, an updated assessment of the effect of the incident on the patient, a chronology of the steps taken to investigate the incident, and an executive summary summarizing what was learned from the investigation.

To determine whether submitted investigation reports met the Department's requirements for thoroughness, we reviewed a sample of facility investigation reports on file at the six field offices we visited. We randomly selected for review the investigation reports relating to a total of 43 of 2,610 most-serious occurrences at hospitals overseen by the six field offices. Our sample consisted of eight most-serious occurrences at hospitals overseen by the New York City office and seven most-serious occurrences at hospitals overseen by each of the other five offices.

We found that investigation reports had been submitted as required for 41 of the 43 most-serious occurrences in our sample (reports had not been submitted for two of the seven most-serious occurrences at hospitals overseen by the Hudson Valley field office). However, 3 of the 41 submitted reports did not meet the Department's requirements for thoroughness, as follows:

- one report (at the Hudson Valley field office) did not include the proximate cause of the adverse incident, the steps taken to investigate the incident, a summary of the actions taken to correct the problem, and much other required information, and

- two reports (at the Troy and New York City field offices) did not include required information on the current status of the patient.

We therefore conclude that some of the investigation reports considered complete by the medical facilities are not in fact complete, because they do not contain certain information that is required by the Department. In the absence of this information, the usefulness of the NYPORTS database could be compromised in future efforts to improve patient care and reduce medical error. In addition, the absence of this information from the investigation reports may indicate that some hospitals are not always sufficiently diligent in their response to adverse patient incidents.

Department officials told us that the field offices are expected to review submitted investigation reports to determine whether the reports do, in fact, meet the Department's requirements. In addition, the NYPORTS database includes data fields that are to be used by the field office to indicate that it has completed its review of the facility investigation report.

However, the Department has not developed written procedures to guide the field offices in their review of investigation reports. As a result, the investigation reports are less likely to be reviewed in accordance with expectations and may not be reviewed at all. For example, while we found written documentation indicating that 35 of the 41 submitted investigation reports in our sample were reviewed by the field office (e.g., we found handwritten review notes on some investigation reports), we found no such documentation for the other six reports. It is thus possible that these six reports, which included two of the three reports that did not meet the Department's requirements for thoroughness, were not reviewed at all by the field offices.

We further determined that the field offices often fail to complete the NYPORTS data fields that indicate the investigation report has been reviewed by the field office. These data fields were not filled in for 63 percent of the investigation reports (1,414 of 2,241) that were submitted by medical facilities during our audit period. It is possible that, in some of these cases, the field offices reviewed the investigation reports, but failed to document their review on NYPORTS; however, such a widespread lack of documentation undermines the Department's ability to determine whether the field offices are in fact reviewing investigation reports as expected.

We recommend the Department direct the field offices to use NYPORTS to document their review of investigation reports, monitor NYPORTS to determine whether the reviews are documented, and take corrective action when reviews are not documented. We also recommend that the Department develop written procedures to guide the field offices in their review of 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.

In response to our preliminary audit findings, Department officials stated that they would clarify documentation expectations with field offices and hospitals, and would improve how information was recorded on NYPORTS.

Recommendations

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.

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.

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.

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.

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.

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

Recommendations (Cont'd)

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.

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

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.

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.

TIMELINESS OF INFORMATION

If information relating to adverse patient incidents is not reported in a timely manner, the information is more likely to be missing when the Department and medical facilities use the NYPORTS database to try to improve patient care and reduce medical error. While this information is to be reported by medical facilities within certain statutory timeframes, we found that the information often is not reported within these timeframes and may be reported significantly later than required. We recommend the Department improve its monitoring of facility compliance with reporting time requirements, and more actively enforce the requirements.

Occurrence Reporting

Hospitals, which have access to NYPORTS through the Health Provider Network, are required to report all suspected most-serious occurrences within 24 hours of the date of the occurrence or the date the hospital has reasonable cause to believe that such an incident occurred. Within seven days of the suspected occurrence, hospitals must submit written notification to the Department either affirming the suspected occurrence or explaining that another type of event actually took place. Clinics, which do not have access to the Health Provider Network, are required to report all suspected most-serious occurrences to the appropriate Department field office within 24 hours or one business day of the occurrence. Within five days of the suspected occurrence, clinics must submit written notification to the Department either affirming the suspected occurrence or explaining that another type of event actually took place. In addition, beginning April 1, 2003, the Department began requiring both hospitals and clinics to report suspected less-serious occurrences within either 24 hours or 30 days, depending on the nature of the less-serious occurrence.

For all types of occurrences, both the date the occurrence took place and the date the occurrence was reported by the medical facility are recorded on NYPORTS. If a facility subsequently determines that a reported occurrence was not actually an occurrence, the occurrence is deleted from NYPORTS.

The reporting time requirements for most-serious occurrences are stated in the Public Health Law and State regulations (New York Codes, Rules and Regulations), while the reporting time requirements for less-serious occurrences are stated in the Department's NYPORTS Users Manual, which the Department considers written policy. The Users Manual also contains the reporting time requirements for most-serious occurrences. The field offices are expected to monitor the medical facilities' compliance with required reporting timeframes and issue citations for noncompliance when, in the judgment of the field offices, the noncompliance is sufficiently severe.

To determine whether medical facilities have reported occurrences within the required timeframes, we used computer-assisted audit techniques to analyze the 65,822 occurrences reported on NYPORTS during our audit period. We first determined that the time requirements did not apply to 58,879 of the occurrences, because they were less-serious occurrences that took place prior to April 1, 2003, the date on which the time requirement for less-serious occurrences became effective. We then determined that many of the remaining 6,943 occurrences were not reported within the required timeframes, as follows:

- A total of 5,777 occurrences should have been reported within 24 hours. We determined that, according to the dates recorded on NYPORTS, 932 of these occurrences (16 percent) were reported within 24 hours. However, 4,845 of these occurrences (84 percent) were not reported within 24 hours. Moreover, when we analyzed the 4,845 occurrences that were reported late, we found that they were reported an average of 40 days late (i.e., 40 days after the date the occurrence took place). One occurrence was reported 832 days (2.3 years) late.

- A total of 1,166 occurrences should have been reported within 30 days. However, according to the dates recorded on NYPORTS, 134 of these occurrences (11 percent) were not reported within 30 days.

As a result of such reporting delays, information about occurrences is less likely to be available for analysis when the Department and medical facilities use the NYPORTS database

to try to improve patient care and reduce medical error. We determined that these reporting delays could be reduced if certain improvements were made in the Department's monitoring of facility compliance with reporting requirements and its enforcement of the requirements. For example, while officials at all seven field offices stated that they monitor the timeliness of facility reporting for most-serious occurrences, officials at five field offices (Buffalo, Long Island, Rochester, Syracuse and Troy) stated that they do not monitor the timeliness of facility reporting for less-serious occurrences. In addition, we identified only four instances in which a field office issued a citation to a medical facility for late reporting, even though we identified almost 5,000 occurrences that were not reported on time and twenty medical facilities (19 hospitals and one clinic) that repeatedly failed (i.e., at least 50 times) to report their occurrences on time.

In response to our preliminary audit findings, Department officials stated that our analysis of reporting timeliness is not accurate. They indicated that, while our analysis is based on the Department's written reporting requirements, contained in State regulations and the NYPORTS Users Manual, these requirements are not used by the Department. Rather, different timeframes are used and reporting time is measured from the date the facility becomes aware of the occurrence, not the date the occurrence took place. According to Department officials, hospitals are expected to report all most-serious occurrences within seven days of the day they first become aware of the occurrence, and are expected to report all less-serious occurrences within 30 days of the day they first become aware of the occurrence. Similarly, clinics are expected to report all most-serious occurrences within five days of the day they first become aware of the occurrence, and are expected to report all less-serious occurrences within 30 days of the day they first become aware of the occurrence. The officials stated that the requirements contained in the Public Health Law and State regulations were not modified in 1998 when NYPORTS was implemented.

We note that the revised reporting expectations described by Department officials were not in writing, were not issued to the medical facilities, and were not incorporated into the NYPORTS database (the database is set up to record the date the occurrence took place, not the date the facility first became aware of the occurrence). We therefore question how the

Department intended to monitor the facilities' compliance with these revised expectations.

We further note that, even if facility reporting practices could be analyzed in terms of these revised expectations, it is likely that many occurrences would still be found to have been reported late. For example, as was previously noted, we identified 4,845 occurrences that were reported an average of 40 days after the occurrence took place. A total of 487 of these 4,845 occurrences were reported more than 90 days after the occurrence took place. Thus, regardless of which particular revised expectation is used in assessing these occurrences, (whether seven days for most-serious occurrences at hospitals, five days for most-serious occurrences at clinics, or 30 days for all less-serious occurrences), it is likely that many of these 487 occurrences would be found to have been reported late.

We recommend the Department revise all existing written requirements (State regulations and NYPORTS Users Manual) governing the timeliness of occurrence reporting so that they are consistent with the Department's expectations. We further recommend the Department improve its monitoring of facility compliance with reporting time requirements and its enforcement of the requirements. If the revised reporting expectations are to be used, they should be formalized and issued to the field offices and the medical facilities, and the relevant dates should be incorporated in the NYPORTS database. In addition, an exception reporting system should be developed to identify medical facilities that repeatedly fail to comply with reporting time requirements. The actions taken by the field offices to correct the reporting practices of these facilities should be monitored by the Bureau. To ensure consistent enforcement practices, written guidelines for the enforcement of reporting timeframes should be added to the Department's guidelines for enforcing NYPORTS reporting requirements.

Investigation Reporting

Hospitals and clinics are required by law to investigate all most-serious occurrences and report the results of their investigations to the Department. Hospitals are required to complete and report their investigations within 30 days, and clinics are required to complete and report their investigations within 45 days. In addition, according to Department policy, a

hospital can receive an extension of up to 15 additional days to complete its investigation. Such extensions must be approved in writing by the Department. The facility investigation report is entered on the NYPORTS database, and the date the report is submitted is recorded on the database. If the submitted report is updated by the facility, the date of the update is substituted for the date of the submission.

To monitor the timeliness of facility investigations, the field offices rely on a report that is generated by NYPORTS (the Past Due Report). In this report, the date the investigation report was submitted or updated is compared to the date the occurrence reportedly took place. An investigation is considered past due if the investigation report is not submitted/updated within the required timeframe.

To determine whether investigation information was reported within the required timeframes, we compared the two dates used in the Past Due Report (the date the occurrence took place, and the date the investigation report was submitted/updated) for each of the 2,241 investigations that were completed during our audit period. All 2,241 investigations were completed by hospitals. Since NYPORTS does not indicate whether an extension was approved for a hospital investigation, we could not fully evaluate whether the investigations were completed within the required timeframe (30 days without an extension and up to 45 days with an extension). Accordingly, for the purpose of our analysis, we determined whether the investigations were completed within 45 days, the maximum time allowed for a hospital investigation.

We found that, according to the dates recorded on NYPORTS, (the date the occurrence took place, and the date the investigation report was submitted/updated) 953 of the 2,241 investigations (43 percent) were completed within 45 days. However, 1,288 of the investigations (57 percent) were not completed within 45 days. Of these 1,288 investigations, 79 percent took between 45 and 90 days to complete; and 21 percent took more than 90 days to complete.

As a result of such delays, the information contained in investigation reports is less likely to be available for analysis when the Department and medical facilities use the NYPORTS database to try to improve patient care and reduce medical error. To reduce such delays, the Department should follow up

promptly on overdue investigation reports, as we recommend earlier in this report. We also recommend the Department clarify an inconsistency in its measurement of investigation time. While the Public Health Law states that investigations into most-serious occurrences should be completed within a certain number of days of the date the hospital or clinic becomes aware of the occurrence, the Department's written policy states that the investigations should be completed within a certain number of days of the date the occurrence took place, and NYPORTS is programmed to use the date of the occurrence, rather than the date the facility became aware of the occurrence, when measuring investigation time. We recommend the Department modify its policy and NYPORTS so that they are consistent with the law.

In addition, earlier in this report we noted that partial investigation reports are sometimes submitted by medical facilities, and consequently, a data field needs to be added to NYPORTS to indicate when the investigation is considered complete by the facility. We recommend that this new data field be used in the generation of the Past Due Report. Thus, the revised Past Due Report should compare the date the facility became aware of the adverse incident to the date the investigation was considered complete by the facility.

We also note that some investigations during our audit period were not completed within the required timeframes because two field offices (Rochester and Syracuse) did not require hospitals to investigate one type of most-serious occurrence (medication errors that result in serious patient harm) until early 2002 (Rochester) and April 2003 (Syracuse). However, the Department required that this type of occurrence be investigated beginning in June 2000.

In response to our preliminary audit findings, Department officials stated that they would modify NYPORTS and the Department's investigation policy to comply with the law, and would communicate these changes to the field offices and medical facilities.

Recommendations

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.

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.

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.

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.

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.

VALIDITY AND CONFIDENTIALITY OF INFORMATION

If the information on NYPORTS is to be reliable, data entry errors must be minimized and changes to information recorded on the system must be authorized. If NYPORTS information is to remain confidential, as is required by law, access to NYPORTS must be restricted to authorized users. We examined the controls that have been established by the Department to protect the validity and confidentiality of NYPORTS information. We found that these controls are generally adequate. However, certain improvements could be made that would enhance this protection.

Incorrect information may inadvertently be entered on automated information systems such as NYPORTS. To provide some protection against such errors, automated controls (called edits) should be developed to identify, or prevent the entering of, data that is obviously incorrect (e.g., impossible dates such as the fortieth day of a month). We found that such a control is needed to prevent obvious errors when the date of an occurrence is recorded on NYPORTS by medical facilities. We used computer-assisted audit techniques to analyze this date for all 65,822 occurrences recorded on NYPORTS during our audit period, and identified 256 dates that were obviously incorrect. For example, at the time of our review in May 2003, NYPORTS indicated that several occurrences had taken place in December 2003, which at that time was still several months in the future.

While the number of errors that we identified was relatively small in relation to the total number of occurrences, the errors easily could have been prevented by an automated control that checked the validity of the dates. We recommend that such a control be developed. In response to our preliminary audit findings, Department officials stated that they would develop such a control.

In certain circumstances, medical facilities may need to delete an occurrence that is recorded on NYPORTS. For example, the facility may determine that a previously reported occurrence

was not actually an occurrence after all, or may realize that the same occurrence was mistakenly reported more than once. According to Department procedures, before deleting a most-serious occurrence, a facility should receive approval from the appropriate field office.

To determine whether this approval was received as required, we reviewed all 176 most-serious occurrences that were deleted from NYPORTS during our audit period by medical facilities overseen by the six field offices we visited (such deletions are recorded on NYPORTS). We found that 85 of the 176 deletions (48 percent) had been approved by the field office. However, we found no indication that the remaining 91 deletions (52 percent) had been approved. A total of 69 of these 91 deletions were made by medical facilities overseen by the New York City field office.

If NYPORTS records can be deleted without proper authorization, the integrity of the information on NYPORTS could be compromised. We recommend that action be taken to strengthen the controls over such deletions. In response to our preliminary audit findings, Department officials stated that they would change the process for deleting occurrences to strengthen controls over the process.

Only authorized users should have access to the information on NYPORTS, and their access should be restricted to the information and functions necessary to perform their duties. According to Department procedures, field office users of NYPORTS who require changes in their access privileges are required to fax a standardized form to the Bureau requesting such changes. However, officials at two field offices (Long Island and New York City) told us that they do not use the standard forms to modify user access to NYPORTS. Rather, they contact the Bureau via phone or e-mail to request a modification. Officials at another field office (Hudson Valley) told us they were unaware of how to go about modifying user access.

If changes in user access are not properly documented, inappropriate changes could go undetected and the confidentiality of NYPORTS information could be compromised. We recommend that all changes in user access be processed in accordance with Department procedures.

Recommendations

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

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

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

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Dennis P. Whalen
Executive Deputy Commissioner

April 5, 2004

William P. Challice
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Albany, New York 12236

Dear Mr. Challice:

Enclosed are the Department of Health's comments on the Office of the State Comptroller's (OSC) draft audit report (2003-S-27) entitled "Maintaining Information on Adverse Patient Incidents at Hospitals and Clinics."

Thank you for the opportunity to comment.

Sincerely,

Dennis P. Whalen
Executive Deputy Commissioner

Enclosure

cc: Mr. Conroy
Mr. Heigel
Mr. Howe
Mr. Osten
Mr. Reed
Mr. Scott
Mr. Van Slyke

Department of Health
Comments on the
Office of the State Comptroller's
Draft Audit Report 2003-S-27
Entitled "Maintaining Information on Adverse Patient Incidents at Hospitals and Clinics"

The following are the Department of Health's (DOH) comments concerning the recommendations contained in the Office of the State Comptroller's (OSC) draft audit report (2003-S-27) entitled "Maintaining Information on Adverse Patient Incidents at Hospitals and Clinics."

General Comments:

The Department appreciates the recommendations of the Office of the State Comptroller regarding improvements to NYPORTS. NYPORTS is a nationally recognized model mandatory adverse event reporting system. There are several important clarifications that must be offered as a preface to these responses.

Section 1: General Response to Narrative Sections

1.1 Audit Observations and Conclusions - Unreported Occurrences

In this section, the report discusses underreporting and references a quote from the New York State Patient Occurrence Reporting and Tracking System (NYPORTS) Annual Report 2000/2001 as follows: "Although reporting in 2000 and 2001 shows improvement, it is clear that there are still a large number of cases that remain unreported." This quote, as used in the audit report, is taken out of context and suggests that the Department is aware of, and tolerant of, facility underreporting. Although not specifically stated, this quote refers to improvements in reporting noted for Code 605 (death following specific procedure). The Department uses Code 605 as a "marker code"; this means that it matches well with the Statewide Planning and Research Cooperative System (SPARCS) database and therefore, can be used to validate reporting in NYPORTS. The number of unreported occurrences decreased in 2001, as compared to the numbers identified in 1999 and 2000. The Department views this improvement in Code 605 reporting for the year 2001 as a positive trend but would like to see this variation decrease further. The quote taken from the Annual Report was intended to reference the Code 605 exercise specifically; it was not intended to infer that there is acknowledged and widespread non-compliance with reporting requirements.

* Note 1

In addition, the report is critical of the Department's effort to identify unreported occurrences through "systematic analysis" of all NYPORTS codes by stating that "relatively few unreported occurrences are identified by the Department and very few are classified as most serious". The Department disagrees that this is due to inadequate monitoring for unreported occurrences. Rather, this finding confirms the effectiveness of the

* Note 2

* See State Comptroller's Notes, page 55

Department's efforts to ensure complete reporting. The Department identifies unreported occurrences through a multi-faceted approach as follows:

* *Notes 3, 4*

- Review activities through Medicaid Utilization Review;
- The identification of occurrences through complaint investigations and other Department conducted surveillance activities; and
- Identification by comparisons between SPARCS and NYPORTS data by the SUNY School of Public Health.

The Department's efforts to identify unreported occurrences utilize existing methods of analysis that matches NYPORTS reports with the SPARCS database. The School of Public Health uses this "matching" method to identify potential occurrences in the SPARCS database, and by comparing them with NYPORTS, lists of potential occurrences are generated. These lists are then validated by the facility, as in the code 605 exercise, or by the Island Peer Review Organization (IPRO). This method has limitations, as relatively few NYPORTS codes match well, moderately, or even marginally with the SPARCS database. Some codes do not correlate at all. Validation exercises have been focused on certain codes that provide good matches or fit Medicaid Utilization Review criteria based on a very specific targeted sampling methodology, which are more likely to produce positive yields than a random sampling methodology.

* *Notes 2, 3*

A recent report compiled by IPRO compared the School of Public Health's Strategic Predictive Model with Other Mortality Reviews used by IPRO, to determine effectiveness in identifying cases with the potential for unexpected mortality and other quality issues related to the patient's death. All cases identified through this process are reviewed. The findings of this comparison show that this model is consistently useful in identifying cases with unexpected mortality and other quality issues as compared with other models.

The number of codes that are "systematically analyzed" can be increased with improved sampling methodology, which is under development by the School of Public Health. Until such time, the Department will continue to rely on the established methods to identify unreported occurrences.

NYPORTS is the Department's premier patient safety initiative. It is the largest adverse event database in the nation, which is the true measure of program effectiveness. Analysis of the NYPORTS data enables the Department to positively affect patient safety, by returning strategies for systems improvements culled from the database to the provider community.

The Department strikes a balance between expending resources to ensure complete reporting and using resources to harvest lessons learned that will ensure improved healthcare in New York State. The Department continuously monitors the database for apparent low reporting and analyzing the data contained within the database. Hundreds of thousands of tax-payer dollars are already dedicated to assure complete reporting through the existing methods; the cost benefit has reached a point of diminished returns. That is, the cost of finding an unreported event beyond utilizing the methodologies already in place or under development is disproportionate to the prudent use of taxpayer dollars for the

* *Note 5*

improvement of patient safety. This delicate balance between monitoring and analyzing the database will be increasingly difficult to maintain as more extreme and costly processes for detecting unreported occurrences are set in place in response to the audit.

As a result of the audit report, the Department will reassess the scope of the NYPORTS program. This reassessment may result in modification or elimination of defined reporting categories or possibly periodic suspension of the obligation of reporting into select categories to focus efforts on others. Statutorily defined categories will not be altered.

* Note 5

Completeness of Information - Department Enforcement of Reporting Requirements

The Department disagrees with OSC's contention that there is no formal criteria for determining when enforcement of violations of incident reporting requirements should occur. The Bureau of Hospital and Primary Care Services has long had an enforcement policy that applies to all regulations under our jurisdiction. This policy will be revised to specifically address NYPORTS.

* Note 6

Timeliness of Information - Occurrence Reporting

The report contends that the Department does not adhere to its written reporting requirements. Section 405.8 of 10NYCRR states, " hospitals shall report such incidents within 24 hours of when the incident occurred or when the hospital has reasonable cause to believe that such an incident has occurred." By regulation, these requirements apply to the most serious occurrences (900 codes) as defined by statute. However, the Department has also applied these reporting requirements to the non-statutorily defined 900 code occurrences to require facilities to focus their efforts on serious occurrences. For non-900 code occurrences, the Department has developed written policies that allow facilities additional time to report. The Department based their NYPORTS reporting requirements for most serious and less serious occurrences on the provisions set forth in statute and regulation. For other codes, the Department has set longer reporting timeframes as outlined in the User's Manual. The Department feels that it has not only adhered to statutory and regulatory requirements; it has in some cases exceeded requirements.

* Note 7

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.

Response #1:

The Department has undertaken efforts to identify unreported occurrences through efforts taken by its subcontractors, the School of Public Health and IPRO. Existing sampling methodology which is utilized by the School of Public Health and IPRO generates a list of potentially reportable occurrences that are then validated by the facility or by IPRO. As

* See State Comptroller's Notes, pages 55-56

discussed previously, the ability to "systemically analyze" codes depends upon its ability to match to a sufficient degree with SPARCS. Many codes, including some of the most serious codes, are poor matches with SPARCS, and as a result, do not lend themselves easily to this type of analysis. NYPORTS codes were chosen based upon their potential to positively and significantly impact patient safety; they were not chosen based upon their ability to match with SPARCS to validate completeness of reporting.

The School of Public Health is currently developing a sampling methodology that may be applied to a greater number of codes. For example, they currently have the ability to generate lists of potentially unreported events for the following 900 codes: 913, 916, 922, 923, 938, and 963. While this listing is preliminary, the School of Public Health feels they may be able to extend this methodology to identify additional 900 codes requiring Root Cause Analysis (RCA).

In addition, the audit report states that the Department does not have adequate methods to identify outpatient occurrences. The School of Public Health was recently approved by the Data Protection Review Board to access outpatient data. This request was not previously made because SPARCS did not begin collecting outpatient data statewide until September 2003. Since access has been approved, the School of Public Health will begin analysis when the data becomes available.

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.

Response #2:

A policy directive that modifies existing hospital enforcement criteria to specifically address NYPORTS has been drafted by the Bureau and shared with the hospital program directors from all regions at a recent meeting. In addition, this directive will be reinforced with regional office coordinators through a conference call to be scheduled during April 2004. Those parts of the revised policy directive that introduce new responsibilities have been shared and discussed with regional office staff to ensure full understanding of the expectations relative to NYPORTS policy and procedure. This policy directive will be finalized for implementation June 1, 2004.

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.

Response #3:

The Bureau will monitor NYPORTS related activities at the regional office level through communications provided by the regional office, as specified in the policy directive to be issued.

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.

Response #4:

If unreported occurrences are identified through Department–sponsored analysis of NYPORTS data, the regional office will apply criteria as specified in the NYPORTS policy directive to determine whether to cite or to recommend enforcement. The regional office will then issue Statements of Deficiencies or recommend enforcement action as applicable.

Occurrences identified by IPRO retrospective review activities will be evaluated for citation or enforcement based on existing Department criteria. The Department will consider the "date the facility became aware of the occurrence" as the date the facility receives IPRO notification of unreported occurrences.

In instances where the facility and IPRO have subsequent discussions regarding the reportability of an occurrence, the "date the facility became aware of the occurrence" will be the date of the final decision letter issued by IPRO.

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.

Response #5:

All occurrences provided from clinics that were not entered into NYPORTS at the time of the audit will be entered electronically within six months. Regional offices have been directed to ensure timely input of clinic reports to prevent significant backlogs from occurring.

Recommendation #6:

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

Response #6:

The draft policy directive requires the regional office NYPORTS coordinator to generate a monthly past due report, and follow up on those occurrences that appear on the report. Facilities will be notified by letter of their past due reports and will be expected to submit overdue investigative reports within ten days of notification. Facilities that do not comply by the specified date will be cited for late reporting.

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.

Response #7:

Regional offices have been directed to follow up on missing investigation reports identified during the audit. Regional offices will contact those hospitals with missing investigative reports and require them to submit the missing information to the system. Should a hospital not comply, it will be cited.

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.

Response #8:

The Department has requested that its subcontractor add a data field to indicate whether the investigative report is considered complete by the facility.

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.

Response #9:

The Bureau has created a review instrument based on national standards which will be used by regional office coordinators to determine whether submitted facility investigative reports (RCAs) are credible and thorough. The review instrument is to be field tested in the near future, modified according to feedback, and adopted for statewide use in review of RCAs. When a RCA is determined to be credible and thorough by the coordinator, this information will be documented on the review screen. Hospital program directors will periodically review a sample of RCAs from each of their offices to determine whether

reports were reviewed in accordance to expectations and report review activities to central office in their quarterly reports.

Recommendation #10:

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

Response #10:

The Bureau's draft policy directive requires regional office coordinators to document review and oversight activities on the review screen. Modifications will be made to the review screen to accommodate additional fields. Central office will randomly review a sample of NYPORTS cases in the database from each regional office to determine compliance with documentation expectations. Central office will record the results of these reviews and where non-compliance is identified, the regional office will be directed to comply.

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.

Response #11:

Regulations and the User's Manual will be updated to ensure consistency with reporting timeframes, policies, and procedures. Further, NYPORTS will be modified to include a new field that will require the facility to input the date they became aware of the occurrence.

Facilities will be notified of revisions to NYPORTS policy in several ways:

- NYPORTS Statewide Council
- Dear CEO letter
- NYPORTS News and Alert
- NYPORTS Bulletin Board
- User's Manual revision and distribution to facilities

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.

Response #12:

The draft policy directive outlines written policies and procedures that guide the regional offices in citation and enforcement decisions. Central office will receive quarterly reports from each regional office pertaining to oversight activities. Central office will review these reports to monitor regional office oversight.

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.

Response #13:

The Department will work with its subcontractor to develop an administrative report that will be generated by regional/central office staff to identify late reporting facilities. Regional offices will generate past due reports on a monthly basis and follow up as specified in the draft policy directive. Central office will periodically generate the report to determine that regional offices implement policy directives as required. Any regional office not doing so will be directed to comply.

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.

Response #14:

The draft policy directive specifies that reporting timeframes originate with the date that the facility becomes aware of an occurrence, in keeping with current practice of NYPORTS reporting. As noted in Response 11, a field to capture the date that the facility becomes aware of an occurrence will be added to the short form in NYPORTS. The electronic system will be modified to ensure that this date is used as a starting point to calculate past due reports.

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.

Response #15:

The Department is working with its subcontractor to enhance the review screen. Enhancements will include the addition of a field to capture the date that extensions were approved. This date will be used in monitoring facilities for compliance with reporting timeframes.

Recommendation #16:

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

Response #16:

The Department is working with its subcontractor to ensure the validity of critical dates entered into NYPORTS. Validity will be ensured through system enhancements, making it impossible to enter future dates.

Recommendation #17:

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

Response #17:

The Department is working with its subcontractor to eliminate the facility's ability to delete reports of most serious occurrences from NYPORTS. Until the enhancement is in place, facilities will be notified through the News and Alert to contact their regional office if they determine a deletion may be necessary. If the regional coordinator is in agreement, the case will be deleted and the date will be recorded on the NYPORTS review screen.

When the enhancement is in place, the facility will be unable to delete most serious occurrences and the system will direct them to contact their regional office for assistance if a deletion of a serious occurrence is attempted. After consultation with the facility and a determination that the occurrence does not meet reporting criteria, the regional coordinator retains the ability to delete the case from the system. The date of deletion will be entered into the NYPORTS review screen.

Recommendation #18:

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

Response #18:

The Department has issued a directive that will require the regional office to use and retain the standard Health Program Network form, signed by the requestor, to document changes in user access rights.

State Comptroller's Notes

1. We modified our report accordingly.

2. As stated in our report, the coverage provided by the Department's systematic analysis could be very limited, since none of the most-serious occurrences and only a small portion of the less-serious occurrences are included in the Department's systematic analysis. The Department recognizes 54 different types of occurrences, 19 of which are classified as most-serious and 35 of which are classified as less-serious. The Department's systematic analysis of unreported occurrences focuses on five types of less-serious occurrences. We recommend that the Department expand its systematic analysis to include additional types of occurrences, and in particular most-serious occurrences, to enhance its efforts to identify unreported occurrences and focus its efforts on those areas that pose the most risk. (See additional comments in State Comptroller's Note 5.)

3. As stated in our report, while SUNY and IPRO may identify a certain number of unreported incidents, SUNY and IPRO focus their analyses on five types of less-serious occurrences. While IPRO's annual review of 20,000 Medicaid hospital cases is not limited to the five types of less-serious occurrences, the additional coverage provided by these Medicaid reviews is small, as the reviews address a very small portion of the total number of inpatient cases in New York State (a total of about 2.5 million inpatients are discharged each year in New York).

4. We recognize that complaint investigations need to be performed and serve an important purpose, but they cannot be relied on as a primary source of unreported NYPORTS occurrences. As stated in our report, we determined that the Department's field offices usually do not identify unreported occurrences when they investigate complaints. During our audit period of nearly 29 months, the six field offices we visited identified only 20 unreported occurrences while investigating complaints.

5. We agree that the Department's efforts to identify unreported occurrences should not be disproportionate to the prudent use of taxpayer dollars for the improvement of patient safety. As stated in our report, we recommend that the Department consider supplementing its current efforts by using a formal risk assessment process to determine which types of occurrences, and which hospitals, are to be selected for underreporting analysis. Such a risk assessment process should be relatively inexpensive and not resource intensive. For example, during the course of our audit, we compared individual hospital occurrence reporting rates to the statewide average occurrence reporting rates for the 19 most-serious occurrence codes reported on NYPORTS in 2001 and 2002 (statewide average was per 100,000 inpatient discharges reported on SPARCS). Of 263 hospitals, we identified 119 hospitals in 2001 (45 percent) and 114 hospitals in 2002 (43 percent) that had occurrence reporting rates that were

below the statewide average. More specifically, 61 hospitals (23 percent) had occurrence reporting rates that were more than 50 percent lower than the statewide average during both years. While these results may indicate some hospitals that have legitimately low reporting rates, conversely, the results may reflect that hospitals are underreporting occurrences. An assessment of hospitals' policies, procedures, practices and controls for ensuring full reporting may help to distinguish where the risk is more apt to result in real problems. This fairly simple and inexpensive methodology could be used to supplement Department efforts to identify unreported incidents.

6. During our audit we reviewed the enforcement policy noted in the Department's response. As the Department agrees in its response, this policy does not specifically address NYPORTS. As stated in our report, the Bureau of Hospital and Primary Care Services had informal expectations for its field offices when issuing citations for non-compliance with NYPORTS reporting requirements. Not all field offices were aware of these expectations. Moreover, the Department agreed to revise its written policy to specifically address NYPORTS.

7. In response to our preliminary audit findings, the Department stated it does not use the timeframes contained in the State Regulations or the NYPORTS Users Manual. Rather, the Department uses different timeframes and measures reporting time from the date the facility became aware of the occurrence, not the date the occurrence took place. As we stated in our report, these revised reporting expectations were not in writing, were not issued to the medical facilities, and were not incorporated into the NYPORTS database. We identified 4,845 occurrences that were reported an average of 40 days after the occurrence took place. Of these, 487 were reported more than 90 days after the occurrence took place. Regardless of which expectation is used, (State Regulations, NYPORTS Users Manual, or the Department's informal expectations), facilities are not complying with reporting timeframes.

cc: Mr. Conroy
Mr. Heigel
Mr. Howe
Mr. Osten
Mr. Reed
Mr. Scott
Mr. Van Slyke

Department Of Health
Comments On The
Office Of The State Comptroller's
Final Audit Report
2003-S-27 Entitled "Maintaining Information on Adverse Patient Incidents at Hospitals and Clinics"

The following are the Department of Health's (DOH) comments in response to the Office of the State Comptroller's (OSC) final audit report 2003-S-27 entitled "Maintaining Information on Adverse Patient Incidents at Hospitals and Clinics."

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.

Response #1:

The School of Public Health's (SPH) sampling methodology for most serious events has been used to generate lists of potentially reportable NYPORTS occurrences for Codes 913 (Retained foreign body), 914 (Misadministration of radioactive material), 916 (Unexpected cardiac arrest), 922 (Suicide or attempt with serious injury), 938 (Malfunction of equipment), and 963 (Rape by another patient or staff). In the Department's initial response, the codes proposed for analysis were 913, 916, 922, 923, 938, and 963. Code 923 (Elopement from hospital leading to death/serious injury) was dropped from the list of selected codes for analysis and replaced with Code 914 because Code 914 was determined to be a better match with the SPARCS database. The next step in the process is to have IPRO perform chart reviews to determine the validity of SPH's sampling methodology. Assuming that IPRO determines SPH's sampling methodology to be valid, it could be applied to other most serious codes, after appropriate refinement.

In addition, the SPH is currently examining the use of low mortality diagnostic related groups (DRG) to identify potentially reportable unexpected deaths (Code 915). SPH expects to compile and present the preliminary data on this subject in the near future.

Preliminary results of outpatient data analysis have been compiled and show that very few deaths and a small number of potentially less serious NYPORTS reportable events were identified. Outpatient data for most serious NYPORTS events has not been examined, but the SPH is in the process of this analysis. Depending upon the results of the most serious event analysis, the Bureau will determine whether further analysis of outpatient data is warranted from a cost-benefit perspective.

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.

Response #2:

A policy directive issued in June 2004 outlines the expectations relative to issuing citations and referring cases for enforcement. The reporting requirements that pertain to each category of NYPORTS reportable events are specifically defined. NYPORTS has been reprogrammed to provide past due reports that monitor for timeliness of reporting for all regulatory and statutorily mandated timeframes associated with the most serious reporting categories (900 codes). Regional office NYPORTS coordinators generate a monthly report that lists occurrences that were not reported within required timeframes. These occurrences are then grouped and a Statement of Deficiencies (SOD) is issued to each facility that has late reported occurrences. The facility must submit a Plan of Correction to address the deficiencies noted on the SOD, and DOH will accept or reject the plan per routine Department procedures.

Regional offices will refer a facility for enforcement action if events are either egregious or repetitive in nature, per existing Bureau of Hospital and Primary Care Services (Bureau) policy. Egregious events may include, but are not limited to, wrong side surgery events or deliberate concealment/willful non-reporting of deaths or serious injury. Repetitive events will be referred for enforcement if facilities are cited three successive times within one year for the same type of deficiency.

If a facility is referred for enforcement action, the regional office will prepare an enforcement recommendation package and send it to the Bureau for processing and referral to the Department's Division of Legal Affairs.

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.

Response #3:

The Bureau is monitoring NYPORTS activities undertaken by the regional offices in several ways. First, regional NYPORTS coordinators have frequent contact with Bureau staff in matters of code interpretation, system issues, and policy. Feedback is provided to

NYPORTS coordinators individually or to all NYPORTS coordinators statewide, depending upon the situation and/or guidance provided.

Second, each regional office NYPORTS coordinator provides the Bureau with a quarterly Activity Summary Report. This report provides NYPORTS related information as defined by the Bureau and requires sign off from the regional Hospital Program Director.

Third, the Bureau has assigned a staff person to provide oversight by analyzing NYPORTS reporting data and providing quality assurance feedback to both the Bureau and the regional offices.

Issues that are identified through any of the proceeding means will be brought to the attention of the regional offices through meetings and communications with Hospital Program Directors and/or the regional NYPORTS coordinators.

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.

Response #4:

Policies regarding retrospective reviews, such as the IPRO review process and the School of Public Health's Code 605 review, have been included within the NYPORTS Policy Directive to provide guidance to Regional NYPORTS coordinators. The revised IPRO process was implemented in November 2004. In accordance with this policy, regional NYPORTS coordinators will receive lists of non-reported occurrences on a quarterly basis from IPRO and on an annual basis from the School of Public Health. A Statement of Deficiencies will be issued to each facility listing all non-reported occurrences. Each facility will be required to submit a Plan of Correction that will describe their corrective action to address their Statement of Deficiencies.

Enforcement referrals will be made according to the enforcement policy provided within the NYPORTS policy directive.

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.

Response #5:

Regional offices have entered the Diagnostic and Treatment Center (D&TC) occurrence reports that were outstanding at the time of the audit. Support staff in the Buffalo,

Hudson Valley and Long Island regional offices have been trained in NYPORTS data entry to ensure the timely input of future D&TC occurrence reports.

Recommendation #6:

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

Response #6:

Regional NYPORTS coordinators generate past due reports on a monthly basis to monitor for Root Cause Analysis (RCA) timeliness of reporting and issue Statements of Deficiencies as appropriate. Under current NYPORTS policy, facilities can receive a citation for late reporting of their RCA at the 24-hour submission, 30-day extension request and 60-day RCA 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.

Response #7:

The Bureau has assigned a staff person to conduct quality assurance reviews of the database and provide the regional offices with lists of current and past occurrences with overdue investigation reports. Regional NYPORTS coordinators will follow-up with facilities to ensure that these overdue reports are entered into NYPORTS. Facilities that do not comply with the directive to enter this information by the specified date will be issued SODs. The Bureau will monitor regional offices to ensure timely follow-up with facilities.

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.

Response #8:

In October 2004, a field entitled "Date the facility certifies RCA complete" was added to NYPORTS. By entering a date into this field, facilities indicate to the DOH that all outstanding information has been entered into the RCA format.

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.

Response #9:

Following an extensive statewide training effort, the RCA protocol evaluation tool was implemented in November 2004, and is used to evaluate the credibility and thoroughness of each submitted RCA against established criteria. Once the tool is used and the RCA is deemed to be credible and thorough, the regional NYPORTS coordinator will document this status on the NYPORTS review screen.

Additionally, each regional Hospital Program Director reviews a sample of RCAs every quarter to determine whether the reports were reviewed in accordance with Bureau expectations. This second review is documented on the NYPORTS review screen for occurrences in the sample.

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.

Response #10:

A NYPORTS Policy Directive, effective June 2004 directed regional NYPORTS coordinators to use the NYPORTS review screen to document pertinent information, including facility contact and citation history. As part of the NYPORTS quality assurance (QA) review, review screen documentation for most serious events will be monitored for compliance with documentation expectations. The regional NYPORTS coordinators will be notified on a periodic basis of any issues that QA activities have identified.

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.

Response #11:

All written requirements associated with NYPORTS are being revised. The following steps have been taken to modify written requirements and communicate them to both DOH staff and medical facilities statewide:

- A regulatory reform effort to revise 10 NYCRR, specifically 405.8-Incident Reporting, is underway. New regulatory language has been drafted and will be presented for discussion to the Codes Committee of the State Hospital Review and Planning Council (SHRPC) in 2005.
- The NYPORTS User's Manual will be revised and distributed to facilities in 2005.
- The NYPORTS Policy Directive was issued to Regional offices in May 2004 and expanded upon in November 2004 at a regional NYPORTS coordinator's meeting. The enhanced document updated policies and added new procedures for retrospective reviews.
- The Bureau has held four Hospital Program Director meetings where subsequent changes in policy and procedures have been shared and discussed.
- A "Dear CEO" letter was issued to facilities in May 2004 with the purpose of notifying facilities of policy changes regarding NYPORTS.
- Two "NYPORTS News & Alert" newsletters were issued in May and November 2004, addressing audit related issues and revised/new policies.
- Two Statewide Council meetings were held. These meetings addressed audit-related issues and notified providers of new NYPORTS policies and procedures.
- The NYPORTS bulletin board is updated regularly with announcements and key documentation related to NYPORTS, such as the NYPORTS News & Alert and the RCA protocol tool.

New system enhancements are scheduled to be implemented on March 1, 2005. These enhancements will include improved monitoring capabilities for the Bureau and for DOH regional offices, as well as, improved functionality for all users. A statewide training effort will occur in preparation for this system rollout. DOH expectations for the reporting and investigation of adverse events will be clearly documented in these educational sessions.

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.

Response #12:

As stated in Response #2, the Bureau developed a NYPORTS policy directive that guides regional offices in determinations of non-compliance with reporting requirements, citations and enforcement referrals.

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 practice of these facilities.

Response #13:

Regional NYPORTS coordinators have the ability to generate a report that lists occurrences that were cited as part of a Statement of Deficiencies (SOD) for a specified timeframe. The regional office will use this report to track reporting requirements for specific facilities.

As part of the Bureau's quality assurance activities, facility compliance with reporting compliance will be monitored. Regional offices will be 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.

Response #14:

The date field, "Date the facility becomes aware", was added to NYPORTS in July 2004. After this date, all facilities are required to complete this field. Further, the monitoring reports have been modified to utilize this date as a starting point to determine reporting/investigation timeliness.

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.

Response #15:

A date field to capture the date that an extension was approved will be added to the NYPORTS review screen during the system rollout in March 2005. The regional NYPORTS coordinators will record the date in this date field when an extension has been approved.

In the interim, a date field to capture the date that an extension request is made was added to the NYPORTS review page. Calculations determining timeliness of RCA submissions will use the date of awareness as a starting point and the date that an extension is requested as its ending point. This time period will be not more than 30 days. Once an extension is approved, the facility will have an additional 30 days to submit their RCA to the Department. Calculations to determine compliance with the final RCA submission timeframe will be measured from the date of awareness to the RCA submission date. This time period will not be more than 60 days. Facilities that submit their RCAs late at the 30 day or 60 day timeframe will be cited.

Recommendation #16:

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

Response #16:

Several validity controls that address critical dates and the accuracy of other NYPORTS data have been implemented as part of the system enhancements that were made in July 2004. These controls include:

- Inability to enter future dates
- Inability to save a Code 911 unless "operating room" or "ambulatory surgery suite" is chosen in the Location data field
- All medication error codes (Codes 108-110) must have a corresponding 900 code entered into the Detail Code data field

As part of the enhancements to be implemented in March 2005, numerous validity measures will be introduced to improve data quality. Controls for the following critical dates will be added to the system in March 2005:

- Occurrence Date
- Date of Awareness
- Date of Birth
- Admission Date
- Discharge Date
- Readmission Date

Recommendation #17:

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

Response #17:

As specified above, the deletion policy for most serious events went into effect in June 2004. This policy required facilities to contact their regional NYPORTS coordinator prior to independently deleting a most serious 900 code. The regional office will consult with the facility to determine whether the deletion is justified, if necessary. If so, the egional office will delete the occurrence. Deletion requests will be retained to document justification and date of deletion.

Systems modifications were implemented in October 2004 that prohibit facilities from independently deleting 900 code occurrences requiring RCA. The control of this function will rest with the regional offices, pending consultation with the facility. The deletion date and justification will be recorded on the NYPORTS review screen.

Recommendation #18:

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

Response #18:

The Bureau has developed a form that the regional office will submit to request, terminate, or modify user rights access to NYPORTS. This form is found in Appendix B of the NYPORTS Policy Directive.

In addition, the Bureau has distributed a listing of personnel who currently have access to NYPORTS to each regional office. The regional office was asked to review and update the list, using the NYPORTS access form to document any changes in user access rights.