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Conducting Investigations of Adverse Events in Long-Term Care Facilities

By: Louise Lindsey

According to the Centers for Medicare & Medicaid Services (CMS) regulation 42 CFR §483.85, an effective compliance program must at a minimum include these seven elements:

1. Standards, Policies, and Procedures
2. Compliance Program Administration
3. Screening and Evaluation of Employees, Physicians, Vendors, and other Agents
4. Communication, Education, and Training on Compliance Issues
5. Monitoring, Auditing, and Internal Reporting Systems
6. Discipline for Non-Compliance with well-publicized disciplinary guidelines.
7. Investigations and Remedial Measures

It is not insignificant that having written policies, procedures, and standards of conduct tops the list of essential elements necessary to have an effective compliance and ethics program. Written standards, policies, and procedures are required for each of the other six elements.

When it comes to Investigations and Remedial Measures, meticulously written standards, policies, and protocols provide the guidance needed for investigating and resolving suspected, detected, or reported compliance issues. They are a key component in the overall goal of regulatory compliance to protect Medicare and Medicaid beneficiaries from abuse, neglect, misappropriation, exploitation, inadequate care, or supervision.

The need for an investigation is triggered by an “adverse event” which is defined as an “instance which indicates or may indicate that a resident has received poor quality care.” In a long-term care (LTC) facility, the occurrence of an adverse event requires an investigation, documentation, and reporting to proper authorities within expressed regulatory specific timeframes along with the implementation of measures to correct and

prevent reoccurrences.

An investigation within an LTC is the process used by the administration to determine the who, what, when, and where of an adverse event occurrence. Investigations are required for a broad range of issues connected to specific allegations of wrongdoing or suspected compliance irregularities. However, the purpose of all investigations is to discover the relevant facts, and this is accomplished through interviews, reviewing records, and collecting data, information, and documentation.

Falls, resident to resident altercations, staff to resident altercations, medication errors, eloping/wandering, drug diversion, inadequate supervision/monitoring, financial or material exploitation, abandonment, dietary errors, and neglect are all examples of adverse events that require immediate investigation. If these issues are substantiated, it may indicate that a facility is providing substandard quality care and billing for a level of service they did not deliver, which regulators may consider to be fraud.

While each investigation has unique aspects that influence how it is handled, having a specific set of written policies and procedures helps to ensure that investigations are conducted in a fair, transparent, and consistent fashion. The following are some general components to consider in creating policies and procedures for conducting investigations and are applicable to all preliminary inquiries and investigations:

Guiding Principles – Independence, Impartiality, Fairness, and Confidentiality

- I. Management of the Investigation
- II. Interviews
- III. Findings and Conclusions
- IV. Reporting

It should be noted that it is often necessary to employ flexibility to make sure that each investigation is conducted properly based on its own merits.

When an adverse event happens and an investigation is initiated, the role and focus of the investigator should be to systematically find and collect the facts to discover what happened. It is important to avoid blaming or jumping to premature conclusions. Keeping an open mind is critical because what might first seem to be what happened may change when all the facts are discovered. Jumping to conclusions and blaming tend to divert attention from the important aspects of discovering what took place, protecting the resident, and determining the steps to implement to prevent further occurrences.

Because conducting interviews is a critical aspect in virtually all adverse events, the importance of the location and environment in which the investigation's interviews are held and conducted is important. This significance was recently described in an article written by Richard Kusserow of Strategic Management Services. It is titled, "Where to Conduct Interviews During an Investigation," and involves two key points: the importance of location and positioning, and suggestions for selecting the location for conducting interviews.

Kusserow indicates that "investigative interviews must be done discreetly to avoid alarming anyone being interviewed or causing others in the organization to speculate." After determining the persons to be interviewed, there are some things to consider when choosing where to conduct interviews:

- Private area with fewest number of people possible.
- Quiet space without distracting external sounds and where outsiders cannot overhear the conversation.
- Non-threatening space away from the interviewee's office or work location and not in the Compliance Officer's office.
- Small but non-confining room.
- Good lighting to provide close observation of the person being interviewed.
- Area without any or few visual distractions – windows, pictures, etc.
- Telephones shut off or silenced to prevent disrupting the interview.
- Furniture positioned to enable face-to-face conversation without violating personal space.

Notably, it may not be necessary or possible to observe these guidelines when interviewing persons who witnessed the event or who have limited access to information. However, for interviews of individuals who are primarily involved with the incident,

following these suggestions will help to ensure that the investigation is successful.

In some situations, it may be necessary to conduct telephone or video-conference interviews, but personal interviews are preferred where possible.

Interviews must be carefully documented. A good practice will be for the interviewer to prepare a record of the interview, allow the person interviewed to review the record, confirm its accuracy, and sign it together with the interviewer. The person interviewed will be provided with a copy of the signed document.

After the investigator has completed the interviews he/she will evaluate the information that has been obtained during the interviews and the collection of data; assess the credibility of that information; and analyze the information obtained, weigh the evidence, and reach a conclusion regarding the event. This analysis should result in one of two possible outcomes:

- Adverse Event Allegation is Substantiated
- Adverse Event Allegation is Unsubstantiated (it did not occur or there was insufficient evidence of wrongdoing)

Finally, an investigation report should be prepared that contains the findings of fact and an analysis of all the material information gathered. Since the report and any documents obtained by the investigator are considered privileged information, they are not released or disclosed except to the official or entity with the primary responsibility to take actions or make a decision regarding the investigation.

Once the investigation report has been submitted, the investigator should inform the subject of the adverse event and the person who reported the adverse event that the investigation has been completed and a report has been sent to the appropriate officials or committee.

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