
Office of Facilities Regulation
Division of Health Services Regulation
Department of Health
Performance Audit
July 1, 2002 – December 31, 2004

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Auditor General

State of Rhode Island and Providence Plantations
General Assembly
Office of the Auditor General

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JOINT COMMITTEE ON LEGISLATIVE SERVICES:

SPEAKER William J. Murphy, Chairman

Senator Joseph A. Montalbano
Senator Dennis L. Algieri
Representative Gordon D. Fox
Representative Robert A. Watson

We have completed a performance audit of the regulatory functions related to nursing facilities performed by the Office of Facilities Regulation. The Office of Facilities Regulation is organizationally located within the Division of Health Services Regulation of the Department of Health. Our report also highlighted areas related to the oversight of nursing facilities which we believe may warrant further study and legislative deliberation.

Our report is contained herein as outlined in the Table of Contents.

Sincerely,

A handwritten signature in cursive script that reads "Ernest A. Almonte".

Ernest A. Almonte, CPA, CFE
Auditor General

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Executive Summary

Performance Audit – Office of Facilities Regulation – Department of Health

The Department of Health's Office of Facilities Regulation (OFR) did not perform all surveys of nursing facilities required by state law and did not meet state timeframes for investigating complaints for nursing facilities. Nine nursing facilities were issued a 2005 license without the required annual survey in calendar year 2004.

Both federal and state laws and regulations govern the regulation of nursing homes. Because the federal government, through the Medicaid and Medicare programs, is the largest payor of nursing home costs, nursing facilities must comply with federal regulatory requirements to maintain participation in the Medicaid and Medicare programs. The federal government supports these activities with federal grants and the federal requirements are largely complied with by OFR. State laws, in most instances, layer additional requirements over the federal requirements—these additional state requirements are usually not met principally due to lack of resources within OFR.

Federal regulations require a comprehensive certification survey of nursing facilities not later than 15 months after the previous survey; however, a statewide average of 12 months between surveys must be maintained. In practice, the federal certification survey also meets the required annual State licensing survey. State law further requires two unannounced surveys (interim surveys) each year. We found that OFR did not meet this requirement—interim surveys were not conducted for most nursing facilities in both fiscal years 2003 and 2004. State law also requires that any facility cited for substandard care shall be inspected on a bi-monthly basis for the twelve-month period immediately following the citation. We found that six out of seven facilities cited for substandard care between July 2002 and December 2004 were not inspected on a bi-monthly basis as required.

We recommended improvements in procedures to allow the tracking of deficiencies found on nursing facilities surveys throughout the survey process to final reporting. We also recommended that the Department of Health adopt the federal conflict of interest policy for all OFR employees to enhance the integrity of its regulatory process.

We found that OFR, in most instances, met the federal timeframes for complaint investigations but did not meet the more stringent seven-day investigation requirement mandated by state law. We also found that the prioritization of complaints using federal guidelines needs to be improved. The timeframe for investigating a complaint is dictated by the severity category assigned during triage. Because the individuals performing the triage of complaints are responsible for activities which compete for the same resources, there is an inherent risk of prioritizing the complaints in a less severe category to allow more time for investigation. We recommended these functions be segregated and that an immediate supervisory review be performed of complaint triage.

Executive Summary

Performance Audit – Office of Facilities Regulation – Department of Health

The State Long-Term Care Ombudsperson (LTCO) also receives and investigates nursing homes complaints. All LTCO complaints are not forwarded to the Department of Health for consideration and investigation. We believe this may distort OFR's perspective on conditions in a specific nursing home and limit its ability to perform fully its federal and state regulatory functions. We recommended that the LTCO forward all complaints received to the Department of Health to allow concurrent investigations as necessary.

The OFR needs additional resources to perform its mandated federal and state functions. First, we believe that OFR's responsibilities assigned by state law should be reexamined to affirm that these are the functions that best ensure overall quality of care in nursing facilities. State requirements that exceed federal requirements should be evaluated concurrently with estimating the additional resources needed to meet those statutory provisions. For example, meeting a seven-day complaint investigation timeframe may require as many as 11 staff dedicated just to this task.

OFR has prepared a staffing analysis to support its request for additional personnel; however, we found the analysis to be incomplete and unsupported in various respects. While the flaws in OFR's work plan analysis precluded us from concurring with the exact number of additional personnel that are needed, it is clear that additional resources are needed to comply with existing state requirements. We recommended that OFR revise and update its personnel budget request and accumulate data to support its estimates.

OFR does not currently review any financial data or assess the financial position of a nursing facility in conjunction with performing its federal and state regulatory functions. However, there is general agreement that a direct relationship exists between the fiscal soundness of a nursing facility and its ability to provide consistent quality care. Our report includes discussion of how financial condition information could be used as an indicator of increased risk of deteriorating quality of care and prompt more frequent inspections. Cost data currently collected by the Department of Human Services for rate setting purposes may, with minimal supplement, be able to be used to develop a fiscal rating for each nursing facility. This financial rating factor could be provided by DHS to OFR for use in a risk-based model, along with other relevant risk factors to determine frequency of inspection. These issues are discussed in a section of our report entitled *Matters Requiring Further Study or Legislative Deliberation*.

We have also highlighted other matters that require further study or legislative deliberation which are not solely within the control of the Department of Health. We believe these issues warrant consideration as corrective action, statutory changes, and budget appropriations are considered.

II. INTRODUCTION

OBJECTIVES, SCOPE AND METHODOLOGY

We conducted a performance audit of the regulatory functions related to nursing facilities performed by the Office of Facilities Regulation (OFR). OFR is organizationally located within the Division of Health Services Regulation in the Department of Health (DOH). Our audit was conducted in accordance with *Government Auditing Standards*. The period covered by our audit was primarily the fiscal years ended June 30, 2003 and 2004, and the current fiscal year through December 31, 2004.

Our audit focused on evaluating the practices and procedures utilized by the OFR in regulating nursing home facilities within its purview. Our objective was to determine whether these practices and procedures complied with federal and state laws and regulations, and were effective and efficient. We also evaluated the OFR's financing, management, and staffing to identify potential areas that could be improved.

Since we do not possess the clinical or technical training of OFR personnel, our audit objectives did not include (1) evaluating the professional judgment applied by OFR personnel in determining the scope and severity of deficiencies as defined by Federal regulation, (2) evaluating the appropriateness of enforcement actions other than those mandated by federal law and regulation, and (3) evaluating OFR's judgment used to prioritize the severity of alleged complaints against nursing home facilities, or whether those complaints should have been substantiated.

We accomplished our objectives by reviewing applicable federal and state laws and regulations (primarily Chapter 23-17, *Licensing of Health Care Facilities*) as well as the practices and procedures established by the OFR. In addition to interviewing the management and staff of the OFR and the Department of Health, we interviewed personnel within the Departments of Human Services, Elderly Affairs, and Attorney General that have responsibilities related to nursing facilities, and the State Ombudsperson's Office. We reviewed nursing facility survey files, and documentation relating to complaint intake and investigations. For the purpose of assessing the adequacy of OFR's resources, we reviewed available support for budget requests, actual appropriations, and reported expenditures and considered OFR's other responsibilities in addition to the regulation of nursing facilities.

The scope of our audit did not include evaluating the effectiveness of the State's General Laws as currently enacted; however, we have highlighted areas which we believe may warrant further study and legislative deliberation.

BACKGROUND

The Office of Facilities Regulation (OFR) is responsible for ensuring that all state licensed and federally certified health care facilities or providers meet the applicable conditions and regulations of the law. Compliance is formally determined through the licensure and certification process, which involves survey visits, follow-up revisits and other state mandated inspections for continuing compliance. OFR is also responsible for investigating complaints alleged against these facilities.

Authorization for the OFR is established in Chapter 23-17 of the Rhode Island General Laws entitled *Licensing of Health Care Facilities*. The statute authorizes the Department of Health to develop, establish, and enforce standards for the care and treatment of individuals in and by nursing facilities, so that individuals will receive safe and adequate treatment. The OFR is also responsible, under this statute and other sections of the General Laws, to regulate a wide range of facilities from hospitals, assisted living residences and clinical laboratories to phlebotomy stations, tattoo parlors, and body piercing establishments. In total, approximately 690 facilities are subject to regulation by the OFR (see *Appendix B – Summary of Facilities Regulated*). Some facilities, such as nursing facilities and hospitals are also subject to federal oversight and in these instances OFR acts as the state survey agency and provides services to meet federal regulatory requirements. OFR’s staff resources (39 full time equivalent positions as more fully described below) are intended to meet the regulatory requirements outlined in the general laws for all these facilities. The scope of OFR’s duties relating to these other entities includes licensing, conducting inspections, investigating complaints, and enforcing federal and state laws and regulations.

The OFR’s activities are funded through a combination of state appropriations and federal grants with the annual operating budget totaling \$3.7 million for each of state fiscal years 2003 and 2004. Federal grants account for approximately 60% of this total. The Centers for Medicare and Medicaid Services (CMS) provide the majority of federal funding to finance the OFR’s survey and certification activities.

Office of Facilities Regulation – Appropriations and Expenditures			
	SFY 2003	SFY 2004	SFY 2005
Appropriations:			
Federal Grants	\$2,155,803	\$2,254,846	\$2,190,598
General Revenues	<u>1,517,319</u>	<u>1,418,590</u>	<u>1,523,623</u>
Totals	<u>\$3,673,122</u>	<u>\$3,673,436</u>	<u>\$3,714,221</u>
Expenditures:			
Salaries and Benefits	\$3,210,246	\$3,155,651	
Operating	221,732	283,841	
Indirect Costs	<u>365,534</u>	<u>252,953</u>	
Totals	<u>\$3,797,512</u>	<u>\$3,692,445</u>	
Source: State accounting system			

The OFR is currently staffed with 39 employees comprised of 25 field surveyors (two positions are currently vacant), eight administrative/program management positions and six program support/clerical positions. As part of its survey and program management staff, OFR employs 15 nursing professionals, a physician, pharmacist, two nutritionists, one physical therapist, and four clinical social workers. Federal minimum qualification standards for long-term care facility surveyors require that all surveyors must successfully complete a training program and pass a Surveyor Minimum Qualifications Test.

The OFR's major activity is conducting onsite surveys and inspections to determine that residential nursing facilities comply with state and federal laws and regulations. Multi-disciplinary teams conduct surveys in approximately 150 to 200 hours. During state fiscal year 2004 there were 94 licensed Medicare/Medicaid certified facilities operating within the state and six non-certified facilities. There are approximately 10,000 authorized beds within these facilities.

The OFR reports the results of its nursing facility surveys through the national Automated Survey Processing Environment (ASPEN) database maintained by CMS. The CMS makes available to the public each facility's deficiency information (a facility's failure to meet a participation requirement) resulting from recertification surveys through its Nursing Home Compare website – www.Medicare.gov.

Most nursing facilities receive the majority of their revenues through the federal Medicare and Medicaid programs. The Department of Human Services (DHS), in accordance with its *Principles of Reimbursement*, establishes individual per diem rates used to reimburse nursing facilities participating in the Medicaid program. Medicaid reimbursement rates are based on a detailed annual cost report submitted by each nursing facility to DHS' rate setting unit. Medicaid reimbursement rates range, by facility, from \$120 to \$200 per day. Medicaid payments (federal and state) to nursing facilities in state fiscal years 2003 and 2004 totaled \$261 million and \$292 million, respectively.

III. FINDINGS AND RECOMMENDATIONS

STATE AND FEDERAL SURVEY REQUIREMENTS

Background

Surveys are performed of nursing facilities to meet both state and federal requirements. The State maintains an agreement with the federal Centers for Medicare and Medicaid Services (CMS) to conduct Medicare and Medicaid certification surveys for participating health care facilities in Rhode Island. Nursing facilities must comply with federal *Requirements for Long Term Care Facilities* (42 CFR Part 483, Subpart B) to receive payment under the Medicare or Medicaid programs. The Office of Facilities Regulation (OFR), as the state survey agency, is the entity responsible for conducting onsite surveys to certify compliance with the CMS' participation requirements. The OFR performs standard onsite surveys on all certified skilled nursing facilities and nursing facilities not later than 15 months after the previous standard survey; however, a statewide average interval between standard surveys of 12 months must be maintained. During state fiscal year 2004 there were 94 of these certified facilities operating and six non-certified facilities.

Standard surveys are periodic, resident-centered inspections that gather information about the quality of service furnished in a facility to determine compliance with the requirements of participation. Survey procedures and protocols are established in a State Operations Manual (SOM) developed by the CMS based on nursing home survey, certification and enforcement regulations at 42 CFR Part 488. The SOM provides detailed guidance on performing the required tasks as part of a standard survey. Based on the specific procedures detailed in the SOM, a standard survey assesses:

- ❑ compliance with residents rights and quality of life requirements;
- ❑ the accuracy of resident's comprehensive assessments and the adequacy of care plans based on these assessments;
- ❑ the quality of care and services furnished, as measured by indicators of medical, nursing, rehabilitative care and drug therapy, dietary and nutrition services, activities and social participation, sanitation and infection control; and
- ❑ the effectiveness of the physical environment to empower residents, accommodate resident needs and maintain resident safety.

Upon completion of the survey, the OFR prepares a CMS-2567 survey report, also referred to as the Statement of Deficiencies and Plan of Correction. The CMS-2567 formally communicates to the facility the deficiencies identified by the survey team. The report includes numerical deficiency codes, federal regulatory citations and a narrative summary of the evidence and supporting observations for each deficiency. The statement of deficiencies specifically reflects the content of each requirement not met, identifies the specific deficient facility practice, the objective evidence concerning these practices, and the source of the evidence. Each deficiency is assigned a letter code corresponding to a SOM scope and severity grid based on OFR's assessment of the deficiency's effect on resident outcome (severity) and the number of residents potentially or actually affected (scope). (See *Appendix A.*)

Facilities having deficiencies, not involving immediate jeopardy, must submit an acceptable plan of correction within 10 calendar days after receiving the CMS-2567 report. In cases of immediate jeopardy, the facility defers submission of a plan of correction until the immediate jeopardy has been removed. The plan of correction serves as the facility's allegation of compliance; the OFR must then verify the facility's substantial compliance based on a post survey revisit. The post survey revisit confirms that the facility is in compliance, and has the ability to remain in compliance.

OFR personnel upon completion of a survey event (e.g. certification, post survey revisit, etc.) upload survey results to a federally maintained database. Information contained within this database is made available to the public on the CMS website reflecting nursing home comparisons.

Enforcement remedies are imposed when a facility is not in substantial compliance. In instances where immediate jeopardy exists the CMS or state Medicaid agency will impose termination and/or temporary management in as few as two calendar days after the survey that determined immediate jeopardy. Additional remedies such as monetary penalties, directed plan of correction or denial of payment for new admissions may also be imposed. If immediate jeopardy does not exist, the OFR and CMS consider certain minimum factors and determine whether the facility will be given an opportunity to correct its deficiencies before remedies are imposed.

In addition to the federal responsibilities required as state survey agency, the OFR is mandated to perform unannounced inspections and investigations of nursing facilities under Section 23-17-12 of the State's general laws. The law stipulates that each facility shall receive no less than two surveys in addition to an annual licensing survey. These additional surveys are of significantly reduced scope and duration, and do not require completion of the comprehensive checklists completed during the annual survey. Additionally, state law requires that any nursing care facility cited for substandard care shall be inspected on a bi-monthly basis for 12 months following any citation.

Federal and state survey requirements are summarized in the table below:

<i>Comparison of State and Federal Survey Requirements for Nursing Facilities:</i>		
<i>Survey requirement</i>	Federal	State
<i>Annual survey</i>	Survey required between 9 to 15 months following the previous survey to achieve an overall average of 12 months	Annual licensing survey required (G.L. 23-17-7 and 23-17-12)
<i>Unannounced additional surveys</i>	No equivalent requirement	2 required each year in addition to annual licensing survey (G.L. 23-17-12)
<i>Substandard care found during annual licensing survey</i>	No equivalent requirement	Bi-monthly inspections required for the following 12 months (G.L. 23-17-12)
<i>Deficiencies noted during annual licensing survey</i>	Follow-up inspection required – time interval dependent upon the scope and severity of the deficiencies cited	No equivalent requirement

COMPLIANCE WITH STATE AND FEDERAL SURVEY REQUIREMENTS

The OFR maintains an electronic file reflecting the dates and types (annual, interim, follow-up, complaint investigation, etc.) of all federal and state surveys conducted. We reviewed the OFR’s survey statistics for state fiscal years 2003 and 2004 to determine whether the OFR completed the state required surveys for licensed nursing facilities operating in the state. We found that in:

- ❑ State fiscal year 2003 - OFR did not perform an annual survey for six nursing facilities and did not meet the two additional (interim) survey requirement for 93 facilities.
- ❑ State fiscal year 2004 - OFR did not perform an annual survey for nine nursing facilities and did not meet the two additional (interim) survey requirement for 93 facilities.

OFR’s current policy is to complete an interim survey form and a contact report summarizing the areas reviewed and observations made during the interim survey. The scope of the interim survey is outlined in section 23-17-12.1 of the General Laws which requires that the survey address the following areas: health, sanitation, nursing care, dietary, and other conditions immediately affecting patients. In tracking its compliance with state survey requirements, OFR considers required federal follow-up visits and complaint investigations as meeting the state interim survey requirement. Although these activities include an onsite visit

to the facility, the interim survey documentation is not completed. Even when including federal follow-up visits and complaint investigations as meeting the interim survey requirement, OFR's statistics still reflect that 37 facilities in fiscal 2003 and 41 facilities in fiscal 2004 did not meet the state interim survey requirement.

The statute also requires that any facility cited for substandard care shall be inspected on a bi-monthly basis for the twelve-month period immediately following the citation. We were informed that for the purposes of this section substandard care was interpreted to mean substandard quality of care as defined by federal guidelines.

- For the period July 1, 2002 to December 31, 2004, seven nursing facilities were cited with deficiencies meeting the criteria of substandard quality of care. We found that six of these facilities were not inspected on a bi-monthly basis for the succeeding twelve-month period as required.

Federal regulations and state law require OFR to conduct not less than ten percent of nursing facility surveys, in whole or in part, on nights and/or on weekends. State law includes all surveys (an annual survey and two additional surveys) within this requirement. Based upon 100 licensed nursing facilities operating in the state, 300 surveys would be required each year with 30 or 10% performed off-hours. OFR's survey records reflect that OFR conducted only 10 off-hour surveys in fiscal year 2003 and 13 in fiscal year 2004.

OFR management informed us that annual surveys are conducted in accordance with federal requirements and OFR has demonstrated compliance with these federal requirements. Compliance with the federal requirements is a condition of federal reimbursement for its share of OFR's annual operating costs. Compliance with the federal annual survey requirement can be met because federal regulations allow these to be performed as long as 15 months after the previous annual survey provided the average for all facilities is 12 months. CMS monitors the annual survey process through an annual *State Performance Standard Review* and has quality control measures in place where CMS teams perform, on a test basis, concurrent independent reviews and observe the OFR teams conducting annual surveys (*Federal Oversight Support Surveys*).

DOH management informed us that OFR does not have the staff resources to comply fully with Section 23-17-12 of the general laws. Staffing and resource issues are considered in the section entitled *OFFICE OF FACILITIES REGULATION RESOURCES* on page 29.

RECOMMENDATIONS

1. Comply with state survey requirements for nursing facilities.
2. Include only investigations addressing health, sanitation, nursing care, dietary, and other conditions immediately affecting patients as additional required surveys.

Auditee Views:

The Department of Health (DOH) concurs with both recommendations. The DOH has indicated that while some facilities did not receive the three surveys required by state law (annual and two interim), many facilities received more than the statutory minimum number of surveys due to compliance issues and the necessity for increased oversight.

The DOH contends the existing federal and state system used to prioritize surveys and complaint investigations constitutes a risk-based system in implementation. The ability to meet all of the statutory survey mandates for the number of licensed entities is a resource allocation problem. The Office of Facilities Regulation (OFR) is limited in its capacity to supplement lost survey work-time in the event of routine staff attrition due to staff turnover or hiring caps.

The DOH contends that the intent of the statutory language regarding off-hours surveys was to match the federal criteria which only involves 10% of the annual surveys be conducted off-hours.

DOH has indicated that the OFR will request the necessary resources to implement these recommendations.

MATTERS REQUIRING FURTHER STUDY OR LEGISLATIVE DELIBERATION:

- ❑ Reexamine the need to have more stringent state survey requirements (frequency) than those required by CMS. The additional state survey requirements, which are not currently being met, impact the amount of additional staffing required for OFR to meet its statutory responsibilities.
- ❑ If the need for additional state surveys is affirmed, then consider modifying the statute to allow a risk-based approach to determine the frequency of additional surveys beyond the annual licensing / federally required Medicaid and Medicare survey. State law requires two additional surveys each year in addition to the annual licensing and federally required Medicaid and Medicare survey. A risk-based approach could consider factors such as results of previous surveys, responsiveness to deficiencies, number of patients, financial condition (refer to *Fiscal Monitoring of Nursing Facilities* section of this report), nursing hours per resident and other factors considered to be appropriate risk factors or indicators of quality care. This risk-based approach may already be allowed by statute (G.L. 23-17-12). A risk-based approach would allow the OFR latitude to use its resources more effectively to monitor those facilities deemed to be most at risk.

ANNUAL LICENSING INSPECTION

State law requires that health care facilities shall be licensed, annually. DOH is the licensing agency. Section 23-17-7 of the general laws provides that a license, unless sooner suspended or revoked, shall expire by limitation on the thirty-first day of December following its issuance and may be renewed from year to year after inspection, report, approval, and collection of fees by the licensing agency (DOH). The inspection shall be made any time prior to the date of expiration of the license.

We found that OFR did not conduct an annual state licensing inspection for six nursing facilities during calendar year 2003, and nine nursing facilities in calendar year 2004. Additionally, OFR did not conduct a licensing inspection for 14 of the State's 15 hospitals. Lack of an inspection should have precluded these facilities from receiving a license for 2004 and 2005 until OFR performed the annual inspection required by the licensing statute. However, in each case, OFR issued the license without an inspection.

OFR considers the comprehensive Medicare / Medicaid survey as the required state licensing inspection. Since federal requirements allow some nursing facilities to be inspected at an interval not to exceed 15 months, certain facilities are not inspected during a specific calendar year.

We were advised by OFR management that each hospital was accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), a national accrediting body, and that OFR relied upon triennial JCAHO accreditation as a substitute for the annual inspections.

RECOMMENDATION

3. Comply with state licensing requirements by conducting a state licensure inspection of each nursing facility and hospital prior to the license expiration date.

Auditee Views:

The DOH concurs with this recommendation and has indicated that compliance with state licensing inspection requirements for all facilities subject to OFR oversight necessitates additional surveyor personnel. The DOH has not conducted annual surveys of hospitals for at least 30 years despite the statutory requirements.

MATTERS REQUIRING FURTHER STUDY OR LEGISLATIVE DELIBERATION:

- ❑ If JCAHO accreditation (performed once every three years) is deemed to be equivalent or an acceptable alternative to an annual inspection performed by the OFR, then the statute could be changed to permit this substitution for annual licensing purposes. The Department of Health's request for additional personnel includes resources to inspect all 15 hospitals on an annual basis.

The DOH licensing office is responsible for processing and approving license renewal applications and issuing licenses for all health care licensees except for providers regulated by OFR.

We were informed that the OFR supervisory personnel responsible for coordinating and overseeing annual facility inspections also review and approve the applications for facility license renewals. Accordingly, we believe these individuals have incompatible functions since they have the authority to issue a facility license without requiring an annual licensure inspection for which they are also responsible. Lack of a state license would disqualify a facility from eligibility for Medicaid and Medicare financing from CMS.

DOH should assign responsibility for reviewing whether state statutory licensing requirements have been met to an individual or office independent of the inspection process.

RECOMMENDATION

4. Assign responsibility for verifying compliance with licensing requirements and issuing renewal licenses to an individual or office independent of the inspection process.

Auditee Views:

The DOH disagrees with this recommendation and does not believe that it is necessary to segregate responsibilities for verifying compliance with licensure requirements from the inspection process.

DOCUMENTING AND TRACKING DEFICIENCIES

The OFR does not currently have formal policies or procedures in place that enable the tracking of survey deficiencies throughout the survey, quality control and reporting processes. These processes could be significantly improved by requiring, that once identified, deficiencies and any subsequent decisions to either modify or delete those deficiencies be documented and retained.

The OFR, as the state survey agency, is the entity responsible for conducting onsite surveys to certify compliance with the Centers for Medicare and Medicaid Services' (CMS) participation requirements. The CMS provides state survey agencies with a State Operations Manual (SOM) detailing survey protocols and procedures.

The workflow for the annual survey process is outlined in the table below:

<i>Nursing Facility Annual Survey Process Flow</i>
<input type="checkbox"/> Team members note potential deficiencies during onsite survey.
<input type="checkbox"/> Daily decision-making considers potential deficiencies as part of team meetings.
<input type="checkbox"/> Information Analysis for Deficiency Determination – final decision making – discussion and determination of which deficiencies will be communicated to facility management at the exit conference. Deficiency decisions and substance of the evidence are documented on a <i>Surveyor Notes Worksheet – CMS-807</i> .
<input type="checkbox"/> Exit conference is held with facility personnel where observations and preliminary findings (deficiencies) are discussed – facility has opportunity to present additional information.
<input type="checkbox"/> Survey team prepares preliminary CMS-2567 report indicating deficiency codes, regulatory citations and a summary of the evidence and supporting observations.
<input type="checkbox"/> Preliminary CMS-2567 undergoes an internal quality control review by two or more OFR supervisors and the team coordinator.
<input type="checkbox"/> CMS-2567 report is revised by the team coordinator as necessary based on quality control review and team members are apprised of changes in CMS-2567.
<input type="checkbox"/> Team members may appeal changes in CMS-2567 through informal quality control appeal process.
<input type="checkbox"/> CMS –2567 is provided to the nursing facility.
<input type="checkbox"/> Nursing facility provides plan of correction and can appeal deficiencies cited in CMS-2567 through Informal Dispute Resolution (IDR).
<input type="checkbox"/> CMS-2567 is uploaded to federal database – results of survey are available on CMS website.
<input type="checkbox"/> Follow-up process on deficiencies reported in CMS-2567 begins.

Any member of the survey team while completing their assigned survey responsibilities can identify a deficiency, defined as a facility’s failure to meet a participation requirement. Surveyors document any concerns regarding potential deficiencies on a number of standard survey forms including the *Surveyor Notes Worksheet* and *Resident Review Worksheet*. Survey teams meet daily to discuss findings to date, areas of concern and any need to modify the focus of the survey.

Federal survey procedures require that survey teams conduct an analysis of information gathered during the survey for deficiency determination purposes. The objective of this process, also referred to as decision-making, is to review and analyze all information collected and to determine whether or not the facility has failed to meet any regulatory requirements. Team coordinators or a designee are required to document the deficiency decisions and the substance of the evidence on a *Surveyor Notes Worksheet, Form CMS-807*.

Our review of 30 survey files revealed numerous inconsistencies in how the deficiency decisions are documented during the decision-making process. In some instances case file documentation clearly indicated the results of the decision-making process, including documentation of deficiencies and the applicable scope and severity. In other instances case files did not document the results of the decision-making process, making it impossible to determine what was discussed and considered. Since survey files contained varying degrees of decision-making documentation, we were unable to determine in all cases, which deficiencies were to be communicated to the facility’s management at the exit conference.

We believe that documentation of the decision-making process could be enhanced, and allow for proper tracking of deficiencies as the process ensues, by requiring the substance of the evidence, the corresponding deficiency number and scope and severity levels be reflected in survey files. Without this documentation we could not verify that all deficiencies (i.e., participation requirements) identified by individual team members were discussed and evaluated during decision-making.

Federal survey protocol requires that subsequent to the decision-making process, an exit conference be conducted to inform the facility of the team's observations and preliminary findings. The exit conference also gives the facility an opportunity to discuss each finding and provide any additional information pertinent to the identified findings. While federal guidelines as documented in the State Operations Manual do not specifically address exit conference documentation, our review of survey files and discussion with OFR personnel revealed inconsistencies in documenting the content and results of the exit conference.

We noted that some team coordinators complete a Contact Report after the exit conference documenting the results of the survey to that point, including the exit conference. However, we also noted that the Contact Reports do not always indicate who attended the exit conference, which deficiencies were presented or if additional evidence was presented by the facility that would result in the modification or deletion of previously identified deficiencies. Discussions with OFR personnel disclosed that most surveyors complete the Contact Report after the survey report (CMS-2567) is finalized, and do not utilize the report as a mechanism to document the exit conference. In these instances the Contact Report would only reflect that an exit conference was conducted, and not a description of the deficiencies discussed or any additional evidence presented. Since current policies and procedures do not require the formal documentation of either the specific deficiencies presented at the exit conference, or whether additional evidence was presented resulting in a deficiency being deleted, we were unable to verify that all preliminary deficiency findings were addressed in the initial CMS-2567 survey report.

Based on the decision-making process and the results of the exit conference the survey team prepares the preliminary CMS-2567 report indicating the deficiency codes (data prefix tags), regulatory citations and a summary of the evidence and supporting observations. Each deficiency is assigned a letter corresponding to a SOM scope and severity grid (see *Appendix A*) based on OFR's assessment of the deficiency's effect on resident outcome (severity) and the number of residents potentially or actually affected (scope).

Once the survey team finalizes the preliminary CMS-2567 report, the document undergoes an internal quality control review. The quality control process requires that the survey team coordinator meet with two or more supervisory level personnel to review the preliminary CMS-2567 and address any concerns regarding the preliminary survey report, including the appropriateness of the deficiency coding (requirement classification) and corresponding scope and severity level, the adequacy of the evidence supporting the deficiency and whether explanatory language should be enhanced, altered or deleted. We were informed that the quality control process might result in deficiencies being deleted or reclassified, scope and severity being modified or explanatory language being altered or

deleted. OFR's current policies and procedures do not require that the preliminary CMS-2567 report be retained, or that the rationale supporting the deletion or modification of deficiencies contained in the initial report be documented.

While we recognize that the OFR's quality control process is essential in producing complete, accurate and objective survey reports, retaining the preliminary survey report and documenting the basis for all decisions resulting in report modification could strengthen controls over the process.

OFR should establish policies and procedures to enable the tracking of deficiencies throughout the survey process. These procedures should require that the specific deficiencies resulting from the decision-making process be documented, including the supporting evidence, and that any subsequent decisions significantly impacting the reporting of those deficiencies be documented. Implementation of these procedures would enhance the integrity of the survey process, and provide valuable guidance to surveyors for addressing similar situations during future inspections.

RECOMMENDATION

5. Establish written policies and procedures enabling the tracking of deficiencies throughout the survey, decision-making, quality control and reporting processes. Procedures should require that the specific deficiencies resulting from the decision-making process be documented, as well as the basis for any subsequent decisions significantly impacting the reporting of those deficiencies.

Auditee Views:

The DOH concurs with this recommendation, but also notes that no state or federal mandates exist explicitly delineating the tracking of pertinent information throughout the survey process. The DOH has adjusted its internal quality control process to include maintaining the survey teams' draft document for future quality review and assessment, as well as to document any informal appeals.

QUALITY CONTROL APPEAL PROCESS

The OFR should establish formalized procedures for appealing decisions resulting from its internal quality control process.

As previously described, the OFR has implemented a quality control process designed to ensure that CMS-2567 survey reports are complete, accurate and adequately supported by reliable evidence. The quality control process requires that the survey team coordinator meet with two or more supervisory level personnel to address any concerns regarding the preliminary survey report (CMS-2567), including the appropriateness of the deficiency coding (requirement classification) and corresponding scope and severity level, the adequacy of the evidence supporting the deficiency and report language.

Since the team coordinator is the only survey team member responding to questions regarding the team's presentation of the deficiency and the supporting evidence, that individual may not be the most appropriate team member to address quality control concerns. For example, since individual disciplines vary by team coordinator, including nurses, social workers, dieticians, etc., OFR team coordinators are occasionally required to address concerns outside their own area of expertise. OFR management informed us that in those instances other team members are requested to respond to the deficiency or evidence issues. Conversely, some OFR field surveyors indicated that, in certain instances, deficiencies were either modified or deleted without the opportunity to directly participate in the quality control review process.

Once the quality control process has been completed, the team coordinator communicates any CMS-2567 report modifications or deletions resulting from the process to other team members. OFR management and survey staff informed us that an informal appeal process exists if any team member disagrees with a modification or deletion made during the quality control process. This function has been delegated to senior supervisory personnel within OFR. We were informed that in some instances this informal appeal process has resulted in the reinstatement of deficiencies in the CMS-2567 report that had been previously deleted in the quality control process. The OFR has not retained any documentation resulting from this informal appeal process.

OFR does not currently have formal written procedures documenting the existence of a post quality control appeal process, when appeals are appropriate, what OFR personnel are responsible for hearing appeals and rendering decisions, and the required documentation resulting from the process.

RECOMMENDATION

6. Establish written policies and procedures that clearly define how the internal appeal process should be conducted and documented.

Auditee Views:

The DOH disagrees with this recommendation and does not believe that a "formal" appeals process is necessary or warranted. The DOH will document informal appeals and expand the appeals review to the Division level.

LIFE SAFETY CODE SURVEY RESULTS

The OFR should formally request guidance from CMS to enable the OFR to report the results of 22 previously completed recertification surveys through the national ASPEN database. The OFR's inability to report the most recent survey data results in incomplete and outdated information being provided for public access on CMS' Nursing Home Compare

website. The lack of complete survey data also diminishes the value of various database managerial reports generated by the system.

The OFR, as part of its annual facility recertification process, must conduct, or have conducted, a Life Safety Code survey for nursing facilities. The Life Safety Code (LSC) is a set of fire protection requirements designed to provide a reasonable degree of safety from fire. LSC surveys cover construction, protection, and operational features designed to provide safety from fire, smoke, and panic.

Our review of survey files and information recorded in the federal ASPEN database revealed various annual survey results that have not yet been reported through the national database. OFR personnel informed us that the results of both the standard survey and LSC survey are required to be input before the survey results file could be uploaded (i.e., reported) through the database. We were informed that the documentation supporting various facilities' LSC survey results is not available.

OFR personnel indicated that prior to state fiscal year 2004 the state Fire Marshall's Office was responsible for conducting LSC surveys and providing the results to OFR. (OFR personnel currently perform the required LSC surveys.) OFR and the state Fire Marshall's Office have attempted to locate the LSC survey results without success.

Due to the unavailability of the LSC survey results, the OFR has been unable to report the results of 11 facility surveys conducted between September 2001 and December 2003; two of these facilities have subsequently closed. An additional 11 surveys, completed between August 2003 and November 2004, have not been reported through the federal database, since the OFR cannot upload any subsequent survey results in the ASPEN database for these facilities.

The CMS makes available to the public each nursing facility's deficiency information resulting from annual surveys through its Nursing Home Compare website. The inability to upload survey information due to the absence of LSC restricts the public's access to current survey information.

The database was also designed to produce summary managerial reports to coordinate and monitor state recertification activities. For example, the Survey Frequency report allows CMS and the State to monitor compliance with the 12-month average survey requirement. Since the database does not contain all current survey information, the Survey Frequency report is invalid for this purpose.

OFR has contacted and discussed with the CMS arrangements for an interim solution allowing prior survey information to be reported without LSC results. To date no arrangement has been reached.

RECOMMENDATION

7. Request written guidance from CMS to establish a process enabling the reporting of previously completed survey results through the national survey database.

Auditee Views:

The DOH disagrees with this recommendation and does not believe that a “formal” request to the Centers for Medicare and Medicaid Services (CMS) is necessary at this time. The DOH recognizes the need for accurate and timely information on nursing home surveys and is committed to eliminating this problem in the future.

The DOH, the State Fire Marshall’s office, and the CMS have worked formally and informally over the past twenty-four months to correct this situation. The final conditions necessary to resolve the problem are being completed at this time.

CONFLICT OF INTEREST POLICY

Both CMS and the State are responsible for evaluating the need for preventative measures to protect the integrity of the certification program. Federal employees are required to make a declaration of any outside interests and to update the declaration whenever such interests are acquired. The CMS State Operations Manual (SOM) indicates that the same declaration should be required of state employees, including all state surveyors and their supervisors, whose positions may create conflicts of interest.

Accordingly, SOM Section 7202, *Conflicts of Interest for Federal and State Employees*, contains written guidance about what constitutes a conflict of interest and certain requirements intended to detect and report conflicts of interest. The SOM identifies typical situations raising potential conflict of interest questions for federal and state employees of an agency representing the Medicare/Medicaid survey and certification program. Examples of conflicts of interest disqualifying a surveyor from survey participation include, an individual currently working, or working within the past two years, as an employee, officer, consultant or agent for the facility, or an individual having any financial or ownership interest in the facility.

DOH has a written conflict of interest policy that incorporates the state ethics law and certain additional DOH requirements concerning other employment, volunteer work and gifts. This policy is included in the DOH Employee Handbook, and requires that any employee who seeks or currently has external employment or engages in voluntary activities in the same area the employee regulates, inspects or evaluates must inform the supervisor and office chief, in writing, and provide information related to the activities. However, the DOH policy does not identify or consider the stricter CMS requirements as outlined in the SOM.

In addition, OFR does not require written employee declarations of possible or actual conflicts of interest, and does not have written documentation, as required by the DOH

Employee Handbook, of any potential and actual conflicts that certain employees have reported to management.

We became aware that an OFR employee was a part-time employee of a hospital and was also responsible for supervising complaint investigations regarding hospitals. We were informed that the employee did not participate in, or supervise, any complaint investigations related to the facility in which employed. However, we noted that the individual was routinely listed as the survey agency contact person for complaints at the facility, and signed correspondence to the facility indicating involvement in the regulatory process.

DOH should require OFR employees to prepare periodically a written declaration that they are aware of CMS conflict of interest requirements. The declaration should require the employee to document any actual or perceived impairment as defined by CMS, or certify that no such conflicts of interest exist.

RECOMMENDATIONS

8. Require employees to formally declare any outside conflicts of interest as described by the CMS State Operations Manual and to update the declaration whenever potential conflicts exist.
9. Adopt CMS *Conflicts of Interest for Federal and State Employees* policy for OFR employees.

Auditee Views:

The DOH concurs with these recommendations, and agrees a more formal system for documenting reviews of conflicts of interest is necessary. However, the DOH contends that no conflict of interest actually exists.

COMPLAINT INVESTIGATION REQUIREMENTS

Background

The Office of Facilities Regulation (OFR) is responsible for investigating complaints (including entity reported incidents) within certain time parameters established by state law and federal guidelines. Federal guidelines require that each complaint be prioritized based on the potential impact of the facility's noncompliance. The applicable timeframe for investigation of a complaint is derived by the categorization assigned during triage. The state timeframes for investigation of a complaint are much more stringent requiring that immediate jeopardy complaints be investigated within 24 hours and all others within seven days.

Complaints are categorized by OFR staff based upon information reported at intake. Priority levels and the corresponding time periods for investigation are summarized below.

<i>Complaint Category</i>	<i>Description</i>	<i>Timeframes</i>	
		<i>Federal (1)</i>	<i>State (2)</i>
<i>Immediate jeopardy</i>	Facility's noncompliance with one or more conditions or requirements indicates immediate corrective action is necessary because serious injury, harm, impairment or death to a resident, patient or client has, or is likely to occur.	2 working days	24 hours
<i>Non immediate jeopardy – high</i>	Facility's noncompliance with one or more conditions or requirements may have caused, harm that impairs mental, physical and/or psychosocial status.	10 working days	7 days
<i>Non immediate jeopardy – medium</i>	Facility's noncompliance with one or more conditions or requirements may have caused harm or potential of more than minimal harm that does not significantly impair mental, physical, and/or psychosocial status.	45 working days	7 days
<i>Non immediate jeopardy – low</i>	Complaints that allege discomfort that does not constitute injury or damage.	next onsite survey	7 days
<i>Administrative review</i>	Complaints not needing an onsite investigation -- further investigative action (written/verbal communication or documentation) initiated and information gathered is adequate in scope and depth to determine that an onsite investigation is not necessary.		Not applicable
<i>No action necessary</i>	Adequate information has been received about the incident/complaint such that the state agency can determine with certainty that no further investigation, analysis, or action is deemed necessary.		Not applicable

(1) Federal guidelines established by CMS dictate the time period in which the OFR must investigate a complaint based on priority levels. Effective January 1, 2004 the CMS updated its policy regarding the investigation of complaints prioritized as Non Immediate Jeopardy Low and modified all priority definitions. The revised policy indicated that an onsite investigation was not required to be scheduled for Non Immediate Jeopardy Low complaints that may have caused physical, mental and/or psychosocial discomfort, but did not constitute injury or damage. Instead, these allegations could be investigated at the time of the next onsite survey as opposed to the previous 120-day requirement. Based on this policy revision all Non Immediate Jeopardy Low complaints exceeding the federal time requirements (120 days) occurred before January 1, 2004.

(2) G.L. Section 23-17.8-9 requires the investigation and evaluation of complaints shall be made within twenty-four (24) hours if there is reasonable cause to believe the patient's or resident's health or safety is in immediate danger from further abuse and neglect and within seven (7) days for all other reports.

In April 2003 the OFR began recording all complaints, including facility reported incidents, in the ASPEN Complaints/Incidents Tracking System module (ACTS) of the federal Automated Survey Processing Environment (ASPEN) database.

State law requires investigations of a complaint shall include 1) a visit to the facility, 2) an interview with the patient or resident allegedly abuse, mistreated, or neglected, 3) a determination of the nature, extent, and cause or causes of the injuries, 4) the identity of the person or persons responsible for the injuries, and all other pertinent facts. The determination must be in writing.

The OFR received 1,037 nursing facility complaints in state fiscal year 2004 and resolved 743.

COMPLIANCE WITH STATE AND FEDERAL COMPLAINT INVESTIGATION REQUIREMENTS

OFR investigated 91% of the complaints within the required federal timeframes. Conversely, more than 90% of the 811 complaints requiring investigation by OFR during fiscal 2004 were not investigated within the more stringent state timeframes.

We obtained a detailed listing of all complaints and facility reported incidents entered into the ASPEN system for the state fiscal year 2004; we then noted the priority classification, and the intake and completion dates for each complaint to determine the extent of OFR’s compliance with federal and state complaint investigation requirements.

<i>Fiscal 2004 Complaints – Compliance with Investigation Timeframes:</i>					
<i>Complaint Category</i>	<i>Number</i>	Federal Complaint Investigation Timeframes		State Complaint Investigation Timeframes	
		Met federal time requirements	Exceeded federal time requirements	Met state time requirements	Exceeded state time requirements
<i>Immediate jeopardy</i>	2	1	1	0	2
<i>Non immediate jeopardy - high</i>	2	2	0	2	0
<i>Non immediate jeopardy - medium</i>	17	4	13	3	14
<i>Non immediate jeopardy - low</i>	783	725	58 *	75	708
<i>Administrative review</i>	7	7	0	0	7
<i>Referral</i>	0	0	0	0	0
<i>Total complaints requiring investigation</i>	811	739	72	80	731
		91%	9%	10%	90%
<i>No action necessary</i>	226				
<i>Total all complaints</i>	1,037				

* All Non immediate jeopardy low complaints exceeding the federal time requirements occurred before January 1, 2004 when the time requirement was 120 days rather than the current requirement which is at the time of the next survey.

OFR management informed us that all efforts are made to comply with federally mandated complaint investigation requirements, and for the majority of complaints, OFR is able to comply with these requirements. However, we were also informed that, in addition to the OFR's other mandated responsibilities, onsite complaint investigations cannot be conducted within the seven-day requirement with current staff resources. OFR has informally estimated that a complaint's intake and triage process requires approximately three hours and that investigations require 15 hours. Since the OFR currently conducts an overwhelming majority of its complaint investigations while performing annual inspections, compliance with the state complaint investigation statute would require a significant increase in personnel. OFR has not estimated the number of additional positions required to comply fully with the statute.

RECOMMENDATION

10. Comply with federal and state complaint investigation requirements.

Auditee Views:

The DOH concurs with this recommendation and has indicated that compliance with federal and state complaint investigation requirements will necessitate additional personnel.

MATTERS REQUIRING FURTHER STUDY OR LEGISLATIVE DELIBERATION:

- ❑ Complaint investigation requirements outlined in state law are much more stringent than federal law and regulation. Full compliance with state law regarding complaint investigation will require significant dedicated resources to meet the 7-day investigation requirement. Easing the state timeframe for investigation of complaints could allow resources to be used for more frequent and comprehensive surveys of facilities which have heightened quality of care risks. Conversely, lessening the state onsite survey requirement makes resources available to investigate complaints more timely. Consideration should be given to achieving the optimal mix of timely complaint investigation and frequency of onsite surveys to ensure quality of care.
- ❑ Federal complaint triage categories are specifically defined by CMS but only general terminology (e.g., complaints involving abuse, neglect or mistreatment) has been defined in State law. Performing complaint investigation under two sets of requirements is administratively burdensome and difficult to interpret and apply. Federal regulations must be met as a condition of participation in both the federal Medicare and Medicaid programs. Therefore, consideration should be given to better aligning State complaint categories with federal complaint triage categories. State timeframes for investigation could still be more stringent than federal timeframes, however; the universe of complaints requiring investigation and the triage categorization could be the same.

COMPLAINT PRIORITIZATION CONTROLS

The OFR should strengthen internal procedures to ensure that complaints are prioritized consistently and in accordance with federal criteria.

Federal guidelines require that upon intake a technically qualified individual evaluate each complaint received and assign a priority level based on federal criteria. Each criterion reflects the impact that a facility's noncompliance with established requirements may have on residents ranging from serious injury, harm or impairment, to physical, mental or psychosocial discomfort that does not constitute injury or damage. The priority classification dictates the timeframe in which the OFR must investigate each complaint. This time period ranges from two days for an *immediate jeopardy* priority compared to a *non-immediate jeopardy-low* priority, which does not require OFR to investigate until the facility's next annual onsite survey.

Two OFR supervisors are responsible for overseeing facility inspections and complaint investigations for specific nursing facilities. Accordingly, these two individuals are also responsible for evaluating reports of abuse, and assigning the appropriate priority levels, for complaints relating to the specific nursing facilities for which they are assigned. While certain advantages may exist in vesting responsibility for prioritizing complaints and investigating those complaints with the same individual, there also exists a degree of incompatibility with those functions. Since the OFR has limited resources to perform surveys and investigate complaints, there is an inherent risk of prioritizing complaints as *non-immediate jeopardy - low* and deferring investigation until the next annual survey. We noted that the OFR received 1,037 complaints in state fiscal year 2004 of which 680 were facility reported incidents. OFR personnel classified 226 intakes as no action necessary, and of the remaining 811 complaints requiring action, 783 were assigned a priority of *non-immediate jeopardy - low*.

The scope of our audit did not include evaluating the appropriateness of the complaint priorities assigned by OFR personnel, however, federal guidelines require that the survey agency be able to share the logic and rationale utilized in triage and prioritization of the allegation. We inquired of OFR personnel as to the rationale supporting the prioritization of various allegations, and were informed that the specific federal criteria were not always utilized, and that professional judgment and common sense were also used as factors. While we did not specifically attempt to assess the validity of OFR categorization of complaints at intake because specific skills and industry knowledge are required and judgment is employed, we did observe complaints classified as *non-immediate jeopardy - low* where that categorization would be questionable.

CMS performs various quality control and oversight functions of OFR. One of those areas is an assessment of OFR's prioritization and categorization of complaints. The results reported in the CMS' *State Performance Standard Review Summary* for the period October 1, 2002 to September 30, 2003 indicate that OFR did not meet the required standard of following written criteria for prioritizing and categorizing complaints. The report indicated

that only 60% of complaints were prioritized and/or categorized according to written criteria (as required the State uses the federal criteria for categorization of nursing facility complaints).

OFR should strengthen its controls over complaint prioritization by having personnel other than those ultimately responsible for complaint investigation prioritize each complaint. Since complaint prioritization dictates the required timeframe for investigation, and since complaints may be an important early indicator of other quality of care problems, this function (complaint intake categorization/prioritization) warrants an immediate supervisory review to ensure compliance with federal requirements and to meet the overall mission of OFR with respect to its regulation of nursing facilities.

RECOMMENDATIONS

11. Strengthen internal procedures by segregating the complaint prioritization and investigation functions.
12. Require an immediate supervisory review of complaint prioritizations.
13. Adhere to federal criteria for categorizing/prioritizing complaints.

Auditee Views:

While the DOH agrees with the report's emphasis on the seriousness and need for ongoing controls and quality reviews regarding complaint prioritization, the DOH does not believe the recommendations are appropriate. The DOH does not believe an inherent conflict exists between the triage of complaints by program managers and establishing time lines for investigation.

The DOH contends a significant effort to increase the efficiency and effectiveness regarding this issue has been in process for some time. The federal state agency performance measurement system reviews this area in two ways: how accurately the agency triages complaints and whether complaints are investigated within the prescribed timelines. The current draft federal report on the triage performance measure indicates the state agency increased their compliance from 60% in the 2003 report to 87.5% in the 2004 report for nursing homes and 100% for all other non-long-term care providers, indicating the progress of the state agency to improve in this area.

FACILITY INVESTIGATION REPORTS

Federal regulations (42 CFR 483.13) require that long-term care facilities ensure that all alleged violations involving mistreatment, neglect or abuse are thoroughly investigated, and that the results of all investigations are reported to officials, including the state survey agency, in accordance with state law within five working days of the incident. Regulations

also require that if the alleged violation is verified, appropriate corrective action must be taken.

State law (Section 23-17.8-2) requires that any individual in their professional capacity, or within the scope of their employment at a health care facility, who has knowledge or reasonably believes that a resident has been abused, mistreated, or neglected, must report the incident to the DOH. Telephone reports are required within 24 hours or by the end of the next business day, and must follow-up with a written report within three days.

We randomly selected 15 facilities from each of state fiscal years 2003 and 2004 and reviewed OFR complaint files to determine whether investigations were adequately documented and whether the OFR had received facility incident reports as required. We tested a total of 139 complaints of which 43 were facility reported incidents requiring the facility submit the results of investigation. Our review disclosed that 15 of the investigation reports had not been submitted by the facility as required.

RECOMMENDATION

14. Enforce the requirement that facilities thoroughly investigate alleged violations involving mistreatment, neglect or abuse and submit written reports as required.

Auditee Views:

The DOH concurs with this recommendation and will investigate initiatives to improve the response rates from facilities and take enforcement against facilities not in compliance.

INTERAGENCY COORDINATION – COMPLAINT PROCESSING

Coordination Among State Agencies

Multiple state and state affiliated agencies are currently involved in receiving, referring, or investigating nursing facility complaints in some manner. The state Departments of Health, Elderly Affairs, Attorney General and the Long Term Care Ombudsperson have all been assigned some degree of responsibility regarding complaint investigations through the State's General Laws. Coordination between these agencies is essential to process and investigate nursing facility complaints effectively and efficiently.

Chapter 23-17.8 of the General Laws, entitled *Abuse in Health Care Facilities*, requires the Director of the Department of Health or designee investigate and evaluate reports that a patient or resident in a facility has been abused, mistreated or neglected. The OFR, as part of its federal responsibilities, is required to investigate these complaints, and accordingly, has been assigned this state responsibility as well. Complaint investigations and evaluations must, in accordance with state law, be made within 24 hours if the resident is believed in

immediate danger, and seven days for all other reports. The statute requires that the OFR immediately notify the Attorney General upon receipt of a report under this Chapter.

Chapter 42-66 of the General Laws, entitled *Elderly Affairs Department*, stipulates that any person with reasonable cause to believe that a person 60 years of age or older has been abused, neglected, exploited or abandoned shall make an immediate report to the Department of Elderly Affairs (DEA). The DEA must immediately investigate the report to determine the circumstances surrounding the allegation and its cause. DEA officials informed us that the department primarily investigates only allegations related to elderly residing in the community and not in long-term care facilities. We were also informed that if the DEA receives a complaint involving an elderly individual residing in a nursing facility, DEA refers the complaint to the Long Term Care Ombudsperson (LTCO), but not to the OFR. DEA personnel indicated that this referral was appropriate since under Chapter 42-66.7, *Long Term Care Ombudsperson Act of 1995*, the department established the Ombudsperson position for the purpose, in part, of “receiving, investigating and resolving through mediation, negotiation, and administrative action complaints filed by residents of long-term care facilities...”

In order to enhance interagency cooperation, Section 42-66.7-13 of the General Laws requires the Director of Elderly Affairs to establish an interagency agreement among the Departments of Elderly Affairs, Health, Human Services and Attorney General to ensure a cooperative effort in meeting the needs of the residents in long-term care facilities. No interagency agreement has been executed between the aforementioned parties, however, we were informed that one is in process.

The interagency agreement should clearly define the roles and responsibilities of each department in the complaint intake and investigation processes, and require that the DEA refer all nursing facility complaints not only to the LTCO, but to the OFR as well.

RECOMMENDATION

15. Coordinate with the Department of Elderly Affairs to establish an interagency agreement defining the roles and responsibilities of each agency. The agreement should require that the DEA refer all nursing facility complaints involving abuse, neglect or mistreatment to both the ombudsperson and the OFR.

Auditee Views:

The DOH concurs with this recommendation and is currently engaged in an interagency workgroup to matrix the appropriate links and crossovers regarding complaint intake, processing and investigation.

The Department of Elderly Affairs concurs with this recommendation.

Coordination with the State Ombudsperson

The CMS State Operations Manual, which in part governs the federal recertification survey process, indicates that the OFR, as the state survey agency, should coordinate with the State Ombudsperson and establish procedures to:

- ❑ notify the ombudsperson of decisions to initiate proceedings to terminate, or not renew a provider agreement,
- ❑ notify the ombudsperson of voluntary terminations and planned terminations,
- ❑ consider ombudsperson information about facilities and the credibility of providers' allegations of compliance, and
- ❑ share Statements of Deficiencies and Plans of Correction.

Federal survey protocols stipulate that OFR should notify the ombudsperson prior to initiating a survey to identify any potential concerns about the facility, and at the completion of the survey process invite the ombudsperson to attend the exit conference. We were informed that these procedures are generally adhered to, however, a formal memorandum of understanding should be executed to include the above requirements.

Section 42-66.7-5 of the Ombudsperson Act empowers the LTCO to identify, investigate, and resolve complaints that relate to action, inaction or decisions that may adversely affect the health, safety, welfare, or rights of residents. The law also requires the ombudsperson to make appropriate referrals of investigations to other state agencies, such as the DOH. The General Laws also provide that nothing in the statute's confidentiality provision shall be construed to prohibit the disclosure of information to refer to other appropriate state agencies investigating civil, criminal or licensing violations.

We were informed by the LTCO that not all complaints alleging abuse, neglect or mistreatment are forwarded to the OFR, primarily due to federal confidentiality laws. LTCO personnel indicated that in certain cases individuals request that the complaint not be referred to another entity, and that federal law prohibits the disclosure of the identity of any complainant or resident unless express consent is given.

The federal long-term care ombudsman law requires the state agency (DEA) to develop the policies and procedures, in accordance with the provisions of the law, regarding confidentiality, and the disclosure by the ombudsman of files maintained by the program. In our opinion, nothing contained within the federal ombudsman law would be construed as preventing disclosure of nursing facility complaints by the LTCO to the state regulatory agency. In fact, we believe the sharing of complaint information and results of investigations is encouraged. If federal confidentiality provisions are believed to prohibit the ombudsman from disclosing the identity of complainants or residents to OFR, allegations of abuse, neglect, or mistreatment could be transmitted excluding this identification.

While we recognize the LTCO's authority to investigate independently all complaints filed with, and forwarded to, that agency, we also believe that all complaints involving abuse, neglect or mistreatment involving nursing facilities must be referred to OFR to fulfill

effectively its federal and state regulatory responsibilities. The existence of nursing facility complaints unknown to OFR could compromise the ability to evaluate quality of care risks and prioritize survey resources.

The memorandum of understanding between the agencies should require that the LTCO forward to OFR all nursing facility complaints involving abuse, neglect, and mistreatment. The memorandum should also address any confidentiality concerns, thereby providing a mechanism allowing the LTCO to transmit complaint information, including the facility and substance of the allegation, without identification of the complainant.

RECOMMENDATION

16. Execute a memorandum of understanding with the long-term care ombudsperson addressing federally required procedures. The memorandum should also require that the ombudsperson forward all nursing facility complaints involving abuse, neglect, or mistreatment to OFR, in accordance with applicable confidentiality restrictions.

Auditee Views:

The DOH concurs with this recommendation.

The Long Term Care Ombudsperson (LTCO) concurs that a memorandum of understanding should be executed, and has been working with the OFR to draft that document. The LTCO also indicated that the memorandum of understanding should address confidentiality concerns and provide a mechanism to allow the LTCO to transmit complaint information.

OFFICE OF FACILITIES REGULATION RESOURCES

The Office of Facilities Regulation needs additional resources to meet both federal and state survey and complaint investigation requirements for the various types of health care facilities under its control. The failure to meet state survey requirements and timeframes for state and federal complaint investigations is outlined in the preceding sections of this report entitled *STATE AND FEDERAL SURVEY REQUIREMENTS* and *COMPLAINT INVESTIGATION REQUIREMENTS*. The Department of Health has prepared a staffing analysis to support its request for additional personnel; however, we found the analysis to be incomplete and unsupported in certain respects. While the flaws in OFR's work plan precluded us from concurring with the exact number of additional personnel requested by the Department, it is clear that additional resources are needed. The number of additional personnel required would also be affected by any statutory changes contemplated for survey and complaint investigations and the volume of complaints anticipated.

As part of its annual federal budget request, and to demonstrate the need for additional field survey personnel, OFR has prepared a detailed work analysis documenting federal and state survey activities for both fiscal years 2004 and 2005. The analysis identifies the types of service providers requiring federal certification or licensure surveys (e.g., skilled nursing facilities/nursing facilities, home health provider agencies, hospitals, etc.), the number of each type of provider, and the total estimated hours to perform the required surveys for each provider type. The analysis also reflects estimated hours for complaints and state licensing requirements for nursing facilities, hospitals, assisted living residences and certain other providers. For example, OFR's 2005 work plan indicates that 93 nursing facilities require surveys during the fiscal year, and estimates that each survey will require an average of 145 hours to complete resulting in 13,485 total field surveyor hours needed. OFR estimated that it would intake 800 complaints for nursing facilities and require 2,000 hours to intake and triage these complaints, and an additional 7,500 hours to investigate 500 of these complaints (15 hours per complaint investigation).

We found that OFR did not maintain adequate documentation supporting the estimated hours for each required activity (e.g., recertification surveys, follow-up surveys, complaint investigations, etc.). OFR provided us federal database reports reflecting time as reported by OFR survey staff for the year ended September 30, 2002 as support for the estimated hours in the work plan for federal fiscal year ended September 30, 2004. While we recognize that this data was the most recent complete year available at the time the plan was prepared, we believe more recent accurate data should be utilized to estimate hours and specifically quantify the number of additional field surveyor positions required.

We also noted inconsistencies in the data used in the work analysis when compared between sources of data and between years. For example, we noted differences between the hours reflected in the database reports and the estimated hours used in the work plan. Annual survey hours per the 2002 database report were 11,410; however, the 2004 and 2005 work plans estimate 15,675 and 13,485 hours, respectively. Additionally, OFR's 2005 work analysis utilized an estimate of 145 hours per nursing home survey compared with 165 in the 2004

analysis. A variance of 20 hours per survey applied to the 93 required surveys results in a difference (1,860 hours) of more than one full time surveyor position.

OFR management and staff advised us that the estimates were derived using a combination of historical data from the federal survey databases (OSCAR and ASPEN), and actual time reported by surveyors on their bi-weekly time sheets. OFR personnel indicated that generally the database hours are low since these databases only reflect field survey hours, and that the time sheets, which reflect total hours charged to funding sources (state versus federal) and do not provide detailed time by activity (survey versus complaint), are high. OFR management and staff could not provide an explanation of the specific methodology used to calculate estimated hours. Without the support used to generate the estimates, we were unable to utilize the analysis as a valid mechanism to quantify the specific amount of additional personnel required.

OFR's staffing analysis also does not fully consider "down time" for surveyors caused by leaves of absence, extended sick leave or other issues. For example, an individual previously on medical leave has returned to work and is restricted to office work rather than performing onsite surveys because of health considerations. This type of unavailability for survey work is not factored into the annual work plan. Additionally, the requirement that 10% of surveys be performed during "off-hours" impacts the analysis due to overtime/comptime considerations.

We also found that the staffing analysis did not reflect the state requirement to investigate complaints within either 24 hours or seven days (depending upon severity). The staffing analysis only considered the resources required to meet the less stringent federal timeframes for complaint investigation. Fully meeting this state requirement would have a significant impact on staffing and may require as many as five additional staff beyond the Department's estimate of additional staffing needs.

The OFR has numerous specific responsibilities mandated by the General Laws for regulating health care facilities. Insufficient resources to meet these obligations causes the department to prioritize its activities to the areas it believes warrant the most attention. This prioritization, while realistically necessary given the resource limitations, is not provided for in statute. Additionally, the gaps in regulatory coverage resulting from this prioritization are not always widely known. The various responsibilities of the OFR compete for resources – effort spent in one area comes at the expense of another. As noted previously, all hospitals require annual licensing inspections by state law; however, only one of the state's fourteen hospitals is currently surveyed each year.

Both the 2004 and 2005 work analysis estimate that 31 field surveyor positions would be required to complete OFR's federal and state responsibilities. The OFR currently has 25 field surveyor positions of which two are vacant. DOH has submitted a fiscal year 2005 supplemental budget request that includes an increase of six full time equivalent positions, (five field surveyors and one clerical) effective January 2005. The estimated cost is \$195,166 in fiscal 2005 (for one-half year) and \$410,717 in fiscal 2006. The overall financing for the six positions is estimated to be 80% state and 20% federal.

RECOMMENDATIONS

17. Revise and update the analysis of OFR responsibilities and current staffing to quantify the amount of additional personnel required. Ensure the analysis reflects all relevant staffing considerations.
18. Prepare and maintain documentation to support estimates used in the analysis.

Auditee Views:

The DOH concurs with these recommendations. The DOH contends that yearly variations in the budgeting and allocation of “average” survey hours are the result of agreements with CMS to include education and training of surveyors in new areas (i.e., Life Safety Code), minor fluctuations in workload requirements or specific survey protocols, and ongoing analysis of national averages as targets for improving survey performance.

FISCAL MONITORING OF NURSING FACILITIES

OFR does not currently review any financial data or assess the financial position of a nursing facility in conjunction with performing its federal and state regulatory functions. However, there is general agreement that a direct relationship exists between the fiscal soundness of a nursing facility and its ability to provide consistent quality care. Financial condition information could be used as an indicator of increased risk of deteriorating quality of care and prompt more frequent inspections. Gathering, analyzing and summarizing relevant financial data and integrating that into the regulatory process without these additional requirements being onerous on either nursing facilities or state agencies appears to be an important goal.

Implementing an effective evaluation process of nursing facilities' financial condition may require modification to existing laws or regulations. We believe that a number of issues impacting a fiscal monitoring process must be considered. Implementation of the process should strive to most efficiently utilize the current structure, information and resources, and minimize any adverse impact on nursing facilities.

Financial Information Currently Existing

Section 23-17-10(b) of the General Laws requires that the licensing agency (DOH), with the advice of the Health Services Council, shall establish rules and regulations to provide for a uniform system of reporting detailed financial and statistical data pertaining to the operation, services and facilities of health care facilities. The periodic reporting shall be concerned with, but not limited to, unit cost utilization charges for facility services, financial condition of facilities and quality of care. Nursing home regulations promulgated by DOH (Section 18.26) require the reporting of this data "at such intervals and by such dates as determined by the Director". DOH does not currently request or receive any financial or statistical data regarding the financial condition of nursing facilities.

The Department of Human Services (DHS), in accordance with its *Principles of Reimbursement*, establishes individual per diem rates used to reimburse nursing facilities participating in the Medicaid program. Reimbursement rates are based on an annual cost report (BM-64) submitted by each nursing facility to DHS' rate setting unit. The cost report, which contains detailed financial information including a Balance Sheet, Statement of Operations (Medicaid reimbursable costs only) and an adjusted trial balance from the facility's general ledger, must be prepared on the accrual basis of accounting and be completed in accordance with generally accepted accounting principles. Financial data reflected on the BM-64 cost report is unaudited and audited financial statements are not required. The rate setting unit performs desk audits and periodic field audits to verify the accuracy of the cost report data. DHS personnel informed us that the financial information reported in the BM-64 cost reports is utilized for rate setting purposes and not to evaluate the financial position or fiscal health of the facility.

DOH officials informed us that DHS has on occasion communicated to DOH certain concerns about a facility's finances based on data obtained as part of its rate setting responsibilities. Additionally, nursing facilities periodically request advances on their Medicaid reimbursement from DHS, and we were informed that DOH is made aware of these requests.

MATTERS REQUIRING FURTHER STUDY OR LEGISLATIVE DELIBERATION:

❑ Form and Level of Required Financial Information

The BM-64 Cost Report provides a valuable and already available initial source of financial data for analysis. With minimal modification this cost report may provide sufficient information to meet this need.

Facilities are currently required to submit cost reports including expenditure and revenue information, a comparative statement of operations (Medicaid reimbursable costs only) and a balance sheet. The cost report also requires schedules of interest and indebtedness, depreciation, service costs from related organizations and payroll and payroll tax information. Analysis of cost report information could provide trend information regarding increases/decreases in accounts payable and receivable, retained earnings and total capital. Requiring nursing facilities to submit certain supplementary financial information such as aged accounts receivable and payable and projected cash flows in conjunction with information in their cost report could provide a basis for an initial determination of a facility's fiscal condition. However, cost reports and any required supplemental financial data represent unaudited information. Cost reports may be prepared by the facility's fiscal officer or compiled by a public accountant, neither of which expresses an independent opinion or any other form of assurance on them. While an owner, partner or officer is required to certify the cost report is true and complete, a risk exists that evaluations could be made on inaccurate financial data.

Audited financial statements of nursing facilities are not currently required by either DOH or DHS. We did not determine the number of facilities that currently have their financial statements audited. Audited financial statements require that an independent public accountant express an opinion on the fairness of the presentation of the statements, and evaluate whether there is substantial doubt about the entity's ability to continue as a going concern one year beyond the date of the financial statements. These statements while providing the financial position, results of operations and cash flows of the facility, as well as additional information in the form of note disclosure, would not provide the level of detail contained within the cost reports. The presentation of the audited financial statements, as well as the level of supplementary information, will vary by facility operations (e.g., other activities included) and proprietary structure. If audited financial statements are deemed essential, a combination of the audited financial statements and the cost reports would likely be required to effectively analyze the financial data. However, since cost reports are prepared on a calendar year basis, audited financials would be required to reflect the same period regardless of the facility's fiscal year end. The benefit of audited financial statements should be considered in light of the increased cost to the nursing facilities and whether such costs qualify for reimbursement under Medicaid.

MATTERS REQUIRING FURTHER STUDY OR LEGISLATIVE DELIBERATION:

❑ **Responsibility for Performing the Financial Evaluation**

The OFR does not currently possess staff qualified to analyze financial data, determine the fiscal stability of a facility or identify deteriorating financial condition. OFR staffing consists primarily of social workers and nursing professionals that could not be expected to accurately review financial information.

DHS' Rate Setting Unit (RSU) is responsible for establishing per diem rates used to reimburse Medicaid participating nursing facilities based on the BM-64 cost reports and in accordance with its Principles of Reimbursement. The RSU performs desk audits and periodic field audits to verify the accuracy of the data. Assigning RSU the responsibility for performing the financial evaluation appears logical based on its staff's level of expertise in analyzing financial data and its past experience with the facilities. However, since the RSU sets the facilities' Medicaid reimbursement rates, assigning RSU the responsibility for determining which facilities would be considered as potential financial risks could be considered incompatible. Consideration must be given to whether the RSU should actively participate in the decision-making process, or be restricted to compiling the appropriate financial data for subsequent evaluation.

❑ **Criteria for Evaluating Financial Condition**

Specific criteria for evaluating the financial condition of nursing facilities does not currently exist in either law or regulation. The criteria should be straightforward and capable of objective measurement. Criteria indicating deteriorating financial condition could include:

- Significant operating losses for two successive years
- Frequent requests for advances on Medicaid reimbursements
- Unfavorable working capital ratios (current assets/current liabilities)
- High proportion of accounts receivable more than 90 days old
- Increasing accounts payable, unpaid taxes and/or payroll related costs
- Minimal or decreasing equity and/or reserves
- High levels of debt and high borrowing costs

Individuals knowledgeable about the nursing home industry should develop criteria indicating both fiscally sound and unsound facilities. The applicable criteria could then be used to develop a fiscal rating (e.g., 1-5 with 1 representing a fiscally sound facility and 5 representing a facility with significant financial problems indicating heightened risk).

MATTERS REQUIRING FURTHER STUDY OR LEGISLATIVE DELIBERATION:

❑ **Utilization of the Financial Data to Enhance Monitoring**

State law currently requires the Director of DOH to establish, by regulation, criteria to determine the frequency of unannounced inspections including, but not limited to, patient acuity, quality indicators, and a facility's past compliance with regulations. The law requires that each facility shall receive no less than 2 surveys in addition to the annual licensing survey. This law appears to allow DOH to establish a more risk-based approach, which could incorporate the evaluation of a facility's financial condition, to determine the frequency of inspections. As described above, the RSU, as an extension of their current responsibilities, could accumulate and analyze relevant financial information and present this data in summary form to the OFR. This financial rating factor could be forwarded to OFR for use in a risk-based model, along with other non-financial risk factors, to determine frequency of inspection.

❑ **Solutions for Financially Troubled Facilities**

Additional regulatory oversight may limit or prevent the effects of fiscal weakness on quality of care but will not improve or resolve the underlying financial issues. In addition, public disclosure of financially troubled facilities may further weaken their condition by making them less attractive facilities to patients and employees.

Consideration must be given as to the appropriate course of action, in addition to increased inspections and monitoring, to address the facilities financial situation. Actions could range from OFR continuing to conduct additional inspections of troubled facilities until quality of care deficiencies are identified, or intervening to assist the facility financially, with specific restrictions and conditions, thereby increasing the likelihood that quality care is consistently maintained. There may be different considerations on the willingness to assist nursing facilities financially depending on whether the facility operates in a for-profit or non-profit mode. Additionally, total capacity within the system (number of available nursing home beds) may impact the decision of assisting a facility vs. closing a facility.

In summary, evaluating the financial condition of nursing facilities provides valuable information in assessing potential quality of care risks, and accordingly, improves the effectiveness of the overall regulatory process. Utilizing financial data, in conjunction with other relevant risk factors (compliance history, severity of complaints, etc.) to increase the frequency of inspections would identify quality of care issues more timely.

CMS Scope and Severity Grid – Deficiencies			
SEVERITY	SCOPE		
	Isolated	Pattern	Widespread
Immediate Jeopardy to Resident Health or Safety	J Plan of Correction Required: Category 3 Optional: Category 1 Optional: Category 2	K Plan of Correction Required: Category 3 Optional: Category 1 Optional: Category 2	L Plan of Correction Required: Category 3 Optional: Category 1 Optional: Category 2
Actual Harm that is not Immediate	G Plan of Correction Required: Category 2 Optional: Category 1	H Plan of Correction Required: Category 2 Optional: Category 1	I Plan of Correction Required: Category 2 Optional: Category 1 Optional: Temporary Management.
No Actual Harm with Potential for more than Minimal Harm that is not Immediate Jeopardy	D Plan of Correction Required: Category 1 Optional: Category 2	E Plan of Correction Required: Category 1 Optional: Category 2	F Plan of Correction Required: Category 2 Optional: Category 1
No Actual Harm with Potential for Minimal Harm	A No Plan of Correction No Remedies Commitment to Correct Not on CMS 2567	B Plan of Correction	C Plan of Correction

Substandard quality of care (SOC) is any deficiency cited at the levels highlighted above in 42 CFR 483.13, Resident Behavior and Facility Practices, 42 CFR 483.15 Quality of Life, or 42 CFR 483.25 Quality of Care.

Substantial compliance

	Remedy Category 1	Remedy Category 2	Remedy Category 3
Remedy Categories	<ul style="list-style-type: none"> ▪ Directed Plan of Correction State Monitor; and/or Directed In-Service Training. 	<ul style="list-style-type: none"> ▪ Denial of Payment for New Admissions, ▪ Denial of Payment for All Individuals Imposed by CMS, and ▪ Civil Money Penalties: \$50 to \$3,000/day \$1,000 to \$10,000/instance 	<ul style="list-style-type: none"> ▪ Temporary Management ▪ Termination ▪ Optional: Civil Money Penalties: \$3,050-\$10,000/day \$1,000 to \$10,000/instance

SUMMARY OF FACILITIES REGULATED

<u>Provider Types</u>	<u>Total Number of Providers</u>
Nursing Facilities	102
Hospitals	14
Rehabilitation Hospital Center	1
Assisted Living Residences	72
ICF/MR - Group Homes	4
Blood Testing Screening Permits	4
Clinical Laboratories	116
Drawing Stations	80
Home Care Providers	14
Home Nursing Care Providers	50
Organized Ambulatory Care	39
Nursing Service Agencies	72
School-Based Health Centers	7
Hospice	8
Freestanding Ambulatory Surgical Centers	7
Freestanding Emergency Care Facilities	1
Kidney Disease Treatment Centers	13
Physician / Podiatry Ambulatory Surgical Centers	3
Outpatient REHAB Centers	10
Tattoo Parlors	53
Body Piercing Establishments	22
Portable X-Ray Services	3
Rural Health Clinics	<u>1</u>
Total	696

Source – Office of Facilities Regulation – January 1, 2005