

# Virginia Department of Health Office of Licensure and Certification

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August 17, 2016

## Adverse Events - Guidelines for Non-Long Term Care Healthcare Facilities

### Introduction

The purpose of this document is to provide guidance to licensed non-long term care healthcare facilities regarding compliance with State and Federal Regulations when patients experience complications and adverse health events.

### Terms

The following terms have the following meanings within this document:

“Adverse event” means an injury caused by medical management, rather than by the underlying disease, which prolongs hospitalization, produces a disability at the time of discharge, or both<sup>1</sup>.

“Adverse outcome” means the result of drug or health care therapy that is neither intended nor expected in normal therapeutic use and that causes significant, sometimes life-threatening conditions or consequences at some future time. Such potential future adverse outcome may require the arrangement of appropriate follow-up surveillance and perhaps other departures from the usual plan of care<sup>2</sup>.

“Adverse serious event” means an adverse event resulting in death or serious physical or psychological injury, or risk thereof.

“Complication” means the simultaneous presentation of two or more diseases or any undesired, but not unforeseeable, result of patient care management<sup>3</sup>.

“Outcome” means the result of the performance (or nonperformance) of a function(s) or process (es).

### Identification and Assessment

- The regulations for the licensure of non-long term care facilities each include requirements for the recording, monitoring, tracking, trending, evaluation of data related to complications and/or reporting adverse outcomes, infections, deaths, medication errors and/or the effectiveness of care for the purposes of problem identification and correction, including at:
  - 12VAC5-381 Regulations for the Licensure of Home Care Organizations
    - 12VAC5-381-180 C; Written Policies and Procedures
    - 12VAC5-381-250; Quality Improvement
  - 12VAC5-391 Regulations for the Licensure of Hospice
    - 12VAC5-391-190 C; Written Policies and Procedures
    - 12VAC5-391-260 B; Quality Improvement

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<sup>1</sup> McGraw-Hill Concise Dictionary of Modern Medicine. © 2002 by The McGraw-Hill Companies, Inc.

<sup>2</sup> Regulations for the Licensure of Hospice, 12VAC5-391-10

<sup>3</sup> Adapted from McGraw-Hill Concise Dictionary of Modern Medicine. © 2002 by The McGraw-Hill Companies, Inc.

- 12VAC5-391-300 C; Hospice Services
  - 12VAC5-410 Regulations for the Licensure of Hospitals in Virginia
    - 12VAC5-410-370 B; Medical Records
    - 12VAC5-410-420 D; Surgical Service
    - 12VAC5-410-441 A; Obstetric Service Requirements; Medical Direction; Physician Consultation and Coverage; Nurse Staffing and Coverage; Policies and Procedures
    - 12VAC5-410-444 B and K; Newborn Service Medical Direction; Physician Consultation and Coverage; Nursing Direction, Nurse Staffing and Coverage; Policies and Procedures
    - 12VAC5-410-1240 A; Emergency Services
    - 12VAC5-410-370 A; Post-Operative Recovery
  - 12VAC5-412 Regulations for Licensure of Abortion Facilities
    - 12VAC5-412-210 B; Quality Management
    - 12VAC5-412-320 B; Required Reporting
- Each facility should develop and implement carefully constructed policies and procedures that address expected or unexpected outcomes to assess patient medical needs and ensure that staff is trained in the use of those policies and procedures.
- Facilities are encouraged to make efforts to identify and assess patient medical needs as early as possible.
- When scheduling an appointment, or upon admission/registration, staff should identify and assess if a patient has special medical needs or disabilities that may affect the medical procedure or cause complications.
- As required in regulation, facilities are to monitor patient outcomes for adverse trends, and use such data to effect such system or process changes as to result in improvement in patient outcomes.

### **Educating Staff on Policy and Procedure**

- All staff should be provided notice of the facility's policies and procedures regarding how to handle adverse patient outcomes and their role in quality improvement.
- All facilities should develop training materials and perform training exercises in the event of an adverse patient outcome expected or unexpected.
- Staff should be trained regarding these policies and procedures at orientation and annually.
- All facilities should develop policies and procedures regarding the documentation of adverse events
  - In the event that an adverse event is due to error, the facility should have policies and procedures for documenting the error and follow-up. Follow-up may involve training, discipline, system or process modification, depending on the nature and seriousness of the error and the reason for the error.

### **Reporting**

- Some non-long term care facilities are required by state or federal regulation to report accidents and adverse events.
- All non-long term care facilities may, as a best practice, report accidents and adverse serious events to the Virginia Department of Health Office of Licensure and Certification. These events include but are not limited to:
  - Any serious injury to a patient;

- Medication errors that necessitate a clinical intervention other than monitoring;
- Death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the facility grounds; and
- Any other incident reported to the malpractice insurance carrier.
- Failure of building systems such that patients are adversely impacted or that necessitate evacuation of all or part of the facility.
- Notification of these events should generally be made within 24 hours of the occurrence.
  - Notices should be faxed to (804) 527-4503
  - Each notice should contain:
    - The facility name
    - The type and circumstance of the event being reported;
    - Date of the event; and
    - Actions taken by the facility to protect patient and staff safety and to prevent recurrence (where appropriate).

### **Complaint Process**

- The Virginia Department of Health Office of Licensure and Certification encourages all patients who have complaints to contact facility staff with their concerns first.
- Facilities should have a policy and procedure regarding complaints. Such policies should be provided to patients upon registration and discharge.
- In addition to regulatory compliance inspection, the Office of Licensure and Certification investigates consumer complaints regarding health care services received at the facilities it licenses or certifies.
- If the concerns in the complaint relate to the provision of health care services, an investigation is conducted and complainants receive notice of the results of that investigation.
- A patient may submit a complaint by calling or writing.
- To report a complaint via telephone an individual can call Toll Free: 1-800-955-1819 or (804) 367-2106.
- To file a complaint in writing a patient should visit:  
<http://www.vdh.virginia.gov/OLC/Complaint/> and download a complaint form. Then the complaint form may be submitted via mail, fax or email.

**By US Mail:**

Complaint Intake  
 Office of Licensure and Certification  
 Virginia Department of Health  
 9960 Mayland Drive, Suite 401  
 Henrico, VA 23233-1463

OR

**By Fax:**

1-800-527-4503

OR

**By email:**    [OLC-Complaints@vdh.virginia.gov](mailto:OLC-Complaints@vdh.virginia.gov)