

Colorado Department of Public Health and Environment Health Facilities and Emergency Medical Services Division Policy Manual		Section: Part:
Subject: Long Term Care Complaint Investigations		Page:
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SUMMARY

This Policy and Procedure shall govern the management and oversight of Nursing Home/Long Term Care (LTC) complaints filed with the Health Facilities and Emergency Medical Services Division (The Division). The investigation of complaints is one of the methods used by The Division to respond to concerns by consumers and other parties about the care being delivered to patients or residents of health care facilities. The purpose of this policy is to provide guidelines for The Division staff and its representatives for conducting complaint investigations. These guidelines supplement, and in no way supersede, requirements established by the Centers for Medicare and Medicaid Services (CMS) and/or the Colorado Department of Health Care Policy and Financing when the purpose of the investigation is to determine compliance with Medicare/Medicaid requirements. When concerns arise, refer to the current federal State Operations Manual, Chapter 5, relevant S&C (Survey and Certification) Memos, and the Standards for clarification.

The policies and procedures outlined in this document shall apply to complaints lodged by or on behalf of residents in Nursing Home facilities (Long Term Care Facilities) only.

DEFINITIONS

- (1) "Facility" means the Nursing Home/Long Term Care Facility.
- (2) "Immediate Jeopardy" means a situation in which the provider'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. Immediate jeopardy, immediate and serious threat, and serious and immediate jeopardy are interchangeable terms.

POLICY AND PROCEDURES

It shall be the policy and procedures of the Division:

SECTION 1. LODGING A COMPLAINT

Who May Lodge a Complaint Any party may lodge a complaint. The Division receives complaints lodged by residents, family members, current and former staff of health care facilities, volunteers, guardians, Division employees and other representatives of residents/or patients. In addition, complaints may be lodged anonymously.

Process for Lodging a Complaint Complaints may be lodged by:

- *Telephone: 303-692-2800 or 1-800-886-7689 during regular business hours of 8 a.m. to 5 p.m. When the intake person is otherwise occupied and after hours, complaints are received through the division's voice messaging system. Callers should enter extension 2800 at the prompt.
- *Fax: 303-753-6214, Attention: Long Term Care Complaints.
- *U.S. mail: CDPHE, Health Facilities and Emergency Medical Services Division, Attention: Long Term Care Complaints, 4300 Cherry Creek Drive South, Denver, CO 80246.
- *E-mail: HFDIntake@state.co.us.

SECTION 2. INTAKE & COMPLAINT ASSIGNMENT

General. The Division regulates numerous types of health care facilities. The responsibilities associated with the regulatory functions are allocated among several programs within the Division. This policy addresses only Long Term Care Facilities.

Complaints Must Be within the Division's Jurisdiction.

General. In order for The Division staff to investigate the complaint, the allegation must fall within the purview of the Division's jurisdiction. This jurisdiction is defined by Medicaid/Medicare regulations (State Operations Manual, appendix P and PP) and/or the regulations promulgated by the State Board of Health under 6 CCR 1011-1, Chapter 1 through 25. If the subject of the complaint is not addressed in applicable regulations, the Division is not authorized to take action on the matter. Examples of complaints that are not within the Division's jurisdiction are: billing, labor/employment issues and individuals' professional licenses.

Complaints Outside of the Division's Jurisdiction. If the complaint, in part or whole, appears to be within the jurisdiction of another agency of government, then the Complaint Intake Desk will refer the complaint or part thereof to the appropriate agency and inform the complainant of the referral.

**Concerns Pertaining to Nursing Home Administrators that do not fall under The Division's jurisdiction.* These concerns should be referred to the Nursing Home Administrators Board, at 303-894-7758. The Division's Memorandum of Understanding with the Department of Regulatory Agencies (DORA) is for them to provide the Division with a written report of actions taken as a result of a referral.

**Concerns Pertaining to Physicians and Physician Assistants that do not fall under The Division's jurisdiction.* These concerns should be referred to the Board of Medical Examiners which may be reached at 303-894-7690. The Division's Memorandum of Understanding with the Department of Regulatory Agencies (DORA) is for them to provide the Division with a written report of actions taken as a result of a referral.

**Concerns Pertaining to Nurses and to Certified Nurse Aides that do not fall under The Division's jurisdiction.* These concerns should be referred to the State Board of Nursing, at 303-894-2430. The Division's Memorandum of Understanding with the Department of Regulatory Agencies (DORA) is for them to provide the Division with a written report of actions taken as a result of a referral.

**Concerns Pertaining to Misuse or Over-billing by Medicaid Provider and potential Medicaid fraud by providers (i.e., intent to defraud rather than unintentional errors)* should be referred to the state Department of Health Care Policy and Financing (HCPF) to the Program Integrity Supervisor at 303-866-5421.

**Concerns Pertaining to Misuse or Fraud by Medicaid Clients that do not fall under The Division's jurisdiction.* Concerns pertaining to misuse or fraud by Medicaid clients should be referred to the local department of social services in the county where the client resides

and to Health Care Policy and Finance (HCPF) at the Customer Contact Center 303-866-3573.

**Concerns Pertaining to Employment Issues that do not fall under The Division's jurisdiction.* Concerns pertaining to labor and employment issues should be referred to the state Department of Labor and Employment, Labor Standards, 303-318-8441.

**Concerns Pertaining to Misuse or Fraud by Medicare Clients that do not fall under The Division's jurisdiction.* Concerns should be referred to the Medicare main number, 303-844-4024.

**Concerns Pertaining to Elder Abuse that do not fall under The Division's jurisdiction.* Concerns should be referred to the local Adult Protective Services (APS) office.

**Concerns Pertaining to HIPAA requirements/violations that do not fall under The Division's jurisdiction.* Concerns should be referred to the Office of Civil Rights, 1-800-368-1019.

**Concerns Pertaining to Violation of Civil Rights that do not fall under The Division's jurisdiction.* Concerns should be referred to the Office of Civil Rights, 1-800-368-1019.

**Concerns Pertaining to Employee Safety/Chemical Hazard Issues that do not fall under The Division's jurisdiction.* Concerns should be referred to Occupational Safety and Health Agency (OSHA), at 303-844-5285 or 1-800-321-6742.

Intake

Centralized Intake – Information Obtained During Intake. A complaint may consist of several allegations of noncompliance with Federal or State requirements. An allegation is an assertion of improper care or treatment that could result in the citation of a Federal or State deficiency. Self reported incidents may be referred to the LTC Complaints Manager/Complaint Intake Coordinator for onsite investigation when the Occurrence Program Manager/Occurrence Investigator determines deficient practice under Federal regulations is likely (these intakes will be marked "I" for incident, rather than "C" for complaint). The complaint intake information generally includes:

- *The date the complaint was received;
- *Complainant information, including the name, address, and telephone number – unless the complainant requests anonymity;
- *Individuals involved and affected, including witnesses;
- *Narrative/specifics of the complainant's concerns including the date, and time of the allegation;
- *The complainant's views about the frequency and pervasiveness of the allegation/ whether the allegations appear to be isolated or widespread;
- *Name of the facility including location (e.g. unit, room, floor) of the allegation, if applicable;
- *How/why the complainant believes the allegation occurred;
- *If the complainant alleges harm to a resident, the current status of the resident;
- *Whether the complainant initiated other courses of action, such as reporting to other agencies, discussing issues with the provider, and obtaining a response/resolution or seeking legal advice; and
- *The complainant's expectation/desire for resolution/remedy, if appropriate.

Complaints are entered into ASPEN Complaints/Incidents Tracking System (ACTS) within 2 business days. A complaint record is created in ACTS for each complaint received by The Division that alleges a deficiency in one or more of the requirements may have occurred and only a survey can determine whether a deficiency exists; allegations that are outside the purview of Federal Participation requirements will not be entered or investigated (referrals are made to

appropriate agencies upon intake whenever possible, see above). An alleged event occurring more than 12 months prior to the intake date will not be entered into ACTS and will not be investigated. An alleged event occurring prior to the last standard survey will not be entered into ACTS and will not be investigated, barring extenuating or egregious circumstances, and an onsite investigation will not be conducted.

*Within 5 days of receiving the complaint, the division should mail a letter to the complainant acknowledging receipt of the complaint.*¹ Further, state law requires routine and periodic contact with complainants. This contact is conducted by mail and the letters are generated through automated systems.

Prioritizing Complaint Investigations. An assessment of each intake will be made initially by the Complaint Intake Coordinator using the Complaint Priority Assessment System (COMPASS is a computerized point-based triage evaluation of complainant specifics, resident specifics, harm, scope, effect on current operation, other agency involvement, current complaint allegations, and previous complaint allegations), followed by a secondary review of the priority evaluation by the LTC Complaints Supervisor, or the LTC Program Manager, or the designated Supervisor in charge to confirm the correct priority. Even though the Compass Triage Program initially assigns the priority level, the Manager or Supervisor may change the priority based upon his/her knowledge and/or experience of current clinical standards of practice and Federal requirements. When the priority level is changed from the Compass Triage Program assignment, an explanation is entered in the ACTS note section (existing notes may be edited for grammatical and factual errors, but may not be deleted).

Complaints Received Through Centralized Intake. An automated and standardized system is used to assist the complaint program supervisor in the prioritization of complaints. Complaints are assigned five priority levels, as follows:

**Level A = Immediate Jeopardy: Onsite within 2 working days and exit within 60 days from the start date.* This priority is used when the complaint alleges immediate jeopardy ("A situation in which the provider'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") may be present and ongoing. The Complaint Intake Coordinator will discuss all allegations of Immediate Jeopardy with the LTC Complaints Supervisor or Supervisor's designee as soon as possible. All fires resulting in serious injury or death reported from any source will be in this category.

**Level B = Non-Immediate Jeopardy – High: Onsite within 10 working days and exit within 60 days from the start date.* This priority is used when the complaint alleges a higher level of actual harm that impairs and/or negatively impacts the resident's mental, physical and/or psychosocial status that includes specific information (such as, descriptive identifiers, individual names, date/time/location of occurrence, description of harm, etc.). Some examples of allegations that indicate a higher level of actual harm may be present include: resident is intimidated/threatened; resident is physically abused – spitting/slapping/sticking with sharp object/pushing/pinching; unexplained/unexpected death, with circumstances indicating that there was abuse or neglect; sexual assault/sexual harassment/coercion; falls resulting in fracture (e.g., handrails not secured); inappropriate use of restraints resulting in injury; inadequate staffing which negatively impacts on

¹ In accordance with Section 25-3-102.5 (2)(a), C.R.S., the division must respond to complaints from a nursing home resident, resident family member or representative within five working days after the receipt of the complaint. For 60 days after the receipt date, the department shall update the complainant at least every 14 days until the complaint is resolved and an investigation is finalized. If the complaint is not resolved within this time period, the department shall continue to update the complainant at least every 30 days until the complaint is resolved and the investigation is finalized. However, at the request of the complainant, the division shall not maintain such contact.

resident health and safety; and failure to obtain appropriate care or medical intervention, i.e., failure to respond to a significant change in the resident's condition.

**Level C = Non-Immediate Jeopardy – Medium: Schedule onsite investigation within 30 days of receipt of complaint and exit within 60 days from the start date. This priority is used when the complaint alleges harm that is of limited consequence and does not significantly impair the individual's mental, physical and/or psychosocial status to function. This may include, but is not limited to, problems with odors, cold food, and lost items.*

**Level D = Non-Immediate Jeopardy – Low: Schedule onsite investigation within 30 days of receipt of complaint and exit within 60 days from the start date. This priority is used when the complaint alleges noncompliance with one or more requirements or conditions that may have caused physical, mental and/or psychosocial discomfort and does not constitute injury or damage. An onsite investigation may not be scheduled, but the allegation will be reviewed at the next onsite survey.*

**Level E = Administrative Review/Offsite Investigation: These complaints are conducted the same as Level D. All complaints require at least one onsite visit.*

SECTION 3. COMPLAINT INVESTIGATION PROTOCOL

Scope of the Investigation

The investigation is designed to determine whether or not the facility is compliant with relevant statutes and regulations. Further, the focus of the investigation should be on whether deficient practice has occurred and the outcome or potential outcome to the resident(s). The investigator shall determine compliance with:

*Applicable federal regulations;² and/or

*Applicable state statutes and regulations when investigating licensed only facilities or when specific allegations of state violations are investigated.

The initial focus of the investigation is limited to the issue raised by the complainant and must address those aspects necessary to resolve the complaint. However, if during the course of the investigation the investigator determines that there may be other areas of deficient practice, the investigator may investigate these other potential deficiencies.

When Investigations May be Conducted. Investigations to determine compliance with federal standards may be conducted at any time, including weekends, 24 hours per day. If the onsite investigation is conducted prior to 8:00 a.m. or after 6:00 p.m., or on Saturday or Sunday, the investigator should take into consideration the staffing available and the activities of the residents/patients (e.g., religious services).

Conducting the Investigation - Offsite and Onsite Tasks

General. Investigations will be conducted by at least one Surveyor Minimum Qualifications Test (SMQT) qualified surveyor/investigator. Investigations rely primarily upon three investigative techniques:

*observation of facility practice,

*interviews, and

*record review.

Investigations typically require conducting tasks offsite as well as onsite (at the facility that is the subject of the investigation).

² Please note that facilities/agencies that do not accept Medicare or Medicaid funds, i.e., private pay facilities, only need to be in compliance with applicable State statutes and regulations.

Offsite Tasks

**Interviewing the Complainant.* Except where the complainant has asked to remain anonymous and does not provide an address or phone number, the investigator will contact the complainant, prior to the onsite visit, to request additional information and get information about witnesses and others who might have information relevant to the complaint.

**Checking External Sources*

--Contacting the local ombudsman. The investigator will contact the local ombudsman to determine if there are related concerns or other complaints with similar issues or characteristics.

--Contacting other state agencies. The investigator may contact any other state agencies that are involved in the investigation to ensure that investigative processes are coordinated.

--Accessing other sources of information. The investigator may contact any other entity that may be important or salient to the complaint investigation. For example, the investigator may want to review information about recent care provided to the subject of the complaint at other facilities (such as a recent hospital visit).

**Checking Internal Data Sources*

--Reviewing the Quality Measures. For complaints involving Medicare/Medicaid certified nursing homes, the investigator should review the quality indicators.

--Checking the occurrence reporting system. The investigator will check the occurrence system to determine whether there are related occurrence reports. (Occurrences reporting is mandated by statute 25-1-124 C.R.S., and by regulation 6 CCR 1011-1, Chap. II, Sec. 3.2.)

--Checking the complaint tracking system. The investigator will check the complaint tracking system to determine if there have been similar complaints filed or deficiencies written over the last six months in the same facility.

--Checking the survey tracking system. The investigator will check the survey tracking system for the results of the last annual survey and any compliance concerns.

Onsite Tasks

**Unannounced visits.* Onsite visits shall be unannounced in order to observe the routine delivery of care and to be in compliance with CMS requirements.

**Arrival at the facility.* Upon arriving at the facility, the investigator will check in and meet the facility administrator or person in charge and:

--introduce him/herself as CDPHE staff;

--explain that the visit is in response to a complaint registered against the facility;

--explain the general process of investigating complaints, including that the investigation process is designed to protect the anonymity of the complainant and determine whether the concerns are valid and if so, the scope of the problem;

--state that the investigator will ask for assistance of the facility staff when needed (a list of key personnel and their functions may be helpful); and

--state that the investigator may interview residents and such interviews will be conducted privately unless that resident requests otherwise.

**Selecting a sample to protect anonymity of the subject(s) of the complaint.* The investigator may request a resident roster and a layout of the facility. In some cases, additional information about the residents may be requested, such as information about their specific care needs. The investigator will select a sample of three residents with characteristics pertinent to the subject of each allegation in the complaint. Selecting a

sample helps protect the anonymity of the resident or family member who filed the complaint and also assists the investigator in determining whether the deficient practice, if substantiated, is isolated or more widespread.

**Record Review.* The investigator will review pertinent resident's health information (such as care plans and medication administration records) as well as other relevant facility records (such as staffing schedules).

**Interviews.* The investigator will interview the residents, family members, facility staff, and other interested parties as appropriate. Whenever possible, the investigator should interview any facility staff who are directly knowledgeable about the issue for the resident who is the subject of the complaint. Due to turnover, however, such staff may no longer be working at the facility. The investigator may make reasonable attempts to contact staff who are no longer working at the facility, particularly if their input will help to address the current and present risk to facility residents.

**Observation of Resident Care and Services.* The investigator should observe the delivery of care and services relevant to the complaint allegation.

**Departure from the Facility and Exit Conference.* Upon leaving the facility, the investigator should apprise the administrator or person in charge regarding the status of the onsite portion of the investigation, i.e., whether the investigator will be returning to the facility. At the conclusion of the investigation, the investigator should conduct an exit conference with the facility administrator or the person in charge.

SECTION 4. FINDINGS AND COMPLETION OF THE INVESTIGATION

Citing Deficient Practice. If the evidence indicates that the facility failed to comply with applicable federal and/or state requirements, the investigator will cite deficient practice listing statutory and/or regulatory violations. The cited deficiencies are called the CMS 2567 form or "deficiency list."

Inability to Cite Deficient Practice. In some cases, the investigator may be unable to cite deficient practice. Please note that this finding does not disprove the allegation; rather, it indicates the Division will be unable to take regulatory action. There are several reasons why an investigator may be unable to cite deficient practice, including the following:

**Inability to find sufficient collaborating evidence.* The investigator may not be able to find sufficient evidence to establish that the allegation and/or deficient practice occurred.

**No current deficient practice.* Sometimes deficient practice may have occurred that the facility recognized and corrected, including through the facility's Quality Assurance process, prior to the onsite investigation. In addition, deficient practice will not be cited if the incident occurred prior to or on the date of exit for the last standard recertification survey, even if the identified deficient practice was not investigated during the recertification survey.

**Allegation or portion thereof is not addressed in regulation.* The basis for citing deficient practice is noncompliance with federal and/or state rules and regulations. The regulations establish the standards to which facilities are bound to adhere and which the Division has the jurisdiction to enforce. If the allegation is not addressed in regulation, it falls outside of the purview of the Division.

Completion of the Investigation and Notification of Findings

**Onsite Investigation Completion.* The onsite investigation is complete after the investigator determines whether or not deficient practice has occurred, informs the facility of the deficiencies and outcome of the investigation and conducts an exit conference. The investigator will subsequently write the 2567 or deficiency list, if appropriate.

***Communication with the Complainant.** The findings of the investigation will be provided to the complainant in writing when a current address is provided, in addition, the investigator will call the complainant and notify them of the results.

***Communication with the Facility.** The investigator should disclose findings at the exit conference. The CMS 2567 form (deficiency list) shall be mailed to the facility on or before the 10th business day after exit. The correspondence that accompanies the deficiency list will notify the facility of the deficient practice. If a Plan of Correction (POC) is required, appropriate deadlines according to CMS guidance will be followed. Revisits will be conducted according to CMS guidance.

***Post investigation referrals** regarding the conduct of licensed professionals shall be referred in writing to the licensing boards.

Approved by:  Nancy McDonald Title: Division Director Date: 2/13/2013