Complaint Investigations of Minnesota Health Care Facilities

Report to the Minnesota Legislature explaining the investigative process and summarizing investigations from July 1, 2003 to June 30, 2006 and Information on Deficiencies Issued by OHFC from October 1, 2005 to September 30, 2006

Minnesota Department of Health

March 2007

MINNESOTA MDH DEPARTMENT OF HEALTH

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Introduction

Minnesota Statutes, section 626.557, requires the Minnesota Department of Health (MDH) to annually report to the Legislature and the Governor information about alleged maltreatment in licensed health care entities.

Minnesota Statutes, section 626.557, subdivision 12b, paragraph (e), states:

> Summary of reports. The commissioners of health and human services shall each annually report to the legislature and the governor on the number and type of reports of alleged maltreatment involving licensed facilities reported under this section, the number of those requiring investigation under this section, and the resolution of those investigations. The report shall identify:
> (1) whether and where backlogs of cases result in a failure to conform with statutory time frames;
> (2) where adequate coverage requires additional appropriations and staffing; and
> (3) any other trends that affect the safety of vulnerable adults.

In order to provide an appropriate context for the information specified in the law, this report will also address the Department's complaint investigation responsibilities relating to health care facilities. This report will provide summary data relating to the number of complaints and facility reported incidents received during state FY 04 to state FY 06; will provide summary data as to the nature of the allegations contained within those complaints and reports; describe the Office of Health Facility Complaints (OHFC) process from the intake function to completion of the investigative process; and then address issues relating to the performance of its responsibilities. This latter category will include information on the ability to conform to statutory requirements, the effectiveness of current staffing, and any trends relating to the safety of vulnerable adults. Since the complaint investigation function is also a critical component of the federal certification process, information as to the federal requirements and performance evaluations will be included. Expanded information on OHFC's issuance of federal deficiencies related to nursing homes is included in Part 2 of this Report.

Part 1: State Fiscal Year Information

Background

There are over 2,000 licensed health care entities in the state. Licensed health care entities include nursing homes, hospitals, boarding care homes, supervised living facilities, home care agencies, hospice programs, hospice residences, and free standing outpatient surgical facilities. The licensure laws contained in Minnesota Statutes Chapters 144 and 144A detail the Department's responsibilities in this area. In addition, MDH is the survey agency for the purpose of certifying a health care facility's participation in the Medicare and Medicaid programs.

The purpose of licensing and federally certifying health care facilities is to protect the health, safety, rights and well being of those receiving services by requiring providers of services to meet minimum standards of care and physical environment. The licensure laws at the state level and the federal certification requirements provide for the development of regulations that establish those minimum standards. MDH rules, the Vulnerable Adults Act (VAA), the Patients Bill of Rights, and federal

Medicare and Medicaid certification regulations are the primary legal foundation for patient/resident protection efforts.

In addition to the development of the regulations, the licensure and certification laws also provide the structure for monitoring performance in two ways: the survey process and a distinct mechanism to respond to complaints about the quality of the care and services provided. This report will focus on the complaint investigation process.

The Office of Health Facility Complaints is a program within the Minnesota Department of Health's Division of Compliance Monitoring. OHFC is responsible for investigating complaints and facility reported incidents of maltreatment in licensed health care entities in Minnesota.[1]

State and federal laws authorize anyone to file a complaint about licensed health care facilities with OHFC. State law also mandates that allegations of maltreatment against a vulnerable adult or a minor be reported by the licensed health care entity. Maltreatment is defined in Minnesota Statutes 626.557 (Vulnerable Adults Act) as cases of suspected abuse, neglect, financial exploitation, unexplained injuries, and errors as defined in Minnesota Statutes 626.557, subd. 17(c)(5).[2]

OHFC Responsibilities

OHFC is responsible for the receipt of all complaints and facility reported incidents; for gathering information that will assist in the appropriate review of this information; for evaluation and triage of this information and for selecting the level of investigative response. In addition, OHFC is required to notify complainants and reporters as to the outcome of the review and any subsequent investigation. These specific functions will be addressed later in the report.

A Director and an Assistant Director manage OHFC. There are 15 investigators assigned to the Office; 12 investigators are assigned to the St. Paul office and the remaining 3 are located in the MDH offices in Fergus Fall, Duluth and Rochester. There are 2 individuals responsible for the intake of complaints and facility reported incidents. There are 5 support staff assigned to the Office. In addition to the complaint related activities, OHFC is also responsible for the activities related to the processing of criminal background checks and set asides. Two additional staff are assigned to this activity.

[1] Statutory authority for OHFC is found in Minnesota Statutes 144A.51 to 144A.54. In addition to the requirements of state law, OHFC is also the entity responsible for reviewing and investigating complaints under the federal Medicare and Medicaid certification requirements.
OHFC is the "lead agency" for the purposes of reviewing and investigating facility reported incidents of maltreatment under the provisions of the Vulnerable Adult Abuse Act, Minnesota Statutes 626.557 and the Reporting of Maltreatment of Minors Act, Minnesota Statutes 626.556.

[2] While OHFC does conduct investigations relating to the maltreatment of minors in MDH licensed facilities, the information presented in this report will be based on complaints and facility reported incidents involving vulnerable adults. OHFC investigates very few cases involving a minor each year.

TABLE 1
OHFC BUDGET AND STAFFING HISTORY

Fed Fiscal Year	Investigators	Supervisor Managers	Intake Staff	Admin. Staff	Total Staff	OHFC Funding
FFY06	15	2	2	5	24	Total Oper. Budget: $2,418,480 Medicare 38.60% Medicaid 29.20% State Licensure 32.30%
FFY05	15	2	2	5	24	Total Oper. Budget: $2,266,286 Medicare 38.6 0% Medicaid 29.2 0% State Licensure 32.30%
FFY04	13	2	2	5	22	Total Oper. Budget: $1,910,796 Medicare 37.30% Medicaid 28.90% State Licensure 33.8 0%

OHFC Funding sources are Medicare, Medicaid, and State Licensure Fees

How OHFC Receives Information

Concerns about issues or situations in licensed health care entities come to OHFC in one of two ways: **a complaint or a facility reported incident**. **A complaint** is an allegation relating to maltreatment or any other possible violation of state or federal law that is made by an individual who is not a designated reporter. **A facility reported incident** is received from a designated reporter in a facility and describes a suspected or alleged incident of maltreatment as defined in the Vulnerable Adults Act.

Table 2, below, includes the numbers of complaints and facility reported incidents received during the past three state fiscal years by facility type.

Table 2: Complaints & Facility Reported Incidents by Facility Type
FY04, FY05, FY06

Complaints Received	**FY04**	**FY05**	**FY06**
Nursing Home	838	866	886
Hospital	316	340	293
Home Health	324	362	313
Other Licensed Entities	124	105	123
*** Total Complaints Received**	**1602**	**1673**	**1615**
Facility Reported Incidents	**FY04**	**FY05**	**FY06**
Nursing Home	3785	2849	3176
Hospital	156	169	131
Home Health	303	318	319
Other Licensed Entities	92	112	49
**** Total Facility Reported Incidents Received**	**4336**	**3448**	**3675**
***** Grand Total**	**5938**	**5121**	**5290**

As shown in Table 2, OHFC yearly receives several thousand complaints and facility reported incidents. **It is important to note that OHFC reviews every complaint and facility reported incident**. State and federal law require that these complaints and facility reported incidents be reviewed to make a determination as to what investigative process will be employed to resolve the allegation.

Types of Maltreatment Allegations and Other Concerns Received by OHFC

Each complaint or facility reported incident might contain more than one allegation, each of which must be reviewed for investigative purposes. For example, an allegation that a resident was neglected might state the nature of the specific concern but also indicate that inadequate staffing was also a concern. Complaints and facility reported incidents are coded to identify various categories of maltreatment and other violations of state and federal law. Table 3 illustrates the recording of all allegations for nursing homes for state FY04, FY05 and FY06; the maltreatment allegations and concerns identified by complainants and the maltreatment allegations and concerns contained in facility reported incidents. Tables 4, 5 and 6 on the following pages summarize all allegations for the other licensed health care entities.

Table 3: Nursing Home Allegations from Complaints and Facility Reported Incidents FY04, FY05, FY06

	FY 2004	FY 2004	FY 2005	FY 2005	FY 2006	FY 2006
Allegations : Abuse	**Comp**	**FRI**	**Comp**	**FRI**	**Comp**	**FRI**
Emotional Abuse	37	168	33	171	29	156
Physical Abuse	53	310	55	205	64	227
Sexual Abuse	15	92	14	106	20	78

	FY 2004	FY 2004	FY 2005	FY 2005	FY 2006	FY 2006
Allegations : Exploitation	**Comp**	**FRI**	**Comp**	**FRI**	**Comp**	**FRI**
Exploitation by staff	9	62	10	67	12	69
Exploitation by other	4	76	4	90	7	99

	FY 2004	FY 2004	FY 2005	FY 2005	FY 2006	FY 2006
Allegations : Neglect	**Comp**	**FRI**	**Comp**	**FRI**	**Comp**	**FRI**
General Health Care	316	351	352	276	385	318
Falls	54	980	58	782	49	766
Medications	51	90	45	76	52	101
Decubiti	33	10	18	5	21	0
Dehydration	10	1	4	0	3	0
Nutrition	9	2	5	2	10	2
Neglect, Failure to notify MD	6	0	6	1	3	1
Neglect of Supervision	33	417	44	365	28	413

	FY 2004	FY 2004	FY 2005	FY 2005	FY 2006	FY 2006
Allegation : Unexplained Injury	**Comp**	**FRI**	**Comp**	**FRI**	**Comp**	**FRI**
	18	968	14	456	29	829

	FY 2004	FY 2004	FY 2005	FY 2005	FY 2006	FY 2006
Allegations : General	**Comp**	**FRI**	**Comp**	**FRI**	**Comp**	**FRI**
Patient Rights	131	39	133	58	142	57
Nursing, Infection Control, Medications	136	10	120	2	120	4
Other	120	10	137	6	125	10

Table 4: Hospital Allegations from Complaints / Facility Reported Incidents
FY04, FY05, FY06

	FY 2004	FY 2004	FY 2005	FY 2005	FY 2006	FY 2006
Allegations : Abuse	**Comp**	**FRI**	**Comp**	**FRI**	**Comp**	**FRI**
Emotional Abuse	1	2	1	9	2	9
Physical Abuse	10	10	4	2	11	12
Sexual Abuse	10	24	0	0	11	21
Accident	0	0	0	0	0	0

	FY 2004	FY 2004	FY 2005	FY 2005	FY 2006	FY 2006
Allegations : Exploitation	**Comp**	**FRI**	**Comp**	**FRI**	**Comp**	**FRI**
Exploitation by staff	1	1	1	6	4	2
Exploitation by other	0	0	0	0	2	0

	FY 2004	FY 2004	FY 2005	FY 2005	FY 2006	FY 2006
Allegations : Neglect	**Comp**	**FRI**	**Comp**	**FRI**	**Comp**	**FRI**
General Health Care	34	1	29	4	57	5
Falls	4	5	4	7	6	1
Medications	9	4	5	2	6	3
Decubiti	9	2	7	0	11	1
Dehydration	0	0	0	0	0	0
Nutrition	0	0	0	0	0	0
Neglect, Failure to notify MD	0	0	0	0	0	0
Neglect of Supervision	6	78	3	10	10	67

	FY 2004	FY 2004	FY 2005	FY 2005	FY 2006	FY 2006
Allegation : Unexplained Injury	**Comp**	**FRI**	**Comp**	**FRI**	**Comp**	**FRI**
	5	8	1	4	4	7

	FY 2004	FY 2004	FY 2005	FY 2005	FY 2006	FY 2006
Allegations : General	**Comp**	**FRI**	**Comp**	**FRI**	**Comp**	**FRI**
Patient Rights	119	18	158	13	114	0
Nursing, Infection Control, Medications	64	0	50	12	17	0
ER Services	11	0	11	0	25	3
Discharge Planning	15	1	5	0	13	1
EMTALA	20	0	19	0	17	2
Other	27	0	64	4	19	0

Table 5: Home Health Care Allegations from Complaints / Facility Reported Incidents
FY04, FY05, FY06

	FY 2004	FY 2004	FY 2005	FY 2005	FY 2006	FY 2006
Allegations : Abuse	**Comp**	**FRI**	**Comp**	**FRI**	**Comp**	**FRI**
Emotional Abuse	21	15	25	24	19	22
Physical Abuse	20	31	13	7	18	20
Sexual Abuse	9	11	17	36	10	15
Accident	0	4	0	11	1	15

	FY 2004	FY 2004	FY 2005	FY 2005	FY 2006	FY 2006
Allegations : Exploitation	**Comp**	**FRI**	**Comp**	**FRI**	**Comp**	**FRI**
Exploitation by staff	24	75	29	48	17	55
Exploitation by other	6	20	6	16	8	12

	FY 2004	FY 2004	FY 2005	FY 2005	FY 2006	FY 2006
Allegations : Neglect	**Comp**	**FRI**	**Comp**	**FRI**	**Comp**	**FRI**
General Health Care	92	32	119	28	99	28
Falls	14	40	13	51	7	60
Medications	39	12	30	17	24	12
Decubiti	9	0	6	0	9	0
Dehydration	2	0	0	0	1	0
Nutrition	3	0	0	0	0	0
Neglect, Failure to notify MD	3	0	1	0	0	0
Neglect of Supervision	31	33	14	14	20	58

	FY 2004	FY 2004	FY 2005	FY 2005	FY 2006	FY 2006
Allegation : Unexplained Injury	**Comp**	**FRI**	**Comp**	**FRI**	**Comp**	**FRI**
	5	34	1	4	8	18

	FY 2004	FY 2004	FY 2005	FY 2005	FY 2006	FY 2006
Allegations : General	**Comp**	**FRI**	**Comp**	**FRI**	**Comp**	**FRI**
Patient Rights	65	9	76	12	82	12
Nursing, Infection Control, Medications, Shortage Staff	31	2	59	1	42	2
Other	24	2	3	1	21	0

Table 6 : Other Licensed Entities Allegations from Complaints / Facility Reported Incidents
FY04, FY05, FY06

	FY 2004	FY 2004	FY 2005	FY 2005	FY 2006	FY 2006
Allegations : Abuse	**Comp**	**FRI**	**Comp**	**FRI**	**Comp**	**FRI**
Emotional Abuse	11	23	6	6	1	2
Physical Abuse	9	23	7	14	7	6
Sexual Abuse	4	8	1	3	2	1
Accident	0	3	0	1	0	0

	FY 2004	FY 2004	FY 2005	FY 2005	FY 2006	FY 2006
Allegations : Exploitation	**Comp**	**FRI**	**Comp**	**FRI**	**Comp**	**FRI**
Exploitation by staff	6	7	5	2	1	1
Exploitation by other	0	7	1	1	1	2

	FY 2004	FY 2004	FY 2005	FY 2005	FY 2006	FY 2006
Allegations : Neglect	**Comp**	**FRI**	**Comp**	**FRI**	**Comp**	**FRI**
General Health Care	22	17	16	13	22	9
Falls	2	24	2	12	1	1
Medications	8	11	8	20	6	2
Decubiti	1	0	3	0	1	0
Dehydration	0	0	0	0	0	0
Nutrition	1	0	0	0	0	0
Neglect, Failure to notify MD	0	0	0	0	1	0
Neglect of Supervision	17	54	3	25	14	9

	FY 2004	FY 2004	FY 2005	FY 2005	FY 2006	FY 2006
Allegation : Unexplained Injury	**Comp**	**FRI**	**Comp**	**FRI**	**Comp**	**FRI**
	4	17	6	9	1	9

	FY 2004	FY 2004	FY 2005	FY 2005	FY 2006	FY 2006
Allegations : General	**Comp**	**FRI**	**Comp**	**FRI**	**Comp**	**FRI**
Patient Rights	53	5	44	7	59	1
Nursing, Infection Control, Medications, Shortage Staff	19	1	6	2	17	0
Other	34	3	19	33	25	0

How OHFC Reviews Information – the Intake and Triage Processes

As described below, the OHFC review process consists of an intake process and triage process.

The need to set priorities or to triage the allegations is specifically recognized in both state and federal law. The VAA requires that each lead agency "…shall develop guidelines for prioritizing reports for investigation." Minn. Stat. 626.557, subd. 9b. In addition, the Centers for Medicare and Medicaid Services (CMS) also requires that the state survey agencies develop triage criteria to govern the review of complaints and facility reported incidents. CMS also specifies time frames for the initiation and completion of certain types of investigations.[3]

Intake Process

Intake staff review each complaint or facility reported incident as it is received. Intake staff are trained to follow specific protocols and policies in assessing which investigative option the complaint or facility reported incident should be assigned. In many situations, intake staff will request that additional information be provided for review. For example, intake staff will often request that a facility submit medical records and its own investigative reports to be reviewed as the result of a submission of a facility reported incident. Intake staff may also request more information from complainants to assist in the OHFC review process, receiving and placing over 8600 telephone calls a year related to complaint and facility reported incident activity

In situations when it is apparent that a complaint does not allege a violation of state or federal law, intake staff will assist in identifying appropriate referrals to other agencies, such as the Office of the Ombudsman for Older Minnesotans or to a licensure board.

There are multiple ways to address concerns about the care and services provided in our health care facilities. OHFC encourages residents, patients and families to raise concerns directly with the facility. Facility staff are more available and accessible, which hopefully will lead to a prompt resolution of the complaint or concern. Working with a family or resident council in a nursing home or other residential facility can provide a forum for raising issues and requesting that action be taken to address the concerns.

Minnesota also has a strong and effective ombudsman program that can work with residents, family members and others to advocate for changes within a facility outside of the regulatory process.

[3] Chapter 5 of the State Operations Manual outlines the state survey agency responsibilities for the complaint review and investigation process. The State Operations Manual is published by CMS and is required to be used by the survey agencies in implementing the Medicare and Medicaid certification process for nursing homes. Online access to the SOM, publication 100-07, is available at the following website:
http://www.cms.hhs.gov/Manuals/I0M/list.asp

The complainant is informed if the allegation has been referred to another agency and that no further action will be taken by MDH.

Triage Process

Once the intake process is completed, the information will then be reviewed to determine the extent of any further investigative review by OHFC. This information is reviewed on a daily basis. Intake staff will automatically start the process for an onsite investigation if serious allegations, such as sexual or physical abuse, are identified or allegations of potential immediate jeopardy concerns are noted.

OHFC has adopted a policy and procedure that outlines the factors that are considered to triage the complaints and facility reported incidents. This process will determine the extent of its investigative review. The policy and procedure is attached as Appendix A. OHFC also places a priority on those situations when action needs to be taken to determine whether an alleged perpetrator may be subject to disqualification or a referral to the Nursing Assistant Registry with a finding of abuse or neglect.

A number of investigative options are possible, ranging from taking no further action to the initiation of an onsite investigation. Intermediate steps are also considered, such as requesting additional information from a provider if not already requested by Intake staff; requiring facilities to review complaint allegations and submit documentation for a desk investigation; making referrals to other entities such as the Office of the Ombudsman for Older Minnesotans or the appropriate licensure boards; or providing information to the Licensing and Certification program to review at the next scheduled survey of the facility as an "area of concern." The results of the triage process for state FY04, FY05 and FY06 are shown in Table 7.

The following investigative options are possible:

> **No further review or investigation will occur.** This would happen when there is no alleged violation of rules or regulations, when sufficient information is not available or when requested medical and other records have been reviewed and no possible violations were identified. In addition, a review of information submitted by the facility may indicate that appropriate corrective action had been taken. The complainant or reporting entity is notified that OHFC has reviewed the information and no further investigative action will be taken. The complainant or the reporting entity is told to contact OHFC if there are questions regarding this decision.
>
> **The complaint could be handled as a desk investigation.** In this situation, OHFC will contact the facility, indicate that a complaint has been filed, and require the facility to submit to OHFC information relating to the allegation and the steps taken to address those concerns. This information is reviewed and, if no further action is required, the complainant is notified that the OHFC has reviewed the complaint; if the facility's information is accepted, no determination as to whether the complaint is substantiated will be made. Generally, the desk investigation is used in situations when concerns about resident care have been raised, but a review of the records and information provided from the facility would be considered reliable and credible and an onsite investigation would not add to the investigative review. For example, if concerns were raised about the appropriateness of a medication regimen or the failure to obtain medical or other treatments, a review of the records may provide sufficient

information. Dirty rooms, cold food and medication errors not resulting in harm are also common allegations.

The complaint is referred to the Licensing and Certification Program as an "area of concern". The allegation is shared with licensing and certification staff and will be reviewed during the next survey process. These "areas of concern" are usually of a general nature not involving an allegation of abuse or neglect. Examples of such complaints include neglect issues that do not result in actual harm or that are not recurring; verbal or mental abuse that does not result in a resident feeling frightened or threatened; patient rights issues; physical plant complaints that do not pose immediate threat to the safety of patient/residents; and dietary and housekeeping complaints that do not impact care.

The complaint or facility reported incident could be assigned for an onsite investigation. Complaints and facility reported incidents that are determined to require this level of investigation are typically the most egregious and serious in nature. Examples would include situations when a potential immediate jeopardy concern has been identified; or when serious neglect concerns are raised such as situations causing fractures, pressure ulcers, or significant weight loss. Other examples will be addressed in the section describing the time frames for the initiation of the investigation. When a complaint is assigned for an onsite investigation, a letter is sent to the complainant notifying that this is the investigative procedure that will be used and a case number and the name of the investigator assigned is in the letter. When the onsite investigation is completed, a copy of the final report is provided to the complainant.

Table 7: Complaints and Facility Report Incidents Assigned for Further Review
FY04, FY05, FY06

	FY04	FY05	FY06
Onsite	516	474	442
Desk	152	146	150
Refer to Survey	64	148	206

Onsite Investigations

After it has been determined that an onsite investigation of a complaint or facility reported incident is required, further prioritization is completed to assure a timely response based on the nature of the allegation. For example, an onsite investigation of a complaint or facility reported incident that alleges immediate jeopardy must be initiated within two working days of receipt of the allegation. Immediate jeopardy includes those situations which are, or have the potential to be, life threatening or resulting in serious injury.

Complaints, which allege a violation of the Emergency Medical Treatment and Active Labor Act (EMTALA), often referred to as "patient dumping", must be investigated within a two-day period.

Complaints and facility reported incidents that allege a higher level of actual harm will be investigated onsite within 10 working days of receipt of the complaint, and consist of situations that result in

serious adverse consequences to patient/resident health and safety but do not constitute an immediate crisis and delaying an onsite investigation would not increase the risk of harm or injury. This would include situations when neglect has led to pressure sores or significant weight loss, when physical abuse has been alleged, unexplained or unexpected death which may have been the result of neglect or abuse; physical abuse of residents; mental or emotional abuse which threatens or intimidates residents; or failure to obtain medical intervention.

Complaints and reports assessed as not having a higher level of actual harm, but having the potential to do so, are assigned for onsite investigation within 45 days. These types of complaints and facility reported incidents include resident care issues, inadequate staffing which has a negative impact on resident health and safety, and patient rights issues.

Resolution of Onsite Investigative Reviews Conducted in State FY04, FY05, FY06

All onsite investigations are governed by the requirements defined in state laws and the federal laws and regulations governing the Medicare and Medicaid certifications programs. OHFC is responsible for forwarding all investigative reports to the facility and complainant when an investigation is completed. The VAA requires that investigations be completed within 60 days. If this is not possible, OHFC is required to provide an estimate as to when the investigation will be completed.

When an onsite investigation is completed, the findings are either substantiated, unsubstantiated or inconclusive. **A substantiated finding means** a preponderance of the evidence shows that the allegation occurred. **An unsubstantiated finding means** a preponderance of the evidence shows that the allegation did not occur. **A finding of inconclusive means** that there is less than a preponderance of evidence to show that the allegation did or did not occur.

Of the 442 onsite investigations assigned in SFY06, 314 were completed in SFY06. Table 8 conveys all onsite investigations COMPLETED in the state fiscal year, including any onsite investigations that were not completed in the previous state fiscal year. In SFY05 there were 103 onsite investigations that carried over to SFY06, were completed in SFY06 and are reflected in the total of 417. There were 128 onsite investigations that were not completed in SFY06, but were completed by the end of calendar year 2006. This 128 will be reflected in SFY07 data.

Table 8: Results of Completed Onsite Investigations FY04, FY05, FY06

	FY04		FY05		FY06	
	Number	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Substantiated	192	37.2	165	34.8	164	39.0
Inconclusive	165	32.0	172	36.0	124	30.0
Un-substantiated	159	30.8	137	29.0	129	31.0
Total	516	100	474	100	417	100

All VAA investigative reports are referred to the Medicaid Fraud Division of the Attorney General's Office and the long-term care ombudsman receives copies of all public reports. If maltreatment is

substantiated, a copy of the report is provided to the MN Department of Human Services, MDH Licensing and Certification, the city and/or county attorney, the local police department, and any affected licensing board.

Public reports of all onsite investigations for the past two years are available on MDH's website: http://www.health.state.mn.us/divs/frp/directory/surveyapp/provcompselect.cfm

If OHFC makes a finding of maltreatment involving a nursing assistant working in a nursing home, those findings are reported to the Nursing Assistant Registry (NAR). The NAR is responsible for notifying the nursing assistant and informing the nursing assistant of the appeal rights. Once a finding is entered on the Registry, the individual is permanently prohibited from working in a nursing home. These individuals are also referred to the Minnesota Department of Human Services for disqualification, as are other individuals who have maltreated an individual, for whom disqualification is required.

Number of employees with substantiated maltreatment findings:

FY04	FY05	FY06
92	66	75

Number of hearings requested:

FY04	FY05	FY06
20	33	18

Number of people referred to the Nursing Assistant Registry with substantiated findings of abuse, neglect, or exploitation:

FY04	FY05	FY06
64	58	75

Evaluation of the OHFC Complaint Process

Case Backlog and Conformance to Statutory Time Frames

One of the areas required to be addressed in this report is whether or not there is a backlog of cases and whether or not OHFC investigative activities conform to statutory time lines.

Under the provisions of the VAA, OHFC as the "lead agency" has a number of specific time frames to meet. These include providing information on the initial disposition[4] of a report within 5 business days from receipt; completing the final disposition within 60 days of its receipt; providing a copy of the investigative report within 10 days of the final disposition to parties identified in the VAA and responding to requests for reconsideration within 15 days of the request.

The most significant time frame relates to the completion of the final disposition within 60 days. As defined in the VAA, the final disposition is the determination as to whether or not the maltreatment

[4] As defined in the VAA, the initial disposition is the lead agency's determination as to whether the report will be assigned for further investigation.

report will be substantiated, inconclusive, etc. Conformance to this time frame will be discussed later in this section.

While no other specific time frames are contained in state law, the time frames imposed on OHFC under the federal certification program are significant. Each year, CMS conducts performance reviews of each state survey agency. One of the performance standards relates to the "conduct and reporting of complaint investigations…". The standards focus on the following areas:

- whether the state agency follows appropriate guidelines for the prioritization of complaints;
- are various types of complaints - such as those alleging immediate jeopardy, a violation of EMTALA, or nursing home complaints alleging higher levels of "actual harm" - initiated and/or completed within designated time lines;
- is the appropriate data entered into the federal system on a timely basis.

The federal thresholds for being in conformance with these elements are high, 90% or higher. CMS review for FFY 06 did not identify any significant concerns with OHFC's triage process, how investigative priorities are set, and the general timeliness of our activities with respect to initiating investigations.

The federal review indicates that the policies and procedures used by OHFC are appropriate to identify the cases that require more intensive levels of investigation. While OHFC has generally met the time frames for the initiation of onsite investigative reviews, completion of the investigative reports does not meet the 60 day time limit in the VAA. The average completion days for reports, which would include VAA mandated reports, has been approximately 107 days each of the past 3 state fiscal years. To a large extent, delays in completion of reports are attributed to ongoing case assignment to the investigators and the need to meet the federally mandated time lines for the start of the federal process. For FY 04, 64% of the onsite investigations needed to be initiated within 10 days or less. This percentage was 59% in FY 05 and was 66.6% in FY 06. In order to meet the federal performance standards, pressure is placed on the investigators to initiate an increasing number of investigations. This delays the ability to complete already assigned investigations.

While this delay is a concern, steps have been taken to speed up the process in situations when the investigation has resulted in a substantiated finding, when correction orders or federal deficiencies will be issued, or when findings leading to the potential disqualification of an individual will be made. In these situations, actions are required by the facility to take steps to come into compliance with state or federal regulations, the process for disqualification of an individual needs to commence, or referrals of substantiated findings to law enforcement personnel or to appropriate licensure boards needs to be made.

Adequacy of Staffing

As noted previously, OHFC is beyond the final disposition time frame of 60 days mandated by the VAA. To a certain extent, additional staffing resources would assist to reduce the time frame by reducing the number of new assignments given to the current complement of investigators. However, the need for new staff and the attendant costs need to be weighed against the potential benefits to be achieved and how this would improve the safety of patients and residents. The federal budget

authorized OHFC to hire an additional supervisor in FFY06. This hire was completed near the end of FFY06. The filled complement of investigators for calendar year 2006 averaged 13.

A more important variable relating to the adequacy of staffing is determining whether more investigative reviews, especially onsite investigations, will improve the safety of vulnerable adults. Several factors need to be taken into consideration, including the time for completion of onsite investigations and the types of issues that may not get reviewed as part of the complaint process.

Over the past few years, there has been an increase in the average number of hours for the completion of onsite investigations, whether or not the investigation is subsequently substantiated.

The average hours for completing an investigation are as follows:

	FY04	FY05	FY06
Complaint substantiated	39.1 hrs	45.0 hrs	51.6 hrs
Complaint unsubstantiated	23.8 hrs	29.2 hrs	30.0 hrs
Inconclusive	25.2 hrs	32.6 hrs	37.7 hrs

There needs to be further analysis of these numbers to determine whether or not the hours could be reduced. OHFC is devoting more time to serious allegations which will be more complicated to review. As discussed above, the appropriate triage and priority assignment for complaints is a major emphasis of CMS. OHFC is seeing a slight increase in the number of investigations that need to be assigned in less than 10 days. This means that cases involving higher levels of harm are increasing and it is reasonable to assume that these cases will be more clinically complicated. As hours for completion increase, this will reduce annual caseload for the investigators.

The current triage and priority setting process used by OHFC has been reviewed and accepted by CMS. MDH federal performance reviews indicate that CMS has accepted OHFC's performance as it relates to review and priority setting and time frames for complaint initiation. This means that the most serious investigations are getting the appropriate level of investigative review by OHFC.

It is increasingly difficult to find qualified replacements for investigators leaving their employment with OHFC. The time devoted to hiring and training has an impact on workload performance. In the next year we will be reviewing workflow and other components of the process to find ways to improve compliance with timelines.

Part 2: The Authority and Responsibility of the Office of Health Facility Complaints Regarding Federally Certified Nursing Homes

The Office of Health Facility Complaints (OHFC) is responsible for the review of complaints and facility reported incidents from all licensed and federally certified health care facilities in the state. While not specifically required to be included in this report under the reporting provisions outlined in Minnesota Statutes §626.557, subdivision 12b, clause (e), the Department believes that it is appropriate to provide information relating to the activity and performance of OHFC under the federal certification requirements; this provides a more complete picture of the work of the program.

OHFC is a distinct program within the Department's Compliance Monitoring Division. OHFC has statewide jurisdiction and is responsible for complaint and facility reported incident investigations in all licensed and certified health care facilities in the state. These facilities include hospitals, nursing homes, boarding care homes, supervised living facilities (SLF) and home health care providers, including assisted living home care providers. Specific responsibilities mandated by the Centers for Medicare and Medicaid Services (CMS), which is the federal agency responsible for the certification of these facilities, include the investigation of alleged violations of the Emergency Medical Treatment and Labor Act (EMTALA) by hospitals; conducting complaint investigations authorized by the CMS Regional Office in accredited hospitals; investigating complaints against certified health care facilities or providers; and investigating facility reported incidents submitted by certified facilities under federal law.[5]

During Federal Fiscal Year 2006[6] (FFY06) OHFC conducted 473 on-site investigations, of which 346 were in nursing homes. Part 2 of this report addresses the activities and responsibilities of OHFC as they relate only to certified nursing homes.

While some OHFC staff are located outside of the Department's St. Paul location, the Office does not assign investigators to precise geographical districts such as those created by the Division's Licensing and Certification Program. All investigative findings are reviewed in the St. Paul office. Final reports, correction orders and federal deficiencies are issued from that office. The data provided in this report and in past reports are compiled on a statewide basis. Unlike the Licensing and Certification Program, the classification of data by geographic districts is not a relevant factor in reviewing OHFC operations.

Legal Authority

The authority for the OHFC to conduct investigations in nursing homes is found in Minnesota Statutes §§144A.51 -.54[7]; in Minnesota Statutes §626.557[8] and in federal statutes and regulations[9]. As the "state survey agency" for federal certification purposes, the Minnesota Department of Health is responsible for performing the complaint related functions described in federal law. These functions have been assigned to the Compliance Monitoring Division and OHFC is the designated entity within the Division responsible for these activities.

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[5] Certified nursing homes and Intermediate Care Facilities for the Mentally Retarded are required under federal regulations to report to the appropriate state authority allegations of mistreatment, neglect and abuse. See 42 CFR 483.13(c) and 42 CFR 483.420(d).

[6] FFY 06 runs from October 1, 2005 to September 30, 2006.

[7] Minn. Stat. §§ 144A.51-.54 establishes the Office of Health Facility Complaints and outlines its responsibilities to investigate complaints against health care facilities and providers.

[8] Minnesota Statutes §626.557, also known as the Vulnerable Adult Abuse Reporting Act, provides the authority and responsibility of a "lead agency," in this case, OHFC, to review and investigate allegations of maltreatment, i.e. abuse, neglect and financial exploitation reported by health care facilities.

[9] Sections 1819 (g)(4) and 1919(g)(4) of the Social Security Act require that the State survey agency maintain procedures and staff to investigate complaints of violations by nursing homes; 42 CFR 488.332 is the regulatory provision addressing state agency responsibilities for nursing home complaint investigations; and 42 CFR 488.335 requires that the state survey agency investigate all allegations that an individual in a nursing home might have abused or neglected a resident or misappropriated the residents property. This section requires that substantiated findings of abuse and neglect be reported to the state's Nursing Assistant Registry or to the appropriate licensure boards.

OHFC is required to follow the provisions of federal law as well as the provisions contained in the State Operations Manual (SOM), which is published by CMS. The SOM details the duties and responsibilities of the state survey agency and is the document that includes the various interpretive guidelines for certified facilities. Chapter 5 of the SOM details the specific requirements that are to be followed while conducting complaint investigations.

In addition to the specific laws requiring the establishment of a complaint office, state and federal law outlines the authorities for issuing correction orders, federal certification deficiencies and imposing fines or other remedies for facility noncompliance.[10] Under these provisions, OHFC has the authority to make findings, issue deficiencies and state licensing correction orders, issue state penalty assessments; and recommend to the CMS Regional Office the imposition of remedies against certified facilities. OHFC also makes determinations of maltreatment against facilities and individuals under the state VAA law and under the provisions of federal regulations. Facility and individual requests for reconsideration or requests for administrative hearings on those findings are processed by OHFC. OHFC staff are also responsible for the review of set-aside requests for individuals that have been disqualified under the provisions of Minnesota Statutes, Chapter 245C. OHFC staff are involved in any hearings or judicial challenges related to those decisions.

Combination of State and Federal Provisions

Federal and state provisions authorizing investigations and detailing the requirements to be followed by health care facilities do not create significant conflict with each other. For that reason, OHFC combines its federal and state authorities and responsibilities when conducting investigations in nursing homes. Reasons that support and justify this combined approach include the following:

1. The state licensure and federal certification regulations applicable to nursing homes are generally consistent. Thus, a finding of noncompliance under the federal certification program often supports a finding of noncompliance under state law. Appendix I of the Department's Annual Quality Improvement Report on the Nursing Home Survey Process, dated December 15, 2005 provides greater detail on the relationship between the state and federal regulations. A copy of this report can be found at the following web site: http://www.health.state.mn.us/divs/fpc/aqirnhs2005.pdf

2. Both the state VAA law and the federal regulations impose similar obligations on nursing homes relating to the internal investigation of abuse or neglect allegations. The federal provisions require that the nursing home report allegations consistent with state law, therefore, the submission of a report required by the VAA law meets this federal obligation.

3. The provisions of the VAA requiring that the lead agency make determinations as to the culpability of individuals for abuse or neglect and the federal requirements addressing abuse and neglect findings against nursing assistants and other individuals working in certified nursing homes are also consistent.

[10] Minnesota Statutes §144A.10 specifies the authority to issue correction orders and penalty assessments to nursing homes. Federal authority for the issuance of remedies can be found in 42 CFR Part 488. Chapter 7 of the SOM also addresses the specific duties of the state survey agency relating to nursing home enforcement.

Specific Components of the Investigative Process for Nursing Homes

Intake and Triage

The intake and triage process used by OHFC to review complaints and facility reported incidents is explained in Part 1 of this report.

Federal policy specifically assigns time lines to specific types of complaints. See §§ 5020 to 5030H in Chapter 5 of the SOM. There are no corresponding state timelines for the initiation of an onsite complaint investigation.[11]

The OHFC triage policy incorporates the more precise federal requirements for determining the type of allegations and the timeline for the initiation of a complaint investigation. It is these provisions that mandate that investigations of allegations of immediate jeopardy are to be investigated within 2 days and that investigations of allegations of "high actual harm" are to be investigated within 10 days. 91% of the total number of onsite nursing home investigations (315 of the 346) conducted by OHFC fall within those two categories.

Table 9 identifies the number of investigations that needed to be initiated within 2 days and the number of investigations that needed to be initiated within 10 days. The compliance percentage is also included.

Table 9: FFY06 OHFC Onsite Nursing Home Complaint and Facility Reported Incident Investigations Required within 2 or 10 Days

Type of complaint or incident	Number of onsite investigations	Number of onsite investigations within required time	Percent within required time
Nursing home	346 total	310 of 315	98.4%
Nursing home required within 10 days	280	276	98.57%
Nursing home required within 2 days	35	34	97.10%

[11] In accordance with Minn. Stat.§626,557, subd. 9c, OHFC is required to notify the reporter that the report has been received and provide information on the initial disposition of the report within 5 business days of the receipt of the report. As defined in section 626.5572, subd. 12, the "initial disposition" is the lead agency's determination as to whether the report will be assigned for further investigation. The VAA requires that the lead agency complete its investigation within 60 calendar days of the receipt of the report or provide information as to the reason for the delay and the projected completion date. See section 626.557, subd. 9c (d).

Abbreviated Standard Surveys

Chapter 5 of the SOM outlines the protocols to be followed by the state survey agency for complaint investigations. Due to the similarities between the state and federal regulations for nursing homes, these federal protocols are utilized for nursing home investigations under both federal and state law.

Complaint investigations in certified nursing homes are referred to as abbreviated standard surveys. This term is defined in § 7001 of the SOM as follows:

> **Abbreviated Standard Survey** means a survey other than a standard survey that gathers information primarily through resident-centered techniques on facility compliance with the requirements for participation. An abbreviated standard survey may be premised on complaints received; a change in ownership, management, or director of nursing; or other indicators of specific concern.

Section 7203 E, of Chapter 7 of the SOM outlines the expectation for an abbreviated standard survey:

> This survey focuses on particular tasks that relate, for example, to complaints received, or a change of ownership, management, or Director of Nursing. It does not cover all the aspects covered in the standard survey, but rather concentrates on a particular area of concern(s). The survey team (or surveyor) may investigate any area of concern and make a compliance decision regarding any regulatory requirement, whether or not it is related to the original purpose of the survey complaint.

Sections 5400 to 5450 of the SOM contain specific requirements and outline specific tasks to be completed during the abbreviated standard survey. These tasks include the following:

- **Section 5410 - Offsite Survey Preparation:** This includes the review of the allegation as well as other information that may have been received during the intake/triage process. It is during this process that other information regarding the facility such as prior survey and complaint history and discussions with the ombudsman about similar complaints would occur.
- **Section 5420 - Entrance Conference/Onsite Preparatory Activities:** On site investigations must be unannounced and at the time of the entrance, the general purpose of the visit will be provided. The investigator needs to assure that the confidentiality of individuals identified as part of the complaint, such as the reporter or specific residents, be protected.
- **Section 5430 - Information Gathering:** In addition to determining whether the complaint is substantiated, the OHFC investigative process is also required to determine the degree of facility compliance with the regulations and to determine if other residents, not specifically identified in the allegation, are at risk. Since Section 5430 addresses this process it is provided in its entirety.

> The order and manner in which information is gathered will depend on the type of complaint that is being investigated. Conduct comprehensive, focused, and/or

closed record reviews as appropriate for the type of complaint. It is very important to remember that the determination of whether the complaint happened is not enough. The surveyor needs to determine noncompliant facility practices related to the complaint situation and which, if any, requirements are not met by the facility.

Perform information gathering in order of priorities, i.e., obtain the most critical information first. Based on this critical information about the incident, determine what other information to obtain in the investigation.

Observations, record review and interviews can be done in any order necessary. As information is obtained, use what has been learned to determine what needs to be clarified or verified as the investigation continues.

Observe the physical environment, situations, procedures, patterns of care, delivery of services to residents, and interactions related to the complaint. Also, if necessary, observe other residents with the same care need. After determining what occurred, i.e., what happened to the resident and the outcome, investigate what facility practice(s) or procedures affected the occurrence of the incident.

EXAMPLE

It was verified through the investigation that a resident developed a pressure sore/ulcer which progressed to a Stage IV, became infected and resulted in the resident requiring hospitalization for aggressive antibiotic therapy. Observe as appropriate: dressing changes, especially to any other residents with Stage III or IV pressure sores; infection control techniques such as hand washing, linen handling, and care of residents with infections; care given to prevent development of pressure sores (such as turning and repositioning, use of specialized bedding when appropriate, treatments done when ordered, keeping residents dry, and provision of adequate nutritional support for wound healing).

Record review: If a specific resident is involved, focus on the condition of the resident before and after the incident. If there are care issues, determine whether the appropriate assessments, care planning, implementation of care, and evaluations of the outcome of care have been done as specified by the regulatory requirements.

EXAMPLE

For a complaint of verbal and physical abuse, review the record to determine the resident's mood and demeanor before and after the alleged abuse. Determine if there are any other reasons for the change in the resident's demeanor and behavior. Determine whether an assessment has been done to determine the reason for the change in mood and behavior. Does the record document any unexplained bruises and/or complaints of pain, and whether they occurred in relation to the alleged incident?

Interviews: Interview the person who made the complaint. If the complainant is not at the facility at the time of the survey, he/she should be interviewed by telephone, if possible. Also, interview the person the complaint is about. Then, interview any other witnesses or staff involved. In order to maintain the confidentiality of witnesses, change the order of

interviews if necessary. It may not always be desirable to interview the person who made the complaint first, as that may identify the person as the complainant to the facility. Interview residents with similar care needs at their convenience.

As interviews proceed, prepare outlines needed for other identified witnesses and revise outlines as new information is obtained.

It is important to note that OHFC has the authority to investigate the allegations that initiated the onsite investigation, and an obligation to expand that review to assure that similar concerns do not affect other residents in the facility. For this reason, OHFC will review records of a number of residents, make required observations in the areas identified as a concern, review incident reports to determine frequency of concerns or whether there is a possible pattern of noncompliance, and complete other tasks as necessary to determine whether the facility is in compliance with a regulation and the scope and severity of any noncompliance. If during the course of the investigation other unrelated findings of noncompliance are identified, OHFC investigators are required to issue appropriate deficiencies or state correction orders. All OHFC investigators are considered qualified surveyors and have passed the federally required SMQT tests.

- **Section 5440 – Information Analysis:** This is the step that determines whether the information obtained during the investigation will substantiate the complaint and determine if the nursing home has violated any regulatory provisions, and whether corrective action had been initiated by the facility. Information gathered by the investigator is reviewed by either the Director or Assistant Director of OHFC. Decisions are made as to whether the information supports the investigator's recommended deficiencies or correction orders or whether additional information is needed.
- **Section 5450 – Exit Conference:** Once the information analysis has been completed, including the required supervisory reviews, the investigator will advise the facility administrator whether deficiencies or correction orders will be issued.

Differences Between the Investigative Process and the Survey Process

OHFC is required to follow the federal regulations and the policies and procedures developed by CMS. However, there are some key differences in the process for an investigation as compared to a survey of a nursing home. One key difference is that most of the information required to support compliance during a survey process is gathered while the team is onsite. Therefore, at the time of the exit conference, the nursing home is notified of these findings. The nursing home is provided information identifying the findings of the survey process and informed that the survey team's supervisor will consult with Central Office staff, as appropriate, and make final decisions.

In contrast, OHFC investigations can rarely be concluded at the time of the onsite investigation, and for that reason, an exit conference is not conducted at the end of that onsite visit. The onsite investigation is in fact just one of the initial stages of the investigative process. It is the time when records are reviewed and obtained, when individuals needing to be interviewed will be identified and some of these interviews will be conducted.

Often the investigative activity is based on the off-site review of records, determining if additional records might be required and completing interviews of the individuals identified as having information or potentially having information related to the allegations.

The supervisory review of the draft deficiencies or correction orders is similar to the supervisory review process used in the Licensing and Certification Program. The investigator follows the same process used to draft the deficiencies by the survey team. This includes necessary references to the interpretive guidelines for nursing homes and conformance to the Principles of Documentation also issued by CMS. The draft deficiencies are then reviewed by the OHFC managers, similar to the process followed by the supervisors and managers in the L&C program. Since OHFC staff and L&C staff are part of the same division, there are opportunities for informal discussion about deficiencies among the staff of those programs. OHFC and the Licensing and Certification Program managers consult with the Compliance Monitoring Division Director's Office prior to issuing immediate jeopardy findings.

Only when this process is completed and determinations made as to whether the allegations will be substantiated or not, and whether deficiencies or orders will be issued, will the "exit" conference be initiated. This is conducted as a phone call with the facility's administrator. The date of this exit is the date that is identified on any deficiencies or orders issued as a result of the investigation. OHFC places priority on the completion of any necessary federal certification deficiencies and these will be issued shortly after the exit conference, in compliance with federal timelines.

Once deficiencies are issued, the OHFC investigator will complete the required investigative report. Federal provisions as well as the VAA specify the components that are to be contained in these reports. As noted previously, the VAA requires that the investigative reports be completed within 60 days of the date the report was received. Information relating to OHFC's compliance with this provision is contained in Part 1 of this report.

The conclusion of the report identifies whether the allegations are substantiated, unsubstantiated, or inconclusive. If maltreatment findings are substantiated, the report also identifies whether the facility or an individual is responsible.

Immediate Jeopardy and Substandard Quality of Care Determinations

If it is determined that investigative findings identify that substandard quality of care[12] exists, a partial extended survey will be completed. This is defined as follows:

[12] "Immediate jeopardy" is defined as a situation in which the facility's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident.
"Substandard quality of care" means one or more deficiencies related to the requirements under 42 CFR 483.13, resident behavior and facility practices (Tags 221-226), 42 CFR 483.15, quality of life (Tags 240-258), or 42 CFR 483.25, quality of care (Tags 309-333), that constitute either immediate jeopardy to resident health or safety (level J, K, or L); a pattern of or widespread actual harm that is not immediate jeopardy (level H or I); or a widespread potential for more than minimal harm, but less than immediate jeopardy, with no actual harm (level F).

> **Partial extended survey** means a survey that evaluates additional participation requirements and verifies the existence of substandard quality of care during an abbreviated standard survey.

During FFY 06, OHFC conducted 14 partial extended surveys out of the 346 on-site nursing home investigations. The completion of the partial extended survey was required as the result of the issuance of 21 federal deficiencies. Of the twenty-one, 20 were both immediate jeopardy (IJ) and substandard quality of care tags (SQC), and 1 was SQC only. Table 10 summarizes the tags issued.

Table 10: Deficiencies Issued as a Result of Partial Extended Survey FFY06

Nursing Home	Tag and Scope and Severity	Immediate Jeopardy	Substandard Quality of Care
#1	F223J, F225J	Yes	Yes
#2	F223K, F225K	Yes	Yes
#3	F309J, F324J	Yes	Yes
#4	F225K	Yes	Yes
#5	F225J	Yes	Yes
#6	F223J, F225J	Yes	Yes
#7	F223J, F225J	Yes	Yes
#8	F223J, F225J	Yes	Yes
#9	F223H	No	Yes
#10	F223J, F225K	Yes	Yes
#11	F309J	Yes	Yes
#12	F309J	Yes	Yes
#13	F333K	Yes	Yes
#14	F309J	Yes	Yes
	21 tags	20 tags	21 tags

In addition, OHFC issued 2 tags, F441 at scope and severity level K and F490 at scope and severity level J, both immediate jeopardy deficiencies, at 2 nursing homes. Those 2 tags did not meet the criteria for substandard quality of care.

The requirements for a partial extended survey are specified in Section III of Chapter 7 of the SOM and provide as follows:

> When conducting the extended/partial extended survey, at a minimum, fully review and verify compliance with each tag number within 42 CFR 483.30, Nursing Services; 42 CFR 483.40, Physician Services; and 42 CFR 483.75, Administration. Focus on the facility's policies and procedures that may have produced the substandard quality of care. As appropriate, include a review of staffing, inservice training and the infection control program. An extended/partial extended survey explores the extent to which structure and process factors such as written policies and procedures, staff qualifications and functional responsibilities, and specific agreements and contracts of the facility may have contributed to the outcomes. If the extended/partial extended survey was triggered by a deficiency in quality of care, conduct a detailed review of the accuracy

> of resident assessment. During the partial extended survey, consider expanding the scope of the review to include a more comprehensive evaluation of the requirements at 42 CFR 483.13, 42 CFR 483. 15, and/or 42 CFR 483.25 in which substandard quality of care was found.

However, determining whether a partial extended survey will be required as a result of an OHFC investigation is not as precise as determining whether an extended survey will be required as the result of findings made during a survey. In survey situations, one of the final stages of the survey is deficiency determination. If that process identifies immediate jeopardy concerns or findings constituting substandard quality of care, the facility is informed that the survey will be expanded and an extended survey will be conducted.

An investigative situation often requires follow-up interviews and record review that cannot be completed during the onsite investigative visit. Therefore, it is not always possible to precisely determine whether a partial extended survey will be needed while the investigator is onsite. In situations when immediate jeopardy may be identified, the OHFC investigator consults with OHFC managers to discuss the findings and determine whether facts support the IJ recommendation. OHFC managers also discuss these findings with the Director's Office before the final IJ determination is made.

As outlined in the triage policy, allegations that appear to create an immediate jeopardy situation must be investigated onsite within 2 working days. In these situations, the investigator reviews the allegation and if it appears the IJ allegation will be substantiated, then determines whether sufficient corrective measures have been implemented by the facility to assure that residents are not at risk. If the allegation was triaged at the IJ level, verifying whether or not an IJ exists can often be made at the time of the onsite investigation.

There have been situations when the initial allegation was not triaged at the IJ level, and subsequent investigative findings identify the existence of the immediate jeopardy and that acceptable corrective action has not occurred. An example would be a situation when it is determined, after the onsite investigation, that the facility failed to appropriately identify or investigate abuse allegations and the perpetrator is still in the facility. In these situations, the investigator may have to return to the facility in order to complete the partial extended survey.

Similarly, if based on the onsite review it appears that deficiencies comprising substandard quality of care are identified, the investigator discusses these issues with OHFC management and a decision may be made to complete the necessary steps required for the partial extended survey, even if a final determination has not been made. This assures that sufficient information is gathered onsite and will also avoid another onsite visit to the facility if the substandard quality of care determination is finalized at a later date. A final decision as to whether a facility meets the criteria for substandard quality of care cannot be made until deficiencies have been identified and the scope and severity of those deficiencies has been determined. If substandard quality of care is determined and the partial extended survey has not been conducted, it will be necessary for the investigator to complete the partial extended survey before the investigation can be concluded.

Results of OHFC Complaint Investigations FFY06

During FFY06, 58 of 346 onsite nursing home investigations resulted in the issuance of 103 federal certification deficiencies. These deficiencies were issued to 50 separate nursing homes. 5 nursing homes were issued deficiencies as the result of more than one OHFC onsite investigation.

A total of 49 state licensing correction orders were issued to 29 different nursing homes during FFY06 as a result of an onsite OHFC investigation. All correction orders were found to be in compliance within the required time period and no state penalty assessments were issued as a result of those 49 correction orders. The potential fine amounts for these correction orders ranged from $0 per day/per order to $500 per day/per order.

Table 11: Deficiencies and Correction Orders Issued FFY06

Note: Deficiencies and Correction Orders do not correspond as listed

Deficiencies:*	Correction Orders:
F155 – Notification of Rights and Services 1-D	MN Rule 4658.0085 Notification of Change in Resident Health Status (7) $350 daily
F157 – Failure to Report Significant Change 6-D; 4-G; 2-J	4658.0400 Comprehensive Resident Assessment (3) $300 daily
F203 – Transfer or Discharge 1-D	4658.0405 Comprehensive Plan of Care (2) $300 daily
F204 – Orientation for Transfer or Discharge 1-D	4658.0450 Clinical Record Contents (2)$300 daily
F206 – Permitting Resident to Return to Facility 1-D	4658.0520 Adequate and Proper Nursing Care, subp. 1 (11) $350 daily
F223 – Residents to be Free from Abuse 1-H; 3-J; 2-K	4658.0525 Rehabilitation Nursing Care, subp.3B (1) $350 daily, subp.5B (1) $350 daily subp.9 (1) $350 daily
F225 – Not Employ Persons Guilty of Abuse 7-D;1-E; 4-J; 4-K	4658.0530 Assistance with Eating (1) $350 daily
F241 – Dignity 1-D	4658.0610 Dietary Staff Reqmts, subp. 7 (1) $350
F246 – Accommodation of Needs 1-E	4658.0615 Food Temps (1) $350
F272 – Comprehensive Assessment 2-D; 2-G; 1-J	4658.0800 Infection Control (1) $300 daily
F280 – Comprehensive Care Plan 1-E	4658.1320 Medication Errors, subp. B1 (2) $500, subp. C (1) $500
F282 – Services Provided in Accordance with Care Plan 1-G; 1-J	4658.1350 Disposition of Medications (1) $300
F309 – Failure to Provide Necessary Care 3-D; 5-G; 4-J	4655.1400 Responsibilities of the Administrator in Charge (2) $50
F314 – Proper Treatment for Pressure Sores 3-G	MS 144.651 Health Care Bill of Rights, subd 6 (1) $250, subd. 10 (1) $250, subd. 14 (2) $500, subd. 29 (2) $250
F315 – Urinary Incontinence 1-D; 1-E	MS 626.557 Reporting of Vulnerable Adults, subd 3(a) (1) $250, subd 4 (2) $100
F323 – Accident 1-E; 1-G; 1-J	
F324 – Provide Supervision Prevent Accidents 2-D; 5-G; 1-J	
F326 – Nutrition 1-D	
F327 – Hydration 1-G	
F328 – Special Needs 1-D; 1-G	
F333 – Medication Errors 3-D; 1-G; 1-K	
F364 – Food 1-E	
F371 – Sanitary Conditions Food Prep and Serve 1-E	
F385 – Physician Service 1-D	
F426 - Pharmacy Services and Procedures 4-D	

F441 - Infection Control 1-K	
F442 - Preventing Spread of Infection 1-E	
F444 – Washing Hands when Indicated 1-D	
F490 – Effective Administration of Facility 1-H; 1-J	
F492 – Compliance with Federal, State, Local Laws 1-D	
F493 – Governing Board 1-F	
F497 – Regular Inservice Education 1-E	
F514 – Clinical Records Meet Appropriate Stnds 3-D	

- pending IIDR review: (1) 157s/sJ, (1) 223s/sJ, (1) 225s/sK, (1) 272s/sJ, (1) 309s/sJ, (1) 324s/sG

58 post certification revisits were conducted by OHFC during FFY 06. These revisits were generally conducted onsite. A phone or written verification of compliance occurs rarely, if at all.

During FFY 06, 29 federal civil money penalties (CMPs) were recommended by OHFC. CMS imposed 30 civil money penalties. OHFC recommended the imposition of 2 denial of payments for new admissions and 2 were imposed by CMS.

During FFY 06, the remedies, other than civil money penalties, recommended and imposed as the result of onsite investigations is as follows:

TYPE	RECOMMENDED	IMPOSED
State Monitoring	12	1
Discretionary Denial of Payment	2	2
23-Day Termination	10	0

During FFY 06, the following civil money penalties were recommended and imposed:

TYPE	RECOMMENDED	IMPOSED
Per Instance	29	30
Per Day	0	0

CMS imposed CMPs twice when OHFC did not recommend and the imposition of one CMP recommended by OHFC is pending. One of the amounts of the per instance CMPs recommended by OHFC was increased by CMS prior to issuance.

Referrals to the Nurse Aide Registry or to Licensure Boards

OHFC is required to make referrals to appropriate licensure boards under the provisions of Minn. Stat. §626.557, subd. 9c, clause (g) that states:

> (g) The lead agency shall routinely provide investigation memoranda for substantiated reports to the appropriate licensing boards. These reports must include the names of substantiated perpetrators. The lead agency may not provide investigative memoranda for inconclusive

> or false reports to the appropriate licensing boards unless the lead agency's investigation gives reason to believe that there may have been a violation of the applicable professional practice laws. If the investigation memorandum is provided to a licensing board, the subject of the investigation memorandum shall be notified and receive a summary of the investigative findings.

It is the practice of OHFC to refer all substantiated maltreatment reports involving licensed nurses to the Board of Nursing (BON). The report, including private data, is sent without identifying any particular nurse. The BON then determines which nurse(s), if any, to contact. In addition, if an investigation identifies that maltreatment by unlicensed personnel occurred due to inadequate training, supervision, or direction by a licensed nurse or nurses, the report will be forwarded to the BON for review.

Similarly, the nursing home administrator is responsible for the operation and management of the nursing home. In accordance with the Board of Examiners for Nursing Home Administrators (BENHA), OHFC refers all substantiated maltreatment reports to BENHA for its review.

42 CFR 488.335 (f) also requires that OHFC report substantiated findings of abuse, neglect or misappropriation of resident property to the Nurse Aide Registry. During FFY 06, 75 such findings were made against nursing assistants and submitted to the Registry.

Access to OHFC Investigative Reports

A copy of each completed OHFC investigation, including a copy of any deficiencies or correction orders issued as a result of the investigation, can be accessed at the following link: http://www.health.state.mn.us/divs/fpc/directory/surveyapp/provcompselect.cfm

Timelines for the Issuance of Deficiencies and Conducting of Revisits

Minnesota Statutes §144A.101 contains two provisions setting timelines for the performance of survey related functions – the issuance of federal deficiencies and the timing of revisits when remedies are in place. These provisions do not apply to the complaint investigation process. Minnesota Statutes § 144A.101, subdivision 1 states that this section "applies to survey certification and enforcement activities by the commissioner related to **regular, expanded, or extended surveys** under Code of Federal Regulations, title 42, part 488." As previously discussed, complaint investigations conducted by OHFC are "abbreviated standard surveys" or "partial extended surveys." Specific definitions of the terms "abbreviated standard survey," "extended survey," and "partial extended survey" are found in 42 CFR 483.301. The term "expanded survey" is defined in Section 7001 in Chapter 7 of the SOM. The Department is not aware of a federal definition for a "regular" survey, and it has been the Department's interpretation that this term means a "standard survey" as defined in 42 CFR 483. 301.

The Department believes that it is appropriate to evaluate how well OHFC complies with these measures as they are important to the certification process.

Issuance of Certification Deficiencies

Minnesota Statutes §144A.101, subdivision 2 requires that draft statements of deficiencies be provided to the nursing home at the time of the exit conference and that completed statements of deficiencies be issued within 15 working days of the exit.

As previously discussed, the exit conference process for an OHFC investigation is different than the process used for standard surveys. This exit is conducted by phone and the investigator informs the facility administrator of the conclusion of the investigation and whether deficiencies will be issued. At the time of this phone call, the contents of the statement of deficiencies have been reviewed and approved for mailing. Of the 58 sets of federal deficiencies issued in FFY06, 56 were issued within 15 working days of the date of exit.

Timelines for Survey Revisits

Minnesota Statutes §144A.101, subdivision 5 requires that revisits be conducted within 15 calendar days of the date that corrections will be completed by the nursing home in situations where a category 2 or category 3 remedy is in place. **A revisit cannot occur until the nursing home has submitted a Plan of Correction (PoC) that is accepted by the Department.** The Department's compliance with this provision is discussed in the Department's 2006 Annual Quality Improvement Report on the Nursing Home Survey Process. Thirty-five revisits were identified as not complying with the statutory provision; 9 of those were revisits conducted by OHFC. A summary of these 9 situations follows:

- Two facilities submitted a PoC with an identified date of correction that predated the acceptable plan of correction by 15 days and the post certification revisits (PCRs) were completed within five days of receiving acceptable PoCs. The timing of the revisits did not result in the facilities having increased financial loss.

- One facility submitted a PoC with an identified date of correction that predated the acceptable PoC. The PCR was completed more than 15 days after receiving the acceptable PoC. The timing of this revisit did not result in the facility having increased financial loss.

- One facility submitted a PoC with an identified date of correction that predated the acceptable PoC more than 15 days. The PCR was completed more than 15 days after receiving the acceptable PoC. The timing of this revisit did not result in the facility having increased financial loss

- Two facilities submitted a PoC with an identified date of correction that predated the acceptable PoC. The PCRs were completed within 15 days after receiving the acceptable PoC. The timing of the revisits did not result in the facility having increased financial loss.

- One facility was notified of mandatory denial of payment for new admissions subsequent to the 1st PCR of a complaint survey. Prior to the effective date of this remedy a recertification survey was completed and the facility was found to not be in compliance. The 2nd PCR was completed more than 15 days after the PoC date of completion due to federally required coordination of the complaint and survey deficiencies revisits. The facility did incur financial loss. This was caused by failure to correct and the timing of MDH revisits based on federal mandates.

- One facility was notified of the imposition of a remedy of denial of payment for new Medicare and Medicaid admissions pursuant to the 1st PCR. The 2nd PCR was completed within 15 days after receiving the acceptable PoC but more than 15 days of the listed PoC completion date. The facility did incur financial loss, however, this was caused by failure to correct as opposed to the timing of MDH revisits.

Independent Informal Dispute Resolution (IIDR) and Informal Dispute Resolution (IDR)

Any deficiency issued by OHFC is subject to the IIDR or IDR process utilizing the same process that is in place for deficiencies issued by the Licensing and Certification program.

During FFY06, 36 of the 103 deficiencies issued by OHFC were the subject of either an IIDR or IDR. Table 12 summarizes the type of review requested and scope and severity (s/s) of tags disputed.

Table 12: IDR and IIDR Reviews Requested and Tags Disputed FFY06

	IDR	IIDR
Total requested	22	24
# of tags disputed	42	56
# that involved OHFC	4	15
# of OHFC tags disputed	5	31
Scope and severity of OHFC tags	1 D, 1 E, 1 G, 1 H, 1 J	1 D, 2 E, 1 F, 7 G, 2 H, 12 J, 6 K
Resolution of OHFC tags	All 5 tags valid	5 ALJ reviews involving 8 tags completed: 6 tags valid: 1 @ s/s D; 3 @ s/s G; 2 @ s/s K; 2 tags recommend as deleted: 1@ s/s G; 1 @ s/s K 3 ALJ reviews pending - 6 tags: 1 @ s/s G; 4 @ s/s J; 1 @ s/s K 7 reviews withdrawn by nursing home prior to IIDR involving 17 tags: 1 @ s/s E 1 @ s/s F 2 @ s/s G 2 @ s/s H 8 @ s/s J 2 @ s/s K

Reconsiderations and Appeals

Under the provisions of the VAA and federal regulations relating to findings of maltreatment against nursing home personnel, if a facility or an individual is determined to have neglected, abused or financially exploited a nursing home resident, the facility or individual can request an informal reconsideration. If the facility or individual is not satisfied with the decision after this reconsideration process, a fair hearing under the provisions of MN Statute 256.045 can be requested. A hearing judge employed by the Department of Human Services conducts the fair hearings. During FFY 06, 33 hearings were requested as the result of 75 substantiated findings in nursing home investigations.

Under the federal regulations, specific findings of neglect, abuse or financial exploitation are also submitted to the Nurse Aide Registry once any requested reconsiderations or hearings have been completed. During FFY 06, findings of neglect, abuse, or financial exploitation for 75 individuals were added to the Registry.

Under the provisions of Minnesota Statutes §626.557, subd. 9d, clause (b), a vulnerable adult or other interested party not satisfied with the results of an investigation can request a review of these findings under the provisions of Minnesota Statutes §256.021. During FFY06, 4 requests were made for these reviews.

Areas of Focus in FFY06

OHFC was able to hire an additional supervisor, however, that did not occur until the last quarter of the federal fiscal year. This additional supervisor will assist with managing workflow to improve compliance with state and federal timelines for initiating and completing investigation. According to CMS' most recent evaluation of timeliness of complaint and incident investigations, OHFC continues to properly triage and meet the 2 and 10 day onsite time frames to begin investigation of the most serious complaints and incidents reported. OHFC did not, however, meet the standard for completing onsite investigations for complaints and incidents triaged as non-immediate jeopardy – high, within the required 20 working days.

Minnesota was and continues to be an outlier in terms of the number of deficiencies issued on complaint investigations. Although OHFC issued 25% more deficiencies in FFY06 than in FFY05, Minnesota is still well below the number of complaint deficiencies issued by the other 5 states in Region V. We have initiated contact with those other states to research and ascertain what might account for such a large deviation. Areas being researched include the number of staff in other states assigned to conduct complaint investigations, the types of complaints completed in those states, whether complaint staff in those states have obligations similar to those of OHFC under the VAA; the level of state and federal funding supporting the complaint functions; and any state laws that have different complaint procedures than what is used in Minnesota.

OHFC did not complete its review of the differences between language in the state VAA and the federal regulation relating to the reporting and possible investigation of injuries of unexplained sources and it did not develop the statewide training for facilities on awareness of abuse and neglect of residents and internal investigation of these incidents. The review of the VA language will be completed in FFY07 and covered in the abuse training. We are also aware that CMS plans to issue additional interpretive guidance relating to abuse issues, however, we do not have any firm information as to the timing of this release.

Areas of Focus for FFY 07

1. Comparison with Region V States

Complaint activities are increasingly being scrutinized by CMS Regional Office staff to assure that complaint allegations are appropriately triaged, that required investigations are initiated within the

specified time limits and that the complaint process, including any issued deficiencies, is completed in accordance with the federal process.

During the past year, there have been discussions between CMS Regional Office personnel, OHFC staff and Division management regarding the significant difference in the number of complaint investigations and the number of deficiencies issued as the result of complaint investigations between Minnesota and the other states in CMS Region V.

Tables 13 and 14 identify the number of complaint investigations conducted in FFY06 by states in Region V and the number of deficiencies that have been issued as the result of these investigations. Minnesota is an outlier compared to the other states in our CMS Region. Division staff have been researching information about the complaint processes in these other states and will work with Regional Office staff on these matters. Areas being researched include the number of staff in other states assigned to conduct complaint investigations, the types of complaints completed in those states, whether complaint staff in those states have obligations similar to those of OHFC under the VAA; the level of state and federal funding supporting the complaint functions; and any state laws that have different complaint procedures than what is used in Minnesota.

Table 13: FFY06 Complaint Surveys in Region V by State & Nursing Home Count as of 9/30-06

Illinois	2,876 surveys (816 nursing homes)
Indiana	1,462 surveys (526 nursing homes)
Michigan	681 surveys (429 nursing homes)
Minnesota	307 surveys (404 nursing homes)
Ohio	2,122 surveys (980 nursing homes)
Wisconsin	871 surveys (403 nursing homes)
Region V	8,3 19 surveys (3558 nursing homes)

source: Federal CASPER (Certification and Survey Provider Enhanced Reporting) System

Table 14: FFY05 Deficiencies by Scope and Severity Issued as a Result of a Complaint Survey in Region V by State

S/S	B	C	D	E	F	G	H	I	J	K	L	Total
Region V	129	99	2,773	728	83	855	10	0	248	50	22	4,997
Illinois	69	44	774	126	35	288	4	0	138	15	16	1,509
Indiana	5	4	588	248	8	277	4	0	28	25	5	1,192
Michigan	3	0	362	83	4	128	0	0	24	1	1	606
Minnesota	0	0	40	8	0	17	1	0	6	5	0	77*
Ohio	40	41	670	158	21	70	0	0	20	0	0	1,029
Wisconsin	12	10	330	105	15	75	1	0	32	4	0	584

source: Federal CASPER (Certification and Survey Provider Enhanced Reporting) System

* This table does not include 36 deficiencies included in the Department's count of 103 deficiencies issued in FFY06 as the deficiencies were subject to IDR and IIDRs. See Table 12 for more information.

A report on the complaint process issued by the Department of Health and Human Services Office of Inspector General in July 2006 recommended some changes to the federal complaint process: strengthen the oversight of nursing home complaint investigation by requiring state agencies to meet

the 10-day timeframe for investigating compliance alleging actual harm; conducting additional follow-up to the State Performance Standard Reviews; and offer additional training on ACTS (federal data system for entering complaints) to regional offices and state agencies. As noted in a General Accountability Office report issued in December 2005, CMS is working on revised definitions of actual harm and immediate jeopardy that might alter the triaging decisions currently utilized by OHFC.

2. Accuracy and Consistency

As part of its 2007 Quality Improvement Plan, OHFC will continue its focus on ensuring the accuracy and consistency of the investigative process, ensuring compliance with state and federal requirements for triaging complaints and facility reported incidents and improving communications and coordination with internal and external stakeholders.

An additional supervisor was added to OHFC's staff in August of 2006. This position was added to assist with improving and maintaining consistency and quality in investigator orientation and training, the review of documents, to reduce the completion time of reports, and as a resource for guidance of staff.

The CMS evaluation of FFY06 Performance Standards for OHFC (Appendix C) indicates OHFC meets performance standards on prioritizing complaints and incidents, the timeliness of complaint investigations onsite within the required 2 and 10 working day thresholds and the quality of investigations. OHFC did not meet the standard of completing all of the 10 working day threshold complaints within the required 20 working day timeframe. CMS raises concerns about completing the investigations within the timeframe. A corrective action plan is required and OHFC is looking at whether it can meet the standard with projected staffing levels as 2 FTE positions were eliminated from the federal FFY07 budget.

Investigation of complaints in Intermediate Care Facilities for the Mentally Retarded (ICFsMR) has historically been conducted by the Minnesota Department of Human Services as that department is the lead agency per Minnesota's Vulnerable Adult law. CMS has recently questioned this process due to the federal certification of those facilities. Coordination of reviews with the Department of Human Services is being worked on. Investigations in ICFsMR may be an area of expansion for OHFC in FFY2007 and beyond.

OHFC is in the process of developing a process to enter data in the federal ACTS system on complaints investigated as desk reviews and referred to survey as areas of concern. A considerable amount of staff time is spent on these activities and is currently not captured or reflected in the federal data system.

Specific guidelines for writing investigative reports have been developed and revised and are currently being implemented, resulting in improved consistency across investigative reports.

OHFC staff is also involved in background study reconsideration reviews. Individuals who seek employment in licensed health care facilities and home care agencies must undergo background checks. When an individual is disqualified from employment due to a previous criminal conviction or finding of maltreatment or neglect against a vulnerable adult or minor child, the person may request a

reconsideration for employment in settings licensed by the Department of Health. The nature and complexity of the disqualifications has expanded considerably in recent years, resulting in more review time per reconsideration and creating a significant backlog in the timeliness of completing reviews. An additional position was added to the Background Study Unit in February 2007 to improve the timeliness of reconsideration reviews.

3. Training

As a result of an allocation from monies collected through Civil Money Penalties, OHFC will develop state wide training programs to better assist facilities to be aware of allegations of abuse and neglect, to provide information as to the steps to be taken in the facility's internal investigation and to provide information as to the type of allegations that need to be submitted to the state agency under federal and state requirements. This statewide training will follow the model used for training sessions conducted during the past year through collaborative efforts between MDH, providers, advocates, and other stakeholders. Survey staff and investigators will participate in the training initiatives. This training was to be undertaken in calendar year 2006 and unfortunately was unable to be initiated in that time frame. OHFC will be looking at abuse training materials developed by 2 states that received CMS grants to develop curriculums in their states for provider training.

OHFC staff will also participate in education offerings about culture change in nursing homes.

A copy of OHFC's Quality Improvement Plan for 2007 is included as Appendix B.

Appendix A: OHFC Policy and Procedures

MINNESOTA OFFICE OF HEALTH FACILITY COMPLAINTS

Policy and Procedures

_____
Arnold Rosenthal, Director

SUBJECT:

Prioritization of complaints/reports

I. The Office of Health Facility Complaints will prioritize all complaints and reports of maltreatment related to possible violation of the rules, regulations and statues in order to insure appropriate response and to manage the workload.

II. Procedures

A. Investigation of complaints which allege immediate jeopardy will be initiated within two working days of receipt of the allegation. Immediate jeopardy are those situation which are present and on-going and are life threatening or have the potential to be life threatening; could result in potentially severe temporary or permanent injury, disability or death; present a serious safety hazard to patient; creates a condition which needs immediate attention. (If the immediate jeopardy has been removed, a two day investigation is not required.

1. Neglect which is life-threatening

2. Physical plant problems which could be life-threatening

3. Inadequate temperature which may be life-threatening

4. Physical or sexual abuse when the perpetrator is still working in the facility and no action has been taken to protect patient/resident

B. Investigation of complaints, which allege a higher level of actual harm, will be initiated within ten working days of receipt of the allegation. Actual harm situations are those that result in serious adverse consequences to patient health and safety but do not constitute an immediate crisis. To delay an investigation would not increase the risk of harm or injury.

1. Neglect which results in actual harm to the resident/patient, i.e., fractures, dehydration, decubitus, and significant weight loss which are avoidable; death; laceration requiring medical treatment; inadequate pain management; inappropriate use of restraints resulting in serious injury,

failure to obtain appropriate medical intervention, medication errors resulting in the need for medical attention

2. Physical abuse

3. Mental abuse resulting in the patient/resident feeling intimidated/threatened

4. Inadequate staffing which has a negative impact on resident health and safety

5. Resident to resident abuse in which no action has been taken to protect resident

C. Investigation of complaints which have not resulted in a higher level of actual harm but which have the potential to do so will be initiated within 45 days of receipt of the complaint or will be referred to survey as an "Area of Concern" if a survey will be initiated with 180 days.

1. Resident care issues

2. Inadequate staffing which has a negative impact on resident health and safety

3. Patient rights issues

D. Investigation of complaints which will be referred to L & C as "Areas of Concern" for consideration during the survey.

1. Neglect issues which do not result in actual harm or which are not recurring, i.e., medication errors in which no adverse consequences occur

2. Verbal or mental abuse which does not result in resident feeling frightened or threatened

3. Patient rights issues

4. Physical plant complaints which do not pose immediate threat to welfare of patients

5. Dietary complaints

6. General complaints which do not govern care of patient and which do not fall within category A or B

7. Housekeeping complaints

E. Complaints for which no determination may be made.

1. Complaints which do not provide enough information

2. Complaints which are not a violation of the rules and regulations

3. Self investigations done by the facility

4. Too much time evolved since incident or situation occurred

5. Cases in which further investigation is not necessary (medical record review does not reveal problems

P:HFC001
1/12/00
Revised 4/7/03
Revised 1/25/05

Appendix B: OHFC Quality Improvement Plan

2007 Quality Improvement Plan for
Office of Health Facility Complaints

Vision of Minnesota Department of Health:

Keeping All Minnesotans Healthy

Mission of Office of Health Facility Complaints Program:

To protect and improve the health, safety, comfort and well-being of individuals receiving services from federally certified and state licensed health care providers.

This mission is accomplished through:

1. Investigating complaints by or on behalf of patients, residents, and clients of federally certified and state licensed health care providers;

2. Investigating facility reported incidents made by federally certified and state licensed health care providers;

3. Enforcing compliance with federal and state statutes, regulations and guidelines.

Purpose of the Ongoing OHFC Quality Improvement Plan:

To ensure that activities carried out by OHFC staff are performed accurately and consistently over time and by all staff in accordance with established state and federal requirements to protect patient, resident, and client health, well-being, safety and comfort; to identify areas for improvement in performance and in systems, and to make those improvements.

Intent of the OHFC Quality Improvement Process:

Identify and correct known, suspected or potential problems with the investigative, intake, communication, and other processes and identify opportunities for further improvements.

Goal 1. Ensure accuracy and consistency of the investigation process.

Objective 1. Identify acceptable outcome measures of investigative performance, analyze information and develop methods to reduce variation.

Expected Outcome: Investigative techniques and decision-making process will be applied in a timely, accurate and consistent manner by OHFC investigators.

Actions:
A. Investigators will participate in state and federal training.

B. Investigators will receive onsite mentoring and coaching from experienced investigators and/or supervisors.
C. OHFC policies and procedures will be reviewed annually and updated as appropriate.
D. Supervisory/management review of substantiated maltreatment and 2567s prior to being issued: (i) will continue to be used to identify variations in investigative processes and documentation, with individual mentoring and coaching provided to investigators; (ii) will be shared with investigators as a group through staff meetings, in-service training, and updating of policies and procedures, as appropriate.
E. Investigators will participate in monthly staff meetings.
F. Timeline requirements for initiation and completion of investigations will be reviewed with investigators at a staff meeting. Reports on timeline compliance will be provided to program manager/supervisory staff and investigators on a monthly basis, and action plans will be developed as needed to ensure timely initiation and completion of investigations.

Data/measurement:
A. Staff participation in training will be documented.
B. Supervisory/management staff will document coaching and mentoring of investigative staff.
C. Supervisory/management staff will document policy & procedure review.
D. Variances will be noted by OHFC supervisory/management staff and will be communicated to OHFC staff, division management, training staff, etc. as appropriate.
E. Attendance at staff meetings will be documented. Occurrence of staff meetings will be documented in Groupwise.
F. Reports from federal data bases will be reviewed on a monthly and quarterly basis to track compliance with timeline requirements.
G. Meet CMS Performance Standards.

Goal 2. Ensure compliance with state and federal requirements for triaging complaints and facility reported incidents.

Objective 2. Identify acceptable outcome measures of intake performance, analyze information and develop methods to improve performance.

Expected Outcome: Intake procedures, triage process/procedures and decision making process will be applied in a timely, accurate and consistent manner by OHFC intake staff.

Actions:
A. Intake policies and procedures will be reviewed annually and updated as appropriate.
B. OHFC will provide training to intake staff to assure they are up to date on state and federal regulations, procedures, processes, systems (e.g., ACTS), etc.
C. Intake staff will participate in staff meetings.
D. Supervisory staff will continue to conduct ongoing review of a portion of all complaints and facility reported incidents to assure proper review and provide necessary direction and assistance to Intake staff.

Data/measurement:
A. Supervisory/management staff will document policy & procedure review.

B. Staff participation in training will be documented.
C. Attendance at staff meetings will be documented. (Or Occurrence of staff meetings will be documented in Groupwise)
D. Variances in intake and triage procedures will be noted by OHFC supervisory/management staff and will be communicated to OHFC staff, division management, training staff, etc. as appropriate.
E. Meet CMS Performance Standards.

Goal 3. Improve communication and coordination with internal and external stakeholders.

Objective 3: Ensure integration and coordination of quality improvement findings and activities with pertinent staff and external stakeholders as appropriate.

Expected Outcome: Informal and formal information collection methods will demonstrate improvements in stakeholder satisfaction with OHFC communication and quality improvement activities.

Actions:
A. OHFC staff will participate in videoconferences, in-service programs, and all other available training.
B. OHFC supervisor/manager (and staff) will review form letters used to communicate with providers, licensed and unlicensed health care provider staff, and consumers, and update content of form letters as appropriate.
C. OHFC supervisor/manager will provide prompt review of requests for reconsideration.
D. OHFC will work with division / MDH staff to develop a satisfaction survey for providers and consumers.
E. OHFC will provide prompt follow-up of provider /consumer concerns by reviewing any pertinent findings with all staff.
F. OHFC will continue its participation on the Commissioner's Long-term Care Committee

Data/measurement:
A. Staff participation in training will be documented.
B. OHFC supervisor/manager will document review and updating of form letters.
C. OHFC supervisor & manager will monitor compliance with 15 day time frame (Minnesota Statutes 626.557, Subdivision 9d(b)) and will identify targets for improvement (which may be stated as a quality improvement initiative).
D. Once developed and collected, satisfaction survey results will be reviewed on an on-going basis and will be tabulated on a quarterly and annual basis.
E. Feedback from providers/consumers during follow-up after concerns have been addressed, and results of satisfaction survey, will be monitored by program supervisor/manager.

Appendix C: FFY06 State Performance Measures Review Report

Q6 Prioritizing complaints and incidents

	Criterion:	Met
Threshold (90%)	LTC Score:	97.5
	# of complaints reviewed	40.0
	# of complaints prioritized accurately	39.0
Threshold (90%)	NLTC Score:	100.0
	# of complaints reviewed	6.0
	# of complaints prioritized accurately	6.0
	Narrative of Findings / Outliers:	See Attachment 4
	Action(s) Taken: (CMS & SA)	

Attachment 4(Q6)

Nursing homes:

Forty complaints and incidents that required a Federal onsite survey that were received by the SA between October 1, 2005 and August 18, 2006 were reviewed. Of those, 97.5% were triaged correctly. The following case was not triaged correctly:

Trevilla of Golden Valley MN00011503 SA triaged Non IJ-High. RO triaged IJ

According to the State Policy and Procedures, the triage should be a level "A" (IJ) under #1, "Neglect which is life-threatening." In this decision, we are considering that if the immediate jeopardy has been removed, a two day investigation is not required, according to the SA policy and procedure, however, based on the finding below, this is still an IJ.

The resident had been reported to have eloped from the facility on more than one occasion and this time was gone for a possible time period of 2 hours. He was found in the center median of a highway by police officers, who returned him to the facility and that was reported to be the first that the facility had been aware of the elopement. Elopements pose an immediate danger to the health and safety of an individual and with out assurances that another elopement can not occur, there is immediacy. Triaging this as an IJ would

allow for a two day evaluation of the potential systemic failure instead of waiting 10 days. State comments were considered in this assessment.

NLTC:
Six complaints and incidents that required a Federal onsite survey that were received by the SA between October 1, 2005 and August 18, 2006 were reviewed. Of those, 100% were triaged correctly.

Q7 Timeliness of complaint and incident investigations

Criterion: Not Met

Criteria 1:	**Total Reviewed**	**# w/in 2 days**	**% Investigated**
LTC Score:	29	29	100.00
ESRD Score			N/A
HHA Score			N/A
Non-Accredited Hospital			N/A
Deemed-Hospital	1	1	100.00

Criteria 2:	**Total Reviewed**	**10 Day Average**	**# of Intakes Completed within 20 working days**	**% Investigated**
LTC:	239.0	7.0	61	25.5

Criteria 3:	**Total Reviewed**	**45 Day Average**	**# of Intakes Completed within 60 days**	**% Investigated**
Accredited-Hospitals:	30.0	31.4	30	100.0

Narrative of Findings / Outliers:

Criterion 1: Immediate Jeopardy

LTC: Ten incidents and 19 complaints from the ACTS database where a case was triaged as an immediate jeopardy were reviewed to determine if the onsite investigation was started within two working days of when the incident/complaint was

received. In 100% of the LTC cases reviewed, the State met the two working days timeframe to begin the investigation.

ESRDs: There were no immediate jeopardy complaints or incidents to review.

HHAs: There were no immediate jeopardy complaints or incidents to review.

Non-Accredited Hospitals: There were no immediate jeopardy complaints or incidents to review.

Accredited Hospitals: One complaint from the ACTS database where a case was triaged as an immediate jeopardy was reviewed to determine if the onsite investigation was started within two working days of when the survey was authorized. In 100% of the cases reviewed, the State met the two working days timeframe to begin the investigation.

Narrative of Findings / Outliers:

Criterion 2: LTC, Non-Immediate Jeopardy – High

The average interval between when 239 incidents that required onsite investigation and complaints triaged as non-immediate jeopardy – high were received and investigated, based on the ACTS database, was 7 days. This MET the threshold 10 working day average. These same incidents and complaints were reviewed to determine if all investigations were completed within 20 working days. 25.5% of the investigations were completed within 20 working days. This DID NOT MEET the threshold of all investigations being completed within 20 working days. See tab 12 for the 178 cases that were not completed within 20 working days:

The SAs comments were reviewed and based on our review of the data, the measure was not met.

Narrative of Findings / Outliers:

Criterion 3: Accredited Hospitals, Non-Immediate Jeopardies

The average interval between when 30 complaints triaged as non-immediate jeopardy were authorized and investigated, based on the ACTS database, was 31.43 days. This MET the threshold 45 calendar day average. These same incidents and complaints were reviewed to determine if all investigations were completed within 60 calendar days. 100% of the investigations were completed within 60 calendar days. The following 1 case was not completed within 60 calendar days. The RO approved an extension on conducting this survey. Therefore it is not an error case.

Provider ID	Complaint #	C/O Date	Auth Date	Invest Date	Intervals
24-0002	C/O #MN11494	10/27/05	10/27/05	2/13/06	109 days

Action(s) Taken: (CMS & SA)

Criterion 2: LTC, Non-Immediate Jeopardy – High
Action(s) Taken: The SA should develop a system to ensure that complaint and/or incident surveys are completed timely and entered into ACTS. The system should include steps for monitoring / auditing for completion of complaint and/or incident surveys by the 20th day. Per the State Budget Request, the Regional office will meet quarterly with the SA to ensure progress is being made during this process and to address any possible constraints. The plan for the development, implementation and monitoring of the system is due to the RO by April 11, 2007.

Q8 Timeliness of EMTALA investigations

	Criterion:	Met
Threshold (80%)	Score:	90.0
	Total Reviewed	10.0
	# investigated according to CMS Policy	9.0

Narrative of Findings / Outliers:

Ten EMTALA investigations that were conducted at non-accredited and accredited hospitals between October 1, 2005 and August 18, 2006, based on the RO EMTALA Log were reviewed for Q9. An investigation was conducted according to CMS policy if it had no more than two review requirements (out of a maximum of five) that it did not meet. The SA investigated 9 cases according to CMS policy. The SA did not investigate the following 1 case according to CMS policy (requirements that were not met are listed):

Virginia Regional Hospital 24-0084 12/29/2005
• Was not completed within 5 working days RO authorized 12/21/05 survey date was 12/29/05 6 days after authorization
• The packet was not forwarded to the RO until 01/23/06 17days late

Action(s) Taken: (CMS & SA)

Q9 Quality of Investigation

	Criterion:	Met
Threshold (80%)	Score:	97.5
	Total Reviewed	40.0
	# investigated according to CMS Policy	39.0

Narrative of Findings / Outliers:	See Attachment 5
Action(s) Taken: (CMS & SA)	

Attachment 5(Q9)

Forty onsite complaint investigations that were conducted at Medicare/Medicaid certified nursing homes between October 1, 2005 and August 18, 2006 based on ACTS, were reviewed for Q9. An investigation was conducted according to CMS policy if it had no more than two review requirements (out of a maximum of six) that it did not meet. All complaint investigations that were reviewed were investigated according to CMS policy. The SA investigated 39 cases according to CMS policy. The SA did not investigate the following one case according to CMS policy (requirements that were not met are listed):

Provider Name	Provider Number	Complaint Number	Date of Survey
Courage Residence	245519	MN00012338	6/30/06

- Criteria 1
- Criteria 2
- Criteria 3
- Criteria 4
- Criteria 5
- Criteria 6

Summary: The file contained no evidence that an onsite investigation had been conducted for the resident named in the complaint or for two additional unnamed residents mentioned in the complaint who had the same catheter issues as the complainant. Interview with administrative personnel reported that the facility was requested to do an internal review of the allegation. There was no documentation to indicate that this allegation related to infection control practices had been investigated.