PERFORMANCE AUDIT

HOSPITAL INSPECTION PROGRAM

From The Office Of State Auditor
Claire McCaskill

Facility inspections and investigations could be more effective by using a risk-based system to target hospitals.

Report No. 2002-47
June 26, 2002
www.auditor.state.mo.us

Office of
Missouri State Auditor
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June 2002

YELLOW SHEET

Using a risk assessment system would increase the effectiveness of hospital inspections, and target resources in potentially substandard facilities

This audit reviewed hospital inspections and complaint investigations performed by the Department of Health and Senior Services staff and identified ways to use resources more effectively. The following highlights our findings:

Inspections not targeted to at-risk facilities

Department staff work reactively by conducting broad inspections when due by law and focused investigations on complaints. This approach does not consider factors that could identify facilities potentially providing substandard care. Under the current approach, department staff routinely inspect all systems of a hospital's operations for state law compliance, even though the law allows inspections limited to specific systems. (See pages 4 and 6)

High-priority complaint investigations initiated more quickly

A 2000 department internal review showing untimely complaint investigations prompted the department to focus full-time resources to high-priority complaints. This shift in focus worked. Prior to the change, the department had 19 high-priority complaints with untimely investigations, but only had three untimely investigations after the change. (See page 4)

Some on-site complaint investigations not always timely conducted

Auditors found 18 complaints with untimely on-site investigations. The elapsed time between receiving the complaint and starting the required on-site investigation ranged from several weeks to more than a year. In two of these cases, the on-site investigation had not started as of the end of audit fieldwork. (See page 4)

Deficiencies cited in inspections not effectively tracked until recently

Before July 2001, department staff recorded investigation and inspection results on separate systems. As a result the number, severity and frequency of deficiencies were not tracked or monitored for trends, which would be useful in assessing risk. (See page 7)

Many complaint investigations unfounded

During the audit period, bureau staff did not cite deficiencies in 55 percent of the 491 investigations of complaints considered "of less serious concern." Surveyors stated the concerns of complainants often proved to be inaccurate after reviewing medical records and interviewing hospital staff. (See page 4)

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HOSPITAL INSPECTION PROGRAM

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The State Auditor's Office audited the hospital inspection program of the Department of Health and Senior Services, Bureau of Health Facility Regulation (bureau). The objectives of the audit were to determine whether (1) surveyor resources were effectively managed, (2) complaint investigations were timely conducted, and (3) inspections of hospitals and hospital-based nursing facilities were properly performed.

Bureau officials have made improvements to serious complaint response time and identification of high-risk hospitals, but more can be done to ensure effective resource management A risk-based approach to determining (1) the timing, frequency and scope of facility inspections and (2) the investigation of complaints would enhance the changes being made.

The audit was conducted in accordance with applicable standards contained in *Government Auditing Standards,* issued by the Comptroller General of the United States, and included such tests of the procedures and records as were considered appropriate under the circumstances.

Claire McCaskill
State Auditor

January 17, 2002 (fieldwork completion date)

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RESULTS AND RECOMMENDATIONS

Resource Management Needs Improvement

Department of Health and Senior Services - Bureau of Health Facility Regulation (bureau) officials can better manage resources for investigating complaints and inspecting[1] hospitals and hospital-based nursing facilities. Bureau staff conduct focused complaint investigations and routinely inspect facilities when required by state or federal law. The following problems exist with current practices:

- Surveyors did not timely investigate some complaints.
- Some inspection tasks did not meet federal or state guidelines.
- Resources to substantiate a complaint's significance before investigating on-site are not used effectively.
- Data on cited facility deficiencies useful to a risk-driven system have not been tracked until recently.

Increasing inspection and investigation responsibilities of the surveyors has contributed to these problems. As a result, the inspection program is not as effective as it could be, and some facilities may be allowed to provide substandard care without proper detection. A risk-driven system would improve resource management and result in more frequent and extensive reviews of facilities seemingly providing inappropriate or substandard patient care.

Bureau complaint investigation and inspection procedures

Bureau staff review the operations of hospitals and hospital-based nursing facilities for compliance with state and federal health care standards during complaint investigations, Medicare surveys, and licensing inspections. The bureau employs environmental sanitarians, nurses, and dieticians to conduct these procedures. *(See Appendix II, page 11, for a more detailed discussion.)*

Complaint investigations

Investigations are initiated by an on-site visit or an information request about a complaint followed by an on-site visit. During the on-site visit, bureau staff will observe procedures, review records and interview hospital personnel. The bureau prioritizes complaints into five categories.

- Priority I complaints include allegations of immediate and serious threat to the health and safety of patients. The Centers for Medicare and Medicaid Services of the U.S. Department of Health and Human Services (federal medical services) requires

[1] Throughout this report, "inspect" refers to the processes performed by bureau staff for both surveys for compliance with healthcare standards required by federal regulations and inspections for compliance with healthcare standards required by state licensing law.

surveyors to investigate Priority I complaints within 2 working days. Approximately 7 percent of all complaints are classified as Priority I.

- Priority II, III, and IV complaints represent less serious concerns. Surveyors usually investigate Priority II and III complaints before the next regularly scheduled facility inspection and Priority IV complaints during the next regularly scheduled facility inspection. Approximately 61 percent of all complaints are classified as either Priority II or III.

- Priority V complaints have no reasonable basis to investigate, or are referred to other organizations to investigate.

Bureau staff must notify and obtain authorization from federal medical services officials before conducting any investigation related to federal standards of accredited facilities. However, bureau staff may investigate complaints on accredited hospitals without authorization if the complaint alleges a violation of state law. Table 1.1 lists the time frames to initiate complaint investigations.

Table 1.1: Complaint Investigation Time Frames

Priority	Type	Time frame (working days)
I	All	2
II	All	10
III	Accredited hospital	45[1]
III	All except accredited hospitals	60
IV	Accredited hospitals	45[1]
IV	All except accredited hospitals	Next scheduled inspection

[1] From the day federal officials notify the state a review under federal law is necessary. An investigation for compliance with state laws is to be conducted within 60 days for Priority III complaints or the next scheduled inspection for Priority IV complaints, if federal officials have not responded by then.

Source: Bureau complaint policy

Audit staff reviewed complaints received by the bureau from October 1, 1999, to December 31, 2001. *(See Appendix I, page 10, for a more detailed discussion of the audit scope and methodology.)*

Inspections

Through contracts with federal medical services, bureau staff inspect hospitals and hospital-based nursing facilities for compliance with federal health and safety requirements. State law requires the bureau to inspect all licensed hospitals and hospital-based nursing facilities for compliance with state health and safety requirements. Audit staff observed three inspections. *(See Appendix I, page 10, for a more detailed description of the audit scope and methodology.)*

Surveyor resources can be used more effectively

Bureau management has not developed a good system to focus review resources on facilities at greatest risk of non-compliance with federal and state law. Bureau staff work reactively by conducting broad inspections when due by law, and focused investigations on complaints. This system does not consider factors that could identify facilities providing more substandard care. Most complaints are investigated individually, which limits staff time available for inspection responsibilities. This method of allocating resources is not efficient or effective because most complaints are unfounded as discussed below. Additionally, increased complaint volume caused bureau staff to be slow investigating some complaints.

Surveyors can be more productive

Most complaint investigations do not yield deficiencies

Complaint investigation results suggest resources could be used more effectively. About 55 percent of 491 complaints investigated over the 27 months reviewed were unfounded. These investigations involved Priority II and III complaints, considered "of less serious concern," and occurred between October 1, 1999, and December 31, 2001.

Bureau staff cited deficiencies[2] even less frequently for complaint investigations under state law when federal medical services officials determined the complaint not worthy of investigation under federal law. In these instances, the bureau cited deficiencies in 69 of 204 investigations (34 percent). Surveyors stated the concerns of complainants often proved to be inaccurate based on reviews of medical records and interviews of hospital staff.

Timeliness improved for some complaint investigation

In a July 2000 internal review of complaint investigations, bureau management noted some complaints were not investigated within the required timeframes due to the high volume of complaints received. In response, beginning January 1, 2001, some surveyors were assigned full-time to investigate Priority I and II complaints.

This change has been effective. During the 15 months prior to the change, 10 of 45 Priority I and 9 of 122 Priority II complaint investigations were not timely initiated; however, since January 1, 2001, only one Priority I and two Priority II complaint investigations were not timely initiated.

However, some timeliness problems still exist in the complaint investigation process. Bureau staff initiated on-site investigations of 18 Priority I, II or III complaints by requesting facility records, but the on-site investigation did not occur timely[3] as summarized in Table 1.2. As of January 17, 2002, staff had not started an on-site investigation in two of these complaints. The elapsed time from complaint receipt to on-site investigation ranged from several weeks

[2] Noncompliance with applicable federal or state standards.

[3] Judgmentally determined based on when the complaint was assigned for investigation taking into consideration the time frames for each priority type discussed on page 3.

to more than a year. Staff canceled the investigation on one complaint (00-069) because too much time (18 months) elapsed from the receipt of the complaint.

Table 1.2: Untimely On-site Complaint Investigations

Complaint Number	Priority	Complaint Receipt	On-site Investigation	Elapsed Days from Receipt to On-site
00-007	II	October 6, 1999	December 10, 1999	65
00-009	II	October 6, 1999	November 4, 1999	29
00-069	III	December 3, 1999	Not done	N/A
00-140	I[1]	January 28, 2000	April 19, 2000	82
00-148	II	February 3, 2000	Pending	714[2]
00-154	II	February 14, 2000	May 8, 2000	84
00-222	II	April 3, 2000	October 18, 2000	198
00-230	II	April 10, 2000	August 18, 2000	130
00-245	II	April 24, 2000	August 22, 2001	485
00-366	II	August 17, 2000	August 23, 2001	371
00-378	II	August 23, 2000	December 5, 2000	104
00-382	II	August 29, 2000	March 20, 2001	203
00-398	II	September 5, 2000	November 20, 2000	76
01-167	III	March 13, 2001	Pending	310[2]
01-196	III[3]	March 28, 2001	August 21, 2001	146
01-211	III	April 5, 2001	July 31, 2001	117
01-214	III	April 9, 2001	August 21, 2001	134
01-222	III	April 19, 2001	October 10, 2001	174

[1] Complaint involved an issue which is to be investigated within 21 days.

[2] As of January 17, 2002 the on-site visit was still pending.

[3] Reassigned as a Priority IV case 4 months after the complaint was received with no explanation.

Source: Auditor review of bureau complaint files

Bureau officials stated they adopted the policy for on-site investigation of virtually all complaints to respond to citizens and reduce the risk of missing a significant facility weakness. The same risk still exists if overworked staff pursue unfounded concerns. This policy needs to be evaluated since less than half of the investigations result in cited deficiencies. Other resources such as the hospital quality assurance staff, ombudsman,[4] or local health departments could conduct a preliminary investigation to substantiate the complaint. This approach would free up staff time and allow more timely investigations of serious cases.

Investigation policy ties up resources

[4] Ombudsmen assist long-term care residents in hospital-based nursing facilities with problems or complaints as part of a program that receives state and federal funding.

Investigation and inspection responsibilities have increased

Bureau staff receive more complaints and conduct more inspections than in prior years. Table 1.3 lists the number of complaints received annually for the 5 years ended June 30, 2001.

Table 1.3: Complaints Received

State Fiscal Year Ending June 30	Total Complaints Received
1997	78
1998	100
1999	243
2000	410
2001	442

Source: Department of Health and Senior Services budgets

Federal law changes in 1999, which require hospitals to notify patients of their right to file a grievance with the hospital and/or bureau, contributed to the sharp increase in complaints. Additional contributing factors include publicity about significant deficiencies found at some hospitals and health care industry changes impacting patient care. In addition to the increasing complaint volume, a new 2001 state law[5] requires biannual inspections of the state's 57 hospital-based nursing facilities. This law increased the bureau staff's workload by adding a second state inspection beyond the federal inspection already conducted by the bureau.

A risk-driven system would enhance targeting of facilities for inspections

Bureau management should determine the scope of each inspection by assessing the likelihood of non-compliance with healthcare standards. Risk indicators, including prior review results and complaints received could be used for these purposes. Using this approach, minimal-risk facilities would receive more limited inspection focusing on the most significant systems, while higher-risk facilities would receive more extensive or frequent inspections.

Under the current system, bureau staff conduct hospital and hospital-based nursing facility licensure inspections which routinely review all systems of a hospital's operations for state law compliance even though the law allows inspections limited to specific systems.

To implement a risk-driven inspection system, the bureau must develop and track indicators to set quality of care expectations at each hospital and hospital-based nursing facility. These expectations could be used to determine the timing and scope of the inspection. Additionally, for non-accredited hospitals, the bureau could use the risk indicators to determine the appropriate frequency for specific hospital inspections. Bureau staff routinely inspect each of these hospitals once every 3 years, which is not required by federal law. The federal law only requires

[5] Section 198.525, RSMo 2000

inspection of 33 percent of the non-accredited hospitals each year. Consequently, bureau staff could inspect at-risk non-accredited hospitals more frequently and still comply with federal law.

Trend analyses are needed

Deficiencies cited from inspections and investigations at each hospital need to be tracked. The number, severity and frequency of deficiencies at facilities would be useful in determining risk. Before July 2001, the results of inspections and investigations were recorded on separate systems. Consequently, officials could not analyze the deficiencies to identify trends. In July 2001, the bureau staff began using a new computer system to record the results of inspections and investigations performed. Division and bureau officials intend to use this new computer system to evaluate and track the deficiencies cited most often. But as of the end of our fieldwork, there were no plans to use the data to determine the timing and scope of inspections. This improved tracking of deficiencies will allow better monitoring of program results and provide necessary data for a risk-driven inspection process.

Some inspection activities were untimely

The inspection workload of the staff impacts work results. Audit staff observed three inspections and determined that none of the facilities received a deficiency report within the required time frames. Bureau staff transmitted the reports 5 days late for 2 inspections and 10 days late for 1 inspection.[6] Additionally, surveyors erroneously excluded an identified deficiency from the report for one of the facilities. Bureau officials did not detect the oversight until our inquiries about 2 months after completion of the inspection.

Bureau management previously noted untimely reports of deficiencies from periodic internal reviews; however, actions taken have not been effective. Since completion of the inspections we observed, bureau officials have implemented a computerized tracking system to help monitor deficiency reports and ensure they are transmitted timely. These reports need to be prepared timely to ensure more immediate corrective action.

Conclusion

Bureau officials need to better manage the increasing workload caused by more complaints and state law changes. Although some changes have improved the response time to serious complaints and overall identification of high-risk hospitals and hospital-based nursing facilities, more can be done to ensure resources are used effectively.

Recommendations

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

1.1 Establish a risk-based approach to assessing Priority II and III level complaints that effectively uses available resources.

[6] After completion of an inspection, bureau staff must prepare deficiency reports within 10 calendar days for inspections done under federal law or 10 working days for inspections done under state law.

1.2 Establish a risk-based approach to determine the timing, frequency, and scope of facility inspections when allowable by law. This approach would include indicators, such as prior review results; number, type and frequency of complaints; and other factors.

1.3 Establish time frames for on-site investigation of complaints for which records have been requested from facilities.

Department of Health and Senior Services Responses

The Division of Health Standards and Licensure agrees that a system of risk-driven approach for investigations conducted on an annual basis could be utilized. However, the Division does not support such an approach for investigations of complaints. We will not support a system that could put Missouri citizens at risk. If one patient in the state of Missouri has the potential to be harmed or receive poor quality of care due to a risk-driven approach, then it is not a viable alternative to our present system.

If we would go to a risk-driven system such as you have indicated, there is a possibility of a complaint, that was truly substantiated and with a serious threat to the patients of Missouri, not being investigated. The Division has noted that, on more than one occasion, a complainant has not provided us with enough information; and the complaint has been given a lower priority. When the complaint is investigated, it has been substantiated and the findings are much more serious than was first realized. The lack of sufficient information from the complainant is of no fault of the person taking the information. The complainant may not have had the knowledge of what to report, only that something about the care that they or their loved one received was not appropriate.

The Division of Health Standards and Licensure does not agree with the auditor's suggestion to use outside resources such as the facility quality assurance staff, ombudsman, or local health departments to conduct a preliminary investigation to substantiate the complaint. The following reasons are the basis for our decision:

If we contract this process out, we could not ascertain confidentiality or the quality of the reviews.

We would have to budget for this contract service with outside agencies. At the present time, our surveyors on many occasions are able to complete more than one survey process at the time of the complaint investigation. Often more than one complaint is investigated at the same time. The current process utilizes our resources in a fiscally responsible manner.

The recommendation to use the facility's quality assurance staff to conduct a review of the complaint is not feasible. It is often the case that when an investigation, either for a complaint or for an annual review, is conducted quality assurance is cited as having deficiencies. It is the stance of the Division of Health Standards and Licensure, that investigation of complaints by the facility's quality assurance staff is a significant conflict of interest, causing under reporting of actual substantiated deficiencies. This may cause a rise in deficient practice that could cause harm to the residents of Missouri.

In response to the untimely on-site complaint investigations as listed in Table1.2 of the draft audit report, review of these records was done with the following notations made.

Many of the records were requested in advance to review, so that a risk-driven approach to the investigation could be taken. After review of these records, we could determine if a surveyor needed to be on-site sooner than first determined. This was done according to our own internal policy under licensing in an effort to utilize our resources in the most responsible manner. Keeping the safety of the patients of Missouri always in the forefront, it is difficult to always distinguish when to request records, because it does allow the facility to know that an investigation is being conducted. According to Medicare protocols, complaint investigations are not to be announced prior to the on-site survey and the complainant is to remain anonymous.

The delay of more than one of these complaints was due to the fact that a survey activity was scheduled at a later date and the survey activity would be combined. The bureau administration made the decision it would be a more responsible use of our resources to delay an on-site complaint investigation and combine with previously scheduled survey activity.

Delay of more than one of these complaints was due to bureau administration waiting for a determination from Medicare whether to investigate under Medicare regulations. If the complaint had been investigated under licensing, a second visit would have been indicated when authorized by Medicare. The bureau administration made the decision it would be a more responsible use of our resources to delay until a determination by Medicare was made.

As you identified in your report, the Division of Health Standards and Licensure has recently implemented an internal tracking system. This system has made the tracking of survey processes much more efficient. Bureau administration believes that using internal quality assurance tools, such as the tracking system, will aide in the implementation of future processes that will enhance the use of our limited resources and at the same time assuring quality health care to Missouri citizens.

APPENDIX I

OBJECTIVES, SCOPE AND METHODOLOGY

Objectives

The objectives of this audit were to determine whether (1) surveyor resources were effectively managed, (2) complaint investigations were timely conducted, and (3) inspections of hospitals and hospital-based nursing facilities were properly performed.

Scope and Methodology

Audit procedures included:

- Review of the computerized complaint tracking system for complaints received from October 1, 1999, through December 31, 2001, and the related hardcopy complaint files for complaints received from October 1, 1999, through June 18, 2001.

- Observation of the procedures performed by the surveyors during the inspection of the nursing facility at Boone Hospital Center and Cedar County Memorial Hospital and the inspection of Royal Oaks Hospital. Review of the related statements of deficiencies, plans of correction, and other documentation prepared by the surveyors. The inspections occurred during August and September 2001.

- Review of relevant statutes, regulations, and the State Operations Manual of the Department of Health and Human Services - Centers for Medicare and Medicaid Services.

- Interviews of staff of the Division of Health Standards and Licensure and the Bureau of Health Facility Regulation.

- Review of other records and procedures of the Bureau of Health Facility Regulation as necessary.

APPENDIX II

BACKGROUND

Overview

Within the Department of Health and Senior Services - Division of Health Standards and Licensure, Bureau of Health Facility Regulation (bureau) staff review the operations of hospitals and hospital-based nursing facilities for compliance with state and federal standards for health care during Medicare surveys, licensing inspections, and complaint investigations. The bureau employs environmental sanitarians, nurses, and dieticians to conduct these procedures.

Inspections

Federal regulations require bureau staff to inspect hospital-based nursing facilities no later than 15 months after the previous standard inspection. Bureau staff inspect about 57 hospital-based nursing facilities. Bureau surveyors must conduct specific tasks designed to evaluate the quality of care provided by focusing on resident outcomes.

Federal regulations also require the bureau to annually inspect 33 percent of the hospitals not accredited by the Joint Commission on Accreditation of Healthcare Organizations. About 31 of the 144 licensed hospitals in Missouri are not accredited by the commission. The bureau surveyors must review patient records and hospital procedures, interview facility staff and patients, and observe the facility, equipment, supplies, and patient care.

State law requires bureau staff to conduct annual inspections of all licensed hospitals for compliance with state health and safety requirements. Under state law effective in 2001, the bureau staff must conduct 2 inspections annually of each of the 57 hospital-based nursing facilities. The new law essentially requires the bureau to conduct one additional inspection annually of each of these facilities because the annual federal inspection performed by the bureau fulfills the requirement for one of the inspections.

After completion of an inspection, bureau staff must prepare and send to the hospital or hospital-based nursing facility a statement of deficiencies within 10 calendar days for inspections done under federal law or 10 working days for inspections done under state law. The written statement of deficiencies must clearly identify the specific deficient practice. Officials of the hospital or hospital-based nursing facility must provide bureau staff with a written plan of correction for all deficiencies contained in the statement of deficiencies within 10 days. Bureau staff must evaluate the adequacy of the written corrective actions and ensure they are placed in operation. A revisit to the hospital or hospital-based nursing facility is often necessary to verify the implementation of the corrective action.

The time required of bureau staff to conduct an inspection usually varies according to the facility size. Often a team of three bureau surveyors will spend 3 days at the facility conducting the inspection.

APPENDIX II

Complaint investigations

Bureau staff investigate complaints about hospitals and hospital-based nursing facilities. Most of the complaints are concerns from individuals about care they or a family member received in a facility. On-site investigations are usually done. Sometimes, copies of medical records are obtained from the facility for review prior to the on-site investigation. Often, a surveyor spends a day at the facility reviewing records and interviewing hospital personnel to determine the validity of the complaint and whether the hospital has violated state or federal laws. Deficiencies discovered during complaint investigations are reported to the facility and the facility must develop and implement measures to correct them.